OPTN Histocompatibility Committee
Meeting Summary
December 13, 2022
Conference Call

John Lunz, PhD, D(ABHI), Chair
Gerald Morris, MD, PhD, Vice Chair

Introduction

The Histocompatibility Committee (the Committee) met via Citrix GoToMeeting teleconference on 12/13/2022 to discuss the following agenda items:

1. Welcome, Updates
2. Project Presentation: Network Operations Oversight Committee
3. Project Prioritization and Sequencing
4. Closing Remarks

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

1. Welcome, Updates

The Chair welcomed Committee members and gave an overview of the agenda for the meeting. He noted that the Change Calculated Panel Reactive Antibody (CPRA) Calculation implementation is now set for January 26, 2023. Staff explained there is now a two-factor authentication required for application programming interface (API) uploads.

Summary of discussion:

There was no further discussion by the Committee.

2. Project Presentation: Network Operations Oversight Committee

A visiting OPTN Board of Directors Member gave a presentation on a new project from the OPTN Network Operations Oversight Committee (NOOC) going to January 2023 public comment. She explained the OPTN Contractor owns and operates the OPTN Computer System to facilitate the match function and other support for the 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 currently bound by System Terms of Use, but member organizations are not, and security frameworks vary by member. The goal of this project is to define how members interact with the OPTN Computer System and the associated security process.

The proposed project will:

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 an 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 current proposed timeframe is as soon as possible, but within 24 hours of declared security incident

The recommended approach to enhance OPTN security policy is:

1. Institutional members must adhere to security framework policy developed by the OPTN that includes:
    - Compliance with National Institute of Standards and Technology (NIST) 171 framework controls specified by the OPTN
    - Annual member attestation of meeting baseline requirements
    - Independent external audit every 3 years
2. Consequences for non-compliance to security framework may include:
    - Notice and timing for remediation, partnership with the OPTN contractor for risk management
        - Escalation to NOOC for non-compliance concerns
    - Potential to deactivate system access for OPTN Member institutions in extreme situations to manage risk
        - Process to reactivation
3. Incident Response:
    - Report to the OPTN within specified timeframe of security incident at an OPTN Member institution

Feedback from the OPTN Executive Committee was overall supportive. Concerns were raised on member costs and scope of members based on member type and size. The OPTN Executive Committee suggested ensuring consistency with standards across healthcare industry and transplant systems.

The presenter asked the Committee for feedback on:

- What would be the anticipated changes in HLA lab operations?
    - Could this vary across different labs?
- Are there additional considerations for lab members that the NOOC needs to account for in the proposal?
- What support will labs need to implement this?

Summary of discussion:

The Chair stated increased security is an important concept going around healthcare systems in general. He noted the system is vulnerable as enhancements are made to the system. He suggested as the number of API utilized to port data across systems increases, lab informatic systems or other vendor software could facilitate this. He encourages broader engagements with vendors to protect and facilitate data. A member suggested involving the vendors and their security requirements in this proposal. The presenter asked why external access from these vendors are thought to be a vulnerability.

The presenter stated a large part of the conversation had by the NOOC revolves around the way that different people access the system. The Chair stated he uses personal devices and company provided devices when accessing the system, so he hopes that any system would not prohibit this dual use. A member agreed. The presenter asked how this would differ in reporting. A member asked if browsing patient information on personal devices will be targeted by this proposal, or if this only involves data being entered into the OPTN Computer System. The presenter stated the proposal will focus on personal

devices being hacked and the implication on the OPTN contractor. Guidance will be provided to determine this.

A member stated adequate safety will require institutions to administer secure computers to staff for OPTN usage. The presenter stated personal devices with required baseline security to access systems would be interesting to consider. She stated there are 49 independent HLA laboratories and 94 hospital-based laboratories that are OPTN members. She stated security could vary between these two member types.

A member asked how the OPTN contractor being vulnerable to attack is being addressed. The presenter stated that the OPTN contractor must notify HRSA or any member affected within one hour of being hacked.

The Chair asked what is considered a member. He asked if that is the overarching organization or the individual that is employed there. The presenter stated that the member is the actual organization, or HLA lab. The responsibility of the individuals under the member are also the responsibility of the member. This is the complication with personal devices.

A member stated that if virtual private network (VPN) is on personal devices, these devices are deemed to be safe, and this should be provided by employees' organizations. The presenter said this ensures actions are being taken on the organization's network. She asked how many members are required to do that by their institutions.

A member suggested requiring members to have an internal policy that deals with security breaches.

3. Project Prioritization and Sequencing

The Chair stated the Committee needs to reach consensus on project prioritization and ideal sequencing.

The Chair noted that Updates to Histocompatibility Policies and Guidance is set for August 2023 public comment due to anticipation for Centers for Medicare and Medicaid Services (CMS) Final Rule determination regarding virtual and physical crossmatching guidelines.

The Committee's priority will focus on removing calculated panel reactive antibody (cPRA) greater than 98% signatures for the kidney candidate form. This will reduce unnecessary administrative burden and can be completed for August 2023 public comment. Additionally, the Committee will focus on revising donor and recipient histocompatibility forms to update data collection on crossmatching and HLA typing for solid organ transplantation. The Vice Chair explained this will be an effort to collect data on whether a transplant did or did not occur based on crossmatch. This could potentially be ready for January 2024 public comment. Additional priority will focus on requiring molecular blood (ABO) typing for all donors to increase the accuracy and specificity of ABO typing. The Committee would develop questions for an organ procurement organization (OPO) audience on barriers to molecular ABO typing.

The Committee hopes to gain feedback on:

- Where do you typically have your ABO typings performed?
    - Where do you typically have your ABO subtypings performed?
- Who do you ask to resolve ABO typing discrepancies?
- Do any of your HLA lab partners offer molecular ABO typing or subtyping?
- Do any of your donor hospitals offer molecular ABO typing or subtyping?

<u>Summary of discussion:</u>

Members agreed to focus on removing cPRA greater than 98% signatures for the kidney candidate form.

A member asked whether the totality of the kidney candidate form will be examined to see if other areas of the form would need updating. The Chair responded yes.

The Vice Chair stated requiring molecular ABO typing is to address safety in cases of massive transfusion and allocation of non-A1 organs. He stated the Committee would need to determine if OPOs have access to molecular ABO typing currently. The Vice Chair noted the target audience is OPOs rather than HLA labs who are less likely to perform this testing.

A member agreed that it is important to get feedback from the OPO community. The member commented that it is one thing for an OPO to have the ability perform molecular ABO typing, but it is another thing if the OPO can perform molecular ABO typing every day. The Vice Chair reemphasized asking the OPO on feasibility is the most direct path forward. The Chair noted the lectin test currently used is not adequate and requiring molecular typing can help improve allocation and improve donor safety.

4. Closing Remarks

The Chair thanked the Committee for their participation and encouraged members to send any additional project ideas to Committee leadership.

Summary of discussion:

The Past Chair asked if the Committee could focus on requiring HLA typing for all match runs. The Chair responded that can be examined as future work. He listed future priorities as:

- Require HLA Typing Before Match Run for All Organs
    - This is already occurring for >96% of all thoracic match runs, and may be less time sensitive
- Update HLA Typing to WHO Nomenclature in UNet
    - Pending further consensus in the field on updated serologic groupings, p groups, and molecular antigen groups
    - Enterprise level IT effort
- Revise HLA Matching in Kidney Allocation
    - Base HLA matching points on haplotype frequency, potentially including DQ
- HLA equivalency table updates
    - Add Aw4
    - Expand p-groups

Upcoming Meetings

- January 10, 2023, 12 p.m. EST, teleconference

Attendance

Committee members:

- Andres Jaramillo
- Caroline Alquist
- Gerald Morris
- Hua Zhu
- John Lunz
- Kelley Hitchman
- Laurine Bow
- Manu Varma
- Omar Moussa
- Peter Lalli
- Qingyoung Xu
- Reut Hod Dvorai
- Valia Bravo-Egana
- William Goggins

SRTR Staff

- Katherine Audette

HRSA Representatives

- Jim Bowman
- Marilyn Levi

UNOS Staff

- Amelia Devereaux
- Alex Carmack
- Alex Tulchinsky
- Courtney Jett
- Susan Tlusty