OPTN Data Advisory Committee
Meeting Summary
October 20, 2025
Conference Call

Jesse Schold, PhD, MStat, Med, Chair
Lisa McElroy, MD MS FACS, Vice Chair

Introduction

The Data Advisory Committee met via teleconference on 10/20/2025 to discuss the following agenda items:

1. Welcome, agenda review, and announcements
2. Second check-in, OPTN Organ Procurement Organization Committee (OPO), HRSA Directive for OPTN DCD Policy Development project
3. Review agenda for October 27 DAC Meeting: Update on Rabies Proposal

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

1. Welcome, agenda review, and announcements

No decisions were made.

Summary of discussion:

A brief overview of the agenda items was provided.

2. Second check-in, OPTN Organ Procurement Organization Committee (OPO), HRSA Directive for OPTN DCD Policy Development project

The Committee unanimously endorsed the project.

Summary of Presentation:

The OPTN Contractor provided a refresher on DAC's role in the second check-in and stated that the project was scheduled for special public comment. The directive was previously discussed at DAC's 9/8/2025 meeting. The OPTN Contractor reminded members that the purpose is to review and understand directive goals, impacts to OPTN data registry, and their alignment with OPTN Principles of Data Collection. Further, the Contractor mentioned that the Committee will return for a third check-in if changes are made to the proposed data collection based on public comment feedback.

The Chair of the OPTN Organ Procurement Organization (OPO) Committee presented on the HRSA Directive for OPTN DCD Policy Development.

The intent of the proposal is to:

- Improve safeguard for potential DCD patients in the organ procurement process
- Require information to be shared with patient families regarding DCD organ procurement
- Require a process by which an unplanned DCD pause may be requested

- Require OPOs to inform the OPTN within 24 hours of any unplanned DCD pause
- Require OPOs to inform the OPTN and HRSA when the donation process resumes following an unplanned DCD pause

The OPO Chair stated that the timeframe for a potential pause in DCD process could include from when patients are authorized to when cross clamp occurs. Patients for whom a pause is called may not proceed to donation; however, the proposal aims to collect information that will identify the concern or problem that led to the pause being requested.

In impacts to data collection, the proposed policy changes ensure availability of OPTN records on all patients for whom an unplanned DCD pause could be called. This includes requiring OPOs to register all authorized potential deceased donors in the OPTN Donor Data and Matching System to ensure all have a donor ID, even when the individual does not move forward with the donation. It also proposes new requirements to *OPTN Policy 18.5.C: Required Reporting by OPOs.* This requires reporting of unplanned DCD pauses within the OPTN Patient Safety Reporting Portal within 24 hours after the OPO becomes aware of the request. The Chair stated that “reportable pauses are expected to be rare events." He continued that the OPTN will monitor reportable pause volume and consider if implementation in the OPTN Donor Data and Matching System is needed or if Patient Safety reporting is sufficient.

The workflow will include requiring OPOs to report pauses per policy within 24 hours using an Excel template provided by the OPTN. The template will be included in the OPTN Public Comment proposal. Patient safety staff will ensure the template is completed upon receipt of the report. Patient Safety staff will follow-up with the individual submitting the report if the outcome of the pause has not been reported by the OPO within seven days of the pause being reported. The reports will be provided to HRSA and monthly to the OPTN Membership and Professional Standards Committee (MPSC), and HRSA or MPSC may request medical records if needed.

The Chair outlined the information that will be collected when the DCD process is paused, resumed, and stopped.

If paused:

OPTN donor ID

Date and time the OPO began evaluating the donor

Date and time the OPO became aware of the request for an unplanned DCD pause

Role of the stakeholder requesting the unplanned DCD pause

Rationale for requesting the unplanned DCD pause

Dates and times that the following individuals were notified of unplanned DCD pause: Patient’s agent, patient’s healthcare team, hospital leadership team, OPO leadership team, and transplant programs with an organ offer acceptance

When the DCD process resumes:

OPTN donor ID

Actions taken by the OPO to address the unplanned DCD pause

The transplant programs and procurement staff notified of the unplanned DCD pause

Date and time when the DCD donation process resumed

Rationale for resuming the DCD donation process

When the DCD donation process is stopped:

OPTN donor ID

Actions taken by the OPO to address the unplanned DCD pause

Date and time when the DCD donation process was stopped

Rationale for stopping the DCD donation process

The transplant programs and procurement staff notified that the DCD donation process was stopped

The speaker noted that current reporting on disposition requires changes to capture outcomes reported for patients whom authorization for donation is granted but no organs are recovered. The workgroup considered two options for capturing disposition.

Disposition form: "Were organs recovered?"

If OPO answers 'no,' an organ-by organ disposition is not collected

If OPO answers 'yes,' the OPO must disposition all organs separately

Option 1: Add new disposition codes

- Add disposition reasons for organs not recovered
- Disposition would be required for each organ regardless of if organs were recovered or not
- No OMB impact
- Recommended by workgroup

Option 2: Allow for more reporting at case level

- Additional questions could be added to collect information about case outcome and whether or not a non-recovery is related to a DCD pause
- Would not collect organ-by-organ dispositions in the case of non-recovery
- Subject to OMB approval

The speaker reviewed potential next steps for the policy proposal.

Summary of Discussion:

The DAC Chair asked the OPO Chair to clarify whether under Option 1, if no reasons for the pause need to be reported in circumstances where no organs are recovered? The OPO Chair responded that for each organ, there has to be a disposition provided. A member asked if the donor electronic health record notes referred to OPO or hospital notes? The speaker said this referred to the OPO electronic donor record. The member continued that in their hospital system, OPO notes are not included in patient charts, which could lead to some confusion or problems. The OPO Chair said that the proposed policy would not require an OPO to document the patient chart; however, the OPO might be required to retain copies of the patient chart. Later, another member added that they also thought the "OPO EHR notes" should be more clearly stated so it isn't confused with hospital EHRs.

A member asked about method of notifications to transplant teams if there already is an offer made. The speaker said it would be up to the program but would likely be a phone call or text message.

A member inquired how donor hospitals would be educated on these policy changes and whether they have new responsibilities. The OPO Chair said that OPOs must notify all participants, including hospital care staff. A HRSA attendee added that the OPTN's reach extends to OPOs and OPOs must be responsible for upholding policies, and that an additional requirement for the donor hospital is not

within the OPTN's purview. HRSA staff added that HRSA and CMS have been meeting on this topic and that CMS is well apprised of the process and the proposed policy.

A member asked if there would be a template for information needed from OPOs. The speaker said that the excel template shown with the policy could be used, and that the person or role calling the pause would be responsible for completing the template.

HRSA added that the directive arose from a specific case and that there are public facing materials around those compliance actions and corrective actions. HRSA staff continued that in most cases the reporting was from a member of the hospital team or a family member and this effort is partly to ensure all parties know there is an opportunity for a reassessment of the circumstances.

The DAC members then considered whether or not to endorse the proposed data collection. The meeting's chat function was used to capture the members' decisions. The Committee unanimously endorsed the proposal. The DAC Chair thanked the OPO Chair and the DAC members who participated on the directive's workgroup and added that it appears everyone is aligned with the proposal.

3. Review agenda for October 27 DAC Meeting: Update on Rabies Proposal

No decisions were made.

Summary of discussion:

The OPTN Contractor presented a potential draft agenda for 10/27/2025:

- Update on rabies directive proposal
- Discuss if DAC will submit a public comment

A member asked if the government shutdown changes the timeline for the DCD proposal. HRSA responded that the proposal would move forward given that it is considered a patient safety concern.

Upcoming Meeting

- October 27, 2025

Attendance

- **Committee Members**
  - Jesse Schold
  - Lisa McElroy
  - Rebecca Baranoff
  - Cassie Hertert
  - Michael Ison
  - Paul MacLennan
  - Christine Maxmeister
  - Nancy McMillan
  - Sumit Mohan
  - Jennifer Peattie
  - Julie Prigoff
  - Lindsay Smith
  - Allen Wagner
- **HRSA Representatives**
  - Brianna Doby
  - Sarah Laskey
  - Raymond Lynch
- **SRTR Staff**
  - Avery Cook
  - Jon Snyder
- **UNOS Staff**
  - Kevin Daub
  - Bonnie Felice
  - Jesse Howell
  - Lindsay Larkin
  - Meghan McDermott
  - Nadine Rogers
  - Kaitlin Swanner
- **Other Attendees**
  - PJ Geraghty