OPTN Patient Affairs Committee
Meeting Summary
August 20, 2024
Conference Call

Molly McCarthy, Chair

Introduction

The Patient Affairs Committee met via Teams teleconference on August 20, 2024, to discuss the following agenda items:

1. Welcome and Announcements
2. Regional Meetings: Feedback on Engaging Patients and Families
3. Public Comment Preparation
4. Review of Proposal to Revise Conditions for Access to the OPTN Computer System
5. Public Forum

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

1. Welcome and Announcements

The Chair welcomed attendees to the call. The in-person meeting will be held on September 20, and additional information related to public comment review and meeting logistics will be circulated in the coming days. Members were reminded to book their travel to Detroit if they have not already done so.

A change in agenda was acknowledged due to speaker availability. The Committee will receive a previous of the Network Operations Oversight Committee (NOOC) proposal. Due to this late change, the Chair acknowledged that many Committee members have probably not had the opportunity to read this proposal in full.

Members were reminded about the PAC Directory templates that were circulated by email. This is meant to create an inter-committee tool to remember names and faces. In the interest of respecting privacy, members were asked to fill out the form and submit a picture if they wished to participate. Members were encouraged to submit but reminded that this is an optional activity.

2. Regional Meetings: Feedback on Engaging Patients and Families

> The Committee did not make any decisions.

Committee members shared experiences from regional meetings held to date.

Summary of presentation:

A list of meetings that have been held to date was shared with the Committee. OPTN Contractor staff thanked regional representatives for their thoughtful sharing and presentations at the meetings. For this cycle, any patient or caregiver in the meeting was encouraged to introduce themselves and share their story. This model included this open call followed by the PAC member offering a final introduction and leading into the Committee's update.

Summary of discussion:

The Chair sought feedback from Committee members who have attended regional meetings to date. One member shared that he learned a lot listening to the various presentations. Another members shared that he enjoyed the powerful comments and insights, including challenges of managing older recipients who have had their organs for decades with success. One participant shared that a negative story was shared by a recipient at his meeting but recognized that it is important for the clinical audience to hear about challenges post-transplant. There was also a comment shared about expenses related to greater travel with continuous distribution related to longer travel. Some centers choose to contract with private airlines for organ retrieval and then have the expense of the flight. The OPTN Contractor staff noted that while most kidneys fly commercially if too far from donor hospital to allow for courier delivery, charter planes are often used by hospitals to send teams out to recover other organs. A member also shared that a public company that makes transplant devices for organs has now invested in its own fleet of jets to provide this service for organ transport. Committee members also discussed continuous distribution and its determinations for placement order on the match run. There were concerns that factoring in possible outcome could be harmful, with one individual noting that at the time of her transplant her chance of survival was quite poor. There was also concern regarding coastal regions losing part of their 250 nautical mile circle.

The Chair noted that an update on the first year of lung continuous distribution will be offered during the in-person meeting to determine if more transplants have occurred and whether organ non-use has increased or decreased. This was noted as important, as all other organs are moving toward continuous distribution as an allocation model.

3. Public Comment Preparation

> The Committee did not make any decisions.

Committee members received an overview of the process planned to prepare for public comment review.

Summary of presentation:

The Chair shared that two proposals were selected by Committee leadership for full Committee review and response: (1) The Network Operations Oversight Committee's proposal to revise conditions for access to the OPTN Computer System; and (2) the Lung Transplantation Committee's proposal to promote efficiency of lung donor testing. In previous public comment cycles, more proposal might be selected, but the Chair noted that reducing the number allows the Committee to really do a deep dive in what can sometimes be challenging, complex material.

Committee leadership shared that the PAC has historically divided into teams to review selected proposals, with team leaders identified from the Committee membership. Members are asked to review the proposals independently and complete a survey that includes general requests for sentiment and comment alongside any specific questions included in the proposal itself. The team leader will review the results of the survey at the September 10 meeting in Detroit after the Committee here proposal presentations from sponsoring committees. A final Committee response for each proposal will be drafted at the conclusion of these discussions and approved before submission on the OPTN website.

Committee members were asked to review the assigned proposals and complete the corresponding survey once it is circulated. All Committee members were encouraged to review any additional proposals that they wish to share their own personal thoughts on, but were reminded that any individual responses should not imply general PAC support.

Next Steps:

OPTN Contractor staff will prepare surveys and alert committee members to their assigned proposal for review. A review of the survey results and follow-up discussion will take place at the September 10 meeting in Detroit.

4. Review of Proposal to Revise Conditions for Access to the OPTN Computer System

> The Committee did not make any decisions.

The Committee received a presentation from the Chair of the Network Operations Oversight Committee on its proposal to revise conditions for access to the OPTN Computer System[1].

Summary of presentation:

The proposal's purpose is to enhance the security of the OPTN Computer System by revising access conditions. This would expand accountability for securing the OPTN computer system to business organizations who access the OPTN Computer System. The proposal would require all members with system interconnections to the OPTN Computer System to develop an Interconnection Security Agreement (ISA) with the OPTN.

Proposed changes include:

- Require all members, with 3rd party vendors who access the OPTN Computer system through the member, to develop an Interconnection Security Agreement (ISA) with the OPTN

- Require any business member who accesses the OPTN Computer System to follow the same information security requirements as other members

- Require OPTN membership as a condition of access to the OPTN Computer System and reduce potential barriers to OPTN business membership

- Limit reasons for access to the OPTN Computer System

Summary of discussion:

After thanking the NOOC Chair for his presentation, the Committee Chair opened the floor for questions.

The Chair asked if the OPTN computer system is directly involved in organ transplant logistics. While the match run would be consulted to determine donor identification and recipient location, the logistics are not managed within the OPTN system.

The Chair asked if there was a fee or cost associated with getting access to the OPTN Computer system. OPTN Contractor Staff noted that while there may be costs associated to becoming an OPTN members, there is no cost to accessing the system itself. Costs related to membership are related to making sure that the standards are met to meet membership requirements.

A member questioned whether general research would be able to access OPTN data going forward. The SRTR was raised as an example of needing access to the system. The member questioned whether this was restricting individuals based on work or organization function. The presenter noted that SRTR has a separate contract with HRSA related to system access. The presented shared that individuals would not be able to access the OPTN computer system directly solely for the purposes of research. (OPTN

---

[1] https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/revise-conditions-for-access-to-the-optn-computer-system/. Accessed 9/12/2024

dashboards, data, and metrics reports remain available on the website and specific data requests may be submitted to the OPTN for research purposes).

A Committee member asked if there were security profiles or classifications attached to vendors who access the system based upon their data needs. The presenter confirmed that the goal is to allow the user the least amount of access necessary to do their approved job within the system. An example of a hospital quality assurance program staff member was offered and the type of data that they may need access to in order to complete their job. The Committee member followed up to inquire whether permission level was granted manually, but the presenter was not able to answer this question.

A member asked if there was basic anonymization of the data in cases where personal information is not necessary. An OPTN contractor staff member noted that there is anonymization for data requests, but that some identifying information is necessary on match runs to ensure recipient identification on the match run in real time when considering offers.

A member asked if there was a specific security or privacy incident that is causing concern leading to this proposal. The presenter noted that he was not aware of any specific incident, noting that this is seen as part of system modernization.

The rigor involved in any periodic review of access to confirm whether it is still needed or should be revoked was also questioned. The presenter noted that every member organization has two security contacts, and that these members are expected to report changes to access within 243 hours (e.g. someone is fired). OPTN Contractor staff noted that there are existing security audits that members need to go through in terms of reviewing user access to their system. This piece is already in process and this proposal seeks to extend these requirements currently in place for organizational members to extend to business members.

The Chair thanked the presenter for his time, noting that the Committee's questions are demonstrative of many having expertise in this area in their day jobs. With these questions, she noted there was an offer to help as well.

Questions from the online chat regarding this topic will be folded into discussion in the in person meeting next month.

Next Steps:

Committee members will review the written proposal and complete the survey when it is made available in preparation for discussion during the September 10, 2024, meeting in Detroit.

5. Public Forum

No public forum requests were submitted for discussion.

Upcoming Meetings

- September 10, 2024 (Detroit, MI)
- October 15, 2024
- November 19, 2024
- December 17, 2024
- January 21, 2025
- February 18, 2025
- March 18, 2025
- April 15, 2025

- May 20, 2025
- June 17, 2025

Attendance

- **Committee Members**
    - Molly McCarthy
    - Lorrinda Gray-Davis
    - Michael Brown
    - Elizabeth DeVivo
    - Garrett Erdle
    - Calvin Henry
    - Robert F. Johnson
    - Wendy Leavitt
    - Karlett Parra
    - Andreas Price
    - Cathy Ramage
    - Cody Reynolds
    - Michael Slipowitz
    - John Sperzel
    - Jenny Templeton
    - Steven Weitzen
    - Justin Wilkerson
- **HRSA Representatives**
    - Mesmin Germain
    - Robert Johnson
- **UNOS Staff**
    - Shandie Covington
    - Houlder Hudgins
    - Desiree Tenenbaum
    - Lindsay Larkin
    - Kimberly Uccellini
    - Rob McTier
    - Morgan Jupe
    - Cole Fox
- **Invited Speaker**
    - Andrew Kao