

OPTN Operations and Safety Committee

Meeting Summary

January 19, 2023

Conference Call

Alden Doyle, MD, MPH, Chair

Kim Koontz, MPH, Vice Chair

Introduction

The OPTN Operations and Safety Committee (the Committee) met via Citrix GoToMeeting teleconference on 01/19/2023 to discuss the following agenda items:

1. Public Comment Presentation: *Establish Member System Access, Security Requirements, Incident Management, and Reporting Requirements*
2. Review: ABO Determination Policy 2 year Monitoring Report
3. Update: Post Cross-Clamp Test Results Project

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

1. Public Comment Presentation: Establish Member System Access, Security Requirements, Incident Management, and Reporting Requirements

The Committee provided feedback on a public comment presentation from the OPTN Network Operations Oversight Committee (NOOC).

Summary of discussion:

The Chair asked the presenter about the action that would follow a program failing their information security audit. The presenter responded that the NOOC would prefer to coach members who might struggle to meet the proposed requirements. The Chair continued that a process for holding members accountable does need to be developed and welcomed Committee feedback on this. The Chair and presenter agreed that while the OPTN Membership and Professional Standards Committee (MPSC) might not be the correct body to discuss member accountability for these proposed changes, a similar body with information technology (IT) expertise might be a more appropriate fit. The presenter added that the NOOC is currently considering broadening its membership to include individuals inside and outside of the transplant community with IT expertise.

The Chair commented that it could be beneficial to have one IT staff member in the transplant program and another in the hospital, as transplant is just one piece of the larger hospital system. The presenter agreed and added that the development of this framework would help different IT staff understand and work within the requirements. A member asked if the requirements for Organ Procurement Organizations (OPOs) would be similar. The presenter responded that the idea would be for an OPO member to meet similar requirements, but have a different framework to meet their security needs.

The Chair asked if the NOOC is considering which technology should be used by the OPTN, as recent feedback suggests it should be updated. The Chair responded that the OPTN has engaged with some external auditors to assess its IT security. They continued that this proposal presents an opportunity for the OPTN Contractor to assess their own processes.

Next steps:

This feedback will be complied and posted to the OPTN public comment website on the behalf of the Committee.

2. Review: ABO Determination Policy 2 year Monitoring Report

The Committee reviewed results from the ABO Determination Policy 2 year Monitoring Report. The report showed the following:

- The distribution of donors by blood type and the number of transfusions received during their terminal hospitalization remained consistent across the two eras except for Type A donors with 11+ transfusions who saw a significant decrease out of all donors who received 11+ transfusions
- The number of recorded blood type changes increased but it is difficult to determine the reasoning behind ABO changes in each era
- Several patient safety events related to blood typing were reported, including 2 where blood transfusion led to misleading blood typing results in the post-policy implementation era

Summary of discussion:

The Chair reiterated that the report data was based upon voluntary reporting. They asked if the increase in reporting could be due to greater awareness of the issue, greater number of incidences, or due to the Committee's work. The presenter agreed and added that in the time period of when the patient safety events were reported, there was an increase of about 2,000 donors recovered. The Chair requested data regarding the change in the rate of donors upon the Committee's next review of this data.

Next steps:

The Committee will continue to monitor this data.

3. Update: Post Cross-Clamp Test Results Project-

UNOS IT Service Owners presented the an update on the Post cross-clamp test results project.

Summary of discussion:

The Chair asked how timing of infectious disease testing results would impact the system. For example, if a result returns that a donor is hepatitis C positive after the original assessment of the organ by the surgeon, this would have an impact on donor acceptance. The Chair suggested there be a special alert for this situation, so programs can make the most informed decisions when assessing organs for acceptance. The presenter responded that they would take this idea back to their team. The Vice Chair asked if there had been any feedback about the volume of notifications. The presenter responded that there have been comments about the number of notifications, but that this new system aims to help streamline the method of communication from OPO to transplant program by reducing the number of phone calls and emails.

A HRSA representative asked if there was a way to update culture reporting in the system, as these can take one or two days to result. The presenter responded that the OPO is able to log in, upload the culture results, and send a notification to the transplant program. A member expressed their interest in streamlining methods for communication, as every OPO communicates with transplant programs differently. This member also confirmed with the presenter that the system can differentiate between multiple updates to donor information. A member asked if the system is designed to prompt OPOs to follow up on cultures from their donors. The presenter responded that the system does not currently address this issue.

Upcoming Meetings

- February 23, 2023, 2-3pm (ET)- Teleconference
- March 23, 2023, 9am-3pm (CT)- in- person, Chicago

Attendance

- **Committee Members**
 - Alden Doyle
 - Andy Bonham
 - Audrey Kleet
 - Dominic Adorno
 - Mony Fraer
 - Gregory Abrahamian
 - Jami Gleason
 - Jill Campbell
 - Jillian Wojtowicz
 - Julie Bergin
 - Kim Koontz
 - Sarah Koochmaraie
 - Norihisa Shigemura
 - Melissa Parente
 - Renee Morgan
 - Laura Huckestein
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Katherine Audette
- **UNOS Staff**
 - Alex Tulchinsky
 - Betsy Gans
 - Carlos Martinez
 - Courtney Jett
 - Dzhuliyana Handarova
 - Isaac Hager
 - Joann White
 - Kelley Poff
 - Kerrie Masten
 - Kevin Daub
 - Krissy Laurie
 - Lauren Mauk
 - Matt Belton
 - Michelle Rabold
 - Roger Vacovsky
 - Sharon Shepherd
 - Terri Helfrich
- **Other Attendees**
 - Edward Hollinger