OPTN Transplant Coordinators Committee
Meeting Summary
September 5, 2024
In-Person, Richmond, VA

Christine Brenner, RN, BSN, CPTC, CCTC, Chair
Heather Bastardi, RN, MSN, CPNP, Vice Chair

Introduction

The OPTN Transplant Coordinators Committee (the Committee) met via in-person in Richmond, VA and online on Cisco Webex teleconference on 09/05/2024 to discuss the following agenda items:

1. Welcome
2. Public Comment Presentation: Require Reporting of HLA Critical Discrepancies and Crossmatching Events to the OPTN
3. Public Comment Presentation: Revise Conditions for Access to the OPTN Computer System
4. Public Comment Presentation: Continuous Distribution of Hearts Update, Summer 2024
5. Workgroup Report Out
6. Public Comment Presentation: Promote Efficiency of Lung Donor Testing
7. Public Comment Presentation: Continuous Distribution of Livers & Intestines Update, Summer 2024
8. Public Comment Presentation: Continuous Distribution of Pancreata Update, Summer 2024
9. Public Comment Presentation: Continuous Distribution of Kidneys Update, Summer 2024
10. Policy Operationalization Checklist Project
11. Open Discussion & Closing Remarks

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

1. Welcome

The Committee started off the morning compiling additional items for the afternoon's open discussion portion of the day.

Summary of discussion:

No decisions made.

The Committee discussed a variety of topics for further exploration during the afternoon open discussion section, they included:

Compliance monitoring as it relates to PHS guidelines; questions for HRSA on the pre-waitlist referrals work previously done; ideas for modifications to the DonorNet dashboard; and any updates that could be provided on the OPTN contract process.

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

The Committee discussed the public comment presentation from the OPTN Histocompatibility Committee.

Summary of discussion:

The Committee supports this proposal as written.

The chair sought clarity on whether there has been any pushback on this proposal thus far, as it seems a logical and natural policy to create. It was affirmed that there has been minimal pushback, the greater focus has been on clarifying the 24-hour reporting period. A member noted that the change might seem straightforward to those outside HLA labs but could present challenges for supervisors or managers who need to log in and conduct additional reporting. It was highlighted that this might be a lab specific practice and not applicable to others. A member raised their concern about the timeliness of reporting, particularly regarding those responsible for entering information into the patient safety portal.

Next steps:

The Committee will summarize their feedback in a public comment response.

3. Public Comment Presentation: Revise Conditions for Access to the OPTN Computer System

Summary of discussion:

The Committee supports this proposal as written.

The Committee discussed the presentation and submitted the following for official public comment feedback:

The Committee agrees that access to the OPTN Computer System is an important issue. It believes that all users – whether businesses, programs, or individuals – should follow the same security rules consistently.

However, the Committee has some concerns about how this policy will work in practice. It suggests developing clearer, simpler policy language that explains exactly what access businesses and their partners would have to the system. The Committee recommends including specific details about when and how businesses can access the OPTN Computer System, such as when supporting transplant hospitals, histocompatibility labs, or organ procurement organizations.

The Committee believes access should remain limited to what is necessary for each business member's work. It advises that the OPTN should be careful about expanding access for business members. The Committee notes that the current system, where transplant programs, organ procurement organizations, or histocompatibility labs grant specific access to businesses, allows for better control over what each business can access.

Finally, the Committee cautions that stricter security requirements might make it harder for small businesses or companies in rural areas to compete in this field.

Next steps:

The Committee will summarize their feedback in a public comment response.

4. Public Comment Presentation: Continuous Distribution of Hearts Update, Summer 2024

Summary of discussion:

The Committee supports this update.

The Committee discussed the update and submitted the following official feedback:

The OPTN Transplant Coordinators Committee thanks the OPTN Heart Transplantation Committee for updating them on their continuous distribution work. They understand the challenges in creating a fair distribution system for organ transplants.

The Committee has concerns about the likely increased use of ex-vivo perfusion devices. Programs in underserved or low-income areas might struggle to access these devices. The Committee emphasizes that patients in underserved areas should have equal access to heart transplants.

The Committee appreciates that the Heart Committee plans to keep priority points for pediatric candidates in the proposed system. As they continue to develop the system, the Committee recommends that the Heart Committee pay close attention to how patients transition from pediatric to adult status. This transition can significantly affect both pediatric and adult transplant waiting lists.

Next steps:

The Committee will summarize their feedback in a public comment response.

5. Workgroup Report Out

A member of the Committee gave a brief report on their work with the OPTN Task Force, to update the Committee on developments and projects that are under consideration and to ascertain Committee insight.

Summary of discussion:

No decisions made, discussion only.

One member raised concerns about the timing of organ offers, describing a situation where an offer is accepted late at night, but then rejected by the morning surgeon, which creates inefficiencies. Another member acknowledged the issue, explaining that some of this can be attributed to transplant centers being overwhelmed during the week and needing rest on weekends. Members acknowledged this has led to more C-Suite discussions with their transplant centers, but it remains a balancing act.

One member highlighted they use “provisional yes” for all organ types, but specifically lung. They continued that provisional acceptances are often used to avoid putting "no surgeon available" as a reason for decline, which could invite audits. The member emphasized this practice has its challenges, as it can delay the offer process. Another member agreed and noted that their center is becoming stricter with provisional acceptances to avoid holding organs for too long, especially since current rules allow them to only accept one offer at a time.

One member mentioned that once an offer is deemed acceptable, the center has only 60 minutes to decide. This pressure has increased as OPOs are pushing harder for quicker decisions due to new CMS metrics. One member noted that an estimated 8,000 kidneys may go unused this year, although not all of them were likely transplantable. Members agreed that understanding the reasons behind these unused kidneys is important, highlighting factors like poor anatomy being a significant contributor to organ non-use.

Several members expressed frustration with centers that hold onto organs for too long, delaying the process for other patients. There was also discussion about organs out of sequence, which has added complexity to the system.

One member shared a personal experience where a highly sensitized patient with a 98% CPRA (Calculated Panel Reactive Antibody) score had only received one offer in 10 years. When a suitable kidney finally became available, there was a breakdown in communication because of how the offer was made. The OPO had placed the kidney on a pump, but due to missing information, such as laterality, the center did not formally accept it in time. By the time the issue was resolved, the kidney was no longer available. The member expressed concern that OPOs and transplant programs are creating protocols outside of the official OPTN (Organ Procurement and Transplantation Network) guidelines, which undermine the regulatory framework and disadvantages patients.

One member pointed out that the two sides, OPOs and transplant hospitals, are not aligned from a regulatory perspective, which often leads to finger-pointing rather than solutions. Another noted that OPOs are frequently blamed, and there are now efforts to classify centers into tiers based on their level of aggressiveness in accepting organs. However, unlike OPOs, transplant centers do not have the same CMS guidelines, which adds to the complexity. The group acknowledged that significant changes could be coming by the end of the year, with up to 40% of OPOs potentially being merged or shut down, impacting the entire transplant community.

Lastly, a member mentioned the importance of standardizing what a back-up offer means, as it could bring more clarity to the organ allocation process, especially late declines.

Next steps:

None at this time.

6. Public Comment Presentation: Promote Efficiency of Lung Donor Testing

Summary of discussion:

The Committee supports this proposal as written.

The Committee discussed the proposal and submitted the following official feedback:

The OPTN Transplant Coordinators Committee thanks the OPTN Lung Transplantation Committee for the chance to comment on this proposal. The Committee suggests considering the following:

How to implement the recruitment information requirement in DonorNet. The Committee recommends working with the OPTN Contractor IT department to create specific data fields for this information.

The impact on rural programs or those with limited staff. The 2-hour testing requirement before the initial offer might slow down organ allocation, as the process may need frequent repetition. The Committee suggests extending this time to 3 or 4 hours.

The risks of expanding image sharing beyond DonorNet. The Committee advises caution, as viewing patient data on personal devices like phones or tablets could pose security risks.

Next steps:

The Committee will summarize their feedback in a public comment response.

7. Public Comment Presentation: Continuous Distribution of Livers & Intestines Update, Summer 2024

Summary of discussion:

The Committee supports this update.

The Committee discussed the proposal and submitted the following as official feedback:

The OPTN Transplant Coordinators Committee thanks the OPTN Liver and Intestine Transplantation Committee for this update on their continuous distribution work. The Committee recognizes the difficulty in developing an equitable allocation and distribution system. The Committee cautions against unintentionally creating disadvantages by awarding points to patients who are listed at centers which have historically accepted complex offers.

Next steps:

The Committee will summarize their feedback in a public comment response.

8. Public Comment Presentation: Continuous Distribution of Pancreata Update, Summer 2024

Summary of discussion:

The Committee supports this update.

The Committee discussed the update and submitted the following official feedback:

The OPTN Transplant Coordinators Committee thanks the OPTN Pancreas Transplantation Committee for updating them on their continuous distribution work. The Committee agrees that more training is needed for pancreas procurement, as the pancreas is a very delicate organ to procure.

To increase pancreas utilization, the Committee suggests:

Having 1 or 2 specialists in each region who can be resources for pancreas procurements.

Instead of requiring a dedicated pancreas program director (due to low volume), having a lead surgeon with pancreas transplant experience to serve as a "pancreas champion" at programs and centers.

The Committee also recommends the Pancreas Committee review, in collaboration with the Scientific Registry of Transplant Recipients (SRTR), post-transplant survival metrics as well as the current graft failure definition

Next steps:

The Committee will summarize their feedback in a public comment response.

9. Public Comment Presentation: Continuous Distribution of Kidneys Update, Summer 2024

Summary of discussion:

The Committee supports this update.

The Committee discussed the update and submitted the following official feedback:

The Committee supports the idea of setting thresholds for "hard-to-place" kidneys, believing this could improve kidney utilization. They suggest using the top 10 in the allocation sequence as a threshold, which could ensure these hard-to-place organs are allocated and used appropriately.

The Committee also agrees that a clear definition of "hard-to-place" is needed. They suggest that even a scale-based definition could provide valuable insights into why some kidneys are not used or utilized.

Additionally, the Committee encourages and is in support of making offer filters mandatory. This could help identify which types of kidneys programs consider "hard-to-place."

Next steps:

The Committee will summarize their feedback in a public comment response.

10. Policy Operationalization Checklist Project

The Committee finalized their work on the Checklist and discussed work instructions to ease use of the checklist once it is in circulation.

Summary of discussion:

The Committee finalized the document.

Members broke out into 4 discussion groups and reviewed their respective topics: Process Changes; Compliance; Resources; Programming/IT Changes.

Process Changes:

Members discussed the need to identify the starting point for when the change will occur at the center. Additionally, it was highlighted that the risk for change would need to be assessed, so that members can be aware, prior to implementation, of potential process disruptions and work-flow alterations that could affect their day-to-day.

Compliance:

Members proposed committees ask whether a change is driven by patient safety concerns, a minimum quality standard, or simply an administrative requirement. This distinction helps prioritize the importance of the change and determine whether it warrants auditing.

It was acknowledged that depending on the policy, compliance needs might vary, and this would need to be addressed in policy development. It was also noted that external stakeholders can play a significant role in how operationalization plays out. It was recommended to emphasize the importance of understanding who the key stakeholders are and what their roles entail for policy operationalization. For example, external labs might need to align their services with the organization’s processes. Collaboration with external stakeholders is crucial to ensure smooth implementation of compliance-related changes.

A final recommendation was made that policies should give guidance on what is a reasonable expectation for determining compliance.

Resources:

Members recommended toolkits as a suggested option to aid in policy operationalization. These toolkits would provide staff with practical tools, resources, and examples to reduce confusion and streamline the implementation. By offering a "packaged" solution, teams will not have to start from nothing, which can save time and prevent errors.

Programming/IT Changes:

Members focused on the technical aspects of implementing process changes, particularly the need to identify the data required for compliance or operational purposes. Data collection and integration are critical considerations when making policy or procedural updates.

It was recommended that if new policies require changes to how data is recorded or tracked, the EMR systems might need updates. A member suggested that new builds within EMRs need to be considered during the policy process, as making changes to these systems can be complex and resource intensive.

Members also acknowledged IT changes often require additional analysts, developers, and other technical resources. It was emphasized the need to consider the cost of these IT and programming updates early in the process. These costs might include not only labor but also software, hardware, and long-term maintenance.

Next steps:

This feedback will be summarized and incorporated into the Checklist being drafted.

11. Open Discussion & Closing Remarks

Summary of discussion:

No decisions made.

Members discussed the items mentioned at the beginning of the day, including A2B kidney transplants and ABO incompatibility, as well as struggles with the PHS guidelines.

One member expressed concerns about the language in transplant policies regarding ABO incompatibility, suggesting that the term "incompatible" should be changed to "intended incompatible" for A2B kidneys.

An OPTN contractor staff member clarified that current policy identifies incompatibility based on primary blood type and emphasized that not all centers perform A2B transplants. Therefore, it is difficult to assume an A2B kidney is always "intended incompatible."

A member recommended a toggle option within the OPTN DonorNet system as a potential solution, so that staff can indicate whether it is intended incompatible or not. The member highlighted that current OPTN source documentation makes it difficult when in the Operating Room as there is not enough clarity on the permissiveness of ABO incompatibility for A2B kidneys.

A member raised the need to streamline policies and documentation across transplant programs. They mentioned a UNOS release and asked whether all centers had specific language included in consent forms, specifically informing patients that their data would be collected by third parties like UNOS. Other members highlighted that it is part of the language they include for their general informed consent documentation but do not have a specific document for patients to sign regarding 3rd party data collection.

One member described significant operational difficulties and financial burdens their center faces due to PHS-related testing requirements. They noted that the center had spent over $350,000 in nine months on PHS baseline panels, with individual tests costing $2,538 per patient. A key issue is the inability to rerun labs when a patient is readmitted within seven days, leading to corrective action plans and desk

audits. This member questioned the clinical relevance of a strict 48-hour difference between testing panels and suggested the need for flexibility, particularly given varying lab costs and availability across the country. Another member agreed, highlighting the burden this testing imposes, especially for infants.

A staff member explained that any changes to PHS-related policies would require action from the CDC, as the guidelines are based on CDC requirements. They acknowledged that previous feedback had already led to a reduction of the donor behavioral risk assessment window from one year to 30 days, suggesting the possibility of future revisions if the CDC is willing to consider it. A separate staff member added that the requirement for testing during hospital admission is directly tied to CDC guidelines, and any changes must be approved by the CDC.

A member raised concerns that putting policies out for public comment may create the false impression that these policies are community-driven, based on CDC guidelines.

Next steps:

None at this time.

Upcoming Meetings

- October 17, 2024
- November 21, 2024
- December 19, 2024

Attendance

- **Committee Members**
  - Amy Olsen
  - Ashley Hamby
  - Courtney Risley
  - Ashley Cardenas
  - Brandy Baldwin
  - Eve Cabatan
  - Heather Bastardi
  - Katherine Meneses
  - Kati Robinson
  - Stewart Jusim
  - Karl Neumann
  - Kenny Laferriere
  - Stacy McKean
  - Christine Brenner
- **HRSA Staff**
  - Arjun Naik
  - Kala Rochelle
- **UNOS Staff**
  - Cole Fox
  - Stryker-Ann Vosteen
  - Kim Uccellini
  - Lauren Motley
  - Lindsay Larkin
  - Houlder Hudgins
  - Meghan McDermott
  - Ross Walton
  - Shandie Covington
  - Joann White
  - Susan Tlusty
  - Tamika Watkins
  - Kaitlin Swanner
  - Eric Messick
- **Other attendees**
  - Andrew Kao
  - Ty Dunn
  - Gerald Morris
  - JD Menteer
  - Marie Budev
  - Shimul Shah