OPTN Policy Oversight Committee
Meeting Summary
December 12, 2022
Conference Call

Nicole Turgeon, MD, FACS, Chair
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Introduction

The Policy Oversight Committee ("Committee") met via Citrix GoToMeeting teleconference on 12/12/2022 to discuss the following agenda items:

1. NOOC Project
2. Debrief
3. Next Steps

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

1. NOOC Project

The Chair of the Network Operations Oversight Committee (NOOC) provided an update to the Committee on a proposal being developed by the NOOC. This proposal aims to improve the security of the OPTN systems by updating user and program requirements when using the OPTN systems. As the NOOC is an operating committee of the OPTN Board of Directors, this project does not require POC approval to move forward.

Data summary:

Background

- OPTN Contractor owns and operates OPTN Computer System to facilitate the match function and other support for transplant community

- OPTN Policy and Bylaws do not adequately outline requirements for member organization devices and systems that interact with the OPTN Computer System
  - Individuals are bound by System Terms of Use, but member organizations are not

- Not all members adhere to consistent security frameworks

- Goal: define how members interact with computer system and the associated security process

Project Purpose (NOOC)

1. Define baseline security requirements for all OPTN Members that interact with the OPTN Computer System

2. Develop a process to monitor security framework

3. Require notice to the OPTN if an incident occurs at OPTN member institution that accesses the OPTN Computer System or with software that exchanges data with the OPTN Computer System (i.e., ransomware attack of institution's EMR, data leakage at member institution, etc.)

The approach recommended by the proposal would require:

- Institutional members to comply with National Institute of Standards and Technology (NIST) 171 framework controls
- Member attestation of meeting baseline requirements
- Audit every three years
  - For noncompliant members:
    - Notice and timing for remediation
    - The OPTN will have the authority to deactivate system access for OPTN member institution
    - Develop a plan for reactivation
- Required reporting of incidents to the OPTN

The Executive Committee was supportive of improving the security system as well as the need to ensure consistency with standards across the healthcare industry. However, they wondered whether there would be significant impact on members due to cost, and whether this could cause the OPTN to lose members. Finally, they requested more details on how to enforce compliance.

Summary of discussion:

A member asked if there would be an educational component to the policy, as it sounded like this could be a major change for member organizations. The presenter replied that there would be and highlighted that the purpose of the proposal was to be collaborative rather than punitive. The member also asked whether personal devices that access the OPTN systems would be subject to this framework. The presenter responded that their committee was considering different levels of access for different devices, with the understanding that a completely secure approach would be entirely inflexible and unable to meet the demands of programs.

The Chair wondered if the presenter could elaborated on any anticipated member changes in responsibilities. He replied, stating that responsibility changes could vary between member organizations depending on their existing security frameworks; in addition, this proposal would provide more granularity to what needs to be overseen by security administrators.

The Chair asked whether the timing for the Board of Directors Meeting in June 2023 felt right. He responded that there were a lot of details that would still need to be managed, which was in part why it was being submitted for community feedback. However, once there was input on the proposed skeleton, the proposal would answer the broad questions that the Board would be considering. There was significant interest from the Health Resources and Services Administration (HRSA) for this update to progress, and delaying it was likely not an option.

Next steps:

The NOOC will consider the Committee's feedback and inform the POC of their progress prior to the Board of Directors meeting.

2. Debrief

The Chair and Subcommittee chairs provided a brief update from the December 2022 Board of Directors meeting in addition to the Subcommittee meetings that had occurred in November.

Data summary:

Highlighted Feedback:

- Consider impact on transportation in risk/benefit of projects
- Increase focus on efficiency and reducing organ non-use
- Opportunities for enhancing patient engagement
- Importance of appropriate resource alignment for policy priorities
- Post-implementation monitoring: improve parameters of project success

Summary of discussion:

A member supported the feedback emphasizing resource alignment for policy priorities; they felt that there was a delicate balancing act to not just allocate resources to the biggest items, but those that would have the greatest impact per resources allocated.

They continued, noting that the focus on transportation should be addressed by the Committee when reviewing new projects. They suggested that there could be a transportation committee or subcommittee. The Vice-chair supported the suggestion that transportation should be considered in new project review. This could be pertaining to organs, specimens, or humans, but there should be an area for transportation to be addressed.

A member wondered whether post-implementation can help inform the areas where modeling falls short; they felt that frequently they're told certain aspects cannot be modeled – they considered that solid and uniform post-implementation review could substitute for that. The Chair replied that the intersection of efficiency, reducing organ non-use, and equity has been thought to be continuous distribution, it has just taken a long time to achieve that goal. Once in a continuous framework, it becomes much easier to make minor adjustments to optimize those three priorities.

The SRTR representative contributed that accuracy in a predictive model is an ongoing process of refinement. For example, the non-use model is significantly by the acceptance and decline models, which also changes as it is a behavioral model. This was in part why the SRTR has moved away from using organ-specific simulation to an "OASIM", which more completely compares one policy to another. A limitation of the previous models was that they used the acceptance behavior from the previous data cohort to model how acceptance would change with a policy, which was very infrequently predictive of how adaptation to the policy would actually happen.

Finally, they added that, from an SRTR perspective, the work done by the Membership and Professional Standards Committee (MPSC) to separate quality improvement and monitoring/compliance will require a significant amount of work; they suggested it may need an entirely new committee.

Benefit Subcommittee Meeting Summary

The Subcommittee met and agreed not to completely rework how benefit is scored, but did agree on removing strategic plan alignment. They also would like to see more information on the form presented to the Committee members for review when scoring, such as population size. Finally, a question for the POC when reviewing the projects should be whether there are any potential risks or unintended consequences foreseen.

Post Implementation Monitoring Subcommittee

There was concern expressed from the group about how much bandwidth the Committee would have to review projects post-implementation. To account for this, they suggeseted having an automated review process for projects based possibly on size or scope, time after implementation, or priority (due to safety or other emergent issues).

Next steps:

3. Next Steps

The Chair reminded the Committee of the upcoming public comment cycle, as well as the POC's review of projects being released for public comment. In addition, they also reminded the Committee of the upcoming in-person meeting on March 24, 2023.

Summary of discussion:

There was no discussion surrounding this item.

Next steps:

Staff noted that an email will be distributed at minimum a month prior to the meeting requesting flights be booked.

Upcoming Meeting

- January 9, 2022

Attendance

- **Committee Members**
  - Nicole Turgeon
  - Jennifer Prinz
  - Andy Flescher
  - Dolamu Olaitan
  - Gerald Morris
  - Jesse Schold
  - Jim Kim
  - JonDavid Menteer
  - Lisa Stocks
  - Matthew Hartwig
  - Molly McCarthy
  - PJ Geraghty
  - Rachel Engen
  - Stephanie Pouch
  - Peter Stock
  - Kimberly Koontz
  - Scott Lindberg
- **HRSA Representatives**
  - Vanessa Arriola
  - Marilyn Levi
- **SRTR Staff**
  - Ryo Hirose
  - Ajay Israni
- **UNOS Staff**
  - Alex Tulchinsky
  - Anna Wall
  - Cole Fox
  - Courtney Jett
  - Isaac Hager
  - Janis Rosenberg
  - Kaitlin Swanner
  - Kieran McMahon
  - Krissy Laurie
  - Kristina Hogan
  - Kristine Althaus
  - Laura Schmitt
  - Lauren Mauk
  - Liz Robbins Callahan
  - Matt Cafarella
  - Rebecca Murdock
  - Robert Hunter
  - Roger Brown
  - Roger Vacovsky
  - Sally Aungier
  - SaraRose Wells

- o Sharon Shepherd
- o Susan Tlusty
- o Susie Sprinson
- o Taylor Livelli
- o Terri Helfrich
- o Tina Rhoades
- o Tynisha Smith
- o Morgan Jupe
- **Other Attendees**
  - o Edward Hollinger