OPTN Operations and Safety Committee
Meeting Summary
October 20, 2020
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 GoToMeeting teleconference on 10/20/2020 to discuss the following agenda items:

1. OPTN Policy Oversight Committee Update
2. Research Update: Patient Safety Report
3. Research Update: TransNet Dashboard
4. IT Update
5. Additional Projects Update
6. Workgroup Updates
7. Discussion: Committee Projects

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

1. OPTN Policy Oversight Committee Update

The Vice Chair updated the Committee on the Policy Oversight Committee's (POC) strategic policy priorities, project alignment, and project sequencing.

Summary of discussion:

The Vice Chair stated that the POC is working to analyze the projects across the OPTN committees as well as workloads. The Vice Chair explained that the POC is overseeing this in order to sequence projects for efficiency and support the progression of projects.

There were no comments or questions.

2. Research Update: Patient Safety Report

UNOS research staff updated the Committee on trends and patterns in patient safety cases reported to the OPTN, from January 2016 to June 2020.

Data summary:

Data showed a spike in 2019 of patient safety events. There were 27 living donor cases where patients were falsely identified as having diabetes on the waitlist. Although patient safety event data for 2020 are not complete, preliminary data shows to be on course with previous years.

Data showed, over the last three years, that about 50-55% of patient safety cases (excluding non-issues cases) were attributed to transplant programs, about 40-45% were attributed to organ procurement organizations (OPOs), and about 3-6% attributed to labs. However, data from 2020 currently shows about 55% of these cases are attributed to OPOs, while 44% are attributed to transplant programs.

Data showed that self-reported patient safety events have been declining the past three years. However, during the first half of 2020, 41% of patient safety events were self-reported which is higher than the previous year.

Data showed that of the living donor event category of patient safety, cases decreased in 2019, while the other top categories showed an increase (non-issue/reported in error, transplant procedure/process, communication, data entry, and testing). The category of transplant procedure/process had the greatest number of patient safety cases reported within the last four years, 161 total. Of the 161 total patient safety cases related to transplant procedure/process, 142 (88.2%) are sub-categorized as "other". Further elaborating on the "other" sub-category, it was found that the majority of these cases were attributed to the storage of prohibited vessels.

Testing is the fourth most common category of patient safety events in 2019. Over the last four years, the subcategory, "Infectious Disease – Hemodilution error or discrepancy", had the highest count of 24 cases (21.2%) out of 113 total cases.

Recovery procedure/process is the leading category resulting in the discard of organs. Transportation-related reasons is the leading category resulting in the delay of transplant.

Summary of discussion:

The Chair asked whether there were any trends related to discards of organs due to recovery procedure/process. UNOS research staff responded that surgical damage during procurement was the most common factor in organ discard due to recovery procedure/process.

A member asked whether, based on some trends, should the voluntary reporting become mandated in order to have more information, especially regarding those organs that are not transplanted. The Chair responded that the Committee has often discussed the topic of mandatory patient safety reporting. One concern is changing the focus from punitive measures to emphasizing quality improvement. A member stated that another concern is the data does not always show exactly where/when an injury to an organ occurred. Another member emphasized that self-reporting is a hindrance in trying to analyze the current data.

A member suggested looking into the match run for "accepted but not transplanted" data rather than relying on self-reported data. The Chair agreed and added that discard data entered by OPOs which show avoidable discards would also be helpful in analyzing behavior.

A member asked if there was a standard definition for "delay in transportation" and if there was additional data regarding complications in these cases. UNOS research staff responded there is not a defined time period for delay, it is situation dependent.

There were no additional comments or questions.

3. Research Update: TransNet Dashboard

UNOS research staff presented TransNet data from January 2017 – September 2020.

Data summary:

Overall, there were no OPOs which consistently showed a low percentage in terms of donor cases where they were created but not shipped. Data showed generally high usage of TransNet for organs shipped and transplanted.

Summary of discussion:

There were no questions or comments.

4. IT Update: Post-Transplant Reporting Project

OSC received an update from IT regarding the Post Cross Clamp Test Results Pilot.

Summary of discussion:

OPTN Policy 15.4: *Host OPO Requirements for Reporting Post-Procurement Test Results and Discovery of Potential Disease Transmissions* requires host OPOs to report to transplant programs when they receive a donor derived positive infectious disease culture or pathology. Culture reporting methodologies are not standardized by OPOs and the process is often inefficient and redundant because it is manually repeated for each organ transplanted.

The project is piloting a notification system in which OPOs can initiate when results are obtained post cross clamp that may affect recipients. The system allows OPOs to notify transplant programs of test results, and allows transplant programs to acknowledge they have received the notification and reviewed updated test result. Additionally, the system creates an audit log allowing OPOs to see when notifications are sent as well as when/if they have been acknowledged by a transplant program.

The pilot will be released November 19 and continue for three months.

A member asked if the system will monitor when an initial notification was sent. UNOS IT staff responded that the initial notifications will be tracked in the audit log for both OPOs and transplant programs.

Another member asked if the project considered having the initial notifications trigger off of the positive results culture area in DonorNet. UNOS IT staff responded that this type of trigger was not discussed but will bring it back to the workgroup for future discussions. The member asked if a program did not respond to the first email, would there be an opportunity for text message notifications. UNOS IT staff responded the pilot only includes emails, but the national rollout plan does include text message notifications as well.

A member asked when a transplant program is responding to a notification, will they have to search through DonorNet or are the results displayed on one page. UNOS IT staff responded that currently, there is not a capability to link attachments with notifications, but there is a project to address DonorNet attachments and categories. UNOS IT staff explained that the use of the comment field will help allow OPOs to point transplant programs to the exact attachment.

There were no additional comments or questions.

5. Additional Project Updates

OSC received an update regarding their previous project, *ABO Policy Modifications and Guidance*.

Summary of discussion:

Modify Blood Type Determination and Reporting Policies was implemented September 1, 2020. *Guidance on Blood Type Determination* was implemented June 8, 2020 and has had about 675 visitors, making it the 8th most viewed guidance document since early June.

A member asked whether there was a mechanism to re-advertise the guidance to bring more awareness of it to the OPO community aware of its existence. Staff will look into it.

6. Workgroup Updates

The Committee discussed their ongoing projects.

Summary of discussion:

Broader Distribution Data Collection Workgroup

The Workgroup has begun to evaluate data and provide input and recommendations.

Organ Packaging Workgroup

Due to the prioritization of POC recommended projects, this project is currently on hold. The Collaborative Improvement team will continue to work on this project with collaborative efforts from the Committee.

7. Discussion: Committee Projects

The Committee discussed potential new projects.

Summary of discussion:

Upcoming projects

The POC identified the Committee as a recommended collaborator on the following projects:

- Communication enhancements in DonorNet
- Consistent practices in organ recovery process
- Maximizing use of image sharing.

The Chair suggested rolling in some of the Committee's potential project ideas into the POC recommended projects. The Chair explained that data collection on donation after cardiac death (DCD) donors could be merged with the project regarding communication enhancements in DonorNet. Members agreed.

The Chair asked whether there are any projects regarding syncing TransNet data in real time. Staff will look into it.

New project ideas

The members voted on project priority. The following are potential projects, listed from most prioritized to least:

- Defining data fields specific to donation after cardiac death (DCD)
- Putting directed deceased donors on the match run to resolve issues such as ABO verification
- Creating criteria for patient safety reporting
- Analyzing recent policy changes to review their effect on liver discards
- Effects of heparin dosage on DCDs
- Identifying and addressing safety measures that have or may arise during COVID-19

Defining data fields specific to DCD

This project idea was proposed to be combined with the POC recommended project, *Communication enhancements in DonorNet.*

Putting directed deceased donors on the match run to resolve issues such as ABO verification

The Chair explained this project idea would be a way to link directed donor organs from deceased donors to waitlist candidates, so that ABO verification and other safety checks can be performed. The Committee reviewed OPTN Policy 5.4.E: *Allocation to Candidates Not on the Match Run.* The Chair wondered how many transplants result from directed deceased donation.

The Vice Chair asked how this project will align with the strategic priorities. The Chair responded that this potential project could be categorized as a safety measure project.

Creating criteria for patient safety reporting

The Chair suggested a group of members should meet to discuss what situations would merit mandatory reporting. The Vice Chair suggested rather than solely discussing what should be mandatory reporting, the Committee should also discuss how to get actionable information from what is already reported.

Analyzing recent policy changes to review their effect on liver discards

The Chair explained that a recent policy change which allows transplant programs to receive multiple organ for the same recipient has potentially led to an increase in liver discards. The Chair suggested sending a letter to the Chair of the OPTN Liver and Intestinal Organs Transplant Committee to refer this project idea.

Effects of heparin dosage on DCDs

There were no questions or comments regarding this project idea.

Kidney discards due to kidney pump issues (cassette failures)

The Committee decided to combine this project idea with their discussions surrounding mandatory reporting of patient safety events. The Committee believed the cassette failures have been resolved due to the manufacture addressing the issue. The Committee discussed establishing communication lines with manufacturers to address issues as quickly as possible when they occur.

Labeling errors (internal label of extra vessels)

The Chair explained the internal labels must be sterile so it is handwritten because the TransNet labels do not print out sterile. The Chair asked if there is data on how many errors occur because the label is handwritten. Staff will follow up with the OPO Committee regarding their conversations about this topic. The Chair wondered whether a solution is to remove the internal labels completely or develop a labeling process. Staff will share this information with the OPTN Liver and Intestinal Organs Transplant Committee. A member suggested identifying why the internal label was originally added.

Identifying and addressing safety measures that have or may arise during COVID-19

The Chair stated this project idea may have potentially been addressed by recent data collect efforts and programming changes. Staff stated this project idea did not receive any votes. The Committee decided to remove this project idea from the list.

Next steps:

Staff will refine the project idea list and disseminate it to the Committee.

Upcoming Meetings

- November 19, 2020 (teleconference)
- December 17, 2020 (teleconference)

Attendance

- **Committee Members**
  - Alden Doyle
  - Audrey Kleet
  - Charles Strom
  - Christopher Curran
  - Dominic Adorno
  - Gregory Abrahamian
  - Joanne Oxman
  - Kim Koontz
  - Luis Mayen
  - Melinda Locklear
  - Melissa Parente
  - Michael Marvin
  - Rich Rothweiler
  - Steve Johnson
  - Susan Stockemer
  - Susan Weese
  - Vandana Khungar
- **HRSA Representatives**
  - Arjun Naik
  - Jim Bowman
  - Marilyn Levi
  - Vanessa Arriola
- **SRTR Staff**
  - Katie Audette
- **UNOS Staff**
  - Emily Kneipp
  - Joann White
  - Katrina Gauntt
  - Kristine Althaus
  - Lauren Motley
  - Marc Leslie
  - Matt Prentice
  - Meghan McDermott
  - Nicole Benjamin