

**OPTN Data Advisory Committee
Meeting Summary
May 9, 2022
Conference Call**

**Rachel Patzer, Ph.D, Chair
Sumit Mohan, MD, MPH, Vice-Chair**

Introduction

The Data Advisory Committee (the Committee) met via Citrix GoToMeeting teleconference on 05/09/2022 to discuss the following agenda items:

1. Data Lock Implementation Update
2. POC Update – Late Turndowns; Resource Allocation
3. Holistic Data Review
4. Death Verification Update
5. Pre-Waitlist Update

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

1. Data Lock Implementation Update

The Committee reviewed the update to the Data Lock Implementation presented by Data Governance Staff. This was recently approved by the Office of Management and Budget (OMB) in March of 2022.

Data summary:

The Modify Data Submissions Policies proposal was approved in the December 2019 board of Directors meeting. The update impacts 8 forms within the Data System for the OPTN and as well as its import utility. In addition, there will be new member reports available. Software Engineering estimates these changes will be in production in late August 2022.

Summary of discussion:

Staff requested feedback on whether there should be any data validation of the approver’s name. The Chair agreed with Staff’s recommendation that transplant programs will manage their own approvers and that the official OPTN Representative was not necessitating approval from the OPTN position of the same name.

A member inquired whether there would be any outreach to programs that are frequently delinquent on their data submission reports. Staff responded that this could be investigated if compliance is a concern. They also added that, prior to the implementation, there would be educational materials available. The member also asked if there had been any outreach to electronic medical record (EMR) vendors. Staff noted that they had been apprised of the upcoming changes to the data imports from EMRs. IT Staff supporting the development of the project added that there should not be any change to the database structure, but the beta portal would be available for testing for two months prior to the changes going into production.

The Chair wondered when the first monitoring report would be available for the policy. Staff replied it would likely be in the first quarter of 2023.

A member asked if one form was beyond the lock date, would the entire file import fail, or will only the one new form fail to validate. Staff answered that only the one form would fail to validate.

Next steps:

Staff will inform the Committee of any new developments in the process of implementation.

2. POC Update – Late Turndowns; Resource Allocation

The Policy Oversight Committee (POC) reviewed the memo produced by the Committee sponsored Late Turndowns Workgroup, and the Vice-Chair shared the details of the POC discussion. The Vice-Chair also delivered a brief overview of the function of the POC.

Data summary:

The Late Turndowns Workgroup was charged with identifying more information to reduce the rate of late turndowns. The workgroup delivered a memo to POC in January detailing the progress to date and proposed next steps. The POC supported the workgroup's recommendation for an organ-specific approach, and there was the most interest in addressing liver first.

The Vice-Chair proceeded to explain the POC project to update their project benefit scoring. This is being done as part of the process to increase the OPTN project capacity.

Summary of discussion:

A member voiced support for the Late Turndowns Workgroup to start with Liver.

The Chair supported the sentiment that the Committee should remain cognizant of project size and prioritization in their upcoming projects.

Next steps:

3. Holistic Data Review

The Committee continued their discussion from their 4/13/2022 meeting on the holistic data review process.

Data summary:

The Committee proposed the following options as approaches to data review (**bolded** = focus of discussion):

- Expand scope of slated policy projects and include reviews
- Review data by collection forms or system
- Review data elements that raise the most concerns/data quality issues
- **Build on other data reviews in flight or recently completed**
- **Identify most critical data and review first**
- **Review data by subject area/domain**
- **Review correlation between data systems and EHRs (suggestion during call)**

Summary of discussion:

The Chair supported the recommendation that the Committee engage members outside of the DAC from other OPTN Committees and the transplant community. They added that in the most recent POC meeting, interest was expressed from a number of Vice-Chairs in performing this work – data is effectively the resource that drives all improvements.

The Chair clarified that the function of the workgroup would be to review data domains and serve as an intermediary between other committees and the DAC. Once sufficient information has been gathered by the subcommittee from their review and their consult with the sponsoring committee, the full Committee can begin to engage with the process. They added that this plan would need to be proposed to the Board of Directors prior to beginning the actual process, but they hoped it would become part of the Committee responsibilities once it is approved.

A member inquired if there was a way for members to assist in the process if their committee tenure ended in June 2022. The Chair responded that there were ad hoc openings available in some committees and workgroups.

Next steps:

Staff requested volunteers for a subcommittee that would help to develop the focus of the holistic hybrid approach in more detail.

4. Death Verification Update

The Committee received clarification on the recent update to death verification. This was delivered by Executive Staff.

Data summary:

- 1988: OPTN data collection begins
- 2004: OPTN dataset supplemented with external sources of death
- 2013: OPTN establishes death verification process
- 2017: OPTN publishes sensitivity analysis on impact of external sources of death vs OPTN member-reported deaths
- 2022: New, more automated death verification process adopted

The automated death verification process enabled approximately 35,000 new deaths to be considered within the OPTN dataset.

Summary of discussion:

The Vice-Chair requested that the distribution of the data across waitlists, transplants, and living donors. Additionally, they requested information on what proportion of the new deaths reported are from the last 10 and 15 years. Staff replied they would supply that information as soon as it was available.

The incoming Vice-Chair also noted there did not seem to be much clarity surrounding what process is being used to verify death, and requested increased transparency in the process, especially for the Committee. They added that patient outcome and death was possibly the most important variable to discuss with the Committee. In addition, they felt that this update was not highlighted enough to the transplant community, as it has significant risk to invalidate or alter a lot of the research that has used this data in the past decade.

Staff noted that, due to contract limitations with the Health Resources and Services Administration (HRSA), they are unable to be completely transparent about the death verification process, notably the sources of the data. This statement was supported by a HRSA representative.

The Vice-Chair stated it sounded like the Scientific Registry of Transplant Recipients (SRTR) and the OPTN have different verification process; they wondered why the two were different. They also suggested that the two be reviewed as best as they could to understand where the gaps in the processes lie. An SRTR representative noted that one of the primary sources of SRTR verified deaths is

the OPTN death database, but the discrepancy between the two may come from supplemental sources that the SRTR uses.

The Chair contributed that it may serve the Committee well to examine the 6.7% unverified deaths, as those could have large impacts across certain subgroups if the unverified deaths predominantly fall into them. They suggested that, similar to the Data Review Report provided to the Board of the Directors, this investigation could also fall under the purview of the Committee.

Next steps:

The Committee will continue to be updated with relevant details in the OPTN death verification process.

5. Pre-Waitlist Update

The Committee heard an update on their pre-waitlist data collection project.

Data summary:

This project is still under review by HRSA.

Summary of discussion:

The Chair noted that the OPTN Ethics Committee is producing a whitepaper on transparency in transplant program selection.

Next steps:

The Committee will be updated if there is progress on their pre-waitlist data collection project.

Upcoming Meeting

- June 13, 2022

Attendance

- **Committee Members**
 - Rachel Patzer
 - Sumit Mohan
 - Elizabeth Boehnlein
 - Kristine Browning
 - Jamie Bucio
 - Krishnaraj Mahendraraj
 - Melissa McQueen
 - Macey Levan
 - Colleen O'Donnel Flores
 - Daniel Stanton
- **HRSA Representatives**
 - Adriana Martinez
 - Chris McLaughlin
- **SRTR Staff**
 - Bert Kasiske
 - Ajay Israni
 - Jon Snyder
- **UNOS Staff**
 - Roger Brown
 - Brooke Chenault
 - Charles Fenderson
 - Cole Fox
 - Isaac Hager
 - Nadine Hoffman
 - Olga Kosachevsky
 - Maureen McBride
 - Samantha Noreen
 - Liz Robbins Callahan
 - Janis Rosenberg
 - Sharon Shepherd
 - Christopher Sweeney
 - Desiree Tenenbaum
 - Kim Uccellini
 - Scott Verbeke
 - Suhuan Wang
- **Other Attendees**
 - Jesse Schold