OPTN Network Operations Oversight Committee
Meeting Summary
November 20, 2023
Webex

Daniel Yip, MD, Chair

Introduction

The Network Operations Oversight Committee (NOOC) met via Webex on 11/20/2023 to discuss the following agenda items:

1. Welcome
2. Current State of Third Parties in the OPTN Computer System
3. Q&A: Dashboard & Metrics Questions

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

1. Welcome

Dan Yip, Chair of the Network Operations Oversight Committee (NOOC), welcomed committee members and provided an overview of the agenda.

Terry Doolittle, Member Security Program Manager, provided a member security update to the committee and shared that the first round of member attestations have begun.

2. Current State of Third Parties in the OPTN Computer System

Courtney Jett, Policy Analyst, presented on the current state of third parties in the OPTN Computer System. Ms. Jett explained that the goal of the conversation was to review the current state of third-party organizations in the OPTN Computer System for the committee to discuss the future state of third-party access in OPTN Policies and Bylaws. Ms. Jett explained that the committee would be reviewing the potential impact of third parties within the OPTN Computer System, reasons for access to the OPTN Computer System, and the structure for granting permissions to the OPTN Computer System.

Ms. Jett shared background on the current state of third parties in the OPTN Computer System. She shared that the NOOC requested additional information on the third-party impact for systems access and structure of granting current permissions to determine necessary policy and bylaw changes. Ms. Jett shared that the reasons for access from the last business review were de-identified and emailed ahead of the meeting for the NOOC to review. She shared that the OPTN does not have access to copies of the data use agreements (DUAs) or contracts between member organizations and third parties. She shared that the OPTN can determine how many users a third-party has and how many offers are first screened by a user whose role is at a third-party. She shared that currently, six OPTN business members do not have OPTN Computer System access.

Ms. Jett shared that third parties with OPTN Computer System access range in size from 0-177 users whose primary affiliation is with the third-party. Ms. Jett shared third-party response to organ offers from 1/22/2021 to 1/22/2022, noting that 29% of all organ offers were initially responded to by a third-party. She shared that 98.9% of all transplant programs had at least one third-party initial response.

Ms. Jett presented the reasons why third-party users are permitted to access the OPTN Computer System. She explained that all the reasons for access are acceptable per the current *OPTN Policy 3.1.D*. Ms. Jett shared that HRSA has informed the OPTN Contractor that the OPTN may not have authority to allow access to OPTN data for organ transplantation research purposes. She explained that this would require HRSA review and approval through the standard patient-identified data request pathway or organ procurement organizations (OPOs) could provide donor data from their electronic medical records (EMRs). Ms. Jett asked the NOOC to consider if there are any other reasons third-party users should not be permitted access to the OPTN Computer System.

Ms. Jett explained the permissions structure currently in place when granting third-party users access to the OPTN Computer System. She shared that transplant hospitals, OPOs, and histocompatibility labs are added to the OPTN Computer System and may grant permissions to specific types of OPTN patient data within specific applications to users. Site security administrators at transplant hospitals, OPOs, and histocompatibility labs can search for active OPTN Computer System users at other organizations, such as third parties, and add them to existing security groups or create a new security group with appropriate permissions. She noted that users at third-party organizations have no access to OPTN patient data without being assigned permissions by a member institution.

Ms. Jett explained the process of granting organizational permissions to the OPTN Computer System. She shared that third-party organizations provide reasons for required access to the OPTN Computer System and the OPTN Contractor reviews this for alignment with reasons for access in *OPTN Policy 3.1.D*. The OPTN Contractor then reviews DUA excerpts with members to determine that the requirements of *OPTN Policy 3.1.D* are being fulfilled. Then, if reasons for access are aligned and the DUA excerpts fulfill policy requirements, an organization is created in the OPTN Computer System. This does not create any individual user accounts; those must be requested separately by the business point of contact.

Ms. Jett presented how individual user access is granted to third parties. She shared that third-party organizations representatives request accounts for individual users in the OPTN Computer System through a new business user request form to the OPTN Contractor. Ms. Jett shared that this form includes name, position, contact information, associated member institutions, and business functions/job duties. The OPTN Contractor's System Terms of Use and OPTN Policy are linked in the form. She explained that the OPTN Contractor reviews the request and creates a user account if the business functions/job duties are aligned with reasons for access in *OPTN Policy 3.1.D*.

She noted that the OPTN Contractor does not grant access to any data or security group, and that the OPTN Contractor approves credentials, while the institutional member is the one to provide access. Ms. Jett explained that Site Security Administrators at each transplant hospital, OPO, or histocompatibility lab assigns permissions based on Principle of Least Privilege to access data within the OPTN Computer System. She noted that these users are included in the transplant hospital, OPO, and histocompatibility lab user audits performed three times a year to ensure appropriate permissions are granted within the system.

Summary of Discussion:

The committee discussed if there were any reasons why members are granted access to the OPTN Computer System that are not appropriate. A committee member noted that members seeking access to provide family services and support is not a reason to access the OPTN Computer System. Contractor staff noted that this work does fall outside of current policy.

A committee advisor stated that there could be more oversight and regulation of vendors by the contractor, most notably because over one-third of organ offers are made by third parties. The

committee chair suggested that the NOOC inform the contractor of the guidelines for when a third-party may access the OPTN Computer System. A committee member asked if the Membership and Professional Standards Committee (MPSC) could review the applications from third parties. Contractor staff explained that currently, applications are reviewed by the contractor and not by any other OPTN group. The committee member suggested that contractor staff continue to review the applications and have the NOOC provide final approval for access.

A committee advisor commented that the definition of third-party members does not allow the OPTN Contractor sufficient oversight. They stated that they do not believe having the NOOC review and approve applications would make the process any different because third-party members are still handling one-third of organ offers. They noted that the contractor does not have a course of action to take in these situations other than acting through the member the third-party is contracted with. A committee advisor agreed that there may be another pathway to review these requests other than having the contractor solely review the requests. Contractor staff explained that based on previous conversations with the NOOC, the committee wanted to require an additional level of oversight of third parties. They shared that one suggestion was to require them to become OPTN members.

The committee chair asked the NOOC to consider whether there should be a requirement that a user must be a member or a business member of the OPTN in order to access the OPTN Computer System. They asked whether the committee thought there were any negative consequences of requiring membership and how to approach recourse actions if policy is not followed. A committee member commented that there needed to be some form of accountability for third-party users of the OPTN Computer System. A committee advisor commented that because third-party users are granted access through a member they are working on behalf of, there is not consistency in approving these users. The committee advisor suggested that there be a formal process with the contractor to have DUAs and member agreements with every organization that accesses the OPTN Computer System. They also suggested that non-member organizations that access the OPTN Computer System should not be the responsibility of the member they are acting on behalf of but should be the responsibility of the contractor. The committee advisor stated that they did not believe the NOOC should review and approve every non-member and there should be policy and procedures in place so the contractor can act on behalf of the NOOC. A committee advisor commented that it is difficult for members to see what third-party users are accessing within the OPTN Computer System on their behalf, unlike the contractor.

Next Steps:

The committee chair concluded the discussion by summarizing the NOOC's sentiments. They shared that if access is desired to the OPTN Computer System, then a user must be an OPTN member or OPTN business member. They asked Ms. Jett to bring policy language to a future meeting formalizing these points.

3. **Q&A: Dashboard & Metrics Questions**

Contractor staff provided information on the metrics and dashboards, which had been provided to the committee ahead of the meeting,. They explained that the dashboard shows how much data is submitted through the electronic system by utilizing APIs. Contractor staff explained that the metrics provided show different measurements collected by the OPTN, including organ response time, what events lead to unexpected downtime, and additional elements deemed important by the NOOC.

Summary of Discussion:

Multiple committee members and advisors agreed that the dashboards were satisfactory. A committee advisor asked representatives from HRSA if the dashboards were satisfactory in meeting their requirements.

A committee member asked if the dashboards are measuring the right things and how often the dashboards are updated based on suggestions from the NOOC. Contractor staff explained that the metrics are frequently analyzed internally, and reports are provided to the NOOC on a quarterly basis to ensure the right elements are being measured. The committee chair commented that they would like to see improvement in the data electronic submission rates. The committee discussed why the rate of data electronic submission is low in certain areas of data collection and what the potential burden is to members. They discussed that the vendor a member utilizes in their API adoption can affect their submission rate. A committee advisor stated that members are not going to fully adopt APIs if it is not mandated. They commented that if the OPTN wants the utilization of APIs to increase, then the OPTN should mandate the use of APIs because until then, members are going to prioritize other work. The committee chair agreed that until the OPTN makes APIs usage a requirement, then there is going to be slow adoption of APIs. Contractor staff noted that if API adoption became a requirement, it would need to be required through OPTN Bylaws or Policies. A committee advisor suggested that HRSA consider mandating the use of APIs in their modernization efforts.

4. Closed Session

The committee met in a closed session.

Attendance

- **Committee Members and Advisors**
  - Andrew Kao
  - Bruno Mastroianni
  - Colleen McCarthy
  - Daniel Yip
  - Edward Hollinger
  - James Pittman
  - Kelley Hitchman
  - Willscott Naugler
- **HRSA Representatives**
  - Adriane Burton
  - Cle Diggins
  - Cliff Myers
  - Daniel Thompson
  - Jacqueline Rodriguez
  - Manjot Singh
  - Nick Lewis
  - Vanessa Arriola
  - Vinay Vuyyuru
- **UNOS Staff**
  - Amy Putnam
  - Anna Messmer
  - Bonnie Felice
  - Jerry DeSanto
  - Julie Chatman
  - Kristine Althaus
  - Laura Schmitt
  - Lauren Mauk
  - Liz Robbins Callahan
  - Marty Crenlon
  - Michael Ferguson
  - Morgan Jupe
  - Rob McTier
  - Robert Emerson
  - Roger Vacovsky
  - Sara Moriarty
  - Terry Doolittle
  - Tiwan Nicholson
  - Tynisha Smith