

OPTN Network Operations Oversight Committee

Meeting Summary

January 23rd, 2023

Webex

Edward Hollinger, MD, PhD, Chair

Introduction

The Network Operations Oversight Committee (NOOC) met via Webex on 01/23/2023 to discuss the following agenda items:

1. Welcome
2. Progress Update on NOOC Security Project
3. TRF Update
4. Review OPTN IT Project Roadmap

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

1. Welcome

Ed Hollinger, Chair of the Network Operations Oversight Committee (NOOC), welcomed the committee members and gave an overview of the meeting agenda.

2. Progress Update on NOOC Security Project

Terri Helfrich, UNOS Director of Information Security, provided an update on the NOOC security project. Ms. Helfrich presented the proposed timeline for implementation, the controls and proposed scoring, and the proposed monitoring framework. The proposed timeline is contingent upon Board approval in June 2023 and upon budget approval. The timeline was broken into different phases for pre-board actions, the initial project phase, attestations, audits, and continuous monitoring. The group decided to share member expectations from the timeline during regional meetings to give members a better idea of the proposed project timeline. Representatives from HRSA confirmed that the proposed timeline looked acceptable to them as well.

Ms. Helfrich also presented the controls and proposed scoring of the framework. She presented 14 control families and 110 controls that are outlined within those families. The goal is for the NOOC to implement a scoring method around risk and maturity, and provide expectations on scoring. Ms. Helfrich presented an example of a proposed framework that the committee could utilize for the proposed controls. She explained the weight of the scoring, the key of the measurements, and how this would help assess the maturity of a member's system.

Ms. Helfrich presented the proposed monitoring as multiple criteria. The OPTN proposed that the OPTN Contractor collaborate with members to remediate control deficiencies, and have the contractor monitor their scores to provide an overview to the NOOC on a monthly basis. The group also discussed what will occur when a member's score is below the desired threshold and when this issue would escalate to the NOOC, and what escalation to the NOOC means for members.

Summary of discussion:

A committee member asked when they thought the committee would have the control framework ready for members to begin their audit. The committee member worried that with Board approval in June 2023 and the deadline to complete the audit by December 31, 2023, that this would not be enough time for members. They asked when they would have an idea of what the assessment will look like and whether the first attestation could be used as a baseline for members rather than a measure they would be held to. They thought that the first attestation would be utilized by members to show where they are and what areas they may need to improve. Ms. Helfrich informed the committee that the initial attestation would work as a measure to see where members are in the beginning and what controls they already have in place. The goal is to have the assessment sent to members in July and to have their results back by December 31.

A committee member asked if the timeline is directly stated in the proposal so members are aware of the changes and are aware of when they need to be compliant by. If not, they suggested presenting the proposed timeline and receiving feedback on it while it is out for public comment. Rebecca Murdock, Senior Policy Counsel, informed the committee that the proposal is asking for feedback on the timeline at regional meetings and through public comment. The goal is to have the timeline solidified by the time the proposal goes before the Board, so Board members are aware of the impact this will have on members.

A representative from HRSA asked what the expectations are for members whose findings are low. While discussing controls and proposed scoring, a committee member asked if there was a passing score that members must receive or whether there were goals or targets members should strive for. Ms. Helfrich commented that she foresees the OPTN Contractor working with members to remediate control deficiencies with appropriate documentation and plans.

A committee member suggested they consider using a framework similar to what the MPSC uses for corrective action plans. They thought this was a good idea to use in this context, so the OPTN Contractor and members are working together to create a plan of correction and are aware of the plan of action. They emphasized that coaching rather than disciplining members, especially early in the process, will be essential. They also asked whether there was an opportunity to test the attestation the committee has put together for members to receive a baseline, this way members are aware of their status before the policy is implemented. Another committee member agreed that it was important to look at the differences across member types, but they emphasized the importance of looking at the differences within each member type and how size may play a role in a member's maturity level.

3. TRF Update

Michael Ghaffari, Director of IT Software Engineering, provided an update on Transplant Recipient Follow-up (TRF) forms. The OPTN collects follow up data for all transplants in TRF forms until a patient is no longer being followed. In December 2022, it was discovered that some validated adult TRF forms were missing required data. A validated TRF form means that the form has been submitted to the OPTN and the data has been confirmed to be complete and valid. It was discovered that in late August 2022, an error occurred while updating the metadata for the adult TRF forms during the implementation of changes that had been OMB approved. The standard validation for certain fields were inadvertently turned off and resulted in the system not catching when a member submitted a form with missing or invalid data, therefore marking the forms as validated before they should have been.

A formal Root Cause Analysis (RCA) is underway, interviews are being conducted, and the OPTN will share the results with the committee. The OPTN has corrected the metadata driving validation in December when the error was found. The forms will go back to members to complete, and special communication and reports will be sent to the affected hospitals.

This error affected less than 2% of the adult TRF forms submitted and validated between August 30th and December 21st, 2022. There was no impact on patients and there was no impact on compliance reports for patient safety. The OPTN will continue to monitor the incident and will provide updates to the NOOC.

Summary of Discussion:

A committee member asked if there was a list of elements that were missing from the forms. Mr. Ghaffari explained that in situations where a form was submitted too soon, then this could mean that the data could be missing or the data was not validated. There will be a communication directly to the affected members on what data needs to be resubmitted.

A representative from HRSA asked about the effect on patients and whether member institutions will have to follow up with their patients to collect this information. Mr. Ghaffari explained that this is data that members already have, the information just needs to be submitted into the OPTN system. There is no expectation that members will have to collect this information from patients to complete the form. The committee chair also added that this data is something that institutions already collect so they are not going to have to recollect the data, they will just have to input the data on the form.

4. Review OPTN IT Project Roadmap

Amy Putnam, Director of IT Customer Advocacy, presented a review of the OPTN IT project roadmap. Ms. Putnam explained the projects in terms of whether they were Board approved and when they were approved. For proposals that had not yet been approved by the Board, then she included the predicted date they would go before the Board. Ms. Putnam specifically highlighted the impact of the eGFR modification implementation and predictive analytics.

Summary of Discussion:

A committee member asked if the OPTN has the resources available to meet the proposed deadlines for the different projects within the outline. Ms. Putnam explained that the OPTN does have enough resources allocated and they are actively working to increase staffing and create new project manager roles. Another committee member asked if there were any potential projects that may affect resource allocation. Ms. Putnam assured the committee that they feel confident they are in a sound place in terms of resource allocation to address the necessary projects coming down the pipeline.

A committee member asked where necessary process and project improvement costs come into play and how those resources are allocated. Ms. Putnam explained that those projects will fit into the community priority project on the graphic and they are continuing to look ahead to understand the efforts that will be required to complete those efforts in the future. The committee member then asked how the OPTN focuses process improvements. They specifically noted the OPTN Donor Data and Matching System and the improvements that have been made recently and asked how the OPTN collects information on what is working well for members or what maybe users think could be improved. Mr. Ghaffari explained the vision of the OPTN Donor Data and Matching System and the difference between the mobile features and the desktop features. He spoke about improvements that they have planned for the OPTN Donor Data and Matching System.

Attendance

- **Committee Members and Advisors**
 - Bruno Mastroianni
 - Cliff Miles
 - Daniel Yip
 - Ed Hollinger
 - Jeff Sterrette
 - Kelley Hitchman
 - Kim Rallis
- **HRSA Representatives**
 - Adriana Martinez
 - Arjun Naik
 - Cliff Myers
 - Vinay Vuyyuru
- **UNOS Staff**
 - Alex Tulchinsky
 - Amy Putnam
 - Anna Messmer
 - Bonnie Felice
 - Bridgette Huff
 - Courtney Jett
 - Jason Livingston
 - Kristine Althaus
 - Liz Robbins Callahan
 - Marty Crenlon
 - Matt Belton
 - Michael Ghaffari
 - Morgan Jupe
 - Rebecca Murdock
 - Rob McTier
 - Roger Vacovsky
 - Susie Sprinson
 - Terri Helfrich
 - Tiwan Nicholson
 - Tynisha Smith