OPTN Data Advisory Committee
Meeting Summary
August 11, 2025
Conference Call

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Introduction

The OPTN Data Advisory Committee (DAC) met via WebEx teleconference on 08/11/2025 to discuss the following agenda items:

1. Welcome, agenda review, and announcements
2. OPTN Histocompatibility Committee, *Clarify ABO Determination Post Transfusion* proposal, First check-in
3. Workgroup member feedback: OPTN Pediatrics Committee, *Lost-to-Follow-up* project and OPTN OPO Committee, *DCD Directive* project
4. Status updates of HRSA Directive activities
5. Review outline for Annual Data Quality Report – final
6. Updates about Committee-related activities
7. Open forum
8. Closing remarks

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

1. Welcome, agenda review, and announcements

The Chair and OPTN contractor staff welcomed the members to the meeting and outlined the agenda.

Summary of discussion:

No decisions were made during discussion of this agenda item.

The meeting commenced with confirmation of quorum and a brief overview of the agenda. The Committee was informed that the session was being live-streamed. The Committee also received updates about the OPTN public comment, regional meeting, and committee nomination process schedules. Additionally, members were advised of a forthcoming transition from Webex to Microsoft Teams for future meetings. The Chair and OPTN contractor staff emphasized the importance of structured check-ins for committee projects, particularly those with anticipated data collection impacts, and introduced the first check-in presentation from the Histocompatibility Committee.

2. OPTN Histocompatibility Committee, *Clarify ABO Determination Post Transfusion* proposal, First check-in

The Committee received a first check-in presentation from the OPTN Histocompatibility Committee regarding a proposal to enhance data collection and clarify policy addressing ABO typing in transfused donors.

Summary of Presentation:

Decision #1: The Committee endorsed the proposed data collection components.

The check-in was presented by the Histocompatibility Committee Chair. The proposal originated from referrals by the OPTN Operations and Safety Committee and the OPTN Membership and Professional Standards Committee and aims to address clinical safety concerns and data gaps. Those committees asked the Histocompatibility Committee to consider initiating a project regarding issues with how transfused donors are identified and managed and how that information is conveyed to the transplant program. The committees also asked, given the technological changes, if there are opportunities to amend OPTN policy to allow for the use of molecular ABO genotyping to support some of the ABO typing or ABO sub-typing that would be appropriate for patient safety.

The Histocompatibility Committee Chair said that currently the OPTN does not collect information on the use of molecular testing. Therefore, the project proposal has some modifications to how transfused donors are identified and also includes some data collection elements around whether molecular genotyping methods were used. The proposed data collection changes include the addition of new data fields in the OPTN Donor Data and Matching System to capture the following:

- Whether molecular ABO genotyping was performed?
- Whether a pre-transfusion ABO blood type was determined?
- Whether the donor received packed red blood cells or whole blood within the past 90 days?

Responses for each of the data fields will be collected using radio buttons for “yes” and “no.” Other changes proposed included modifications to existing data fields to improve clarity and validation, as well as implementation of pop-up warnings to alert transplant programs to potential ABO typing concerns.

Summary of Discussion:

DAC members’ discussions focused on feasibility, clinical utility, and logistical considerations. Committee members raised questions about the availability of transfusion history data, the prevalence of molecular testing, and the potential cost and timing implications associated with molecular testing. A DAC members asked how often a donor hospital would know whether a donor had a transfusion in the 90-day window described in the proposal. The Histocompatibility Committee Chair said that information is very difficult to ascertain currently and that is one of the reasons the Committee is interested in starting to collect it.

The DAC Chair suggested that the Histocompatibility Committee should consult with the OPO Committee on the logistics of the proposed data collection effort. The Histocompatibility Committee Chair said that they have already done so and that the OPO Committee was generally supportive of the proposal.

The DAC members acknowledged the permissive nature of the proposal, which allows discretion in the use of molecular testing while supporting its inclusion in policy language.

Vote:

Do you endorse the project for continued development?

12 yes, 0 no, 0 abstain

Next steps:

The Histocompatibility Committee will present the proposal to the OPTN Policy Oversight Committee (POC) in September 2025.A second DAC check-in is anticipated in late fall prior to the Winter 2026 public comment cycle. The Committee will monitor developments and assess whether molecular ABO genotyping should remain permissive or evolve into a mandatory requirement based on future data availability.

3. Workgroup member feedback: OPTN Pediatrics Committee, *Lost-to-Follow-up* project and OPTN OPO Committee, *DCD Directive* project

DAC members serving on the Lost to Follow-up workgroup and Donation after Circulatory Death (DCD) Directive workgroup provided status updates about each project to the other members.

Summary of discussion:

No decisions were made during discussion of this agenda item.

OPTN Pediatrics Committee, *Lost-to-Follow-up* project

A DAC member participating in the Pediatrics Committee's Lost to Follow-up workgroup provided an update on efforts to standardize reporting of patients lost to follow-up. The member pointed out that forms are to be submitted until either the patient's death or graft loss. However, OPTN policy does not address lost to follow-up currently. This has prompted the development of criteria for mandatory reporting after repeated failed contact attempts and submission of "not seen" transplant recipient follow-up forms. The workgroup is determining what is the appropriate amount of failed contact attempts before reporting lost to follow-up becomes mandatory. According to the DAC member, the proposed data collection will lead to a better understanding of the factors that are contributing to lost to follow-up, and that will help the workgroup update the reasons provided in the dropdown menus.

The workgroup is developing dropdown options to categorize reasons for lost to follow-up, distinguishing between systemic barriers (e.g., insurance loss, geographic challenges) and patient-specific factors (e.g., relocation, refusal of follow-up). The Committee discussed the relevance of this initiative for both pediatric and adult patient populations. The DAC members serving on the workgroup stated that adult candidates are being addressed as part of the project. DAC members also recommended broader communication with organ-specific committees to ensure alignment and awareness.

OPTN OPO Committee, *DCD Directive* project

The DAC member stated that the DCD Directive workgroup had only held one meeting, and as a result, there was minimal information to share. The member explained that the workgroup is tasked with developing standardized processes for donation after circulatory death (DCD). The Directive responds to recent public concerns about patient safety of donors involving recent DCD cases. The changes being considered intend to enhance patient safety and transparency throughout the entire process. In particular, the directive seeks to add opportunities to pause the process at any time and by anyone involved. The data collection components of the project involve capturing information about when the pauses are requested, by whom, and when the pauses occur. More specifically, the Directive requires developing a process for what a pause would look like if there are concerns for neurological activity, making sure that families of potential DCD patients are educated on what that process looks like and how they could trigger a pause, and then the data collection that would be required as a result.

The member mentioned that the workgroup's first meeting largely focused on operational items. The workgroup was divided into two subgroups. One group will focus on patient and family education and communication about the DCD process. The other group will focus on defining and documenting the process for pausing donation in cases of neurological activity concerns.

A DAC member described their experience involving a potential DCD donation. The member said that the physician was their main point of contact rather than someone from the OPO. The member had been initially informed that DCD donation would be pursued but was subsequently told that their family member's clinical condition prevented DCD from being pursued. The DAC member asked whether the workgroup was contacting specific transplant hospitals about their processes? The DAC member serving on the workgroup stated that the expectation is OPTN policy will be created which would establish the standard actions that all OPOs must follow when approaching families about potential DCD donation and ensuring there is space for that potential. A HRSA representative thanked the member for the question and responded that the directive is intended to establish consistency around the variability in practice across OPOs and transplant hospitals. The Committee emphasized the importance of consistent standards and acknowledged the need for further engagement with patient and family perspectives. HRSA staff stated they would follow up with the DAC members regarding the member's specific experience and opportunities for incorporating family experience into directive development.

Next steps:

The Pediatrics Committee's workgroup will be informed about the importance of cross-committee collaboration to ensure awareness. DAC leadership will remain available to assist with broader dissemination and stakeholder engagement as the project progresses toward public comment.

The DAC representative serving on the DCD Directive workgroup will continue to provide updates as the Directive evolves.

4. Status updates of HRSA Directive activities

Committee leadership provided updates about the HRSA Directives addressing Allocation Out of Sequence and the data collection directive involving pre-waitlist and ventilated patient referral activities.

Summary of discussion:

No decisions were made during discussion of this agenda item.

The Chair stated that he and the Vice Chair are involved in the Allocation Out-of-Sequence Directive effort and provided a brief update. The directive seeks to define and standardize terminology related to "open offers," for example "expedited placement" and/or "out of sequence" offers. The goal is to develop a unified definition that can be used for any OPTN policy intervention that may or may not prospectively be developed. While discussions are ongoing, no formal next steps have been established.

A member asked for clarification about the extent to which Allocation Out of Sequence occurs. A HRSA representative stated that the OPTN designs organ allocation policy and needs to follow those rules to ensure allocation occurs as intended.

The Chair also updated the Committee about the status of the pre-waitlist and ventilated patient referral directive work, also known as the Process Data effort, that the Committee has been deeply involved with since late 2023. The Chair provided the members with a brief history of sharing the

response they were involved with drafting to the 30-day Federal Register Notice as part of the Office of Management and Budget (OMB) cycle. The Chair said that feedback was submitted to the OPTN Board and pointed out that the Board members are different from those who were involved with the Committee's submission regarding the 60-day Federal Register Notice. The 30-day notice highlighted support for the rationale behind data collection while expressing concerns about specific elements, particularly ventilated patient referral data that.

HRSA staff clarified that HRSA adjudicates public comments before submission to OMB and reiterated its focus on data elements rather than implementation logistics.

Next steps:

Members expressed interest in contributing to strategic implementation planning once final data requirements are approved.

5. Review outline for Annual Data Quality Report – final

OPTN contractor staff provided an overview of the Committee's required annual reporting to the OPTN Board of Directors.

Summary of discussion:

No decisions were made during discussion of this agenda item.

The Committee reviewed the proposed outline for the upcoming Annual Data Quality Report, which includes three themes:

- Timeliness of OPTN data submissions over the past three years, analyzed by member type and form.
- Data lock activity trends, focusing on unlocking events for key forms, such as the Transplant Recipient Follow-up Form (TRF), the Transplant Candidate Registration Form (TCR), and the Transplant Recipient Registration Form (TRR).
- Submission rate analysis for transplant centers, identifying centers with rates below 75% and 90%. The Committee discussed conducting qualitative outreach to understand barriers and exploring best practices from consistently compliant centers.

Annual reporting is required for the themes of timeliness and data lock activity trends. The third theme is a proposed analysis of data submission rates. According to OPTN policy, the submission rates are expected to be 100%; however, that is not the case. As a result, an idea would be to talk with some OPTN members who have low submission rates in order to determine why. Then, that information would be shared with the Committee for consideration of next steps. OPTN contractor staff shared potential timelines for the Committee to develop and finalize the two annual reports. It was pointed out that the Committee's 10/27/2025 meeting will be important for reviewing the two reports, and that the 11/10/2025 meeting will be important for discussing the annual presentation to the OPTN Board of Directors.

A member asked if the OPTN members who regularly achieve the 100% submission rate could also be contacted? Knowing what factors lead to such successes also could be helpful in terms of developing any future best practices or guidance. Additional considerations included evaluating the impact of manual versus API-based form submissions and validating data quality beyond timeliness. The Committee

supported expanding the analysis to include high-performing centers and emphasized the importance of actionable insights.

Next steps:

OPTN contractor staff will examine the use of APIs versus manual submission when continuing the review of OPTN members with low submission rates.

6. Updates about Committee-related activities

The Committee received a follow-up on the July meeting's discussion regarding survival after removal from the transplant waiting list. A data transfer issue between UNOS and SRTR was ruled out as a cause of observed discrepancies. SRTR will continue investigating potential causes and provide updates as available.

7. Open forum

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

8. Closing remarks

The meeting concluded with appreciation for member engagement and a reminder of the busy fall schedule, including extended meetings and multiple project check-ins.

Upcoming Meetings

- ~~July 14, 2025~~
- ~~August 11, 2025~~
- September 8, 2025
- October 13, 2025
- November 10, 2025
- December 8, 2025
- January 12, 2026
- February 9, 2026
- March 9, 2026
- April 13, 2026
- May 11, 2026
- June 8, 2026

Attendance

- **Committee Members**
  - Jesse Schold, Chair
  - Lisa McElroy, Vice Chair
  - Rebecca Baranoff
  - Cassie Hertert
  - Paul MacLennan
  - Christine Maxmeister
  - Nancy McMillan
  - Sumit Mohan
  - Jennifer Peattie
  - Julie Prigoff
  - Alicia Skeen
  - Lindsay Smith
  - Allen Wagner
- **HRSA Representatives**
  - Adriana Alvarez
  - Brianna Doby
  - Sarah Laskey
- **SRTR Staff**
  - Avery Cook
  - Allyson Hart
  - Ryo Hirose
- **UNOS Staff**
  - Tory Boffo
  - Brooke Chenault
  - Jonathan Chiep
  - Amelia Devereaux
  - Cole Fox
  - Jesse Howell
  - Lindsay Larkin
  - Leah Nunez
  - Jamie Panko
  - Nadine Rogers
  - Laura Schmitt
  - Susan Tlusty
  - Niyati Upadhyay
  - Sara Rose Wells
- **Other Attendees**
  - Shelley Hall
  - Gerald Morris