

## **OPTN Organ Procurement Organization Committee**

### **Meeting Summary**

**February 16, 2023**

**Conference Call**

**Kurt Shutterly, RN, CPTC Chair**  
**PJ Geraghty, MBA, CPTC Vice-Chair**

### **Introduction**

The OPTN Organ Procurement Organization (OPO) Committee met via Citrix GoToMeeting on 02/16/2023 to discuss the following agenda items:

1. Improve Deceased Donor Evaluation for Endemic Diseases
2. Require Human Leukocyte Antigen (HLA) Confirmatory Typing for Deceased Donors
3. Establish Member System Access, Security Framework, and Incident Management and Reporting Requirements

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

#### **1. Improve Deceased Donor Evaluations for Endemic Diseases**

The Chair of OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC) provided an overview of this proposal. The DTAC Chair explained the possibility of an increase in endemic disease transmission due to the movement of populations and broader organ distribution. The proposal focuses on reducing the transmission of Strongyloides and Chagas due to the high potential for morbidity and potential mortality if transmitted to transplant recipients. The proposed solution is to require universal deceased donor screening tests for Strongyloides and antibody screening tests for deceased donors born in countries currently classified as endemic for Chagas by Centers for Disease Control and Prevention (CDC).

#### Summary of discussion:

A member noted that her OPO recently had a Chagas transmission and expressed concern about gaps that might allow Chagas transmissions to still occur. The member mentioned that it does not matter where the donor was born because if their parents lived in an endemic area, the donor could still potentially transmit the disease. There was also concern about undocumented donors who may not have an accurately recorded background.

Several Committee members expressed concern about the cost and the turnaround time for conducting two tests. Another Committee member believes the testing should only apply to heart donors because the symptoms of Chagas can be effectively treated for the other organs.

#### **2. Require Human Leukocyte Antigen (HLA) Confirmatory Typing for Deceased Donors**

The OPTN Histocompatibility Committee Chair provided an overview of this proposal. The proposal will require confirmatory HLA typing for all deceased donors. The goal is to increase the safeguards for deceased donor HLA typing and reduce the risk of unintended immunological incompatible transplants.

Summary of discussion:

One member asks if there has been consideration of the age and size of the donor to draw out two sets of the bloods from the donor. The Histocompatibility Chair responded by stating that would be up to the histocompatibility lab to determine the typing.

A member expressed concerns about the cost and noted that it could double their HLA lab costs. The member added concern that the HLA labs do not have the resources to handle the increased in testing. She added this could lead to errors because HLA lab staff will be overworked and understaffed. Another member agreed and commented that if transcription errors are the main issue, this proposal doubles the risk for those types of errors.

A member asked about pediatric or expedited cases where there is only one specimen available. The Histocompatibility Committee Chair responded that exceptions could be created for expedited cases.

A member commented that to ensure accurate results, two different individuals and two different testing machines should be used.

Overall, the OPO Committee does not support this proposal based on the data presented and the significant increase in costs for testing.

**3. Establish Member System Access, Security Framework, and Incident Management and Reporting Requirements**

The OPTN Network Operations Oversight Committee (NOOC) representative provided an overview of this proposal. The purpose of the proposal is to reduce the risk to members in security incidents and reduce the risk of a security incident at the member level and providing a problem at the level of the OPTN Computer System and potentially impacting transplant nationally.

This proposal establishes the following:

- Required security training
- New appointment of information security contact
- Member security framework and controls
- Security readiness assessment, attestation, and audit requirements for compliance monitoring
- Security requests for information regarding potential risk to the OPTN computer system
- Incident management response requirements, which could include limiting or temporarily removing access to the OPTN Computer System

Summary of discussion:

A member asks if the intent is to protect the OPTN Computer Systems from malware. The NOOC representative responded that one of the goals is to protect the OPTN Computer Systems, but the main purpose is to protect the entire transplant system. The NOOC representative used an example of how systems are interconnected. A few years ago, a major retailer had a massive data breach, but it was not caused by the retailer but instead was due to a breach with one of their vendors. He added that the same situation could happen to the OPTN and its members since they are interconnected.

A member expressed concerns that the OPTN is trying to dictate arrangements for members when it is really the responsibility of the members to address security requirements.

A member expressed concerns about how breaches are reported and how members will provide transplant services if access to the system is denied. She added that it is impossible to be 100% protected due to the number of devices being used and there are also third-party users to consider.

A member noted that the security aspect of the proposal is less of a concern than the 24-hour notification requirement and how that will be defined.

The NOOC representative added that healthcare systems are targeted due to the large amounts of data, and it is important to have adequate security to prevent crucial information being lost or stolen.

### **Upcoming Meeting**

- March 9, 2023 (Teleconference)

## Attendance

- **Committee Members**
  - Kurt Shutterly
  - PJ Geraghty
  - Bruce Nicely
  - Chad Ezzell
  - Clint Hostetler
  - David Marshman
  - Debra Cooper
  - Donna Smith
  - Doug Butler
  - Erin Halpin
  - Judy Storfjell
  - Larry Suplee
  - Malay Shah
  - Leslie McCloy
  - Meg Rogers
  - Samantha Endicott
  - Sharyn Sawczak
  - Sue McClung
- **HRSA Representatives**
  - Jim Bowman
  - Mesmin Germain
- **SRTR Staff**
  - Ajay Israni
  - Katherine Audette
  - Nicholas Wood
- **UNOS Staff**
  - Robert Hunter
  - Taylor Livelli
  - Terri Helfrich
  - Katrina Gauntt
  - Austin Chapple
  - Courtney Jett
  - Kayla Temple
  - Ross Walton
  - Kevin Daub
  - Kristine Althaus
- **Other Attendees**
  - Lara Danziger-Isakov
  - Bruno Mastroianni
  - John Lunz