OPTN Data Advisory Committee
Meeting Summary
September 28, 2023
In-Person Meeting – Detroit, MI

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

Introduction

The Data Advisory Committee ("Committee") met in Detroit, Michigan on 09/28/2023 to discuss the following agenda items:

1. Workgroup Report-Outs
2. Task Force on Efficiency: Update
3. Presentation of findings from 12-Month Monitoring Report for Updates to Policy 18, Data Submission Requirements and member questions
4. Approval process for non-substantive changes in the data collection form instructions that contain organ-specific or shared data elements
5. Findings from Clinical Data Standards Assessment
6. Status update of Holistic Data Review workgroup activities
7. Educate members regarding DAC's annual deliverables to the Organ Procurement and Transplantation Network (OPTN) Board of Directors
    a. Overview of draft Data Review Report
    b. Overview of draft Data Quality Report
8. Discuss DAC Priorities, review list of projects, and time for members to discuss their project ideas
9. Overview of Office of Management and Budget (OMB) Process

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

1. Workgroup Report-Outs

Members of workgroups that collaborate with the Committee shared progress reports and updates.

Summary of discussion:

The focus centered on familiarizing new members with data review requirements and the value of data quality reporting. Members from the Membership and Professional Standards Committee (MPSC) Performance Monitoring Workgroup and Holistic Data Review (HDR) Workgroup shared the objectives of the workgroups with which they are involved and the progress-to-date of those efforts. A member of the MPSC Workgroup highlighted the importance of the Committee's representation and pursuit of standardizing data definitions and collection. Comprehensive data collection from referral to donation was detailed along with efforts to identify and uniformly capture data at each stage. The Holistic Data Collection Workgroup members reported on their engagements with other committees prior to joining the HDR Workgroup, sharing experiences and insights gained from past collaborations. Both workgroups highlighted the importance of capturing data and consistently defining terminologies.

There was no discussion on this item.

Next steps:

Staff will inform the Committee of upcoming workgroups requesting the DAC's participation. Workgroup members will continue providing updates to the other Committee members.

2. Task Force on Efficiency: Update

Staff provided an update on the OPTN Task Force on Efficiency.

Summary of discussion:

The OPTN Contractor outlined the complexity of allocation efficiency challenges including policy implications, federal requirements, programming inefficiencies, and data collection issues. Concerns about behavioral variation in transplant programs, travel, and logistical inefficiencies were highlighted, with a marked rise organ non-use. To address this, the OPTN Task Force is positioned to enhance allocation efficiency with the goal of addressing the rise in organ non-use and out of sequence allocations. The presentation underscored an approach to engage with the community in a variety of mediums. The Task Force will pilot potential solutions, focusing on community feedback and diversifying opinions; with an aim to prioritize short-term wins, long-term strategies, and innovation.

The Task Force will plan to engage extensively with the community to seek suggestions and feedback on data and recommendations, with the objective focusing on identifying policy changes and opportunities for standardization. Additionally, the Task Force will work collaboratively with committees, by piloting improvement opportunities and ensuring that policy proposals will be sponsored by committees. The Task Force will aim to supplement committee work by providing data and information that some committees may not have access to. The presentation concluded with an explanation of the roles of committees and the Task Force. Committees will remain responsible for sponsoring policies, while the Task Force will focus on policy recommendations, data collection, and pilot projects. Committees will support the Task Force's work, providing input, and assisting in relevant projects.

Members suggested engaging with various community organizations such as the National Kidney Foundation to gather information and recommendations on organ allocation and donation. Several members stressed the importance of data collection and data elements in understanding various issues such as organ non-use, out-of-sequence allocations, and the lack of operational data within existing systems. Concerns were raised about the time lag in gathering data, suggesting quicker, more innovative methods to facilitate data collection. The Committee also emphasized the importance of defining the problem statement, analyzing available data, and anticipating potential roadblocks to preemptively address them.

The Vice-Chair expressed eagerness to receive updates on the finalized Task Force committee members and to access future meetings or opportunities for the Committee to provide input. Members strongly agreed that the Committee should be consulted if the Task Force is considering data collection or review. They also highlighted the need for engagement from all stakeholder organizations to ensure a comprehensive and informed approach to tackling the challenges related to organ allocation inefficiencies. Staff concluded by asking the Committee to brainstorm ideas and share feedback on how the Committee and the Task Force can collaborate effectively to address these challenges and improve organ utilization.

Next steps:

The Committee will review its projects to determine what to recommend to the Task Force.

3. Presentation of findings from 12-Month Monitoring Report for Updates to Policy 18, Data Submission Requirements and member questions

The OPTN Contractors presented the 12-month monitoring report findings and progress related to the data lock implementation.

Summary of discussion:

The Committee discussed the 12-Month Monitoring Report associated with the Data Submission Requirements modifications, also known as the Data Lock Monitoring Report, focusing on the restrictions placed on data alterations to improve the accuracy and timeliness of submissions. The presentation focused on the changes in data submission requirements and implementation of the "data lock". The report evaluated the 'lock' and 'unlock' trends among OPTN members, the reasons why members were unlocking data collection instruments, and the frequency of unlocking across various components of the OPTN Computer System. Furthermore, it analyzed the cadence of field changes before and after the policy's implementation and assessed the impact of the data lock.

Members expressed efficiency concerns about managing change requests. An emphasis on the high occurrence of unlocking events due to delayed reporting was discussed, noting specific points in the year that coincide with data reporting deadlines and center reviews. A suggestion was made to track submissions via an API and explore possible solutions in understanding the impact of the data lock policy. Members expressed the need to reevaluate strategy and solutions for data quality. Several members pointed to the form changes with histocompatibility forms, constraints of submissions, and corrections to candidates' forms (especially kidney transplant forms). Additionally, a member noted the need to differentiate between legitimate and non-legitimate changes with suggestions for performing an audit. Various suggestions were made for best practices, data clarifications, and working with vendors for improved API form development. Additionally, a member proposed inviting IT professionals to Committee meetings for knowledge sharing and strategic planning in partnership with the OPTN Network Operations Oversight Committee. The Chair highlighted the significance of data integrity for research and policy formulation. Staffing issues and the influence of such issues on the quality of data collection were also discussed. Members also discussed needing education modules for supporting members working on data quality compliance. At the end of this discussion, the Committee reached a consensus on changes to reviewing and auditing data accuracy.

Next steps:

Staff will review the recommendations from the Committee and compile them into next steps.

4. Approval process for non-substantive changes in the data collection form instructions that contain organ-specific or shared data elements

Committee members discussed change management in data collection.

Summary of discussion:

Decision #1: The Committee agreed to maintain the current process whereby DAC reviews all changes (substantive and non-substantive) and provides endorsements when appropriate.

The presentation focused on the need for a defined process for non-substantive change. Some key issues identified included a lack of clear accountability for data ownership and stakeholder involvement. The Committee emphasized the need for greater structure and efficiency, while acknowledging challenges to volunteer-driven labor. A call for a more structured approach to defining data ownership, balanced approach to immediate fixes, and long-term strategy were also discussed.

A Committee member expressed concern about the complexity of implementing the discussed changes with shared data elements. In discussing solutions, members proposed enhancing efficiency by proposing a standardized workflow for handling non-substantive changes and establishing clear metrics for more effective and timely decision-making. The Committee members emphasized defining clear roles and responsibilities for committees involving non-substantive changes with an additional focus on acknowledging DAC's expertise and autonomy in handling changes. Some members favored maintaining the current process of allowing DAC to lead and manage changes.

Next steps:

DAC will maintain the existing approach in terms of what changes are reviewed. In addition, the Committee will consult with other OPTN committees and/or experts when necessary to ensure efficient decision-making.

5. Findings from Clinical Data Standards Assessment

Members from workgroups that the Committee are collaborating on shared progress reports and updates.

Summary of discussion:

Members expressed concerns about managing change requests, emphasizing the need for efficient handling and the potential benefit of being able to perform necessary changes. A member suggested an evaluation of clinical data standards and data definitions for items submitted and a plan to address any shortcomings. A reference to leveraging the Holistic Data Review Workgroup to review and evaluate changes for cross-functional perspectives was shared, due to its effectiveness in ensuring modifications to the system. The remainder of the session focused on the inclusion of two OPTN contract requirements requiring the introduction of health data standards into the OPTN Computer System. The impact assessment covered user activities related to data entry, obstruction, reporting, analytics and research. Specific OPTN contract tasks, including Task 3.5.3, were integrated into the standard terms and codes. Task 3.5.2 revised its configuration of forms and interfaces for transmitting data efficiently.

Discussions highlighted the significance of adhering to national health data standards, emphasizing the importance of the Obama High-Tech Act of 2009. The conversation shifted to include the design of registries and their impact on standardization and alignment of business needs. The registry model with its patient-centric approach plays a vital role in standardizing the clinical data collection process. The assessment revealed that most OPTN data elements are mappable or partially mappable, while 20% of the OPTN data remains non-mappable due to misalignment with standards or technical issues. Pain points included data governance, change management, and the need to refine data governance processes for a comprehensive data dictionary.

The discussion moved towards the solution direction, evaluating data entry, obstruction, reporting, and analytics. Feedback from different stakeholders found varying readiness and technological capabilities across OPTN members. The Committee members discussed the role of the Office of the National Coordinator for Health Information Technology (ONC) in terms of its engagement with standardizing health data and emphasized the importance of seeking active engagement from the ONC to align with broader healthcare strategies. The Centers for Medicare and Medicaid Services' (CMS) push for standardized performance and metrics was mentioned, with discussions centering around how this influences the technology roadmap of vendors. The involvement of CMS in adopting data standards was debated. Additionally, discussions regarding European datasets and potential intersections were considered.

The group raised concerns about the present status of standardization in transplant care and how health data standards might influence the registry's patient-centered data collection. Conversations extended to the role of HRSA in mediating between agencies and contractors, with a focus on clarifying their engagement in the process of data standardization.

The conversation began with reflections on the possibility of implementing clinical data standards and the timeline for data transformation. Concerns were expressed regarding the time required for complete data standardization, estimating it to be beyond 24 months. Emphasis was placed on the need for refining definitions and ensuring strategic alignment with the OPTN Board regarding data standardization. Concerns were expressed about spending clinician time and resources on non-substantive changes. The importance of aligning expectations was highlighted.

A member emphasized engaging with a central office responsible for Health IT to ensure no duplicative effort. Discussions highlighted that every transplant center receives payment from CMS, indicating the significance of aligning with national standards and health IT regulations. Acknowledgment of existing loopholes was made, followed by a presentation of a simplified diagram of the operational and analytical environments. A five-year plan was outlined, suggesting the gradual integration of kidney forms as a starting point for mapping. A member's inquiry led to discussions about the 20% of data fields that could not be mapped due to uniqueness in business rules or technical elements. The framework detailed the integration of data governance, change management, and the involvement of various stakeholders. Emphasis on recruiting for various roles was made, in addition for the need for partnerships with contractors, community stakeholders, and clinical informaticists.

Discussions centered on the forthcoming meeting with the chair to share assessment findings and requirements for funding the work. Engaging with the Chair and determining the next steps in terms of funding or project prioritization were discussed. The conversation highlighted potential challenges in mapping 20% of the data fields to a common data model. The discussion elaborated on the need for potential changes to the common data model to accommodate unique data elements in the field. Another discussion centered on potential changes required in common data models to accommodate specific concepts unique to the transplant field, such as relationships between donors and recipients and the need for additional data tables or drop-down additions.

Next steps:

The Committee members emphasized the need to build clear, accurate, and precise data reporting structures for future use.

6. Status update of Holistic Data Review workgroup activities

The Holistic Data Review Workgroup members discussed their progress and the Workgroup's deactivation following completion of its objectives.

Summary of discussion:

A member discussed the progress of the Workgroup, highlighting the activities of the past year. The presentation detailed lessons learned, inclusive of slated changes. Attendees emphasized the need to continue the review of forms and ensure efficient use of clinicians' time. A conversation ensued about the strategic vision behind standardizing data and the OPTN Board's involvement. Discussions took place on the existing process flow for changes and the potential need to reactivate the Workgroup to address broader issues related to standards and data alignment. Attendees emphasized the value of involving clinicians in the clarification of definitions and their role in understanding broader implications of data standardization.

The discussion concluded by highlighting the existence of both specific, smaller-scale issues that might need a workgroup's focus and broader, macro-level problems that might require a strategic approach and alignment with the board's vision. The conversation detailed the need for strategic alignment with the board and the involvement of clinical experts in defining the broader implications of standardizing data practices.

The conversation shifted towards discussing upcoming deliverables for the OPTN Board, including the Annual Data Review Report and Data Quality Report. An outline of these reports, their structure, content, and the timeline for review and finalization was presented. Members discussed the need for feedback on drafts of the reports to ensure alignment and accuracy, which would be reviewed in the upcoming meeting, aiming for finalization by the end of October to present the key takeaways. The necessity of continued work on refining data definitions and the need for a more efficient process to manage member inquiries while adhering to the contract's data quality standards was emphasized. The conversation revolved around the development of reports for the OPTN Board, particularly focusing on the Data Quality Report.

Next steps:

There were no next steps taken.

7. Educate members regarding DAC's annual deliverables to OPTN Board of Directors

Members discussed the DAC's annual deliverables to the OPTN Board of Directors.

Summary of discussion:

The members discussed the process for associated with developing and reviewing the annual deliverables, suggesting that members could share their ideas and proposals through emails or communication with the leadership, leading to the creation of project forms and subsequent discussion within the committee for approval and action. The conversation included enhancements to data related waitlist removal reasons, with the goal being to better understand the outcomes of the removal of patients.

The dialogue highlighted the Committee's role in recommending these improvements to transplant programs and the importance of sponsorships and collaboration in addressing issues related to waitlist removal and other critical data elements. The conversation aimed to align the Committee's efforts with the most impactful and meaningful projects to improve the efficiency and effectiveness of the transplant system. The conversation was centered on multiple points discussing issues and potential improvements within the data systems utilized in various transplant programs. The members highlighted the need for data scalability, refining of existing fields, and producing more informative data.

Members raised concerns about challenges faced across different OPTN committees in terms of simultaneously addressing specific issues related to waitlist removal reasons, activation of patients, and residential location data. They further expressed a desire for more granular and specific information regarding these factors to better understand patient outcomes and data infrastructure. There were discussions on collecting nine-digit zip codes for better contextual understanding of patient environments. The discussion further explored the complex problem of accessing and improving the quality of death data for patient outcomes and clinical studies.

Next steps:

The list of potential projects ideas will be reviewed by the Committee in the future.

8. Discuss DAC Priorities, review list of projects, and time for members to discuss their project ideas

The Committee members were provided with an update on existing DAC projects and on-going activities. They also shared their ideas for potential projects.

Summary of discussion:

The Committee discussed the upcoming OPTN Board meetings on November 29th and December 4th for a report presented by a member. The presentation focused on work priorities, alignment with ongoing projects, annual deliverables, and high impact data elements.

Committee members emphasized the need for efficient collaboration and clarity about ongoing projects, policies, and specific deliverables. They stressed the importance of the Committee's role in understanding the critical data projects. One key focus was the internal Activity Tracker, a spreadsheet maintained on the Committee's SharePoint site where records of ongoing projects are maintained, along with information about their status, and associated members. The intention behind this tool is to offer a comprehensive overview of the projects under discussion or in the pipeline. The goal being to encourage proactive participation and creativity from newer members to further urge contributions.

Several project ideas were identified, including the following:

- Donor perfusion-related data
- Reasons for patient removal from the waitlist
- Reasons for inactivating patients
- Inclusion of census tract-level data
- Being more prescriptive data definition/clarification information to help members
- Replacing HIC with NDI
- Growing data management strategies (example: annual conference, peer group of informaticists to assist OPTN members)
- Share existing resources on DAC's SharePoint site

A push for more prescriptive data definitions/clarifications would help with Electronic Health Records (EHR). Questions surrounding the implementation of this project were asked. A member noted that waitlist removal reasons were not specific, and they would like to see the OPTN adopt more granular descriptions for why patients were inactivated. Contractor support staff noted that both the OPTN Patient Affairs Committee and the OPTN Transplant Coordinators Committee were interested in addressing the same issue, and collaboration could be useful.

The Vice Chair mentioned that obtaining patients' residential location information has been an area of data collection interest, due to the level of detail. In the U.S. Renal Data System (RDS) there are 9-digit zip code data collected. Research literature indicates the benefit of more granular residential data for identifying risk factors and sensitivity for patients. This level of detail would be more beneficial for policy and research. The Vice Chair indicated that this project may be "low hanging fruit."

Next steps:

The members will research implementing some of the discussed projects.

9. Overview of Office of Management and Budget (OMB) Process

Staff provided an overview of the OMB requirements for OPTN data.

Summary of discussion:

Staff provided an overview of the OMB and the five main functions across executive departments and agencies, primarily the review and assessment of information collection requests. Inclusive of this discussion is the presentation of the Paperwork Reduction Act (PRA), which is a law governing how federal agencies collect information from the public. The OMB "Clearance" process requires:

- Detailing how data collection fits with the organization's goals
- A calculation of burden
- The different types of data collected
- Two rounds of public comment on the Federal Register

Under the current OPTN contract, the OPTN Contractor agreed to collect all official OPTN data through OMB approved data collection forms under the PRA. Official OPTN data consists of all data collected by the OPTN Contractor pursuant to federal regulatory requirements (42 CFR 121.11) and to fulfill its obligations under contract with HRSA. The OMB Program for the OPTN is the following:

- OMB Control Number: 0915-0157
    - Information Collection Request (ICR) Title: OPTN Data System
    - Data collection forms in OPTN Computer System (UNet℠)
- OMB Control Number: 0915-0184
    - Information Collection Request (ICR) Title: OPTN Application Form
    - Membership and transplant program forms

The Impacted systems are the following:

- OPTN Donor Data and Matching System (DonorNet®)
- OPTN KPDPP (KPD℠)
- OPTN Data System (TIEDI®)
- OPTN Organ Labeling, Packaging and Tracking System (TransNet℠)
- OPTN Waiting List (Waitlist℠)
- OPTN Patient Safety Portal
- OPTN Membership System

The 2023 OPTN data system OMB package includes the following policy projects:

- Phase 2 LAS Refinements and Clean Up (Updating Mortality Models)
- Enhancements to OPTN Donor Data and Matching System Clinical Data Collection
- OPTN KPD Blood Type Policy Alignments and Donor Re-evaluation Efficiency Requirements
- Improve Deceased Donor Evaluation for Endemic Diseases
- Optimization of Offer Filters
- OPTN DAC, Membership and Professional Standards Committee, and Executive Committee approved data-related removals

The following happened with the OPTN including submitting annually for OMB review. The OPTN has not received substantive feedback to date from OMB or the public on the data collection package revisions.

Improvement opportunities were discussed including, automating OMB package submission by maturing metadata management tolling and sharing with HRSA, understanding the OMB change management process in greater detail to find efficiencies in the review process, and adopting OMB consultation methods for all data collection forms. There was also a recommendation for HRSA to adjust the OMB submission cycle to be aligned with each OPTN Board meeting (two cycles versus one) as well as discuss with HRSA if there are alternative approaches to following OMB process so major and minor

data changes can be implemented timelier. The Chair asked about opt-out preferences and HRSA staff members provided historical knowledge on the opt-out preferences of health data informed from federal agencies.

Next steps:

There are no next steps.

Upcoming Meetings

- October 16, 2023
- November 13, 2023
- December 11, 2023

Attendance

- **Committee Members**
  - Sumit Mohan, Chair
  - Jesse Schold, Vice Chair
  - Rebecca Baranoff
  - Jamie Bucio
  - Kate Giles
  - Dustin Goad
  - Paul MacLennan
  - Michael Marvin
  - Christine Maxmeister
  - Meghan Muldoon
  - Hellen Oduor
  - Jennifer Peattie
  - Julie Prigoff
  - Alicia Skeen
  - Allen Wagner
- **HRSA Representatives**
  - Adrianna Martinez
  - Chris McLaughlin
  - Vanessa Arriola
- **SRTR Staff**
  - Avery Cook
  - Jon Snyder
- **UNOS Staff**
  - Brooke Chenault
  - Jonathan Chiep
  - Nadine Hoffman
  - Michael Hollister
  - Sevgin Hunt
  - Krissy Laurie
  - Ann Marie Leary
  - Eric Messick
  - Lauren Mooney
  - Joel Newman
  - Sharon Shepherd
  - Tynisha Smith
  - Kayla Temple
  - Kim Uccellini
  - Suhuan Wang
  - Divya Yalgoori
  - Anne Zehner
- **Other Attendees**
  - Not applicable