OPTN Data Advisory Committee
Meeting Summary
September 7, 2022
Conference Call

Sumit Mohan, MD, MPH, Chair
Jesse Schold, PhD, M.Stat., M.Ed., Vice-Chair

Introduction

The Data Advisory Committee (the Committee) met via Citrix GoToMeeting teleconference on 09/07/2022 to discuss the following agenda items:

1. Follow-up: Deaths and Graft Failures Data Validation
2. Potential Project Ideas/Sequencing
3. Data Lock Monitoring Plan
4. API Overview and Integration Pipeline
5. SDOH Presentation
6. Annual Deliverables to OPTN Board

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

1. Follow-up: Deaths and Graft Failures Data Validation

The Committee continued their review of the data evaluation performed on deaths and graft failures data as well as the current data use agreements. This was done in alignment with the charge of the Committee to make recommendations to the Board of Directors on ways to improve the completeness, accuracy, and timeliness of OPTN data and to enhance the official OPTN data with elements from other sources.

Data summary:

High level takeaways:

- Majority of new and externally verified deaths were for recipients 5+ years post-transplant and waitlist registrations 3+ years post-removal
- There are a higher proportion of Black and Hispanic/Latino patients for both kidney post-transplant and waitlist registration deaths
- Most externally verified deaths occurred after graft failure (KP/PA/KI) or lost to follow up (HR/LI/LU)
- Lack of clarity in the use of waitlist removal codes, not for transplant

Next steps for discussion:

- How is member compliance for graft failure/deaths data monitored?
- How are we currently providing these external data to members?
- How are we able to use the data we receive?

Site Surveying Monitoring

Site Surveying Monitoring Staff presented on the process for performing site surveys and how data quality is assessed. OPTN Contract task 3.6 requires the ongoing monitoring of OPTN Policies.

Data Reporting

Data use agreements (DUAs) determine which data can be used for operational use and which data can be used for research.

Operational data uses include:

- Facilitate organ placement
- Monitor compliance of OPTN member organizations with federal regulations
- Monitor compliance of OPTN member organizations with OPTN requirements
- Perform transplantation-related public health surveillance
- Identify/evaluate areas important to the management of organ transplants/patient care
- Support evaluation of transplant programs and OPOs by the OPTN and government entities

Summary of discussion:

Site Surveying Monitoring

The Vice-Chair wondered what the validation was performed on recipient forms to ensure the data is correct. Staff replied it was validated against source documentation from the hospital. The Chair inquired whether site surveys have ever focused on the changes to data throughout the process. They speculated that these areas where there is high rate of change could also have a higher error rate, and added that the Scientific Registry of Transplant Recipients (SRTR) have performed research to show that, when variables used in risk adjustment are changed, they are overwhelmingly changed for higher risk adjustment. In addition, they also asked how many programs had been reported to the Membership and Professional Standards Committee because of data quality errors.

Staff replied that, to their second question, it would be very hard to find consistent, egregious, data quality errors because the site survey uses a small random sample of the reports from a program. Therefore, it is difficult to draw conclusions about a program's data quality. Furthermore, a program's data is only analyzed at one point in time, so finding the rate of change in specific data elements cannot be done. The Chair suggested that there could be a larger, more holistic analysis performed by Site Survey Staff to determine the rate of change in programs' data, rather than verifying the accuracy of information for isolated patients. They expressed interest in seeing this information, noting that, if the data is changing, it speaks to either the initial or subsequent submission being incorrect.

An SRTR representative affirmed that, in their analysis, they did find that when a candidate's data changed, it often made the candidates look riskier than before; this often made developing and updating risk adjustment models more difficult because programs would retrospectively change their data, which would in turn impact the risk adjustment model accuracy. They added that this was in part what inspired the "data lock" policy. It was noted that part of the issue is that there is no established threshold for what acceptable data quality is, so each program operates with a different perception. The representative from the Health Resources and Services Administration (HRSA) noted that approximately ten to fifteen years ago, it was noticed that some programs were "wholesale" changing their data which was identified as a data quality concern. The MPSC was notified and did interview one of the programs to determine the cause for large-scale data changes, but there was no administrative action.

A member inquired how this data change was discovered. The SRTR representative replied that it was done because a program changed the data on each candidate within a 24 hour period. They added, anecdotally, that the changes were all done to indicate each candidate had a lower functional status.

Another member suggested that some of the data quality concerns could be the data mapping between some electronic health records (EHRs) and the Data System for the Organ Procurement and Transplant System. If this is not corrected, some data may incorrectly flow automatically from the program's EHR.

The Chair asked how frequently programs withdraw membership from the OPTN. Staff replied that this was an infrequent occurrence, but had a high amount of data quality concerns. The Chair and Vice-Chair agreed that, though there may be data quality concerns surrounding this specific circumstance, the infrequency of it occurring meant the Committee should focus their attention on areas of larger impact. They Chair suggested the Committee consider how different programs report lost to follow-up, as there is large variation in practice as to how this data is gathered, but it is reported in the same format.

Data Reporting

The Vice-Chair suggested that another potential project for the Committee could be to increase the transparency and communication between the OPTN and programs when OPTN data indicates an event has occurred (i.e. death, return to dialysis) that program reported data does not. It was also suggested that another potential project could be for the Committee to develop a "data user's guide" to OPTN data.

The SRTR representative asked if there was any validation done to confirm that a transplant program has reviewed the OPTN data report, or whether it is "rubber stamped". Research staff responded that there was not. It was suggested that there be a series of check and balances to ensure that both the data reported to programs is accurate and their quality check of the data is performed. A member considered that some programs may not understand they even need to validate the data reported by the OPTN to them.

Next steps:

Staff will consider the steps suggested by the Committee and report back with any updates to their analyses.

2. Potential Project Ideas/Sequencing

Staff reviewed the projects that the Committee has expressed interested in addressing, as well as the timeline for which each should be done.

Data summary:

Project prioritization steps:

- Compile potential projects from list sent to Committee for review
- Leadership reviews, discusses Committee priorities and bandwidth
- Committee discusses goals and priorities, arrives at a consensus on priority projects
- Project approval/sequencing with POC
- Development

Projects for Committee consideration:

- Review of post-transplant data submission policies
- Improving/decreasing the number of candidates waitlisted after death
- Improving the OPTN Data Services portal and data services reports for patients

- Data collection on patient referral and evaluation pre-waitlisting (pending HRSA review for authority)

Summary of discussion:

Post-Transplant Data Submission Policies

The Vice-Chair suggested a potential area for improvement with this project would be to increase the granularity of response codes. They felt like it would fall under the purview of the Committee as the response codes are universal across organ types, and they impact data quality. The Chair supported this suggestion.

Post-Death Waitlist Removal Requirements for Candidates

There was no discussion surrounding this item.

Data Services Improvements

There was no discussion surrounding this item.

Pre-Waitlist Data Collection

The Vice-Chair supported the Chair's introduction that the quality of data can and should always be improved, especially in areas where there are known inconsistencies. The Vice-Chair added that the work of the Committee should not always focus on how to better collect the data, but also what sources can be used to supplement OPTN data such that the burden is not all on the OPTN. The ex-officio Chair also stated that part of the discussion can be removing data elements no longer seen as useful.

A member did not support requiring pre-waitlist data collection because it would increase the data burden on programs. They supported requiring this data from dialysis facilities rather than transplant programs, possibly through a data linkage rather than additional data collection. The ex officio Chair stated they were open to different methods of collecting this data, but felt that access to the waiting list was an area that needed greater transparency, which begins with data collection. They noted that the Ethics Committee was producing a white paper on access to the transplant waiting list, which could be informative to how the Committee considers collecting pre-waitlist data. A member suggested requesting a HRSA funded study which does not increase program data collection but investigates the issue within a context outlined by HRSA.

Another member hypothesized that, even if this data were collected, validation of the data could be difficult, as each program has a different practice; in addition, there are many referral sources that potential candidates come from that also have different practices. The Chair that the Membership and Professional Standards Committee (MPSC) was considering adding a metric for transplant programs for waitlist mortality. A member expressed concern that having this metric could have the unintended consequence that programs do not list their sickest patients. The Vice-Chair responded that the conversation should not revolve around metrics, but rather around data collection on practices that bar or disbar candidates from the waitlist. They felt that the analysis of whether the right candidates were getting transplanted was somewhat limited when center-specific listing practices were so varied. The Chair considered that there may be two different questions: what information is needed to understand the changes and inequities in access to the waitlist, and what metrics should be considered when trying to account for that. They also considered that the metrics question may be outside the scope of the Committee. The ex officio responded that the metric evaluation may be outside the scope of the Committee, but the data and quality of the data used to evaluate programs would be within scope. They emphasized that the two questions for the Committee should be: what is in the scope of OPTN data collection and what is the source and validation of pre-waitlist data.

Next steps:

Staff will consider the pre-waitlisting project and graft failures definition project as the Committee's first priority, and the post-death waitlist removals project and data services improvements project as secondary.

3. Data Lock Monitoring Plan

Research Staff detailed the monitoring plan and metrics considered for the Data Lock Policy Implementation.

Data summary:

Reports will be delivered to the Committee at six months, one year, and two years post-implementation. Any reports on usage prior to six months could be challenging due to the time period allowed to complete forms following the implementation date.

Summary of discussion:

The Vice-Chair suggested there could be a bolus effect at the beginning of the policy that could be over-generalized if reporting was done earlier than six months.

The Chair wondered if there would be a spike in the number of data changes prior to or during the data review period of the SRTR, as well as the direction of those changes. A SRTR representative voiced support for the current monitoring plan, and expressed interest in seeing where the spikes in usage were. Staff replied they would review the reports to see if there were any identifiable spikes and added that they do have flexibility within the reports to investigate trends.

The Vice-Chair requested a summary analysis of themes from the unlock rationale field, as they would be interested to see if it is being used for legitimate data changes. If a program were using the same code each time, they considered, it could speak to a data quality concern.

Next steps:

The Committee will receive and discuss the monitoring report at six months post-implementation.

4. OPTN API Overview & Integration Pipeline and Committee discussion of process improvement opportunities

Software Engineering Staff delivered an update on the development and status of OPTN application programming interfaces (APIs).

Data summary:

APIs enable one program to communicate with another – it defines the "black box": functions, inputs, and outputs.

Summary of discussion:

The Chair inquired if there was work being done to streamline the development of OPTN APIs being done with electronic health record (EHR) vendors. Staff replied that there were, but many of the vendors have their own software backlogs which delays the production of OPTN APIs. However, they added that there are quarterly calls to provide an update on the upcoming field and data collection changes. Furthermore, it is likely that industry standard API development models will be adopted by the OPTN for future development of OPTN APIs.

A member wondered what kind of communication is delivered to transplant programs when an API is released to EHR software vendors. Staff responded that there is neither substantial communication, nor

is that communication released to every program when the OPTN shares an API with a clinical software vendor. They considered that these releases are something they would like to increase awareness of. The member agreed and said that, if programs were aware of it, they could apply pressure to vendors.

The Vice-Chair suggested that the API development could be informed by a holistic review of consistent fields across EHR software types. They believed that these could be done as a "proof of concept" to show the benefit across multiple systems without addressing more specific data fields. They also speculated whether there was a way to bypass the clinical software vendors and develop specific APIs for OPTN member organizations. Staff replied that there were some organizations that did use that pathway, but stated that these were organizationally driven efforts that were built in-house. However, these work just as well as the developer APIs, and more information can be found by reaching out to the software development team.

A member asked if transplant programs have any way to request data elements be added to existing APIs. Staff replied that each is different; some are more standardized and are grouped by existing fields, whereas others have more flexibility to be formatted to contain different elements. The member suggested that transplant programs have a survey to determine the barriers that exist preventing programs from using the APIs.

Another member wondered what could be done to increase API utilization for the underused APIs. Staff considered that much of the problem was communication and pre-release coordination: programs should be more aware of what is being released when it is released.

The Vice-Chair asked if there had ever been a data quality concern with APIs, speculating that it could occur through an incorrect mapping. Staff did not recall an instance in which this had occurred, and stated that there was very basic validation for data to ensure that the data collected is reasonable. The Chair noted that this could get more difficult as the data transferred with the API becomes less discrete, suggesting fields like rejection, which is captured in different areas in an EHR, could be difficult to accurately transfer.

Next Steps:

Staff will consider the feedback from the Committee.

5. Social Determinants of Health (SDoH) presentation

Presenters from UNOS Research shared the work of the SDoH project, focusing primarily on the new findings and soliciting the Committee's feedback for future projects. The SDoH project was broken down into two studies, a population study and a waitlist outcomes study. Both studies focused on kidney recipients.

Summary of discussion:

A member inquired which data is from OPTN records and which is from Lexus Nexus. Education level, race/ethnicity, and insurance type are from OPTN data and all others are from Lexus Nexus. From a data quality perspective, a member inquired how well the data from the OPTN and Lexus Nexus correlated. In the first iteration of this project, the Research Department conducted a feasibility study to ensure accuracy between the data sets. In this review, they found extensive overlap in variables between the two and were able to link the data to supplement what each data set provided. Upon successful linkage, the group proceeded with the population and waitlist outcomes studies.

A member suggested utilizing individual-level data, as opposed to zip code data, to be more accurate and directly collated with the individual-level variables used. The member emphasized the greater additional value that individual-level data would have over zip code data for policy development. When

reviewing removal reasons and waitlist mortality, a member suggested delineating the patients who were removed because they were too sick out of the 'other' group to gain a more comprehensive understanding of the outcomes. A member inquired about stratified analysis of race and age or race and income. The presenter responded that the group did this analysis and did not find significant findings when stratified with race and can circulate those findings to the group. A member suggested looking at the interaction between race and age and the interaction between race and income.

A SRTR representative inquired about the cost-specific hazard models for the Fine-Gray approach for competing risk assessment. The presenter did this level of analysis as a sensitivity test for the study. The SRTR representative cautioned that it could inaccurately represent the connection between some variables and suggested additional consideration and context when using this method to reduce the chance of misinterpretation. A member inquired if the presenters were permitted to share the Lexus Nexus data dictionary, but unfortunately, this is proprietary information that is unable to be shared.

The next steps of these projects are to present findings to the OPTN Ethics and Minority Affairs Committees, complete drafting manuscripts for publication and submit to journals, and explore potential uses of these data in OPTN policy evaluation and planning.

Next steps:

Support staff will circulate the meeting materials and continue discussing the opportunities for the next steps of SDoH.

6. Annual deliverables to OPTN Board of Directors

Enterprise Data Management Staff provided a review of the annual deliverables provided by the Committee. They also reviewed the associated timeline for the deliverables.

Summary of discussion:

Review timelines for DAC review and submission

There was no discussion surrounding this item.

Annual Data Review Report

Staff recommended that, for the 2022 Data Review Report, Appendix A should reflect a summary of the changes that align to the 2022 Office of Management and Budget (OMB) package.

Annual Data Quality Report

The Chair expressed interest in reviewing critically where the gaps in data quality are. They suggested examining programs that are consistently late in reporting data, or those that have discordant data discrepancies between different reporting forms; from their perspective, they would like to see the report be more analytical rather than descriptive.

Staff noted that there could be difficulty in reporting on biologically implausible ranges, as the OPTN does not currently have a qualifier of what those would be. However, they did add that identifying and working to develop those ranges could be a Committee project.

A SRTR representative responded that biologically implausible range filtering is currently done on all of the risk adjustment variables in SRTR reports. These ranges were developed by consulting clinical experts in different organ groups at their organization, and then were reviewed with members of the organ-specific committees. Staff expressed that they would be hesitant to adopt these ranges without performing independent literature reviews and source analysis. The Chair requested a further conversation on this topic, considering that they did not feel like all the data definitions within the OPTN

system were subject to this level of stringency. They emphasized that there are definitions which are obviously wrong and should be examined in the data quality report. Staff suggested that, while these may not fit within the contract requirements of the data quality report, it could be produced as an independent report. The Chair disagreed and pointed out that the Board of Directors should be made aware of data quality concerns in the report on OPTN data quality.

Policy and Community Relations Staff noted that the hesitancy to add that analysis to the upcoming Board of Directors report may be a timing constraint rather than a contract restraint.

Next Steps

Staff will develop a format for a data quality report and return to the Committee for review and discussion.

Upcoming Meeting

- September 12, 2022

Attendance

- **Committee Members**
  - Sumit Mohan
  - Jesse Schold
  - Rachel Patzer
  - Jamie Bucio
  - Michael Ison
  - Macey Levan
  - Paul MacLennan
  - Krishnaraj Mahendraraj
  - Bilal Mahmood
  - Michael Marvin
  - Megan Muldoon
  - Benjamin Schleich
  - Farhan Zafar
- **HRSA Representatives**
  - Adriana Martinez
  - Chris McLaughlin
- **SRTR Staff**
  - Bert Kasiske
  - Jon Snyder
  - Bryn Thompson
- **UNOS Staff**
  - Brooke Chenault
  - Isaac Hager
  - Nadine Hoffman
  - Courtney Jett
  - Krissy Laurie
  - Eric Messick
  - Joel Newman
  - Robert Patterson
  - Laura Schmitt
  - Sharon Shepherd
  - Serena Straub
  - Kimberly Uccellini
  - Anne Zehner
- **Other Attendees**
  - Christine Maxmeister