OPTN Network Operations Oversight Committee
Meeting Summary
March 24, 2023
Webex

Edward Hollinger, MD, PhD, Chair

Introduction

The Network Operations Oversight Committee (NOOC) met via Webex on 03/24/2023 to discuss the following agenda items:

1. Welcome
2. OPTN IT Projects Roadmap
3. OPTN Security Project: Public Comment Feedback
4. OPTN Security Project: Incident Handling
5. OPTN Modernization Initiative Discussion

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 and gave an overview of the meeting agenda.

2. OPTN IT Projects Roadmap

Michael Ferguson, IT Portfolio Manager and Amy Putnam, Director of IT Customer Advocacy, presented the OPTN IT Projects Roadmap. The presentation provided an update on the OPTN Data Collection Package and a preview of the scheduling of June 2023 Board projects within the roadmap.

Ms. Putnam provided an update on the OPTN Office of Management and Budget (OMB) Data Collection Package that was scheduled to be implemented on May 31, 2023. It is stated within the OPTN Contract that OPTN data collection must be collected on approved OMB forms. Currently, all the applications, except Waitlist, are scheduled to be approved, while waitlist is scheduled to be approved in 2024. Ms. Putnam outlined the applications included in the May implementation. The specifics on each of these implementations are included in the IT projects roadmap.

Ms. Putnam explained the OPO Integration Pathway and the steps that OPO vendors take when it comes to implementing these data changes. She explained that currently contractors are in the process of developing functionality of these changes and plan to release the new version with functionality in June. Because there are multiple project changes going into the portal at once, it is estimated to take about two months to validate the changes from OPOs to ensure that everything is working appropriately before they release these new functionalities to staff. With all this in mind, it is estimated that the earliest possible date that transplant customers could be able to implement the new functionality would be August, and the earliest date that the OPO data vendors could implement these changes would be August 31.

Ms. Putnam explained what would happen if OPOs had to rush the implementation to meet the original implementation date of May 31. She explained that if it went live on May 31, the upload would still work for about 95% of donor records, however, it means that for every donor OPOs would need to go in and

manually enter around 5% of the data before being able to run a match. For DNR records, because 95% of DNR forms are currently transmitted electronically, if they moved ahead with the May 31 deadline and the changes were not in the system, this would mean that every OPO would need to complete all forms manually. For DDR forms, currently 75% of OPOs transmit forms electronically, this would mean that every OPO would need to manually complete all DDR forms until they were able to accept and validate the new software from their vendors.

Ms. Putnam explained that the process of validating functionality of implementing new data practices is also relevant for transplant centers. Transplant center data functions differ from OPOs because their data touches all areas of hospital functionality, not just transplant. With this in mind, the earliest possible date that transplant hospital members would be able to implement these data changes would be October 31. Currently, 40% of transplant hospitals transmit OPTN Data System forms electronically, so if the change were to go live on May 31, all forms would have to be entered manually.

The OPTN has already presented this information to HRSA, and the group decided that they would like these releases to stay within the fiscal year. So, the OPTN plans to contact each vendor to determine what could be done to try expedite the process so it is complete by the end of the fiscal year. The OPTN and HRSA discussed the OPTN requirement that data must be OMB approved and OPTN data forms must also be OMB approved. HRSA and the OPTN plant to work together to ensure that these operations are implemented in a timely fashion to meet the needs of the community.

Vendors provided feedback that they prefer fall releases and would like the OPTN to avoid January 1 release dates. After communicating with all OPO vendors and transplant center vendors, the decision was made for an OMB 2023 release date of September 14, instead of May 31.

The OPTN plans to alert all committees whose projects will be impacted by this change, inform all integrators of the September 14 date, and send notice to all users making them aware of the change. A representative from HRSA added that they wanted to make sure these data implementations were completed before the end of the current contract period, which currently corresponds with the fiscal year.

Mr. Ferguson presented an illustration on the OPTN IT Projects Roadmap and explained the expected implementation dates of all OPTN projects. He described each project that is included on the roadmap and the expected IT implementation timeframe they are projected to follow. Projects are broken down into the time they were approved by the Board, which includes 2020 approval, June 2021 approval, December 2021 approval, June 2022 approval, December 2022 approval, and the proposals that are expected to be approved at the June 2023 Board Meeting. Also included in the IT roadmap are the resources allocated to improve efficiency, integrate OPTN Computer System APIs, maintain community priority, as well as other administrative requests.

Summary of discussion:

A committee member asked if there are external factors that could challenge the roadmap timeline moving forward. Mr. Ferguson explained that some projects can move from approval to execution rather quickly, but the data collection projects are the projects that would likely have the most effect on altering the timeline. These projects have both an integrator impact and an impact on the overall timeline due to different integrators.

A representative from HRSA suggested the roadmap include critical deadlines for the committee's knowledge. Mr. Ferguson agreed to include this information in the April presentation when the committee takes a deeper dive into the IT projects roadmap. Mr. Ferguson also plans to include some high-level milestones in the roadmap to illustrate how these milestones fit into the standard timeline.

The committee will reevaluate the IT projects roadmap again at their in-person meeting in April.

3. OPTN Security Project: Public Comment Feedback

Dr. Ed Hollinger, Chair of the Network Operations Oversight Committee, presented public comment feedback received on the security project. The committee planned to review the public comment feedback, discuss potential modifications to the proposal based on the feedback, and to begin planning the operationalization of the policy.

During public comment, the committee reached out to different organizations and stakeholders for feedback. This included a presentation at all 11 regional meetings, presentations at multiple OPTN committee meetings, outreach to stakeholder groups such as AOPO and ASHI, and offering a public comment webinar on the proposal. Based on the feedback the project received, there was broad agreement that it is an important and necessary project. Community concern focused on operationalizing the project and how the committee plans to balance access to tools that are needed for transplantation with the resources that are needed for operational security.

Dr. Hollinger continued that themes in feedback focused on protecting patient data, balancing access to the OPTN Computer System with security, plans on how to reduce end-user burden, concerns about implementation being too quick, and recommendations to consider alternative measures. The need to balance access to the OPTN Computer System with security focused heavily on members being able to access the portal from their personal devices. Members commented that the OPTN needs to ensure access to the system doesn't become too cumbersome that it leads to a reduction in efficiency. Members also suggested permitting different levels of access when using a personal device, such as a read-only option. The main concern when it comes to balancing access and information is that there is no inadvertent harm to patients. When it came to reducing the end-user burden, members suggested reducing the duplication of existing training for individuals at member organizations and have the OPTN consider the redundancy of existing measures already in place. Members voiced concern about potential financial or operational burdens connected to these measures.

Dr. Hollinger also presented potential proposal modifications for the committee to consider. These modifications included training requirements, scope for attestations, the inclusion of transplant in business continuity planning, increasing communications on the state of security of the OPTN Computer System, and including guidance and education on using personal devices to access the system. Dr. Hollinger concluded the presentation by asking the committee to consider the operational components of the project.

Summary of discussion:

A committee member shared that when they presented to the Histocompatibility Committee, a member raised a concern about the requirement to have two representatives for each institution for site administrators. The member was concerned that this may be difficult to find in smaller organizations, especially in independent HLA laboratories. Terri Helfrich, Director of Information Security, responded that the explanation for members to have two representatives was to ensure there is a system of checks and balances in place. The concept is that there is not a single person providing access to people within the program while also signing off on an access review. The committee member agreed that this measure is sound but should be clearer in the policy language. Dr. Hollinger commented that the onsite contacts don't have to be IT professionals and that it is important to discuss how people can adhere to these requirements without expanding their resources.

4. OPTN Security Project: Incident Handling

Terri Helfrich, Director of Information Security, presented on cybersecurity incident planning within the proposal. The committee began developing operational guidelines for suspension and restoration of access for user and member accounts for the OPTN Computer System.

Ms. Helfrich presented some of the operational guidelines, including: ensuring every effort is made to continue lifesaving work of transplants, answering whether all threats are required to be assessed independently as there is no "one-size fits all" scenario, whether to allow the OPTN Contractor to act on behalf of the OPTN in specifically prescribed circumstances by the NOOC and what these incidents would be, when to allow the OPTN Contractor to provide fast responses to urgent situations on behalf of the NOOC and OPTN, and whether the NOOC should, at a minimum, review all incidents retrospectively.

Ms. Helfrich also presented on how the OPTN plans to classify an incident or a threat. She broke down an illustration of an example incident classifications. The illustration was divided into six categories which were classification, threat pattern, system impact, data impact, OPTN impact, and what the NOOC's delegated response actions would be. Classification of an incident could be marked as critical, high, medium, or low. Threat pattern could be identified as current or active and fast spreading, current or active and slow to moderate spread, current or active and not spreading, or historical not spreading. The impact the incident has on the system could be classified as critical where functions are out of service, reduced functions of critical systems, non-critical systems are out of service, or reduced functions of non-critical systems. OPTN impact can be categorized as PHI/PII/Proprietary data are impacted, unclassified data is impacted, or no OPTN data is impacted. The NOOC's delegated response actions were left open for the committee to discuss.

The committee discussed possible incidents or situations based on what the OPTN Contract outlines when it comes to revoking member or user access to the OPTN Computer System. The Contract provides language on how the Contractor shall support the NOOC in its efforts to develop criteria for suspending both OPTN member organizations and OPTN member user accounts from the network. The committee discussed certain scenarios and considered what actions they would take if an individual user account needed to be suspended, and what criteria would they need to consider when it comes to suspending access. Some examples of when user account suspension could occur: if there is a compromised OPTN account, if there has been a violation of HIPAA privacy laws, or if a confirmed data leakage by the individual has occurred. The committee was asked to consider if the list of incidents was comprehensive, whether there are incidents listed that shouldn't be, whether incidents should be phrased differently, or any other amendments the committee feels the list should address.

The committee also discussed what criteria to use when suspending member access. The committee considered incidents in the past that have warranted suspension of access and considered a list of potential reasons to suspend access. A few examples were if an administrative account had been compromised, if a malware or ransomware attack was identified and is systemic to the member organization, or if there had been an identification of data exfiltration from the environment.

Re-enabling access to the OPTN Computer System was also considered based on requirements listed in the OPTN Contract. The contract provides language on how the contractor shall support the NOOC in its efforts to develop criteria for what is needed to re-enable accounts after suspension and communicate this to the OPTN member. In the past, when incidents have occurred, the OPTN has asked members for proof from third party vendors to verify that there had been restoration to the system and that the system had been remediated.

Ms. Helfrich asked the committee to consider response time and to think about whether there are situations in which the OPTN Contractor needs to act in an urgent manner on behalf of the NOOC before the committee would be able to consider protections to the OPTN Computer System or associated data. She reminded the committee of the incident classification example and asked them to consider which level of criticality or classification the NOOC would delegate authority to the OPTN Contractor, if at all.

Summary of discussion:

A representative from HRSA asked how the NOOC envisions the process of identifying the need for suspension and whether this would be a proactive or reactive process. They asked if these responses would be triggered by an automated system or whether the OPTN would rely on the organization to notify them and then have the OPTN respond after notification. Ms. Helfrich explained that incidents will have an individualized approach depending on the situation, the threat, or the risk associated with any one of these things.

A committee member commented that the level of threat from a user who has access to APIs versus a user who has access to OPTN Donor Data and Matching System is very different. Someone accessing the OPTN Donor Data and Matching System on their phone and someone accessing the OPTN Computer System from a hospital computer are also very different circumstances. Based on feedback received, it is an important to remember that one size does not fit all when it comes to security incidents. It is important to consider scope and to consider what this could mean in terms of security and monitoring when it comes to individual cell phones, versus a hospital or OPO owned computer.

A representative from HRSA commented that what the committee is discussing in terms of suspension of OPTN user accounts at an individual level is part of a best standard practice. They do not believe it is unreasonable to implement these criteria as members may benefit from the OPTN putting them into place. A committee member commented that members would not disagree that security is a bad idea, but based on feedback they've received, the scope of the security must be taken into consideration. Because most transplant hospitals do not strictly practice transplant, it is important to remember other parts of an institution if an incident occurs and the OPTN is not one of the first people notified of the incident. Another committee member commented that they found people to be overwhelmingly supportive of the security action and the difficult part is how to operationalize these efforts. They asked Ms. Helfrich to disseminate the information shared with the committee, so they can take a closer look and bring feedback to the next meeting.

A representative from HRSA stated the importance of creating a process when the OPTN Contractor would be permitted to act on the NOOC's behalf. They noted that having the ability to act immediately can help ensure other users are not also impacted.

A committee member asked if the committee would have any time to discuss HRSA's recent announcement on the OPTN modernization initiative.

5. **HRSA Modernization Initiative Discussion:**

A committee advisor asked about HRSA's recent announcement to modernize the OPTN. They asked for clarity and more context on the modernization initiative, and thought it was important for HRSA to note the difference in the roles of the OPTN and SRTR. The advisor asked for insight on what HRSA means by a "modular modernization" of the OPTN IT system, and they asked what role the NOOC can anticipate when it comes to the modernization initiative. A representative from HRSA stated that the intent of the modernization initiative is an iterative modernization. They said that technology was not the main factor driving the change, it was patient safety. HRSA restated that the process was iterative. The advisor asked if HRSA could provide context on how they envision this process operating. They asked if, for example,

the plan was to create a whole new system that runs in parallel in a test phase to the current one while they work to modernize the system. A representative from HRSA explained that they are still in the early phases of planning and gathering data, and they hope to provide an update to the community next month.

A committee advisor asked if the NOOC, as the OPTN Committee that currently has oversight and responsibility over the IT system, will be engaged during the process. They voiced their concern that if the NOOC were not collaborated with, and the committee is unaware of any changes, the committee may not be able to make well informed decisions about strategy and innovation. A representative from HRSA confirmed that HRSA plans to engage stakeholders, and because the OPTN Board is a key stakeholder, and as a committee of the Board of Directors, the NOOC is a key stakeholder. They stated that the NOOC will be engaged by HRSA when the process begins.

A committee member asked if HRSA could provide insight on what the end goal of the modernization plan is. A representative from HRSA stated that they plan to issue multiple contracts to help improve the OPTN's operations. The details of how this process will unfold are something that HRSA is still trying to solidify but they ultimately would like to improve the functions of the OPTN system to meet the needs of the community. Another representative from HRSA stated that their focus is on patient's families and to ensure the system is serving their needs. They said that the operationalization of the modernization initiative moving forward will be informed by user and stakeholder research, which the NOOC will be involved with. They hope the community will help them create an understanding of what the "next-gen" of the OPTN will look like.

Next Steps:

A committee advisor asked that the discussion be continued to the next meeting in April as the discussion was cut short due to time.

Attendance

- **Committee Members and Advisors**
  - Clifford Miles
  - Daniel Yip
  - Edward Hollinger
  - James Pittman
  - Kelley Hitchman
  - Kimberly Rallis
  - Melissa McQueen
  - Paul Connelly
- **HRSA Representatives**
  - Adriana Martinez
  - Adriane Burton
  - Chris McLaughlin
  - Cliff Myers
  - Manjot Singh
  - Nick Lewis
  - Vinay Vuyyuru
- **UNOS Staff**
  - Alex Tulchinsky
  - Amy Putnam
  - Anna Messmer
  - Bonnie Felice
  - Bridgette Huff
  - Courtney Jett
  - Jason Livingston
  - Kristine Althaus
  - Krissy Laurie
  - Liz Robbins Callahan
  - Marty Crenlon
  - Matt Belton
  - Michael Ferguson
  - Michael Ghaffari
  - Morgan Jupe
  - Ralph Medina
  - Rebecca Murdock
  - Susie Sprinson
  - Terri Helfrich
  - Tynisha Smith