

OPTN Operations and Safety Committee

Meeting Summary

March 28, 2024

Conference Call

Alden Doyle, MD, MPH, Chair

Kim Koontz, MPH, Vice Chair

Introduction

The OPTN Operations and Safety Committee (henceforth the Committee) met via WebEx teleconference on 3/28/2024 to discuss the following agenda items:

1. Follow Up and Discussion: Transportation Events Data Collection
2. Follow Up and Discussion: New Project Ideas

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

1. Follow Up and Discussion: Transportation Events Data Collection

The Committee followed up on a previous discussion on a transportation events data collection project idea referral from the OPTN Membership and Professional Standards Committee (MPSC). The Committee reviewed patient safety report data and provided a recommendation on the next steps for the project.

The transportation data showed the following:

Summary of data:

The following data was aggregated from the Patient Safety Portal from 12/16/2022 – 12/19/2023. A summary of the data reviewed are as follows:

- 34 reports submitted for 31 events from 12/16/2022 - 12/19/2023
 - 24 submitted by transplant hospitals
 - 10 submitted by organ procurement organizations (OPOs)
 - 3 reports of the same event submitted by both transplant hospital and OPO
- Events by organ
 - Kidney: 19 events and 5 resulted in nonuse
 - Heart: 6 events and 4 resulted in nonuse
 - Liver: 4 events and 0 resulted in nonuse
 - Pancreas: 1 event and 1 resulted in nonuse
 - Tissue typing material: 1 event and 0 resulted in non-use
 - Lung: 0 events

Summary of discussion:

Committee recommendation: Collaborate with the OPTN Expeditious Task Force (Task Force) to develop and conduct a study to better understand organ travel and late turn downs.

The Committee's recommendation will be sent to the MPSC as well as the OPTN Expeditious Task Force (Task Force).

The Committee Chair asked if the data showed then the organ was not transplanted to the intended recipient. Staff reported that of the 31 events, 10 resulted in non-use, 19 were transplanted in the intended candidate, and 12 were not transplanted in the intended candidate but were ultimately transplanted. The Committee Chair commented that these are a lot of events even assuming the data may not be capturing a lot of these instances.

The Committee Chair continued by explaining recent discussions on potential next steps for the transportation events project. There have been discussions among the Task Force about moving some projects forward. One of the projects of interest has been in addressing late turndowns; in gathering more information, there is an idea for conducting a study that would have programs voluntarily report on late turndowns. The Committee Chair stated that with previous discussions with the OPTN Data Advisory Committee (DAC) leadership, it is being proposed that this study may also be an opportunity to collect additional information on transportation events. It is thought that with using the plan-do-study-act (PDSA) methodology to set up a small trial to learn more about what happens with late turndowns and potentially transportation issues. This project would then be handed off to the Committee to evaluate the data and develop a project (with collaboration with the DAC). The details of the study are still to be determined.

The Committee Vice Chair stated that transportation and late turn downs was a topic during the in-person meeting discussions, and this is a way to put those ideas into actual practice. The Committee was asked their thoughts on the proposed approach.

The Committee Chair added that with this study, there would be a monitoring component, similar to the Committee's previous reviews of patient safety portal reports, which the Committee would take the lead on.

A member commented that every time there is a non-use of an organ, it should be investigated. The member continued by stating that if transportation is related to the issue of non-use, it should be a part of the PDSA.

The Committee Chair elaborated on the process of the PDSA. Since the PDSAs are small and iterative, there would be one small study to collect qualitative data and the next version of the study would be more focused and conducted in different regions and allow the opportunity to refine the study with more targeted questions. These studies could help in the future with refining refusal codes that give more insight on what happened, inform future projects, and will provide data to perform more extensive research. The Committee Chair continued by stating that the OPTN OPO Committee discussed late turn downs and there was agreement that this is the right approach to gather additional information.

A Health Resources and Services Administration (HRSA) representative asked if the OPO Committee should be included as a stakeholder on this project. Staff clarified that to the Committee Chair's point, the OPO Committee will be in collaboration on these efforts. During their in-person meeting, the OPO Committee discussed a project idea referral related to addressing late turn downs and the plan will be to collaborate with the OPO Committee to potentially combine efforts on these two projects.

A member asked if the PDSA would be to figure out a way to place an organ that is a late turndown or to determine why there is a late turndown. The Committee Chair stated that the goal of the PDSA is to determine what factors are involved in resulting in a late turndown. The member commented that this seems like a backward approach and stated that the root problem is that there is an organ that is not used regardless of the factors. The member suggested there being a policy in place that would address expedited placement of organs that are late turndowns first and then go back to investigate those late turndown cases further to better understand the cause.

The Committee Chair agreed with this but stated that the PDSAs would better inform the scope of the problem at a granular level. Currently, the problem is anecdotal, but it is unknown as to how often these events occur and how it may differ among regions. Additionally, it could better inform if the timestamps reported as well as the codes that are being entered to depict the disposition of an organ accurately. The Committee Chair continued by stating that there are other studies under discussion that would help in formalizing and studying how there could be a rescue pathway for organs, perfusion for donation after cardiac death (DCD) liver donors and training the OPOs to be able to better manage and evaluate lung donors (i.e., bronchoscopy).

A member stated that for the transportation events project idea, this is an appropriate approach to move forward with and makes sense in collecting more data.

A HRSA representative suggested that at some point with this project, it may be helpful to collaborate with the MPSC to better understand those reasons for turndowns that are legitimate reasons. During the OPO in-person meeting, there was some discussion around this; there may be some instances that may require input from MPSC for compliance issues for future policy changes.

The Committee Chair stated that this would be the idea to better understand what happened that would result in a late turndown or non-use of an organ and help to inform next steps. The Committee Chair asked the HRSA representative for thoughts on including transportation events in this study as it is all often related to these types of events.

The HRSA representative stated that this would be reasonable to consider and would depend on how the study is designed in how best to incorporate/collect this information. The Committee Chair agreed with this.

Staff summarized next steps would include informing the MPSC on the Committee's recommendation on collaborating with the Task Force to develop and conduct a study to better understand organ travel and late turn downs that would better inform a potential future project.

Next steps:

- **Committee recommendation:** Collaborate with the OPTN Expeditious Task Force (Task Force) to develop and conduct a study to better understand organ travel and late turn downs.
- The Committee's recommendation will be sent to the MPSC as well as the OPTN Expeditious Task Force (Task Force).

2. Follow Up and Discussion: New Project Ideas

The Committee discussed and identified potential new projects ideas. In follow up to some of the project ideas, there were projects within each category identified as either a potential project for the Committee to move forward with or a project that is currently in progress:

Group 1: Focus group on improved offer acceptance rates

The project identified to move forward with was previously discussed during the last agenda item where the Committee is recommending a collaboration with the Task Force to develop and conduct a study to better understand organ travel and late turn downs that would better inform a potential future project.

Group 2 – Optimize Organ Use

Committee leadership recommended the Committee move forward with a project that would re-evaluate donor testing requirements by re-evaluating current policy and determining any modifications needed to those requirements.

Group 3 – Enhancing OPTN efficiency

There is current work being done on prioritizing work related to system enhancements. Some of the suggested items proposed by the Committee (both from the 2/7 in person meeting discussion as well as previous discussions) are under consideration. Additional updates will be provided as this work continues to develop.

Summary of discussion:

The Committee will review and further outline the potential new projects identified and determine the sequence of projects.

The Committee Vice Chair explained the re-evaluation of donor testing requirements is to address the current practice and donor testing needs and determining if how it is currently outlined in policy still relevant. OPOs face the challenge of getting certain testing and transplant programs seem to not always get what they need to make an informed decision. The goal of this project would be for the Committee to re-evaluate current practices, what variations are being seen and what is recommended. The Committee Vice Chair added that during the OPTN Policy Oversight Committee (POC), there was discussion on identifying potential projects where quick changes could be made that could benefit the community and this topic came up.

The Committee Chair stated that from the Region 11 meeting, there was discussion on how some of the testing can be harder to access regionally which slows down the process. A member commented by providing an example for liver – liver has a requirement for testing for Hepatitis C. Most programs will request a liver biopsy before they accept that liver. If it is a local OPO, the biopsy will be done intraoperatively and make the decision at that time. If it is coming from an OPO from a greater distance, it is preferable to have the biopsy done prior to the recovery team coming to the transplant program. There are variations in these practices which can have an impact on acceptance practices.

A HRSA representative stated hearing the same concern before regarding serologies - there are public health service (PHS) guidelines for human immunodeficiency virus (HIV), Hepatitis B, and Hepatitis C in checking antibodies and polymerase chain reaction (PCR) nucleic acid amplification tests (NAATs). The HRSA representative asked for clarification if there are issues that may need to be discussed with the Food and Drug Administration (FDA) about screening versus diagnostic testing – are there antibodies that are difficult in having to drive the samples to Clinical Laboratory Improvement Amendments (CLIA) approved labs?

The Vice Chair clarified that for this project idea, the testing is related to organ specific testing before offers can be made. If there is a small regional hospital, those resources at night are limited and by the time test results are reviewed, it may be too old and may need to be retested.

The Committee Chair stated that it was thought that the testing also included infectious disease testing. The Vice Chair stated that this was not discussed during the breakout group discussions at the in-person meeting, however it is something that the Committee could consider including this as well.

The HRSA representative continued by suggesting clarification on the type of testing this project would be focusing on.

A member commented that there was a proposal in the past that addressed Chagas testing for all donors. Staff confirmed that this was a proposal from the OPTN Ad Hoc Disease Transmission Committee (DTAC). The member continued that at their program, they have a serology laboratory in house and were able to bring strongyloides in house that has a turnaround time of a few hours. Their

program was not able to bring Chagas testing in house and when the proposal was out, at the time, they discussed how the best turnaround time for testing can take 3-5 days; a lot of programs must send out for testing as well. There was discussion on the burden this could present in OPOs needing to have this test before going into the operating room (OR) when it is a treatable disease from what is understood.

The HRSA representative stated that it wasn't believed that the Chagas test was needed prior to transplant; the HIV, Hepatitis B and Hepatitis C tests do. There was an ask for clarity on specifically what tests were being referred to from the Region 11 discussion as well as the focus for the Committee's project.

A member voiced support for this project and stated that this would be impactful.

Staff summarized the next steps in gathering current policies related to donor testing for the Committee to review and further outline the project scope. Additionally, the Committee was asked to think about other stakeholders to collaborate with and suggested the OPTN Histocompatibility and Ad Hoc Disease Transmission Committees for consideration in providing additional insight on testing. The Committee was also encouraged to bring forth any additional project ideas the Committee should consider and discuss further.

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

Next steps:

The Committee will review and further outline the potential new projects identified and determine the sequence of projects.

Upcoming Meetings

- April 25, 2024 (teleconference)
- May 23, 2024 (teleconference)
- June 27, 2024 (teleconference)

Attendance

- **Committee Members**
 - Alden Doyle
 - Kim Koontz
 - Andy Bonham
 - Anja DiCesaro
 - Anne Krueger
 - Annemarie Lucas
 - Jami Gleason
 - Jillian Wojtowicz
 - Julie Bergin
 - Kaitlyn Fitzgerald
 - Laurel Avery
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Avery Cook
- **UNOS Staff**
 - Joann White
 - Kayla Temple
 - Carlos Martinez
 - Cass McCharen
 - Kaitlin Swanner
 - Kerrie Masten
 - Laura Schmitt