OPTN Data Advisory Committee
Meeting Summary
May 12, 2025
Conference Call

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Introduction

The OPTN Data Advisory Committee (Committee) met via WebEx teleconference on 05/12/2025 to discuss the following agenda items:

1. Welcome, reminders, and agenda review
2. OPO Committee: *Machine Perfusion Data Collection* (Second check-in)
3. Status of Living Donor Committee's (LDC) *Update and Improve Efficiency in Living Donor Data Collection*
4. Post Implementation Monitoring Review for POC: *Modify Data Submission Requirements*
5. Updates from Committee members who are participating in OPTN workgroups
6. Open forum
7. Closing remarks

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

1. Welcome, reminders, and agenda review

The Committee members were welcomed and a quick overview of the meeting agenda was provided. The Chair expressed appreciation for the members' continued engagement given the breadth of work DAC has been responsible for and maintaining momentum across multiple initiatives.

2. OPO Committee: *Machine Perfusion Data Collection* (Second check-in)

The Organ Procurement Organization (OPO) Committee Chair provided a comprehensive presentation concerning their presented ongoing initiative to enhance data collection related to Normothermic Regional Perfusion (NRP) and machine perfusion. The primary objective of the project is to introduce new data elements and refine existing ones to better capture the use and impact of NRP and machine perfusion. The Committee endorsed the OPO Committee's proposed data collection effort.

Summary of discussion:

Decision #1: The Committee endorsed the data collection activities proposed by the OPO Committee.

The OPO Committee presented its second check-in regarding their ongoing initiative to enhance data collection related to Normothermic Regional Perfusion (NRP) and machine perfusion. The OPO Committee Chair gave the presentation. This project aims to improve understanding of how NRP and machine perfusion affect organ allocation, placement, and recipient outcomes. The OPO Committee has collaborated with multiple OPTN committees—including Heart, Kidney, Liver-Intestine, Lung, Pancreas, Operations and Safety, and the Transplant Coordinators committees.

The primary objective of the project is to introduce new data elements and refine existing ones to better capture the use and impact of NRP and machine perfusion. These additions are intended to support both clinical decision-making and future policy development. The Committee was informed that the proposed data elements are being finalized in preparation for the Summer 2025 public comment cycle.

The proposed NRP data collection enhancements include the addition of several key data points specific to NRP procedures. These include the following:

- **Timing and procedural details**: Date and time NRP ended, organs intended and actually recovered, and whether the NRP was abdominal or thoracoabdominal.
- **Personnel and procedural context**: Identification of the entity performing the NRP (OPO, transplant center, or third party).
- **Clinical metrics**: Total heparin administered, lactate levels, and hematocrit values from the NRP circuit.
- **Additional clinical data under consideration**: Glucose, arterial blood gases (ABGs), ALT, and AST levels to support organ evaluation.

A significant challenge discussed was the current reliance on a single "cross clamp time" to represent the moment of organ preservation. In cases where NRP is used for abdominal organs and standard rapid recovery is used for thoracic organs, this approach fails to accurately reflect the preservation timeline. Two options were presented:

- Add a secondary cross-clamp time to accommodate dual recovery scenarios, and/or
- Replace cross-clamp time entirely with organ-specific flush times. Such times are more precise are already scheduled to be captured in the OPTN Computer System starting later in 2025.

The Committee expressed support for the second option, noting its potential to improve data accuracy and future-proof the system for evolving clinical practices. However, members acknowledged that this shift would require significant training and system updates, particularly in how ischemic time is calculated and reported.

On the machine perfusion side, the OPO Committee initially explored collecting detailed, machine-specific data but ultimately scaled back the scope due to complexity and redundancy with vendor systems. Instead, the proposed data elements include:

- **Perfusion type**: Normothermic vs. hypothermic.
- **Device information**: Brand/type of machine used, with an "other" option for unlisted devices.
- **Timing and logistics**: Time on and off the device, who requested and who managed the perfusion, and the location where perfusion occurred (transplant center, donor hospital, or OPO facility).

A key issue raised was how to document machine perfusion when no transplant recipient is associated with the organ. Since current OPTN data collection forms like the Deceased Donor Registration (DDR) and Transplant Recipient Registration (TRR) are tied to recipient data, a new standalone form is being considered. This form would be completed by the entity performing the perfusion and would capture the relevant data regardless of whether the organ was ultimately transplanted.

Committee members raised several important considerations. For example, regarding terminology, It was suggested that "who performed" the perfusion be revised to "who managed" or "who monitored" to better reflect clinical practice. In addition, concerns were raised about how transplant centers would access perfusion data, especially when procedures occur at donor hospitals or third-party facilities. Members noted variability in documentation practices and the need for standardized data capture. The

importance of successful system integration was also discussed. Transitioning from cross clamp to flush times will require updates to electronic health records (EHR) systems and recalibration of ischemic time calculations. Members emphasized the need for coordination with EHR vendors and robust training for data abstractors. The Committee also discussed the importance of ensuring data integrity. The importance of capturing data on organs that undergo perfusion but are not transplanted was highlighted, as these cases provide valuable insights into perfusion efficacy and decision-making.

Following discussion, the Committee unanimously endorsed the proposed data collection framework for public comment. Members agreed that the changes represent a meaningful step forward in capturing the nuances of modern organ preservation techniques and expressed support for continued collaboration with the OPO Committee as the project advances.

Next steps:

If the OPO Committee decides to make changes to the data collection activities as a result of public comment input, then another presentation will be scheduled with DAC to inform the Committee of the changes.

3. Status of Living Donor Committee's (LDC) *Update and Improve Efficiency in Living Donor Data Collection*

The DAC Chair provided an update about the feedback the Living Donor Committee had provided following their presentation during DAC's 04/14/2025 meeting. The Chair reminded the Committee members about the position they took during the 04/14 meeting. The DAC members discussed the LDC project in light of the information provided since the last meeting, and came to the same conclusion.

Summary of discussion:

Decision #1: The Committee did not change its previous position, which was not to endorse the data collection activities proposed by the Living Donor Committee.

The Living Donor Committee (LDC) Chair and Vice Chair joined DAC's 04/14/2025 meeting to present information about LDC's proposed data collection and to answer questions. The Committee chose not to endorse LDC's proposal as part of that meeting. At the time, the committees agreed to review DAC members' feedback and look for ways to use the information to refine the LDC proposal.

As part of the 05/12/2025 meeting, the Committee reiterated its support for the overarching goal of the project—namely, to better understand the characteristics and outcomes of the potential living donor population. However, members still expressed significant reservations regarding the feasibility, burden, and clarity of the proposed data collection framework.

A primary concern of the Committee's involves data availability and formatting as proposed. It was pointed out that a substantial portion of the proposed data elements—estimated at approximately 50%—are not currently captured in discrete, structured formats within EHRs. Instead, these data points often exist in free-text notes or are not collected at all under standard clinical workflows. This variability across transplant programs raised members' concerns about data quality, consistency, and the ability to automate data extraction.

Committee members also emphasized that the proposed data collection would impose a significant manual burden on transplant centers, particularly given the large volume of individuals evaluated as potential donors compared to those who ultimately donate. The resource implications for centers with limited staffing or infrastructure were highlighted as a major barrier to implementation. Members drew

parallels to the Committee's own work involving the pre-waitlist data directive, which similarly sought to expand data collection upstream in the transplant process. In that case, the Committee's approach was to begin with a limited set of data elements that were already routinely and discretely available, with the intention of expanding over time. The Committee members recommended a similar phased approach for the LDC project, starting with data that can be reliably and uniformly collected across centers.

Members repeated their concerns that as part of the LDC proposal, transplant programs would no longer be required to collect two-year follow-up data on actual living donors. Committee members expressed concern that this would result in a net loss of valuable longitudinal data, especially given that follow-up data—while imperfect—is currently one of the few sources of information on donor outcomes.

As it had done previously, the Committee also requested greater clarity on the specific goals and intended applications of the expanded data collection proposal. While the project has potential research value, members stressed the importance of articulating how the data would be used to inform policy, improve safety, or enhance clinical practice. Questions were also raised about how the data would integrate with existing efforts, such as the Living Donor Collective led by the SRTR Contractor, which currently includes only a subset of transplant programs.

Members noted that documentation practices vary widely across centers, and that not all institutions have the infrastructure to interface perfusion devices or external data sources with their EHRs. This further complicates efforts to standardize and automate data collection.

The Committee did not endorse the proposal in its current form. However, members expressed a willingness to continue engaging with the Living Donor Committee and to provide formal feedback during the public comment period. It was recommended that the LDC return for a third check-in following public comment to share any revisions or refinements based on community input.

Additionally, DAC members who had participated in the LDC's subcommittee discussions voiced frustration that their concerns had not been adequately acknowledged or incorporated into the proposal. They emphasized the importance of ensuring that DAC's role as a data steward is respected and that its feedback is meaningfully integrated into cross-committee initiatives.

The Committee concluded that while the project's goals are commendable, its current design poses significant challenges. A more incremental, resource-conscious approach—grounded in practical data availability and clear policy objectives—was strongly recommended.

Next steps:

The Committee members are aware that the Living Donor Committee plans to submit the proposal for public comment without DAC's endorsement of the data collection effort. The Committee will likely ask the Living Donor Committee to provide an update following public comment.

4. Post Implementation Monitoring Review for POC: *Modify Data Submission Requirements*

OPTN Contractor reminded the Committee that after the final results of a project's post-implementation monitoring have been provided, the Policy Oversight Committee (POC) requires committees to make a presentation about the successes, unintended consequences and limitations, and additional opportunities associated with the project. As part of POC's 06/12/2025 meeting, DAC will provide such a presentation following the 24-month monitoring results associated with the *Modify Data Submission Requirements project*.

Summary of discussion:

Decision #1: The Committee agreed with the information to be presented to the Policy Oversight Committee.

The Committee reviewed the 24-month post-implementation monitoring report for the *Modify Data Submission Requirements* project. The results were first shared with the Committee as part of their 09/10/2024 meeting. The policy changes, which were implemented on 08/30/2022, introduced a formal data lock mechanism and extended submission deadlines for key OPTN data collection forms. The purpose of the review was to assess the policy's effectiveness, identify any unintended consequences, and determine whether further refinements are warranted. The findings and Committee feedback will be presented to the Policy Oversight Committee (POC) at its upcoming June meeting.

The policy was designed to improve the timeliness and integrity of data submitted to the OPTN by:

- Establishing clear submission deadlines for key forms.
- Implementing a data lock after the deadline, preventing further edits unless a form is explicitly unlocked.
- Replacing Policy 18.4, which had previously allowed for more ambiguous post-deadline data changes.

The monitoring report evaluated the policy's impact using several metrics, including form completion rates, frequency of unlocks, and reasons for post-deadline data changes. Highlights included:

- **Improved Completion Rates**: Seven of the eight forms impacted by the policy achieved post-implementation completion rates exceeding 90%, compared to only two forms prior to implementation. This was viewed as a strong indicator of improved compliance and data timeliness.
- **Persistent Unlocking Patterns**: Despite the improvements, the TRF remains the most frequently unlocked form. Additionally, the TCR and TRR forms continue to show spikes in unlocking activity in April and October, coinciding with the release of SRTR's Program-Specific Reports (PSRs). This suggests that some centers may still be modifying data in response to performance reporting cycles.
- **Unlocking Behavior**: Some OPTN members were observed unlocking forms multiple times, often citing the same reason repeatedly. This behavior deviates from the intended use of the unlock function, which was designed for exceptional circumstances.
- **Data Mapping Challenges**: Members reported difficulties mapping data from their internal electronic health records (EHRs) to OPTN forms. These challenges often necessitated manual review and correction, contributing to delays and unlock requests.
- **API Limitations**: While APIs were expected to streamline data submission, some members indicated that API-related issues led to form unlocks. In some cases, the available unlock reason options did not accurately reflect the underlying cause, leading to inconsistent reporting.

Committee Discussion and Recommendations

The Committee acknowledged the policy's positive impact on data timeliness but emphasized that further improvements are needed to ensure data integrity and reduce reliance on post-deadline edits. Key discussion points included:

- **Permanent Lock for Critical Fields**: Members discussed the potential for implementing a permanent lock on critical fields within the TCR and TRR forms. These fields are essential for risk adjustment and allocation modeling, and ensuring their accuracy at the time of submission is paramount.
- **Audit Mechanisms**: The Committee recommended exploring audit strategies to monitor frequent unlocks or suspicious patterns. While auditing every unlock may not be feasible, targeted reviews of high-frequency unlocks or outlier centers could help identify misuse and reinforce accountability.
- **Unlock Restrictions**: Suggestions were made to increase the difficulty of unlocking forms, such as requiring approval from a transplant program director or limiting the number of allowable unlocks per form. These measures could deter unnecessary edits and promote more accurate initial submissions.
- **Data Definition and Training Needs**: Members stressed the importance of refining data definitions and providing training for data abstractors. Inconsistent interpretation of data fields contributes to errors and unlocks. A standardized approach, coupled with educational resources, could improve data quality at the point of entry.
- **Follow-up Form Challenges**: The Committee noted that follow-up forms, particularly the TRF, remain problematic due to the complexity of data collection and variability in clinical workflows. Additional flexibility or revised expectations may be needed for these forms.

The Committee reaffirmed its commitment to improving data quality and integrity across the OPTN system and emphasized the importance of aligning policy with operational realities at transplant centers.

Next steps:

The Committee will finalize its feedback and submit a summary to the POC for review. The feedback will include:

- Recognition of improved compliance and form completion rates.
- Concerns about persistent unlocking behavior and its implications.
- Recommendations for a more stringent data lock process, particularly for critical fields.
- Suggestions for audit mechanisms and enhanced training.
- Consideration of policy revisions to address ongoing challenges with follow-up forms.

5. Updates from Committee members who are participating in OPTN workgroups

Committee members supporting over OPTN workgroups developing data collection proposals provided statuses updates of that work. This included an update about the Pediatrics Committee's Lost to Follow-up effort.

6. Open forum

No requests from the public were received prior to the meeting to address the Committee during open forum.

7. Closing remarks

The Chair thanked the Committee members for their participation. The next meeting is scheduled for 06/09/2025.

Upcoming Meetings (Meetings start at 3:00 pm (ET) unless otherwise noted)

- ~~July 8, 2024~~
- ~~August 12, 2024~~
- ~~September 10, 2024 – In-person meeting, Detroit, MI, 8:00 am – 3:00 pm (ET)~~
- ~~October 21, 2024~~
- ~~November 18, 2024~~
- ~~December 4, 2024 10:30 am – 2:30 pm (ET) – HHS Data Collection Directive Meeting~~
- ~~December 9, 2024 11:00 am (ET)~~
- ~~January 12, 2025~~
- ~~February 10, 2025~~
- ~~March 10, 2025~~
- ~~April 14, 2025~~
- ~~May 12, 2025~~
- June 9, 2025

Attendance

- **Committee Members**
  - Jesse Schold
  - Rebecca Baranoff
  - Kate Giles
  - Paul MacLennan
  - Michael Marvin
  - Christine Maxmeister
  - Nancy McMillan
  - Sumit Mohan
  - Jennifer Peattie
  - Julie Prigoff
  - Allen Wagner
- **HRSA Representatives**
  - Adriana Alvarez
  - Shantel Delgado
  - Marilyn Levi
  - Arjun Naik
- **SRTR Staff**
  - Avery Cook
  - Jon Snyder
- **UNOS Staff**
  - Brooke Chenault
  - Jonathan Chiep
  - Cole Fox
  - Jesse Howell
  - Lindsay Larkin
  - Eric Messick
  - Lauren Mooney
  - Laura Schmitt
  - Ethan Studenic
  - Susan Tlusty
  - Sara Rose Wells
- **Other Attendees**
  - P.J. Geraghty