OPTN

Data Advisory Committee Report to the Board of Directors

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This report reflects the Data Advisory Committee's (DAC) work from December 2023 through October 2024.

Purpose

This report summarizes the efforts of the Organ Procurement and Transplantation Network (OPTN) DAC to improve data collection since the last report submission in November 2023. It includes planned changes to data collection that were sent to the OPTN Board of Directors (BOD) for consideration during the December 2023 and June 2024 meetings. The report covers the period from December 2023 through October 2024.

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 in making 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 Scientific Registry of Transplant Recipients (SRTR) contractor. All substantive changes to OPTN data collection must be approved by the Office of Management and Budget (OMB).

Approach

The DAC oversees 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 from December 2023 through October 2024. 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 and sometimes after the public comment cycle. Once the BOD approves a data collection project, documentation on planned changes is submitted to OMB for review and approval. IT

implementation occurs after receipt of OMB approval.

Report Organization

This report is divided into sections outlining DAC activities from December 2023 through October 2024, and upcoming work for the next year. These sections are:

1. Summary

2. Review of DAC's OPTN Policies 18 and 19

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

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

OPTN System Name	Brand 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

During December 2023 through October 2024, DAC has reviewed and endorsed over ten policy proposals that affect the current OPTN data collection. Table 1 below lists the data collection proposals approved by the OPTN Board of Directors, which are included in the current or future OPTN Data System OMB packages. These approved proposals will result in 96 changes, adding new data (53 fields) and removing data that are no longer needed (43 fields). During this period, DAC has endorsed 6 data definition clarifications.

On February 5, 2024, the OPTN received a data directive from the Secretary of the U.S. Department of Health and Human Services (HHS) to expand the OPTN data collection. This expansion includes ventilated patient referrals for donation, as well as referral and evaluation information about potential transplant candidates. Prior to receiving the data directive, on November 13, 2023, HRSA requested the DAC review a set of drafted data collection forms and instructions. In response to HRSA's request, the DAC quickly established a Pre-Waitlist workgroup and partnered with the already formed Membership and Professional Standards Committee's (MPSC) Organ Procurement Organization (OPO) Performance Monitoring and Enhancement workgroup to review HRSA's drafted materials and provide feedback by

end of January 2024. The DAC and MPSC workgroup chairs presented workgroup feedback to HRSA on January 31, 2024. Materials shared and additional information on this initiative are posted on the OPTN website. As this data collection proceeds to the Federal Register for public comment, the DAC will take the lead in helping the Executive Committee formulate an OPTN response. The DAC expects to provide support for the data directive throughout 2025.

2. Review of DAC's OPTN Policies 18 and 19

Policy 18: Data Submission Requirements

Policy 18 outlines the requirements for submitting data related to organ transplantation. This policy aims to ensure that accurate, complete, and timely data is collected, which supports the evaluation and improvement of transplant programs. In the next year, DAC intends to review and update Policy 18.

Policy 19: Data Release

Policy 19 focuses on the release of data related to organ procurement and transplant. This policy governs the protocols and guidelines for the sharing and dissemination of transplant data. In the upcoming year, DAC will prioritize when to begin partnering with the Network Operations Oversight Committee (NOOC) on a project to formalize OPTN data release requirements to further research and quality improvement.

3. Changes to Data Collection

The DAC also collaborates with OPTN committees to review and advise on changes to data elements supporting OPTN operations and activities.

Review of changes to data collection:

- **Pancreas Disposition Reason Code Changes project**: This project aims to improve the choice list options to comply with the Health Resources and Services Administration (HRSA) data directive from July 1, 2024. This change is also in alignment with the Centers for Medicare & Medicaid (CMS) memo dated August 29, 2024. The revisions in the choice list were specifically made to differentiate between pancreata accepted for bona fide islet cell research and reporting of discards when an organ is recovered for research. The change also involves retrospectively updating reason codes for research pancreata recovered since January 01, 2021. The DAC has endorsed this project.

- **Require Reporting of HLA Critical Discrepancies and Crossmatching Events to the OPTN project**: This project is a proposal from the Histocompatibility Committee. Its purpose is to require reporting of critical discrepancies in Human Leukocyte Antigen (HLA) to gain insight into root cause of these discrepancies. The goal is to develop prevention strategies to reduce the number of these cases. Additionally, the project aims to update the definition of critical

discrepancies to focus on the required reporting of what is most immunologically significant and to align with the required HLA typing resolution. The DAC has endorsed this project.

- **Communicating Post-Transplant Disease project**: The OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC) provided an update to the DAC on the progress of the Communicating Post-Transplant Disease project. The goal is to streamline the process for conducting a follow-up 45 days after a potential disease transmission event (PDTE). These events could include bacterial, viral, fungal, endemic, parasitic, and malignancy related findings. By automating the data collection process, the aim is to create a more efficient and secure data collection for confidential medical peer review completed by the DTAC. The DAC reviewed and discussed this project and has endorsed a formal public comment on this initiative.

- **Deceased Donor Data Collection project**: The OPTN Contractor has presented a proposed plan to DAC to improve data collection on deceased donors. The plan involves the DAC and OPO committees co-sponsoring a project to update the cause of death, mechanism of death, and circumstances of death elements in the OPTN Donor Data and Matching System. Upon receiving input from OPO stakeholders to advocate for the design requirements, the DAC has endorsed developing a draft data collection proposal. The DAC also endorsed preparing for potential public comment in winter 2025 and submitting a proposal to the OPTN Board in June 2025.

- **Transportation Events Data Collection project**: The MPSC referred a project idea to the DAC and OSC in January 2024 for consideration by both committees. According to the MPSC referral, they were interested in DAC and/or OSC pursuing a project collecting data related to transportation events resulting in a donor organ not arriving when expected. The data proposed for collection should help the OPTN evaluate the causes why donor organs do not arrive when expected and the consequences resulting from such delays. The DAC reviewed the project idea and recognized the value of collecting this data. The DAC suggested partnering with the Operations and Safety Committee to define the data collection requirements. The DAC and OSC chairs and vice chairs discussed the potential for a data collection project and identified an opportunity to leverage efforts within the Late Declines Discovery work of the OPTN Expeditious Task Force. The Late Declines Discovery work included members from the Task Force and OPO and OCS committees and primarily focused on obtaining additional details from twelve OPOs regarding instances of late declines. Participants of this work also had the opportunity to report transportation-related events, if they occurred, during the collection timeframe. Upon reviewing the first round of feedback, the group determined that further refinement was needed through a second phase to obtain more meaningful information and establish working definitions before action or recommendations could be made. In identifying the need for further refinements, the group also concluded that it was premature to involve DAC at this stage. Based upon competing priorities within the Task Force, this initiative as well as several others were paused until further notice.

- **Promote Efficiency of Lung Allocation project**: The Chair of the Lung Transplantation Committee provided an update on the efforts to improve lung allocation. This includes a proposal to add the history of anaphylaxis to peanuts and sternotomies. This proposal underwent a public comment period from January to March 2024 and was reviewed by the DAC in spring of 2024. In June 2024, the Board evaluated the proposal. The DAC has endorsed this project.

- **Donor and Recipient Histocompatibility Forms Revision project:** The DAC endorsed the project to address the data collection discrepancies described by DAC support staff. The Histocompatibility Committee is working on identifying the contributing variables. During project development, the importance of data reliability was emphasized, and it was recommended that the OPTN should investigate the sources of these errors and their causes.

- **Amend Adult Heart Status 2 Mechanical Device Requirements project**: The Vice Chair of the OPTN Heart Transplantation Committee presented updates on the committee's project after receiving feedback during the public comment period. The OPTN Heart Committee's goal with this project is to add eligibility criteria requiring a transplant program to demonstrate it attempted supporting a candidate using inotropic therapy before proceeding to implanting an Intra-Aortic Balloon Pump or Percutaneous Endovascular Mechanical Support Device. Changes to existing OPTN data collection are limited to modifying options on existing drop-down lists. The DAC endorsed the Heart Committee's modifications to the data collection requirements.

DAC activities to improve data quality:

- **OPTN data quality update and review**: The DAC made the following short-term recommendations (1-2 years) to the Board last year:

  - Review transplant programs that have higher than average rates of unlocking or editing data to determine necessary actions such as education, additional monitoring, or enhancements.

  - Perform additional analysis to understand the correlation between member data submission approach (electronic or manual) and unlocking activities.

  - Monitor and work with programs experiencing high rates of discrepancies in dialysis dates to identify ways to reduce error rates.

  Qualitative and quantitative analysis for the items listed above are included in the DAC's 2024 Annual Data Quality report.

- **24-month Refusal Code Monitoring report (final monitoring report)**: DAC reviewed and discussed the report. The Chair mentioned that the granular refusal codes have offered better insight into reasons for declining organ offers. This is considered a positive development. However, there is room for improvement in understanding the reasons behind the declines and making the data more actionable. DAC discussed some potential next steps, and the Chair presented outcomes of the project to the Policy Oversight Committee (POC).

- **Data definition revision (date last seen, death, or last seen retransplanted):** The OPTN Contractor raised concerns about data definitions. Several DAC members had questions regarding data definitions and help text updates, which need further discussion.

- **Accessing Kidney Data and Graft Failure Information**: The DAC discussed the importance of data access and sharing between CMS and HRSA. This issue is affecting the Chronic Renal Transplant Registry (CRTR) and research in kidney transplantation. Given their importance for transplantation, DAC is willing to provide expertise and perspectives to support resolving these data sharing issues. It was suggested that potential next steps could include socializing the problem formally and coordinating advocacy efforts.

Please refer to the 2024 Annual Data Quality Report for more detailed information.

DAC awareness items:

- **The OPTN Strategic Plan 2024-2027 proposal**: The OPTN Vice President presented the OPTN Strategic Plan for 2024-2027 to DAC. The BOD adopts a new strategic plan every three years. The strategic plan is not an exhaustive list of the OPTN's work, but rather serves as a high-level framework to guide the OPTN's strategic focus. DAC discussed the plan and recognized that as an OPTN operating committee, the DAC could help shape the BOD's efforts to improve data collection as described in the proposed Strategic Plan.

- **Revise Conditions for Access to the OPTN Computer System**: The NOOC informed DAC about a potential proposal requiring all OPTN members accessing the computer system to sign a data use agreement and report privacy breaches. DAC responded with feedback and plans to continue partnering with the NOOC on this project.

- **Changes to How Members Access SharePoint**: OPTN implemented access changes on March 11, 2024.

- **Overview of MPSC Referral Process**: The OPTN Contractor staff provided an overview of the MPSC referral process to DAC. Committees involved in the referral review process will review MPSC's findings and determine whether a policy project is necessary and/or if data collection requirements require modification.

- **OPO Metrics**: The MPSC presented a potential project topic for developing new OPO metrics. The DAC endorsed the project and assigned resources to support the workgroup activities.

Future Work:

The DAC will continue partnering with OPTN committees on proposed data collection changes to prevent data quality issues.

Summary of OPTN Data Changes:

The DAC is responsible for reviewing and making recommendations to the BOD regarding the collection of OPTN data. This data is important for the functioning of the OPTN, the development of evidence-based policies, and the support of analytic work undertaken by the OPTN Contractor or the SRTR

Contractor.

Table 1 provides an overview of the planned data collection changes pending OMB approval. Once approved, these changes will be scheduled for implementation.

Table 1. Planned data collection changes pending OMB approval (BOD cycle June 2023 – June 2024)

Expected Approval	Proposal Name/Description	Committee	Impacted System	OMB Form Name	Fields Added	Fields Removed	Total Changes
Q1 2025	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
Q1 2025	Improve Deceased Donor Evaluation for Endemic Diseases (1327)	DTAC	TIEDI®	Deceased Donor Registration Form	1	1	2
			DonorNet®	Initial Donor Registration	10	2	12
Q1 2025	Deceased Donor Support Therapy Data Collection (1413)	Operations and safety	TIEDI®	Deceased Donor Registration Form	6	5	11
			DonorNet®	Initial Donor Registration Form	6	0	6
Q1 2025	Amend Adult Heart Status 2 Mechanical Device Requirements (1391)	Heart	Waitlist^SM	Adult Heart Status and HeartLung Status 2 Initial Justification form Medical Urgency Data Form	10	2	12
			Waitlist^SM	Adult Heart Status and HeartLung Status 2 Criteria 4 Extension Justification form Medical Urgency Data Form	4	0	4
			Waitlist^SM	Adult Heart Status and HeartLung Status 2 Criteria 5	4	0	4

				Extension Justification form Medical Urgency Data Form			
Q1 2026	Update Post-Transplant Histocompatibility Data Collection (1270)	Histocompatibility	TIEDI®	Donor Histocompatibility Form	2	6	8
			TIEDI®	Recipient Histocompatibility Form	5	16	21
Q1 2026	Promote Efficiency of Lung Allocation (1439)	Lung	DonorNet®	Initial Donor Registration Form	3	0	3

4. Improve Data Collection Details and Form Instructions

To make minor (non-substantive) changes to labels, values, definitions, and form instructions, it is necessary to obtain input from selected subject matter experts (SMEs) from the DAC or a separate OPTN committee. After SME approval, the revised wording is emailed to the full committee for review before the next DAC meeting. DAC endorsement is necessary before the change is implemented in the OPTN Computer System. Affected OPTN members and stakeholders receive notification about the change through public notices and email notifications.

From November 2023 to October 2024, the DAC endorsed six modifications to instructions in the OPTN Computer System (Table 2).

Table 2: CY2024 Updates to OPTN Computer System Instructions Data Element	Impacted Content
Chronic Steroid Use	Transplant Recipient Registration
Pretransplant Titer Information	Transplant Recipient Registration
Lung CAS Calculator	Waitlist tool
Date Last Seen, Retransplanted or Death	Transplant Recipient Registration
Source of Payment	Transplant Candidate Registration (all organs except VCA) Transplant Recipient Registration Transplant Recipient Follow Up
Donor Acceptance Criteria	Waitlist

Future Work:

OPTN contract staff will continue to collaborate with the DAC by raising pertinent questions as necessary to enhance the accuracy of data collection.

During the DAC's September 2024 in-person meeting, the members brainstormed numerous potential projects for the committee to sponsor in the next couple of years. The Committee will share the top ideas as part of the DAC's presentation to the BOD on November 21, 2024 and revisit prioritizing the backlog of ideas early next year.