

**OPTN Data Advisory Committee
Meeting Summary
April 13, 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 04/13/2022 to discuss the following agenda items:

1. Data Lock Implementation
2. Living Donor Data Collection
3. Pre-Waitlist Project Update
4. Social Determinants of Health
5. Check in #1 – OPO Committee – DonorNet Data Collection
6. Refusal Codes – Monitoring Report
7. Discussion on Holistic Data Review

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

1. Data Lock Implementation

The Committee reviewed updates to the Data Lock project. This extends the time programs have to submit data and requires documentation and authorization for data changes after ‘data lock’. It was Office of Management and Budget (OMB) approved in March 2022.

Summary of discussion:

There was no discussion surrounding this item.

Next steps:

The Committee will consider next steps in assisting the community with the Data Lock Implementation.

2. Living Donor Data Collection

The Committee reviewed progress to the potential Living Donor Data Collection project. This project determine what data should be collected from the living donor collective, as well as future living donors. It is also a collaborative effort between the Scientific Registry of Transplant Recipients (SRTR) and the OPTN.

Summary of discussion:

A representative from SRTR supported what the Chair had mentioned in her introduction. A member added that standardization of reporting could alleviate repeat reporting between SRTR and the OPTN. In addition, it would allow for better tracking of living donors.

A member wondered how this data collection was different than what is already collected. A representative from SRTR responded that, first, half the data collected from living donors is missing, which means there is not a lot of long-term data on living donor outcomes. Second, the Living Donor

Collective (LDC), an external volunteer group that tracks living donor data, is collecting data on living donor candidates, which means they can analyze the barriers for individuals who are not allowed to donate. They added that one of the eventual goals of the project is to collect lifetime living donor data. The member also asked why living donor outcomes are not reported in SRTR reports. The SRTR representative replied that SRTR reporting is informed by OPTN data, and OPTN data both has a large amount missing; in addition, it mostly tracks a programs ability to follow up with a candidate, not their outcome.

It was suggested that there could be a living donor portal in which the donor could update their health status without having to visit a transplant program. It was noted that this was tried in a research study, and living donor follow up information was still very hard to gather. The SRTR representative also contributed that the LDC would likely have better luck with this approach as they would be able to link with the United States Renal Data System. They added that all of this work is in progress, and they speculated that having multiple means of reporting probably would be the best way, as it would give living donors more options to report their information.

Next steps:

The Committee will assist in the OPTN Living Donor Committee’s efforts to submit a report to the OPTN Board of Directors in December 2022.

3. Pre-Waitlist Project Update

The Committee reviewed progress on their potential project collecting pre-waitlist data. This would collect candidate data prior to their waitlisting to increase visibility surrounding listing practices and candidate evaluation. This continues to be an identified priority by the Committee and leadership.

Data summary:

The OPTN Ethics Committee is producing a white paper on Transparency in Program Selection.

Summary of discussion:

There was no discussion surrounding this item.

Next steps:

The Committee will consider steps that can be taken while pending Health Resources and Services Administration (HRSA) feedback on the project.

4. Social Determinants of Health

Two members of UNOS Research Staff presented on their social determinants of health study. This is a periodic study done as a contract deliverable.

Data summary:

Social determinants of health (SDoH) are the conditions in the environment where people live, work, and age that affect a wide range of quality-of-life and health outcomes. Using an external partner, in 2021, 110,000 OPTN records were linked to current address records to identify geographic SDoH measures. This informed the 2022 SDoH study, which comprised two projects:

- (1) Population-based Analysis of Social Determinants of Health and the U.S. Kidney Waitlist

Study Objectives:

- a. What is the relationship between candidate-level SDoH and the SDoH of their places of residence?

- b. Do counties with higher prevalence of chronic kidney disease/end stage kidney disease have proportionally higher numbers of waitlisted candidates?
- (2) Social Determinants of Health and Kidney Waitlist Outcomes

Study Objectives:

- a. What SDoH are associated with waitlist outcomes?
- b. To what extent do SDoH affect waitlist outcomes?
- c. Are some waitlist outcomes more affected by SDoH compared to others?

Summary of discussion:

The Chair wondered how the study team was going to account for and organize all the variables pertinent to social determinants of health. In addition, they asked whether their sample size was indicative of all the transplant patients on the kidney waiting list. Research staff confirmed that the 112,000 OPTN records were all U.S. citizens who had ever been on the kidney waiting list in 2020. Therefore, as there was approximately 99% linkage between OPTN records and geographic data, the overwhelming majority of their data is kidney candidates who were ever on the waiting list in 2020.

The Chair also inquired if there were plans to expand the data to other organs, and if the data would ever be distributed external to the OPTN. Staff noted that there were plans to perform the same evaluation on other organ types. External researchers, they added however, would not be able to access the data due to the agreement with the external partner. OPTN Committees would be able to request data elements for review.

A member asked how the study findings could be relevant to transplant programs. A presenter responded that the end results of the study will be publically available reports to HRSA, and programs will be able to independently evaluate the reports. In addition, it informs future SDoH projects which will also provide more information to transplant programs in the future.

The Vice-Chair wondered what the overarching goal of linking SDoH variables with waitlist outcomes could be. The Chair added that there is lots of data to suggest SDoH variables and waitlist outcomes are linked already, and it would be interesting to see more detail into the additional variables that have not been as heavily reviewed in this evaluation. Furthermore, there is potential to use this data to inform changes to allocation policy based off the findings. A presenter noted that this is the first time that such an in-depth analysis has been performed from the OPTN, due to a previous lack of SDoHs available to be linked to individual patient records. This process serves as a proof of concept for what type of analysis could be built into the more traditional policy analysis done by the OPTN committees.

The Chair advocated for this approach, and considered that this type of data would be very useful for independent researchers, both in its current horizontal form and also in a longitudinal form over time.

Research Staff responded to a comment inquiring about an early preview of findings before going out for public comment stating that these findings will not go out for public comment due to them being HRSA deliverables. It will be presented to the Board of Directors in their June meeting, however.

Finally, Research Staff concluded by stating that much of the data the OPTN collects on SDoH is missing, so a large part of the study effort was determining which SDoH variables could be used, as well as those that would provide the most meaningful data for their project. They added that they had performed causal analysis on each variable to ensure that each one provided independent and useful information for their model.

Next steps:

The Committee will review the final results of the study prior to it being presented to the Board of Directors in June.

5. Check In #1 – OPO Committee – DonorNet Data Collection

UNOS Staff presented on the OPTN OPO Committee’s project DonorNet Data Collection. The project seeks to update the clinical donation after cardiac death (DCD) data reported in the OPTN Donor Data and Matching System to better capture information used by transplant hospitals during organ offer evaluation.

Data summary:

The proposed data elements are included in the table below:

DonorNet Data Element	Purpose
Withdrawal of Life Sustaining Medical Support, Date/Time	DCD - Starts the clock on measuring donor progression to death
Cessation of Circulation, Date/Time	DCD - Second critical time marker in donor progression leading to "Pronouncement of Death" Note: Pronouncement of Death (date/time) currently collected in DonorNet
Flush Time (in situ), Date/Time <ul style="list-style-type: none">• Abdominal aorta• Portal vein• Thoracic aorta• Pulmonary artery	DCD - Signifies the end of agonal phase and warm ischemic time, start of cold ischemic time Note: Currently collected in the DDR:
DCD Hemodynamic Information <ul style="list-style-type: none">• Heart rate• Blood pressure	Strategic and significant to organ suitability for DCD donors <ul style="list-style-type: none">• Same fields and values are collected during donor management, but for a different purpose and a different period of time• Same base data values, but linked differently• Should not be correlated or collected with donor management hemodynamic information, very distinct snap shot in time
Additional Hemodynamic Information <ul style="list-style-type: none">• Left ventricular function• Diastolic measures• End-systolic dimensions• End-diastolic dimensions*Serial capability for each	*Soliciting feedback from Heart Committee

Summary of discussion:

A member wondered which staff from the Organ Procurement Organization (OPO) side inputs the OPTN Donor Data and Matching System data in the system. UNOS Staff responded that OPO coordinators typically input donor information. They also noted this should make the process for finding some of this information easier, as coordinators would not have to search through attachments for the information.

The Chair asked if the workgroup anticipated any pushback surrounding increased data burden on programs, and the presenter noted that they did not; the Technology Tools Workgroup has a number of OPO representatives.

A member also asked how the workgroup determined they should focus on DCD data. The presenter responded that they had solicited feedback from workgroup members, and a number had noted DCD data was not very significantly built into the system. A second member inquired if the workgroup had considered adding a field to include perfusion device usage. The presenter stated that the workgroup was hesitant to add that field due to the potential controversy with normothermic regional perfusion (NRP) and its current usage rate. However, they added that, though it is not part of this project, the workgroup would continue to have discussion about tools to add to the OPTN Donor Data and Matching System. A member suggested that “mode of DCD recovery” be considered to be added.

There were no further questions, and the Committee noted support for the proposal.

Next steps:

The OPO Committee will consider the Committee’s feedback.

6. Refusal Codes - Monitoring Report

UNOS Research Staff presented their three month monitoring report on the update to refusal codes.

Data summary:

Staff reviewed the top reasons for organ refusal on match offers for:

- Kidney
- Heart-Lung
- Kidney-Pancreas
- Intestine

In summary, “Actual or projected cold ischemic time too long” was used for at least 10% of abdominal organ offers. “Epidemic/Pandemic – Donor” was used frequently for kidney and liver offers. “Unacceptable organ-specific test results, specify” was used frequently for thoracic and kidney-pancreas offers.

Additionally, similar patterns appear between organ match types, and refusal reasons do not vary depending on the size of program.

Staff also reviewed the top refusal reasons for organ offers when the acceptance was above and below the median, by organ type. In summary, “Organ size, specify” was used on 31% of heart-lung matches when the acceptance was lower than the median. “Unacceptable organ-specific test results, specify” was used on 42% of lung matches when the organ type was lower than the median. “Candidate transplanted or pending transplant” occurs often for heart-lung matches when the acceptance is lower than the median.

Finally, Staff presented on range refusal reason data.

Summary of discussion:

A member inquired whether “Epidemic/Pandemic – Donor” aligned with positive serological testing, to which the presenter responded that there was separate code for positive serologic testing.

The Vice-Chair wondered about the high usage of “Epidemic/Pandemic – Donor”, noting that many donors likely will have had COVID, and it does not seem to be affecting other organs. The Chair hypothesized that there may be programs who still automatically refuse organs from donors who are COVID positive. A member working at a transplant program noted that they knew of smaller volume programs which were still very hesitant to consider COVID positive donor organs. In addition, they noted reluctance to vaccinate amongst some of their candidates. The Chair also speculated that, due to the

COVID Omicron variant surge in January, the three months of data may be skewed with that code usage. Research staff also considered that programs may be incorrectly using the code when their recipient is COVID positive.

The Vice-Chair inquired whether discarded organs were included in the kidney median acceptance number data, noting that the median used to be 7, and on the graphs it was noted at 667. Research staff responded they would review their analysis of the kidney data.

A member requested that the data be publically available, and staff replied that the plan was to distribute the data through the OPTN website. The member also suggested that the presentation would be helpful in regional meetings.

Next steps:

Research staff will consider DAC feedback and present to relevant committees with the monitoring report.

7. Discussion on Holistic Data Review

The Committee continued its discussion on the framework for holistic data review. The goal is to create a process to routinely review data collected by the OPTN and update when necessary. Staff gave a brief overview of the progress to date, as well as possible options moving forward.

Data summary:

The discussion seeks to answer the questions:

- Who should review the data?
- What should the timing of review be?
- What data should be included in the review?
- What should the actionable next steps for the Committee to take?

In addition, the Committee reviewed six possible approaches to data review:

- 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

Summary of discussion:

The Chair noted that the third option, which addresses data elements that address the most concerns, would not necessarily be holistic, as it would review things as they are identified as most concerning.

A member added that the first option may not be as viable either, as it would slow down progress to suddenly include data review in the scope of approved projects. In addition, it may not be the most resource efficient. They were in favor approaching the evaluation broken down by organ type, as it is already the macro-level organizational system the OPTN uses. It was noted that this approach would need a “second-level” evaluation, as each organ has different relevant data.

A member suggested that the Committee could evaluate Electronic Health Record (EHR) systems and how significantly fields correlate to the Data System for the OPTN. This would enable a smoother flow of data from where it is input to the forms that collect it. The Chair noted this could be difficult due to the

variety of EHRs available, but supported this approach. It was suggested this could also increase accuracy of data if there is similarity between forms.

A member proposed addressing the organs by order of form usage, saying that this would give the Committee “the biggest bang for its buck”. The Chair responded that this would mean the Committee would start with kidney, which SRTR has already reviewed; this was not necessarily a detriment to the approach, but could have some redundancy in the work performed. Staff also noted that the Kidney Committee may have less time to work with the Committee as they are transitioning to continuous distribution next.

Another member countered that if the Committee approaches organs with less data to review than kidney, the projects will likely move faster. In addition, more organs would be able to be reviewed in the same time period. The Chair wondered if, with this approach in mind, projects could be done more simultaneously, rather than sequentially. In addition, it was proposed that the organ-specific committees could do part of the review themselves. The Chair also noted that, for the first review cycle, the Committee may want to start with the smallest organ group rather than the biggest in order to fine-tune their processes without sifting through all data relevant to a larger organ field.

Staff suggested it may be helpful for the Committee to create a roadmap document to identify which elements organ-specific committees should review, as they are specific to the organ, and which would be within the purview of the Committee because they extend across all organ types. They added that the Committee should focus first on two questions: 1) Who is doing the review and 2) Which subject areas will they be responsible for. The Chair supported the OPTN committees being responsible for some of their data.

The Committee reviewed the six possible approaches to data review.

Expand Scope of Current Projects to Include Data Review

There was no discussion on this approach and unanimously chose to discard it.

Review the Data by Form or System

A member noted it was not holistic to review data based off of frequency of appearance on forms. The Committee unanimously discarded this approach.

Review Data Elements that raise the Most Concerns/Data Quality Issues

The Chair said that this is an activity the Committee already performs, to a certain degree, and, again, is not necessarily a holistic approach to review. Staff added that the Committee has and will continue to operate as a resource for committees to review data elements and ensure their necessity. The Chair continued, saying that the OPTN has not taken a holistic review of its data collection for over 15 years, and the scope of this project should not seek to solely address the immediately problematic areas.

An external participant proposed that a crosswalk of all data could exist as a “data dictionary” resource. Staff noted this would further assist committees in reviewing their data, as they could easily review all the elements currently collected. Additionally, they added this is an effort currently underway, and would likely complement the holistic data review project.

Build on Other Data Review in Flight or Recently Completed

The Chair considered that this could be something the Committee adds to their data review checklist, rather than takes as an approach for holistic data review. A member noted that this contributes to projects already underway which would add momentum and be beneficial overall. The Chair added that

this could be part of the recommendations for a regular review schedule, in which Committees examine their own data; for example, the OPO Committee has already started to review its data as seen in their earlier project check in. A member supported this, saying that the holistic data review project would help other committees understand what data they are stewards of and should review.

Identify Most Critical Data and Review First

Staff introduced the approach and stated that this approach could ensure the Committee addresses the areas of greatest need first. If the Committee is reviewing all OPTN data, they could create a checklist of critical items and structure the list into an ordered review that touches on each item. The Chair said that the committees could even be used to identify what their most critical data elements were. Staff also mentioned that they could ask the committees to identify what data is currently input manually so as to accelerate a switch to electronic exchange.

Review Data by Subject Area/Domain

Staff stated that this would fit well within existing processes, as it would identify clear needs for the Committee when considering new members each cycle. In addition, it creates an opportunity for data element creation to be structured in such a way that all fall clearly into an established category (e.g. Master and Reference Data, Horizontal Data, Vertical Data, etc.) A member supported this approach, noting that the categorizations of “Horizontal Data” and “Vertical Data” visualized the concept of data collection well.

A member questioned whether this data would leverage the Scientific Registry of Transplant Recipients (SRTR) special report fully. Staff noted that their report examined data elements that would fall across a couple of the established categories. If this approach were used, the SRTR approach may not provide the best basis for understanding the effects of changing data within each of these specific categories; if a data element were changed in the horizontal data category, how would the Committee understand the impacts of changing it without knowing what else was contained in same category? In addition, this approach would facilitate identifying which data was assigned to a committee.

A representative from SRTR confirmed that they perform program specific reports every three years, following a question from a member.

Staff noted that this approach is a method only for organizing the review, but the Committee still would have to determine which organ is reviewed first. Additionally, this approach would also align with the Committee’s goals to improve the automation of data collection, thereby increasing data quality. Finally, evaluation for Application Programming Interfaces (APIs) could be included in this review to further identify where streamlining can happen.

A member wondered whether there was representation from manufacturers of Electronic Medical Records (EMRs) on any of the committees. Staff responded that they were not on any committees, but IT has a relationship with EMR vendors to ensure that enhancement and interfacing areas are identified. In addition, the Committee has plans to better incorporate standardized code sets so as to align with EMR data collection. It was suggested that the Committee could preemptively evaluate what the scope of existing standardized codes is to avoid creating a crosswalk in this project for data elements that could be standardized.

This approach was supported by the Committee, and staff suggested a hybridization of the most effective ones as suggested by the Committee could be the overall best approach. A SRTR representative added that SRTR would be happy to contribute analysis done in their routine data review to this process.

Staff posed the question whether there are any identifiable areas that the Committee should own. The Chair wondered if it should be anything more than what is “left over” after the committees claim data elements. Staff suggested that they could iterate on the draft crosswalk created and expand it to mock up exactly how much data committees would be responsible for versus how much the Committee would oversee. The Committee could then discuss whether they felt like this was the correct balance. Staff also inquired if there were external stakeholders that the Committee felt should be involved in data review groups. The Chair suggested at minimum HRSA and SRTR, and any relevant subject matter experts should be brought in as needed for workgroups.

Next steps:

Staff will iterate on their draft definition crosswalk to demonstrate what data elements could belong to committees. In addition, Staff will begin considering next steps to move the project forward so that a document can be produced for the December Board of Directors Meeting (Policy Oversight Committee approval, OPTN committees’ support, road map for the Board of Directors).

Upcoming Meetings

- May 9, 2022
- June 13, 2022

Attendance

- **Committee Members**
 - Rachel Patzer
 - Sumit Mohan
 - Kristine Browning
 - Jamie Bucio
 - Colleen Flores
 - Lauren Kearns
 - Macey Levan
 - Krishnaraj Mahendraraj
 - Alicia Redden
 - Benjamin Schleich
 - Daniel Stanton
 - Farhan Zafar
- **HRSA Representatives**
 - Adriana Martinez
- **SRTR Staff**
 - Ajay Israni
 - Bert Kasiske
- **UNOS Staff**
 - Brooke Chenault
 - Wida Cherikh
 - Cole Fox
 - Isaac Hager
 - Nadine Hoffman
 - Robert Hunter
 - Nikki Johnson
 - Tatenda Mupfudze
 - Olga Kosachevsky
 - Andrew Placona
 - Brittany Shean
 - Brian Shepard
 - Kim Uccellini
 - Suhan Wang
 - Anne Zehner
- **Other Attendees**
 - Christine Maxmeister
 - Elizabeth Boehnlein