OPTN Organ Procurement Organization Committee
HRSA Directive for OPTN DCD Policy Development Workgroup
Meeting Summary
October 9, 2025
Conference Call

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Introduction

The HRSA Directive for OPTN DCD Policy Development Workgroup (the Workgroup) met via teleconference on 10/09/2025 to discuss the following agenda items:

1. Welcome & Agenda
2. Project Timeline
3. Review Approach for Reporting Unplanned DCD Pause and Data Standardization Checklist
4. Review Family Education Requirements
5. Review Draft Policy Language
6. Next Steps

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

1. Welcome & Agenda

A co-chair welcomed the workgroup and reviewed the agenda.

2. Project Timeline

A co-chair reviewed the project timeline, including an upcoming meeting with the OPTN Data Advisory Committee (DAC) for endorsement of the approach the workgroup is developing to collect information on unplanned pauses in the Donation after Circulatory Death (DCD) process.

3. Review Approach for Reporting Unplanned DCD Pause and Data Standardization Checklist

A co-chair presented the approach for reporting unplanned DCD pauses and the data standardization checklist for Workgroup consideration.

Presentation summary:

Reporting approach:

- Require reporting of unplanned DCD pauses via the OPTN Patient Safety Reporting Portal to support quick policy implementation
- Since reportable pauses are expected to be rare events, the OPTN will monitor the volume of these reports and consider if implementation in the OPTN Donor Data and Matching System is needed or if Patient Safety Portal reporting is sufficient

Workflow for reporting unplanned DCD pause:

- Organ procurement organizations (OPOs) to report pauses within 24 hours using a template
    - Template to be included in the public comment proposal
    - Final version provided to OPOs upon policy implementation

- Patient safety staff to ensure template is completed upon receipt of the report
    - If information about the outcome of the pause is not included in the initial report, then that information would be reported via follow up with staff rather than additional reports in the Patient Safety Portal
    - Staff to follow up within 7 days if outcome of pause has not been reported
- Patient safety reports for unplanned DCD pauses would be provided to HRSA and reviewed monthly by the OPTN Membership and Professional Standards Committee (MPSC)
- HRSA or MPSC may request medical records if needed

Information on the reporting template would include:

- The OPTN donor ID
- Dates and times when the OPO began evaluating the donor and when the OPO became aware of the request for an unplanned DCD pause
- The rationale for the pause and the stakeholder who requested it
- Dates and times that stakeholders were notified
- If the DCD process resumed after a pause or if the donation process was stopped, and the rationale for those actions

The co-chair reviewed the OPTN Data Standardization Checklist and presented a completed data standardization checklist for the information that would be included in the reporting template for an unplanned DCD pause.

Since the Workgroup previously discussed requiring a disposition to be reported for all authorized donors, the co-chair noted that current reporting on disposition may require changes to ensure outcomes are reported for patients for whom authorization for donation is granted but no organs are recovered:

- Patients who do not expire in a time frame that allows for DCD donation to occur
- Patients for whom the donation process is stopped due to an unplanned DCD pause

Currently, disposition must be reported for any individual for whom at least one organ is recovered:

- "Were any organs recovered?"
    - If the response is "**No**," an organ-by-organ disposition is not collected
    - If the response is "**Yes,**" disposition must be reported for each organ

The Workgroup considered two options for updating reporting on disposition:

- Option 1 - Add new disposition codes:
    - Add disposition reasons for organs not recovered:
        - Outside expiration time for DCD recovery
        - Donation process stopped due to unplanned DCD pause
    - Disposition would be required for each organ including if organs were not recovered
    - Changes would not require approval by the Office of Management and Budget (OMB)
- Option 2 - Allow for more reporting at case level:
    - If the answer to "Were any organs recovered?" is "**No,**" additional child questions could be added to collect information about case outcome, such as whether the non-recovery was related to a DCD pause, or because the patient did not expire
    - Would not collect organ-by-organ dispositions in the case of non-recovery
    - New data collection subject to OMB approval

<u>Summary of discussion:</u>

Topic #1: The Workgroup did not have questions on or suggest changes to the data standardization checklist regarding information to be reported for an unplanned DCD pause.

Topic #2: The Workgroup discussed adding disposition codes so that OPOs can appropriately report disposition from potential DCD donors who do not proceed to donation.

A co-chair recommended that the Workgroup start with Option 1 to support faster implementation and shared that the Workgroup will receive feedback from DAC later this month. A co-chair asked a representative from DAC for comment, and the representative said that adding the disposition codes makes sense to support the faster implementation.

4. Review Family Education Requirements

A co-chair reviewed the proposed requirements for minimum information to be disclosed to DCD donor families.

Presentation Summary:

The co-chair noted that the full list of proposed requirements was distributed to the Workgroup in advance of the call, and explained that the list encompasses:

- Existing OPO requirements for authorization per Centers for Medicare and Medicaid Services (CMS)
- Consent for procedures performed in support of organ donation prior to patient death
- Plan for withdrawal of life sustaining therapies, and plan for continued patient care if the patient does not expire within the appropriate time for DCD donation to occur
- Minimum expectations for disclosure if organ recovery will be performed via thoracoabdominal normothermic regional perfusion (TA-NRP)
- Explaining the unplanned DCD pause and what it would mean for the family

The co-chair encouraged Workgroup members to review the document in full, if they have not done so already, to see if there is anything they feel strongly about changing, adding, or removing.

Summary of discussion:

Topic #3: The Workgroup did not suggest changes to the proposed family education requirements.

There were no questions or comments.

5. Review Draft Policy Language

The Workgroup reviewed the draft policy language, which included:

- Definition of an unplanned DCD pause
- Additional OPO responsibilities regarding information that must be provided to stakeholders regarding the process for an unplanned DCD pause, and responsibilities regarding neurological assessments
- Additional requirements for potential DCD donor evaluation, including confirming the plan for continued care if the patient does not expire in a time frame that allows for DCD donation to occur
- New requirements for a process by which an unplanned pause in DCD donation can be requested, and actions to take in response to a request for an unplanned DCD pause
- New data submission and OPO reporting requirements

Summary of discussion:

Topic #4: The Workgroup discussed potential policy requirements for determining if donation can proceed following an unplanned DCD pause.

One member asked for confirmation that it is the OPO that determines when the pause is released. The member suggested that the person requesting the pause should be the person who is able to release the pause. A co-chair said that the OPO is notified of the pause by whoever is calling it, and the pause is in response to a concern that withdrawal of life sustaining measures is not appropriate in the patient's case. The OPO is expected to discuss that with the person who called the pause, whether that is a family member, the hospital team, the procurement staff, or the transplant center staff. The OPO is expected to address and resolve the concern, and resolving the concern may require involvement from other stakeholders. The co-chair provided an example where a transplant center raises concerns whether withdrawal of life sustaining support is appropriate for a patient. The OPO would then work with the donor hospital staff caring for the patient to talk with transplant center staff about these concerns. The co-chair explained that this requires consensus to move forward, as multiple requests for unplanned pause can be made and must be addressed. The other co-chair added that it is important for there to be a huddle of the appropriate parties to determine if donation is the appropriate course, and in some cases, the person calling the pause may still feel uncomfortable, but the family and attending physician and others still agree with donation and determine that is the appropriate path forward. The co-chair noted that the OPO has the obligation under the proposed OPTN policy to determine if the pause is resolved, but the larger group will work to resolve the pause. The co-chair explained that these situations should be rare, and donation should only move forward after discussion and investigation. The member agreed these pauses will be rare, and said that is why the OPTN should be prescriptive in how the pause is released. The member supported having the person requesting the pause be the person who determines whether the pause can be released. The member supported capturing information on who called the pause and who determined the release of the pause. The member recommended following up with the stakeholder who called the pause to understand the concern and prevent similar situations in the future.

A member said there might be situations where the requestor would refuse to release the pause, even if the family, the OPO, the patient's care team, and the transplant center agree with moving forward with donation. The member agreed that it may be helpful to clarify who can release the pause, but expressed concern with only allowing the requestor of the pause to determine if the pause is released. The member recommended that the decision be made by a collective group instead of one party.

A member suggested that the group should be able to provide sufficient education to the person requesting the pause such that they will agree to release the pause. The member expressed concern that the person who called the pause could be overridden without adequate understanding of why the case is proceeding. A member offered that the clinical care team could be the party responsible for releasing the pause. A member responded that it may make more sense to require the person who called the pause to be involved in addressing the pause and the decision-making of whether to move forward.

A co-chair remarked that it could be the donor family raising the concern and desiring to withdraw authorization, and in that case, it would be important for the clinical care team and the family to address concerns and determine the appropriate path forward without the OPO representatives.

One member said that if a donor family member requests the pause, it could be a lot of pressure for that person to determine whether the pause is released, and the case can move forward. The member said the person who called the pause may not be qualified to determine if the case should move forward.

A HRSA representative asked if the Workgroup considered it within the bounds of this proposed policy to address concerns of improper or inaccurate brain death declaration. A co-chair asked whether the idea would be to consider the same type of process for brain dead donors. The HRSA representative affirmed the question was whether this policy could provide a framework for other scenarios where concerns arise. The HRSA representative explained that, at a system level, it is important to understand if there are common characteristics for unplanned DCD pauses. A co-chair recognized the value of this framework and suggested that a separate project could be initiated to address the brain death perspective. The other co-chair agreed.

One member remarked that neurologic status is a large component of why most pauses could or would be called. The member explained that every OPO has different policies about which patients may be appropriate DCD donors. The member offered that policy could require OPOs to maintain written protocols about how to address and resolve pauses related to neurologic status. The member added that variation in qualifications for DCD donors could make it difficult to standardize a policy for how to address concerns for neurologic status. A co-chair expressed support for policy language ensuring that the patient continues to meet OPO requirements for DCD and hospital requirements for withdrawal of support. A member suggested that requiring OPOs to have a policy on how to resolve these issues with local hospital systems may prompt hospitals to develop these policies. A co-chair expressed concern about requiring an OPO to comply with hospital policy given that hospitals may not have such policies. In those cases, it is difficult for the OPO to remain compliant with OPTN Policy since no hospital policy exists, which could then prevent donation.

A member recommended a checklist for the overall process and standardization of best practices, noting it could provide a framework for any OPO or transplant program to navigate areas of vulnerability.

A HRSA representative explained that most hospitals have an ethics committee and a process for determining futility in care for their inpatients, and that could be an avenue forward in cases where individuals have concerns despite good evidence to move forward.

An attendee and a co-chair thanked the Workgroup for their work.

6. Next steps

The Workgroup's comments will be considered for incorporation into the draft policy language, which will be reviewed by the OPO Committee on 10/23/2025. The Workgroup will receive an update as to whether the Workgroup needs to meet on 11/13/2025.

Upcoming Meeting

- November 13, 2025

Attendance

- **Workgroup Members**
  - PJ Geraghty
  - Rebecca Baranoff
  - Patrice Morris Ball
  - Andrew Flescher
  - Precious McCowan
  - Kyle Herber
  - Rachel Beekman
  - Garrett Erdle
  - Lori Markham
  - Greg Veenendaal
  - Micah Davis
- **HRSA Representatives**
  - Brianna Doby
  - Sarah Laskey
  - Raymond Lynch
- **SRTR Staff**
  - Katie Siegert
- **UNOS Staff**
  - Kaitlin Swanner
  - Susan Tlusty
  - Betsy Gans
  - Bonnie Felice
- **Other Attendees**
  - Doug Fesler
  - John Magee