OPTN

Data Advisory Committee Report to the Board of Directors

Sumit Mohan, M.D., M.P.H., Chair

November 29, 2023

This report reflects the Data Advisory Committee's (DAC) work in the calendar year (CY) 2023.

Purpose

This report summarizes the OPTN Data Advisory Committee's (DAC) efforts to improve data quality since the last report submission (December 2022), inclusive of planned and implemented changes to data collection sent to the OPTN Board of Directors (BOD) for consideration during the December 2022 and June 2023 meetings. This report includes items from December 2022 through October 31, 2023. November and December 2023 items will be included in the 2024 report.

Background

Official OPTN data are defined as data collected by the OPTN pursuant to regulatory requirements (e.g., 42 CFR 121.11) and to fulfill its contractual obligations. The OPTN registry includes data collected about potential donors, deceased donors, living donors, transplant candidates, and transplant recipients required for the matching function and other OPTN activities. The OPTN data is used for policy development, organ placement, compliance, and quality improvement. The BOD approved OPTN Data Collection Principles and operational statements in 2006 and the Data Vision Statement in 2016 to guide OPTN committees to make data collection decisions aligned with organizational goals. DAC is charged with reviewing and making recommendations to the BOD regarding the collection of OPTN data that are pertinent to the operation of the OPTN, necessary for the development of evidence-based OPTN policies, and to support analytic work undertaken by the OPTN Contractor or the SRTR contractor. All substantive changes to OPTN data collection must be approved by the Office of Management and Budget (OMB).

Approach

The DAC is charged with overseeing all recommendations to the BOD regarding specifications for collecting data on all transplant events. It also has responsibility for recommending to the BOD data release policies, data collection procedures, and specific OPTN database elements necessary for data analysis and research functions in support of the OPTN and the Scientific Registry. To that end, as an operating Committee, DAC will assess enhancement opportunities and collaborate with other OPTN committees seeking to modify data collection instruments.

Improving the quality of OPTN data requires ongoing data management activities. This report describes activities conducted by DAC over the calendar year, January through November 2023. This report also includes plans for future work. OPTN data collection projects are the primary vehicle for identifying where data needs to be added, modified, or removed. To improve data quality, the DAC reviews each data collection project before, during, and sometimes after the public comment cycle. Once the BOD approves a data collection project, documentation on planned changes is submitted to the Office of Management and Budget (OMB) for their review and approval. IT implementation occurs after receipt

of OMB approval.

Report Organization

This report is organized in sections that describe DAC activities in CY2023 and planned work for the coming year. These sections are:

1. Summary

2. Manage OPTN data policies

3. Changes to Data Collection

    a. Review of changes to data collection

    b. DAC focused on improving data quality

    c. DAC awareness items

    d. Summary of OPTN Data Changes

4. Improve data collection details and help text instructions

5. Contract deliverable on Clinical Data Standards (PWS 3.5.3)

The text in this report refers to OPTN systems by short name to improve readability.

OPTN System Name	Trade Name
OPTN Donor Data and Matching System	DonorNet®
OPTN Waiting List	Waitlist[SM]
Data System for Organ Procurement and Transplantation Network	TIEDI®
OPTN Computer System	UNet[SM]
Kidney Paired Donation	KPD[SM]

1. Summary

In CY 2023, the DAC reviewed the six-month and twelve-month monitoring reports of Policy 18: Data Submission Requirements in 2023. This included a review of the DAC-sponsored "Data Lock" project and the Data Lock Dashboard tool.

The DAC has reviewed over twenty policy proposals that impact existing OPTN data collection. These recommendations to the BOD will result in 127 changes - adding new data (69 fields) and removing data no longer needed (58 fields). Regarding new OPTN data collection, some DAC members have engaged in workgroups looking to evaluate new and ongoing project proposals. The DAC Holistic Workgroup provided recommendations to reduce user confusion and improve consistency with reporting, ad hoc data quality, and improving data definitions.

To date, DAC has approved 14 data definition clarifications. DAC members also participated in multidisciplinary interviews to evaluate the risks and benefits of modernizing the OPTN data collection by adopting standardized healthcare terminologies and Application Programming Interfaces (APIs).

The DAC members also participated in the Clinical Data Standards assessment and provided input on the needed project resources and timeline.

2. Manage OPTN Data Policies

The DAC has responsibility for evaluating and recommending improvements to data-centric OPTN policies. OPTN Policy 18: Data Submission Requirements includes requirements and timeframes for members to submit and report data. Policy 19: Data Release stipulates the OPTN will release OPTN data according to the Final Rule and other applicable federal and state laws and regulations.

Activities to Date

In April 2023, DAC reviewed a six-month monitoring report of the Modify Data Submission Policies project implemented in August 2022. This project aims to evaluate data quality risks related to the deadlines for submitting OPTN-required data. Data quality risks pertaining to incomplete and inaccurate submissions can lead to erroneous findings and recommendations. Therefore, the OPTN members must "unlock" the forms to make edits after the submission deadline. The DAC analyzed computer logfiles on lock events to assess patterns by form. The DAC members are evaluating the next steps to uncover contributing factors for unlocking events.

The Data Lock Dashboard tool allows members to review potential data quality issues by analyzing recorded validation issues. Members can also see their data compared to national benchmarks and trends.

In September 2023, DAC reviewed the twelve-month monitoring report of the Modify Data Submission Policies project presented by the OPTN contractor. Two major themes emerged from the analysis: timely form completion rates improved after policy implementation and unlocking rates vary by form. DAC plans to continue to monitor unlocking patterns to assess risks in data integrity.

Future Work

The DAC reviews and revises Policies 18 and 19 on an as-needed basis. The DAC consults with other committees on policies that may impact both policies. The DAC will continue to monitor the Modify Data Submission Policies project during this post-implementation period.

The approved policy language within the Modifications to Data Submission Policy requires the DAC to report at least annually to the Board of Directors the following:

- Data submission compliance rates
- Frequencies of data changes following submission, as well as the reported reasons associated with the changes
- Other relevant information identified by the Committee

The DAC will include summary level monitoring information on this policy change in the 2023 Data Quality Report and additional monitoring details during CY2024. The DAC is considering additional steps it can take to reduce the volume of updates that are occurring after form due dates.

3. Changes to Data Collection

DAC partners with OPTN committees to review and advise on changes to data elements to support OPTN operations and activities.

Review of changes to data collection:

- **Improve Deceased Donor Evaluation for Endemic Diseases project**: The OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC) provided a check-in to the DAC on the Improve Deceased Donor Evaluation for Endemic Diseases project. This project's focus is to require universal screening for Strongyloides and targeted screening for Chagas for deceased donors, which requires additional data collection in the OPTN Donor Data and Matching System. The project will add four data collection fields to DonorNet (one of which cascades to the Deceased Donor Registration form in TEIDI). DAC endorsed and created a formal public comment on this project.

- **Align OPTN Kidney Paired Donation Blood Type Matching Policy Alignments and Establish Donor Re-Evaluation Requirements project**: The Kidney Transplantation Committee provided a check-in to the DAC on the Kidney Paired Donation Blood Type Matching Policy Alignments and Establish Donor Re-evaluation requirements project. This project will establish the requirement for donors to be re-evaluated for the KPD system and align the blood type matching eligibility requirements with those in OPTN kidney policy. This project will also remove three data fields and replace those removed fields with one data field. DAC endorsed and created a formal public comment on this project.

- **Optimizing Usage of Kidney Offer Filters project**: The Operations and Safety Committee provided a check-in to the DAC on the Optimization Usage of Kidney Offer Filters. This project aims to develop a more precise offer filter model that evaluates multiple variables to expand utilization. The proposal also includes the addition of one data field in Waitlist. DAC members expressed concern for this proposal as written. In March 2023, Operations and Safety Committee returned to DAC with modifications from the first check-in and DAC submitted a summary of additional comments on this project. DAC endorsed this project.

- **Revise Donor and Recipient Histocompatibility Forms project**: The DAC reviewed the Histocompatibility Committee's project to revise donor and recipient histocompatibility forms to include virtual crossmatching findings. This data collection will inform the community on the success and utility of virtual crossmatching. DAC endorsed proposed changes to data collection and offered to provide DAC support to the project. Second DAC check-in is scheduled in November 2023.

- **Remove CPRA >98% Form for Highly Sensitized Kidney Candidates project**: The DAC reviewed the Histocompatibility Committee's request to decrease the documentation burden for CPRA of

more than 98% for kidney candidates receiving allocation priority. The project proposed removing affected data collection fields to align with current practice. DAC endorsed the removal of proposed data elements.

- **Granular Review of OPTN Living Donor Data Collection project**: DAC reviewed the Living Donor Committee's project to update the OPTN living donor data collection forms. After feedback on the committee's concept paper, they will identify changes to ensure accurate and relevant data collection on living donors. The DAC endorsed this project.

- **Collect Living Donor Candidate and Donation Decision Data project**: The Living Donor Committee's request to collect living donor candidate and donation decision data. The project also aims to collect long-term follow-up data on living donors. The DAC endorsed this project.

- **Collect Donor CRRT, Dialysis, and ECMO Interventions Data project (PC Title: Deceased Donor Support Therapy Data Collection)**: The Operations & Safety Committee presented a check-in to DAC for the Collect Donor CRRT, Dialysis, and ECMO Interventions data. This project will impact offer filters to include options to add filtering to accommodate patients on CRRT and ECMO. DAC endorsed this project.

- **Patient Safety project**: The Membership & Professional Standard's Committee (MPSC) asked DAC to endorse the Patient Safety project to streamline data collection. The proposal included the removal of five data fields from the Safety Situation Form and two sub-category selections from the Living Donor Event Form. DAC endorsed these recommendations with the caveat of harmonizing data elements to prevent information loss.

- **Improving Liver Allocation: MELD, PELD, Status 1A, and Status 1B project**: The Liver & Intestinal Organ Transplantation Committee presented the Improving Liver Allocation: MELD, PELD, Status 1A, and Status 1B project. The proposal included one data collection change with an update to the form instructions. The DAC endorsed this data collection modification.

- **Kidney-Pancreas CD: Data Collection Updates for Continuous Distribution project - Review Board Exceptions, Kidney Minimum Acceptance Criteria Screening Tool, and Potential Medical Urgency Data Collection**: The Kidney Transplantation and Pancreas Transplantation Committees checked in with DAC regarding the Kidney Pancreas Continuous Distribution project. This project requires data collection modifications across the Kidney Minimum Acceptance Criteria Screening tool, Review Board exception request forms, and Medical Urgency forms. The DAC endorsed the development of this project. The respective committees will update DAC as data collection efforts continue. As of September 2023, the BOD has put this project on hold.

- **Promote Efficiency of Lung Allocation project**: The Lung Transplantation Committee presented the Promote Efficiency of Lung Allocation project to the DAC. This project will identify ways to add offer filters for lung allocation. The project will also update offer notification limits, donor acceptance criteria, and lung donor testing requirements. The DAC endorsed this project.

DAC activities to improve data quality:

- **Refusal Code project**: DAC reviewed the nine-month post-implementation monitoring report on the Update to Refusal Code Project in December 2022. DAC members commented on several report items of particular interest. No action items identified at this time. Post-implementation monitoring is in progress.

- **DAC Holistic Workgroup data definition clarification review**: DAC reviewed and provided recommendations to modify 14 form instructions. The modifications provided details on the OPTN business rules for reporting and related documentation steps. The DAC endorsed these changes in October 2023.

DAC awareness items:

- **Predictive Analytics for Adult Kidney Offers**: DAC reviewed the recently implemented Predictive Analytics for Adult Kidney Offers project aimed to increase offer acceptance rates in the OPTN Donor Data and Matching System through user access to a decision-making tool. DAC members responded with questions and suggestions to the pilot program's presentation.

- **Review of National Academies of Sciences, Engineering, and Medicine (NASEM) Recommendations**: The DAC reviewed findings and recommendations on "Realizing the Promise of Equity in the Organ Transplantation System." DAC validated recommendations to standardize OPTN data collection, initiate collection of pre-waitlist data, and improve collaboration with HRSA, CMS, EMR vendors, and other groups.

- **Update Non-Use Reasons in OPTN Computer System**: DAC sponsored a project to review and update the system choice list on organ non-use. The DAC submitted a data request to review the current state and the OPTN contractor shared the analysis findings in the September 2023 meeting.

- **OPO Metrics**: The Membership & Professional Standards Committee (MPSC) presented potential project topics to develop new OPO metrics. The DAC endorsed and assigned resources to support the OPO Metrics project.

- **Establish Member System Access, Security Framework, and Incident Management and Reporting Requirements**: DAC reviewed the Network Operations Oversight Committee's request to add IT security enhancements to the OPTN Computer System and implement electronic tracking of security incidents. This project also involves end-user training. DAC endorsed and developed a formal public comment response.

- **Standardize the Patient Safety Contact Notification Process**: The Ad Hoc Disease Transmission Advisory Committee presented a new project on the upkeep of site-level contact information for the Patient Safety staff. The DTAC proposed including transplant centers in the audit process. The DAC assigned a member to participate in the workgroup and endorsed the data changes at their October meeting.

- **Amend Adult Heart Status 2 Mechanical Device Requirements**: The Heart Transplantation Committee presented the new project Amend Adult Heart Status 2 Mechanical Device Requirements. This project will reserve intra-aortic balloon pump (IABP) exceptions for Status 2

candidates. Data collection on inotrope use will be required to ensure the proper alignment of status 2 candidates without disadvantaging patients needing an IABP. The DAC endorsed the project and requested future check-ins as the project develops.

- **Update HLA Equivalency Tables 2023**: The DAC received an update on the Histocompatibility Committee's ongoing project to revise the HLA equivalency tables. Future updates will be provided to the DAC as needed.

- **Required Reporting of Patient Safety Events**: The Membership and Professional Standards Committee (MPSC) presented their proposal for public comment. This proposal aims to define the patient safety events and "near misses" that will be required reporting. DAC provided a formal public comment response in August 2023.

Future Work

The DAC will continue to partner with OPTN committees on proposed data collection changes to prevent data quality issues. The DAC will also continue monitoring the Modify Data Submission Policy project implementation outcomes.

Summary of OPTN Data Changes

DAC is charged with reviewing and making recommendations to the BOD regarding the collection of OPTN data that are pertinent to the operation of the OPTN, necessary for the development of evidence-based OPTN policies, and to support analytic work undertaken by the OPTN Contractor or the SRTR contractor.

In 2023, 509 data collection changes were implemented in the OPTN computer system (see Table 1). These changes were DAC-approved in CY2022.

Table 1. Data collection changes implemented in 2023 after OMB approval

Proposal Name/Description	OMB Form Name	Fields Added	Fields Removed	Total Changes
Modify Data Collection on VCA Living Donors	Living Donor Registration	54	1	55
	Living Donor Follow-up	17	0	17
Programming VCA Allocation in UNet^{SM}	VCA Transplant Recipient Registration	16	10	26
	VCA Transplant Recipient Follow-up	54	5	59
Modify the Deceased Donor Registration Form	Deceased Donor Registration	24	38	62
Update Data Collection to Align with US Public Health Service Guideline 2020	Deceased Donor Registration	10	0	10
	KPD Candidate Registration	2	0	2
HLA Equivalency Tables (1159)	KPD Donor Registration	2	0	2

Data Collection to Evaluate Organ Logistics and Allocation (1028)	Deceased Donor Registration	0	1	1
Reporting Graft Dysfunction in Heart Recipient	Transplant Recipient Registration (Adult/Pediatric)	16	0	16
	Adult Heart Transplant Recipient Registration	77	1	78
	Adult Heart Lung Transplant Recipient Registration	77	0	77
Modify Graft Failure Definition for VCA	VCA Transplant Recipient Registration	1	0	1
	VCA Transplant Recipient Follow-up	3	1	4
Standardize Kidney Biopsy Reporting and Data Collection	Deceased Donor Registration	18	0	18
Cross organ data alignment	Pediatric Transplant Candidate Recipient Registration	14	7	21
	Pediatric Transplant Recipient Follow-up (1 Year)	12	6	18
	Pediatric Transplant Recipient Follow-up (5 Year)	12	6	18
	Pediatric Transplant Recipient Registration	16	8	24

Table 2 summarizes the planned data collection changes that are scheduled for OMB approval in CY2024. These planned changes will be scheduled for implementation after OMB approval.

Table 2. Planned data collection changes pending OMB approval

Expected Approval	Proposal Name/Description	Committee	Impacted System	OMB Form Name	Fields Added	Fields Removed	Total Changes
2024	Phase 2 LAS Refinements and Clean Up (Updating Mortality Models) (1239)	Lung	TIEDI®	TCR Lung Adult form	3	0	3
			TIEDI®	TRR Lung Adult form	0	6	6
			TIEDI®	TCR Heart Lung Adult form	3	0	3
			TIEDI®	TRR Heart Lung Adult form	0	6	6
2024	Enhancements to OPTN Donor Data and Matching System Clinical Data Collection (1214)	Kidney	TIEDI®	Deceased Donor Registration Form	7	0	7
			DonorNet®	Initial Donor Registration	19	0	19
2024	MPSC, DAC and Ex Comm approved removals	MPSC	Patient Safety	Safety Situation	0	30	30
				Disease Transmission Event	0	2	2

2024	OPTN KPD Blood Type Policy Alignments and Donor Re-evaluation Efficiency Requirements (1384)	Kidney	KPD	Kidney Paired Donation Candidate Registration Form	1	11	12
			KPD	Kidney Paired Donation Donor Registration Form	1	0	1
2024	Improve Deceased Donor Evaluation for Endemic Diseases (1327)	DTAC	TIEDI®	Deceased Donor Registration Form	1	1	2
			DonorNet®	Initial Donor Registration	11	1	12
2024	Optimization of Offer Filters (Mandatory Offer Filters) (1265)	Kidney	Waitlist℠	Kidney Offer Filters Management	21	1	22
			Waitlist℠	Adult Kidney Candidate Listing Registration	1	0	1
			Waitlist℠	Pediatric Kidney Candidate Listing Registration	1	0	1

4. Improve Data Collection Details and Form Instructions

To implement non-substantive changes to shared or organ-specific data collection labels, values, definitions, and form instructions, requires input from hand-picked subject matter experts from DAC or a separate OPTN committee on the suggested update from an OPTN member. After SME approval, the revised wording is emailed to the full committee for review before the next DAC meeting. DAC endorsement is needed before the change is implemented in the OPTN Computer System. Affected OPTN users and stakeholders are notified about the change through public notice and email notifications.

In CY2023 (January 2023 – November 2023), the DAC endorsed 14 modifications to form instructions in the OPTN computer system (Table 3).

Table 3: CY2023 Updates to form instructions

Data Element	Impacted Form
HBV Vaccination Status	Transplant Recipient Registration
Viral Detection	Transplant Recipient Follow-Up

Date: Last Seen, Retransplanted or Death (Recipient)	Transplant Recipient Registration Transplant Recipient Follow-Up
Date of Discharge from Transplant Center	Transplant Recipient Registration Transplant Recipient Follow-Up
Patient on Life Support	Transplant Candidate Registration Transplant Recipient Registration
Patient on VAD	Transplant Candidate Registration Transplant Recipient Registration
Most Recent Hemodynamics: Cardiac Output	Transplant Candidate Registration Transplant Recipient Registration
Events occurring between listing and transplant	Transplant Recipient Registration
Prior Cardiac Surgery (non-transplant)	Transplant Candidate Registration Transplant Recipient Registration
Episode of Ventilatory Support	Transplant Recipient Registration
Total time on perfusion: received at the center on ice	Transplant Recipient Registration
Did patient have any acute rejection episodes between transplant and discharge	Transplant Recipient Registration
Left Kidney Biopsy	DonorNet® Deceased Donor Registration
Right Kidney Biopsy	DonorNet® Deceased Donor Registration

Future Work

Staff will continue to present questions to the DAC as needed to improve data collection accuracy.

5. Clinical Data Standards (PWS 3.5.3)

The Clinical Data Standards (CDS) project is a contract deliverable to uncover operational and technical factors associated with adopting healthcare terminologies and determining approaches to enhance the OPTN computer system to support semantic interoperability. The assessment showed adopting standards is an OPTN-wide transformation. It impacts processes and technology that support data collection, analytics, and research. The custom OPTN integrations with external organizations will need to be maintained until all community stakeholders are able to update local systems to support interoperability using standards. Due to estimated internal and external resources needed to define the requirements, build, and maintain standardized and custom integrations and affected technologies, the contractor is deferring to HRSA on the prioritization, timing and financing for the implementation of this project.

Activities to Date

The contractor completed the assessment between April and July 2023 and reported assessment findings to the following stakeholders:
1. HRSA Contracting Officer Representative and HRSA OIT staff
2. DAC's Holistic Data Review Workgroup
3. Data Advisory Committee (DAC)
4. Network Operations Oversight Committee (NOOC) Chairs

The DAC Chair will provide feedback on whether the DAC supports the OPTN adopting healthcare standards to the BOD during the November 29th board meeting.