OPTN Data Advisory Committee
Meeting Summary
September 8, 2025
Conference Call

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Introduction

The OPTN Data Advisory Committee (DAC) met via WebEx teleconference on 09/08/2025 to discuss the following agenda items:

1. Welcome, agenda review, and announcements
2. OPTN Disease Transmission Advisory Committee (DTAC), *OPTN Directive to Reduce the Risk of Donor Derived Rabies Transmission*
3. OPTN OPO Committee, *HRSA Directive for OPTN DCD Policy Development*
4. Open forum
5. Closing remarks

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

1. Welcome, agenda review, and announcements

The meeting commenced with a review of the agenda items for discussion. Members were also notified that the meeting was being recorded and public access was being livestreamed on Vimeo, and future committee meetings were scheduled through June 2026. Announcements included the release schedule for projects approved in the 2023 OPTN Data System Package. The Office of Management and Budget (OMB) approved the package on 8/21/2025, with Board-approved projects scheduled for release on specific dates in September and October. These projects encompass MPSC data collection removals, amendments to adult heart status mechanical device requirements, updates to kidney paired donation policies, enhancements to donor data and matching system clinical data collection, improvements in deceased donor evaluation for endemic diseases, deceased donor support therapy data collection, and updates to lung mortality model data collection. The Committee was reminded of the ongoing OPTN public comment period, which began on 08/27/2025 and will close on 10/01/2025. Regional meetings were highlighted, with dates and registration links provided for each OPTN region.

2. OPTN Disease Transmission Advisory Committee (DTAC), *OPTN Directive to Reduce the Risk of Donor Derived Rabies Transmission*

The Committee received a presentation from the vice chair of the OPTN Disease Transmission Advisory Committee (DTAC) regarding a HRSA directive that the OPTN take steps to reduce the risk of donor-derived rabies transmission. The presentation served as a combined first and second check-in of the proposed data collection changes. The proposed policy and data collection changes will go out as part of a special public comment period. The directive was prompted by recent incidents of rabies transmission from organ donors, which highlighted gaps in current data collection and policy. The project is tentatively scheduled for initial review by the Policy Oversight Committee (POC) on 10/02/2025, with a special public comment period to follow.

Summary of discussion:

Decision #1: The Committee chose not to endorse the data collection proposed by the OPTN Disease Transmission Advisory Committee.

According to the DTAC vice chair, the project's primary objective is to propose improvements to OPTN policy and introduce new data collection requirements to mitigate the risk of rabies transmission. The anticipated impact includes the addition of new data fields in the OPTN Donor Data and Matching System (also referred to as DonorNet®) and the Living Donor Registration (LDR) Form within the Data System for Organ Procurement and Transplantation Network (also referred to as TIEDI®).

The vice chair stated the OPTN does not currently collect data on rabies risk factors in a standardized manner, which has played a role in the frequency of high-risk rabies exposures among donors remaining unknown. While the Uniform Donor Risk Assessment Interview (UDRAI) form collects some information on animal exposure and bites or scratches, this data is not standardized or easily queried in the OPTN Computer System. Additionally, the living donor medical screening questionnaire does not capture this information during the medical evaluation process.

To address the gaps, the DTAC proposal includes the addition of five new data fields to both DonorNet® and the LDR form. These fields are designed to capture specific rabies risk factors, including direct contact with bats, bites or scratches from wild mammals within the United States, unprovoked bites or scratches from domesticated mammals, and bites or scratches from mammals outside the United States.

A "yes" response to any child risk factor will trigger a policy requirement for the Organ Procurement Organization (OPO) or Living Donor program to consult with the health department and/or CDC for risk assessment. This consultation must be communicated to the transplant program and may be documented in the donor medical record.

The DAC members were asked to provide feedback regarding the proposed data collection changes and to indicate whether or not they endorse it. The DTAC vice chair said that if substantive changes are made based on public comment, the committee will reconvene for a third check-in.

Committee members raised questions regarding the operationalization of the proposed data collection, including the reliability of contacting health departments or the CDC during time-sensitive situations. Questions were also raised about the frequency and impact of rabies transmissions, and the potential for donor loss due to new screening criteria. It was mentioned that based on a review of UDRAI information at several OPOs, the potential for rabies transmission might translate into nine donors per year where the policy changes and data collection would be very relevant. A Committee member asked if there was information about how many donor losses might occur because there was concern that rabies transmission may or may not be associated? The DTAC vice chair said DTAC members have also been concerned about the potential impact on potential donors. However, the number of potential donors who are lost is a difficult question to answer. HRSA staff informed the Committee that the Directive is in response to an actual incident involving rabies transmission. HRSA staff added following the event, several OPOs were consulted as to whether they already had protocols in place that would have prevented the donor from moving forward, and those OPOs did. HRSA staff emphasized that the Directive requires changes to be made, but HRSA and CDC want to work with the OPTN to ensure that the solution is right-sized to the problem.

Members expressed concerns about the clarity of definitions for bites and scratches and how it could lead to inconsistent data reporting. The members stressed the need for standardized terminology, and

the importance of an educational rollout accompanying any policy change. The DTAC vice chair said that they are fully aware of the importance of an extensive educational rollout associated with this, but as of now the details have not been fully developed. The Committee also discussed the utility of the proposed data collection.

The Committee was prompted to consider whether the project aligns with OPTN Principles of Data Collection, whether the data should be collected from OPTN members, whether alternative sources exist, and whether the data collection will provide value to OPTN.

Committee members were asked to indicate their endorsement of the proposed data collection via the Webex chat function. Twelve of the 16 members attending the meeting submitted a response. Eight Committee members did not endorse the proposal, one member endorsed it, and three other members abstained. The Committee agreed to summarize the main points of contention with the proposed data collection and provide the information to DTAC. HRSA staff reiterated that HRSA directed the OPTN to take this action, and while the data collection may need to be iterated on, the OPTN is still being directed to do this. It was noted that while the directive was mandated by HRSA, further iteration regarding the proposed data collection is necessary.

Next steps:

The Committee's feedback will be summarized and shared with DTAC.

3. OPTN OPO Committee, *HRSA Directive for OPTN DCD Policy Development*

The OPO Committee chair presented a preliminary review of a HRSA Directive for policy development related to Donation after Circulatory Death (DCD). The Directive seeks to improve safeguards for potential DCD patients and enhance information sharing with patient families regarding DCD organ procurement. The OPO chair acknowledged the two DAC members participating in the DCD workgroup and thanked them for providing expertise and feedback on data collection methods. The project is scheduled for a special public comment period, with a policy and data collection proposal due to HRSA for review and approval by 11/24/2025. DAC members were asked for initial feedback but no endorsement at this stage; formal endorsement will be sought at a future meeting, likely their 10/20/2025 meeting.

Summary of discussion:

No decisions were made during discussion of this agenda item.

According to the OPO Committee chair, the proposal requires OPOs to implement a process for "pauses" in DCD procurement efforts if there is concern for unrecognized neurological improvement or potential patient pain. Data collection regarding any "pauses" is mandated, with OPOs required to inform the OPTN within 24 hours of a requested pause and to notify when a case is resumed. The Membership and Professional Standards Committee (MPSC) will review the cadence and outcome of pauses on a monthly basis.

The OPO chair said that currently, donor information is entered into the OPTN Computer System when the OPO generates a donor ID, and donor data is collected to support allocation. Donor organ disposition must be submitted within five business days after procurement for individuals from whom at least one organ is recovered. The Deceased Donor Registration (DDR) is submitted for all deceased donors within 60 days after the donor organ disposition form is submitted. The Patient Safety Reporting Portal in the OPTN Computer System intakes reports of patient safety events as required by Policy 18.5.

Pending data collection includes the Ventilated Patient Form (VPF), which is to be submitted for referred, ever-ventilated patients with a documented date of death. At this time, OMB approval of the proposed VPF is still pending. When approved, HRSA will determine when and how the form will be developed and implemented.

The proposal outlines a two-phase approach to data collection. In phase one, OPOs would report unplanned pauses in the DCD process via the OPTN Patient Safety Portal within 24 hours. This would include narrative reporting of key data points such as the date and time of donor evaluation, the rationale for the pause, and notification of relevant parties. Phase two would involve the development of discrete data fields within DonorNet®, development of such fields is contingent upon further analysis and OMB approval.

Additional details about the two phases were provided by the OPO chair. As part of phase 1, there would be immediate reporting of unplanned pauses via the OPTN Patient Safety Portal to support rapid policy implementation. OPOs will be required to register all authorized potential deceased donors (DCD and DBD) in the OPTN Computer System to ensure all potential donors have a donor ID. OPOs must also report disposition for all authorized potential deceased donors, including those with no organs recovered, to ensure outcomes are reported. Unplanned pauses in the DCD donation process must be reported within 24 hours of the OPO becoming aware of the request for a pause. The current functionality only allows the user who submitted the report to access it, so OPOs may need to make subsequent reports regarding resolution or termination of the case if that information is not available within the initial 24-hour report. The DCD workgroup is considering proposing that the OPTN will provide work instructions and a template for reporting.

Phase 2 will involve transitioning to discrete data fields within the OPTN Donor Data & Matching System, contingent on OMB approval. Reporting around the pause could be tied to other actions in the system, such as blocking further allocation from a donor when a pause is reported and allowing further notifications when the pause is resolved.

The DCD workgroup is proposing that when a pause is requested, the following data fields are to be collected:

- Date and time the OPO began evaluating the donor
- Date and time the OPO became aware of the request for a pause
- Role of the stakeholder requesting the pause
- Rationale for requesting the pause
- Date and time certain individuals are informed of the pause (deceased donor's agent, patient's healthcare team, hospital leadership team, OPO leadership team, transplant centers with an organ offer acceptance)

When a pause is resolved, the following data fields are to be collected:

- Actions taken by the OPO to resolve the pause
- Notification of transplant centers and procurement staff
- Date and time the DCD donation process resumed

When a pause is not resolved and the DCD donation process is stopped, the following data fields are to be collected:

- Actions taken by the OPO to resolve the pause

- Notification of transplant centers and procurement staff
- Date and time the DCD donation process was stopped or the case was terminated

The Committee members discussed the operational details, including the registration of authorized potential donors, reporting of case disposition, and limitations of the current patient safety portal. Committee members sought clarification on the criteria for registering donors, the impact of late referrals, and the scope of reporting requirements. The members asked about the OPTN's authority over donor hospitals. They also discussed the role of OPOs in care coordination, and the intended use of the pause mechanism as an emergency safeguard rather than a routine process. The Committee provided their initial feedback regarding the DCD Directive policy development and offered to assist in refining data collection methods.

Next steps:

The Committee offered to assist the DCD Directive workgroup with codifying data fields and structuring them to ensure objectivity and clarity. The OPO Committee will present a second check-in with DAC, which is currently targeted to occur as part of their 10/20/2025 meeting.

4. Open forum

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

5. Closing remarks

The meeting concluded with acknowledgments and reminders of upcoming committee meetings, which are scheduled through June 2026. The committee was thanked for its participation and engagement, with additional topics to be addressed in future sessions.

Upcoming Meetings

- October 20, 2025, 12:00 – 2:00 pm
- October 27, 2025, 3:00 – 5:00 pm
- November 10, 2025, 3:00 – 4:30 pm
- 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
  - Lisa McElroy
  - Rebecca Baranoff
  - Kate Giles
  - Cassie Hertert
  - Michael Ison
  - Christine Maxmeister
  - Lisa McElroy
  - Nancy McMillan
  - Sumit Mohan
  - Paul MacLennan
  - Jennifer Peattie
  - Julie Prigoff
  - Alicia Skeen
  - Lindsay Smith
  - Allen Wagner
- **HRSA Representatives**
  - Adriana Alvarez
  - Brianna Doby
  - Sarah Laskey
  - Ray Lynch
- **SRTR Staff**
  - Avery Cook
  - Ryo Hirose
  - Jon Snyder
- **UNOS Staff**
  - Brooke Chenault
  - Jonathan Chiep
  - Kevin Daub
  - Cole Fox
  - Jesse Howell
  - Eric Messick
  - Carly Rhyne
  - Ethan Studenic
  - Kaitlin Swanner
  - Susan Tlusty
- **Other Attendees**
  - P.J. Geraghty
  - Rachel Miller