

OPTN Operations and Safety Committee

Meeting Summary

April 15, 2021

Conference Call

Christopher Curran, CPTC, CTBS, CTOP, Chair

Alden Doyle, MD, MPH, Vice Chair

Introduction

The Operations and Safety Committee (the Committee) met via Citrix GoTo Meeting teleconference on 04/15/2021 to discuss the following agenda items:

1. Multi-factor Authentication
2. ABO Determination: 6 Month Monitoring Report
3. Trends and Patterns in Patient Safety Cases
4. TransNet Report
5. UNOS Labs: "Understand CIT" Project: Approach to Collecting Transit Data
6. Broader Distribution Data Collection Workgroup
7. Match Run Roles Workgroup Update
8. OPTN Policy Oversight Committee Update
9. New Project Actions

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

1. Multi-factor Authentication

Information technology (IT) staff presented the new multi-factor authentication process that will help safeguard sensitive organ donor and recipient data.

Summary of discussion:

The Committee agreed that the log-on period should be sustained for a period of time in order to limit the number of times transplant staff would need to log-on while in the operating room.

The Vice Chair suggested that IT should ensure that program's technology is up to date so that when multi-factor authentication is rolled out, it does not slow down other essential processes.

There were no additional questions or comments.

Next steps:

IT staff is continuing to assess users' needs. Communication and guidance will be provided to the transplant community, and a phased rollout will begin with Site Administrators.

2. ABO Determination: 6 Month Monitoring Report

The Committee reviewed the 6 month monitoring report for their proposal, *Modify Blood Type Determination and Reporting Policies*.

Data summary:

Data showed no statistically significant change in the distribution of deceased donors by ABO type. The largest shift seen in the data was an increase in type O by 1.4%.

Data showed no statistically significant change in the distribution of ABO type for deceased donors with zero transfusions. Type O showed a slight increase in proportions, while all other blood types showed a slight decrease.

Data showed no statistically significant change in the distribution of ABO type for deceased donors with greater than eleven transfusions. There was a slight decrease in proportion of type A donors, while a slight decrease in proportion of type O, type B, and type AB.

Data showed eleven changes to recorded ABO type in the database pre-policy, and ten changes to recorded ABO type in database post-policy. In the recorded events, for both pre- and post-policy eras, ABO type was most often updated to type A.

Overall, there were no statistically significant shifts in any trend from the pre-policy era to post-policy era.

Summary of discussion:

A member asked for further details on changes to recorded ABO type. Research staff responded that the most frequent change is type O to type A, the second most frequent change is type A to type AB.

The Chair stated that one of the pitfalls of this data is that it does not address incidents where organ procurement organizations (OPOs) enter and validate ABO type, and then cancel and re-add the donor. The Chair stated that Research staff reviewed data related to these types of incidents and that it did not reveal much information. Research staff added that this was an initial review of that data, but they will continue to analyze and provide more context in the next reports.

The Chair stated that the limitations related to knowing the total number of incidents due to OPOs resolving conflicting results, re-entering data, and moving forward with allocation processes. The Chair stated that the Committee could review the patient safety events that are reported as critical in order to gather more detailed information. The Chair added that the Committee could add this situation as a mandatory patient safety event to report.

3. Trends and Patterns in Patient Safety Cases

The Committee reviewed data related to patient safety cases that were reported to the OPTN from January 1, 2017 – December 31, 2020.

Data summary:

Data showed that patient safety events excluding non-issue cases in 2020 increased to 250, compared to 245 events in 2019. UNOS Research Department accounted for reporting about 12% of patient safety events excluding non-issue cases, compared to 20% in 2019.

Data showed about 50% of patient safety cases reported OPOs as subject type, excluding non-issue cases. This is an increase from the past three years, where OPOs had accounted for about 40% of patient safety cases. Patient safety cases with transplant programs reported as subject type decreased to 46% in 2020, compared to 59% in 2019.

Data showed that over the past four years, transplant programs and other as a reporting type oscillate between the majority for patient safety cases, including non-issue events and reported in error events. In 2020, the majority was transplant programs with around 40% of cases.

The COVID-19 pandemic was declared a national emergency on March 13, 2020. There were eight patient safety events prior to this date in March 2020, and twenty patient safety events post this date in March 2020. In April 2020, the number of patient safety events dropped to six. Beginning in June 2020 (twenty three patient safety events), patient safety events return to numbers as seen prior to the COVID-19 pandemic. Data showed a peak in patient safety events in December 2020 with 30 patient safety events.

Data showed, over the last three and a half years, that non-issue/report error was the most frequently occurring category, followed by communication, transplant program procedure/process, living donor event, data entry, testing, labeling, recovery procedure/process, general concern, organ allocation placement, packaging/shipping, other, transportation. During the first six months of 2020, data showed communication, living donor event, data entry, and recovery procedure/process as the most frequently occurring categories of patient safety events. Of note, the first six months of 2020 experience more recovery procedure/process patient safety events than any of the previous years.

Data showed that recovery process/procedure patient safety events which caused or contributed to discard of organ increased in cases. The first six months of 2020 data showed a total of nine cases, when the average of the previous three years was about four events. Of the nine cases in 2020, eight were classified as injury to organ or vessel.

Summary of discussion:

The Vice Chair stated that this report shows trends in reporting, not trends in events because it is voluntary. The Vice Chair asked the Committee, while still vastly underreported, if the increase in reporting of "injury to organ or vessels" is due to broader distribution and programs being more comfortable reporting those programs they do not normally work with or an actual increase in reporting. A member responded that they agreed and believed it was a trend in reporting due to broader distribution. Another member also agreed and stated there is potential to work with OPOs as each OPO has some type of medical subcommittee where surgical errors are reported.

A member asked if there can be analysis of which programs are reporting on whom to understand if the report was entered by a program or an OPO not within their donation service area (DSA). Another member suggested reviewing the trends by abdominal versus thoracic organs. Another member asked if there was a way for the Committee to review blinded reports for deeper dives. Research staff responded they will work to see if these queries are available.

The Chair referenced an Association of Organ Procurement Organizations (AOPO) project that reviewed surgical errors reported by OPOs and analyzed the reports by varying categorization (local recovery, who performed recovery) and the subsequent rates of surgical injuries. The Chair asked if it would be helpful for the Committee to review this type of categorization in order to better understand common errors and areas to provide training opportunities to the transplant community to reduce these common errors. The Vice Chair agreed and emphasized that this data should be used to foster a community of improvement not finger pointing.

A member asked if the Committee could compare rates with OPOs who collect this information to see if there are outliers in the data. The Chair suggested the Committee could review the AOPO data to try to make comparisons.

Another member suggested that an automated survey could be sent out to the implanting team and recovery team to help report quality of surgery and report injury and errors. A member suggested that a data element, such as anatomical injury, could be added to the deceased donor registration (DDR) form. Another member stated that it would be critical to also include a data element to capture if an

anatomical injury led to organ loss. The member explained that broader distribution may lead to an increase in reporting but may not lead to an increase in organ discard due to anatomical injury, because of that it would be important to differentiate types of organ injury to ultimately understand those that lead to organ discard. A member suggested this data element should also be added to the transplant recipient registration (TRR) form to capture data on organs with damage but the transplant programs were able to work around it. Another member suggested data capturing the distinction between unreported organ injury and reported organ injury.

The Vice Chair stated that the goal of the Committee's work is to make transplant procedures safer and to save more lives and more information is needed to work towards that goal. The Committee agreed.

4. TransNet Report

The Committee reviewed trends in TransNet data from January 2019 – January 2021.

Data summary:

Trends show that most OPOs have 100% of cases created and shipped using TransNet, the other OPOs have about 80% - 90% of cases that are created and shipped using TransNet.

There are no consistent trends among individual OPOs.

Trends show that transplant organs shipped using TransNet remains high, the lowest drop was about 95%.

Summary of discussion:

The Chair stated that the compliance over time, across the country, is very good.

A member asked if there is information to understand why TransNet was not used in certain cases. Another member responded that generally it is assumed that there was loss of power or connectivity issues if TransNet was not used. The Chair stated that OPTN policy requires OPOs to document reasoning for not using TransNet. The Chair asked if UNOS auditors review this documentation during auditing. Research staff will confirm this.

The member stated that TransNet works really well but there are occasional software issues that result in difficult situations. The member explained if an OPO shares an organ and then the organ needs to be repackaged at a different OPO, but the initial OPO did not close out and upload the donor, then the new OPO cannot repackage. The member stated this incident occurred recently and their OPO had to create a new donor and override the data of the host OPO. Members agreed and shared additional experiences with the software issues.

The Chair suggested notifying OPOs if a trend over time is found. The Committee agreed.

5. UNOS Labs: "Understand CIT" Project: Approach to Collecting Transit Data

The Committee reviewed data results from the UNOS Labs CIT pilot. The Committee also discussed the current work of a GPS Pilot Project.

Summary of discussion:

UNOS partnered with OPOs and a major courier to understand the feasibility of collecting logistics-based data, collect data to identify key components of CIT, and try to develop an algorithm to project CIT. Additionally, the participating OPOs completed a questionnaire. The results, which align with feedback the Committee has received from the community, from the questionnaire are as follows:

- OPOs have a lot of data on organ procurement, but little data on transplant event

- OPOs have little information on organ transit, but transportation partners are able to fill in the gaps
- None of the OPOs collected any of the 10 transportation-related variables mentioned

The project found that transit/transport time has no clear definition. The project found that emerging services, such as GPS trackers, enable transit time to be collected systematically with no additional data burden. Additionally, the project found that total CIT as a data collection element is often unreliable, and transplant time instead of transplant date would be better to collect in order to have a more accurate calculation of CIT. The project concluded that transit time as defined as courier pickup and delivery is a poor reflection of total CIT.

Based on the Global Positioning System (GPS) Pilot Project, and considering the Committee’s Broader Distribution Data Collection project, the Committee discussed the potential for pushing for universal adoption of GPS trackers on all organs.

The Chair of the Broader Distribution Data Collection Workgroup stated that requiring GPS tracking would capture the needed data that is being discussed within the Workgroup. The Workgroup has been cognizant of data burden, and GPS tracking would take the burden off transplant community members, while allowing for important data to be tracked and analyzed.

6. Broader Distribution Data Collection Workgroup

The Committee received an update on the work of the Broader Distribution Data Collection Workgroup (the Workgroup).

Summary of discussion:

The Committee reviewed the Workgroup’s discussions on data definitions.

Total Cold Ischemia Time Left Kidney/Right Kidney/EnBloc

- A member stated that first anastomosis is not collected by the OPTN, but their programs collect it so it could be easily queried from an electronic medical record.
- The Chair stated that there might be variation in cold ischemic time data due to programs manually calculating cold ischemic time as well as time zone differences.
- The Workgroup Chair stated that a data definition change would not help address variations in cold ischemic time. The Workgroup Chair suggested collecting anastomosis time as it would lend to better data. The Workgroup Chair explained that anastomosis minus cross clamp time would capture an accurate cold ischemic time. The Chair stated that the Workgroup might need to review the data definitions in order to make clear delineations between warm ischemic and cold ischemic times.

Lung(s) perfused prior to transplant

- The Chair suggested the Workgroup discuss how to account for the various steps of an organ’s transport, as some lungs are perfused multiple times due to different sites it travels to.

Kidney(s) received on:

- Staff clarified that “N/A” is not an option. Staff explained there is a discrepancy between the Transplant Recipient Registration (TRR) form and Help Documentation, and they will work to fix this discrepancy of “N/A” appearing.

Left/Right Kidney Final resistance at transplant

- The Chair stated that renal resistance does not take into account kidney size. The Chair stated that pressure and flow data points are more relevant. The Workgroup Chair stated that pump parameters would not change due to broader distribution. The Workgroup Chair added that broader distribution may be considered when deciding whether to take an organ from a greater distance and the quality shown given the pump parameters (i.e. transplant program willing to take an organ from a further distance, therefore increasing cold ischemic time, based on the pump parameters). The Chair confirmed and stated that broader distribution could change decision making around what kidneys to pump and what kidneys not to pump.

Kidney Pump Values: Time/Flow/Pressure/Resistance

- The Committee discussed what time frame is the best to capture. The Chair stated that there is variability in this data depending on who performs the pumping. The Chair suggested clarifying “final” as “host OPO final pump numbers”. The Chair of the Workgroup agreed and added that transplant programs will be using host OPO pump numbers for decision making.
- A member asked whether the workgroup addressing late turn downs has the capability to report organs that are turned down for pump parameters. The Chair suggested to provide the following feedback to the Data Advisory Committee (DAC) Refusal Codes and Late Turndowns Workgroup, expand on refusal code 835: Organ Preservation. The Committee agreed and stated that if the DAC Workgroup is unable to address this then the Workgroup could add a decline reason under final organ disposition for pump parameters.
- The Committee expressed concern over collecting initial, and low/peak data points. The Committee explained that the initial time an organ spends on the pump is not reflective of the organ’s function. The Vice Chair suggested capturing the averages for each pump parameter. The Chair stated that their OPO uses two hours on the pump as a point where the organ has reached an equilibrium.

Transportation Mode

- The Committee agreed this is an important data element to collect.
- The Committee discussed collecting primary mode of transportation mode or most complex transportation mode.
- A member suggested this data element should wait to be included until the Committee knows what is available via GPS tracker. The Committee agreed.
- A member stated that there are instances where there is transport before the OPO hands off to a transplant program. The member explained that an OPO may fly an organ back from Alaska to their core OPO area, then travel by car to a local center. The member stated this is hard to distinguish which mode is primary.

Transport time

- The Chair suggested defining transport time as when the organ leaves the possession of the OPO. The Committee suggested receiving feedback from the Policy Oversight Committee regarding this data element with considerations to the GPS Tracking Pilot

7. Match Run Roles Workgroup Update

The Committee received an update on the progress of the Match Run Rules Workgroup. There were no questions or comments.

8. OPTN Policy Oversight Committee Update

The Vice Chair presented an update on the work of the Policy Oversight Committee (POC). There were no questions or comments.

9. New Project Actions

The Committee discussed moving forward on potential projects.

Summary of discussion:

Organ Preservation Failures

The Committee discussed restarting their project regarding frozen organs. Members expressed interest in starting work back up on this project.

The Chair suggested that the Committee could work to provide education to the transplant community. A member stated that the Workgroup had difficulty pinpointing the underlying issues of frozen organs, therefore making it difficult to determine best practices for education.

A member stated that this is an important topic, but during the Workgroup discussions they had difficulty in how to address the issue because of the absence of data. The member stated that the work regarding this project may be limited unless these issues are part of mandatory reporting.

The Chair stated the scope of this project may be preservation failures, not frozen organs.

The Committee expressed interest in proposing this as a mandatory data reporting event.

There were no additional questions or comments. The meeting was adjourned.

Upcoming Meetings

- May 27, 2021 (teleconference)
- June 25, 2021 (teleconference)

Attendance

- **Committee Members**
 - Alden Doyle
 - Charles Strom
 - Christopher Curran
 - Dominic Adorno
 - Joanne Oxman
 - Kimberly Koontz
 - Luis Mayen
 - Melinda Locklear
 - Melissa Parente
 - Michael Marvin
 - Rich Rothweiler
 - Susan Stockemer
 - Susan Weese
- **HRSA Representatives**
 - Arjun Naik
- **SRTR Staff**
 - Katie Audette
- **UNOS Staff**
 - Alex Tulchinsky
 - Amy Putnam
 - Andrew Placona
 - Casey Humphries
 - Greg Edwards
 - Joann White
 - Katrina Gauntt
 - Kristine Althaus
 - Lauren Motley
 - Leah Slife
 - Matt Prentice
 - Meghan McDermott
 - Nicole Benjamin
 - Randall Fenderson