OPTN Data Advisory Committee
Meeting Summary
July 14, 2025
Conference Call

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Introduction

The OPTN Data Advisory Committee (DAC) met via WebEx teleconference on 07/14/2025 to discuss the following agenda items:

1. Welcome, reminders, and agenda review
2. Disease Transmission Advisory Committee (DTAC), *Require West Nile Virus Seasonal Testing for Donors* proposal; Combined first and second check-in
3. SRTR Contractor presentation of information regarding *Survival After Removal from the Transplant Waiting List Without Transplant* and questions for Committee consideration
4. Discuss feedback and drafted response for OPTN Process Data package (30-day Notice)
5. Open forum
6. Closing remarks

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

1. Welcome, reminders, and agenda review

On behalf of Committee leadership, OPTN contractor staff welcomed the Committee members and others to the meeting. Contractor staff reviewed the agenda and noted that the meeting was being live-streamed. The Committee acknowledged the return of a member whose term expired on 06/30/2025, but was since extended for another year.

No decisions were made during discussion of this agenda item.

2. Disease Transmission Advisory Committee (DTAC), *Require West Nile Virus Seasonal Testing for Donors* proposal; Combined first and second check-in

The Vice Chair of the OPTN Disease Transmission Advisory Committee (DTAC) presented a proposal to require seasonal West Nile Virus (WNV) testing for both deceased and living donors. The proposal is in response to CDC and FDA recommendations and aims to reduce the risk of donor-derived WNV transmission. DAC members expressed general support for the proposed data collection identified in DTAC's proposal.

Summary of discussion:

Decision #1: The Committee endorsed the data collection components of the DTAC proposal.

The Committee received a detailed presentation from the Vice Chair of the Disease Transmission Advisory Committee (DTAC) regarding a proposed policy to require seasonal West Nile Virus (WNV)

testing for both deceased and living organ donors. The proposal is intended to reduce the risk of donor-derived WNV transmission, which carries significant morbidity and mortality for transplant recipients. The policy aligns with recommendations from the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA).

Key aspects of the data collection identified in DTAC's proposal included the following:

- Mandatory WNV testing of all donors will occur from July 1st through October 31st of every year
- Use of FDA-licensed nucleic acid amplification tests (NAT)
- Required reporting of WNV NAT results in the OPTN Computer System

For deceased donors, existing data fields in the OPTN Donor Data and Matching System [also known as DonorNet®] will be made mandatory during the designated risk period. For living donors, a new WNV NAT field will be added to the Living Donor Registration (LDR) form in the OPTN Data System for Organ Procurement and Transplantation Network [also known as TIEDI®]. The systems will enforce validation rules to ensure data entry compliance.

A question was raised about whether the system would enforce the mandatory nature of the WNV NAT field only during the July–October risk period. In response, OPTN Contractor staff clarified that validations would be implemented year-round. While the policy would emphasize seasonal testing, the system would allow data entry outside the risk period to accommodate centers that choose to test year-round. Educational materials would be developed to guide users on appropriate data entry during non-risk periods.

A Committee member questioned the inclusion of "not done" as a response option if testing is mandatory. The member's concern was that allowing this option could undermine the intent of the policy. OPTN contractor staff explained that "not done" is a standard option across all infectious disease fields in DonorNet® and is necessary to accommodate situations where test results are pending at the time of organ offer. The system is designed to allow updates once results become available.

Along those lines, a question was raised about whether transplant centers would be required to unlock and update the LDR form if WNV test results were pending at the time of submission. OPTN contractor staff clarified that the LDR form would not permit submission with a pending result. Instead, centers would be required to wait until final results were available before submitting the form. This approach aligns with existing infectious disease reporting protocols in the system.

A question was raised about whether the seasonal testing period might vary by region, and whether programs would be responsible for monitoring local epidemiological trends. The presenter clarified that the July–October window was selected in consultation with the CDC to be broadly inclusive of national transmission patterns. The intent is to avoid placing the burden of regional surveillance on individual programs. However, a Committee member emphasized that from a compliance standpoint, programs would still need to be aware of and adhere to the defined testing window, and that any future changes to the timeframe would need to be clearly communicated to avoid unintentional non-compliance.

DTAC is scheduled to present the proposal to the OPTN Policy Oversight Committee (POC) on 07/24/2025 for review. If approved by POC, the proposal will be submitted for OPTN summer public comment, with the intention of submitting the final proposal for OPTN Board approval in December 2025.

The Committee was asked whether it supported DTAC moving forward with the proposal for public comment. No objections were raised, and the Committee expressed general support for advancing the proposal.

Next steps:

OPTN contractor staff will ensure system validations and educational materials are developed to support implementation.

3. SRTR Contractor presentation of information regarding *Survival After Removal from the Transplant Waiting List Without Transplant* and questions for Committee consideration

The SRTR contractor presented findings from an analysis of survival among candidates removed from the transplant waiting list for reasons other than transplant or death, particularly those removed due to clinical deterioration. The SRTR contractor asked for DAC members' assistance in identifying reasons for some of the analysis' findings, including the potential that data quality issues are causing some of the results.

Summary of discussion:

No decisions were made during discussion of this agenda item.

The Committee received a presentation from SRTR contractor staff regarding an analysis of post-transplant survival outcomes for transplant candidates removed from the waiting list without receiving a transplant. The analysis focused on adult candidates listed for single-organ transplants (heart, kidney, liver, or lung) between 2003 and 2023 who were removed for reasons other than transplant or death.

The analysis revealed a marked and unexpected increase in one-year survival rates for candidates removed due to deteriorated condition, particularly among liver, heart, and lung candidates beginning around 2015–2017. This trend was not observed in kidney candidates. The increase persisted across multiple timeframes (30-day to 5-year survival) and remained after adjusting for clinical characteristics.

Committee members engaged in a detailed discussion to explore potential explanations and implications of the findings. For example, the Committee members broadly agreed that the most likely explanation was incomplete death data, particularly due to limitations in the Social Security Administration's Limited Access Death Master File (LADMF). It was noted that the LADMF has been the primary source of death verification since access to the full file was restricted in 2011. Members noted that this issue likely affects not only delisted candidates but also waitlist and post-transplant mortality data, albeit to a lesser extent.

The SRTR contractor confirmed that they had received permission from HRSA to purchase data from the CDC's National Death Index (NDI). The SRTR contractor plans to audit a subset of delisted candidates with no known death date to assess whether deaths are being missed. This effort is expected to take time due to data acquisition and processing requirements.

A Committee member proposed a fourth hypothesis based on state-level data suppression. In Colorado, for example, certain sensitive diagnosis codes (e.g., substance use-related liver disease) are excluded from public datasets, potentially leading to underreporting of deaths. This raised the possibility that similar exclusions could affect national data sources. At the same time, some members suggested exploring state-specific death registries or other gold-standard sources to validate findings. It was noted that some states may have more complete or accessible data, and that even partial validation could help quantify the extent of underreporting.

It was emphasized that incomplete death data could introduce systematic bias into risk adjustment models and performance metrics. This is particularly concerning for allocation policy and program

evaluation. Members stressed the importance of understanding how much the registry depends on center-reported deaths and whether external sources alone are sufficient.

A question was raised about whether similar trends were observed in the Medicare population. The SRTR contractor noted that CMS death data have not been received for several years and that the volume of CMS-sourced deaths is too small to meaningfully influence the analysis. Interestingly, the survival trend was not observed in kidney candidates, where CMS data are more prevalent.

The Committee discussed the possibility of isolating the impact of center-reported deaths by removing them from the analysis and relying solely on external sources. The SRTR contractor acknowledged that this was feasible and agreed it could provide valuable insight into the registry's dependence on center reporting.

One member questioned whether the observed survival improvements could reflect actual changes in clinical practice, such as more conservative waitlisting or increased use of destination therapy (for example, the increased use of left ventricular assist devices (LVADs) in heart failure candidates). However, the SRTR contractor and other members expressed skepticism, particularly the use of LVADs as destination therapy, noting that survival gains were abrupt and not supported by known treatment advances. Adjusted analyses also controlled for clinical characteristics, further reducing the likelihood of this explanation.

The SRTR contractor identified several next steps they would pursue, including proceeding with the planned audit using the NDI to assess the completeness of death data for delisted candidates. They will also explore the feasibility of analyzing state-level death data or other gold-standard sources to validate findings. The SRTR contractor will conduct additional analyses excluding center-reported deaths to evaluate the registry's reliance on external sources, as well as continue adjusting for clinical variables and exploring subgroup trends (e.g., by age, organ type, and social security number validity).

The Committee expressed strong interest in continuing this line of inquiry and emphasized the importance of addressing data quality concerns to ensure the integrity of OPTN metrics and analyses.

Next steps:

The OPTN contractor will coordinate with the SRTR contractor to rule out the possibility of data transfer issues. The OPTN contractor also indicated it would support efforts to identify and access alternative data sources for death verification. Additionally, the OPTN contractor indicated it would facilitate communication with HRSA and other stakeholders regarding the implications of incomplete death data on policy and performance monitoring.

4. Discuss feedback and drafted response for OPTN's Process Data package (30-day Notice)

DAC members were joined by members of the Pre-Waitlist Data Collection workgroup and the MPSC's OPO Performance Monitoring workgroup for discussion of the OPTN's Process Data package. DAC along with both workgroups had been instrumental in drafting the OPTN's response to the 60-day Federal Register Notice (FRN). The Committee and workgroup members reviewed the current 30-day FRN concerning proposed data collection forms for pre-waitlist and ventilated patient referrals. Members expressed concern that HRSA had made only a few substantive changes in their proposed data collection forms since the 60-day FRN, particularly regarding the ventilated patient referral form. DAC leadership and the others participating in the meeting agreed that the draft OPTN response to the 30-day FRN should re-iterate the comments made in the OPTN's response to the 60-day FRN while respectively requesting that HRSA and OMB revisit that response when considering public comments for the 30-day FRN.

Summary of discussion:

Decision #1: Members of DAC and the two workgroups agreed to submit a draft response to the 30-day Federal Register Notice reiterating prior feedback and highlighting ongoing concerns. The draft response will be submitted to OPTN leadership for review with a request that it be submitted as the OPTN's formal response.

DAC leadership led a discussion of the information associated with the 30-day FRN of the OPTN Process Data package. The discussion focused on the content of the data elements proposed for pre-waitlist referral (both the referral form and the evaluation form), as well as the ventilated patient referral form. The role the Committee and workgroups had in shaping the OPTN's response to the previous response to the 60-day FRN was also discussed.

Committee and MPSC workgroup leaders noted that HRSA's 30-day FRN posting reflected only a few of the changes the OPTN had recommended in its formal response to the 60-day FRN. This was especially true with regard to the ventilated patient form, which the OPTN's 60-day response had noted would not fulfill the need to provide accurate and timely information for monitoring OPO performance without improvements. HRSA's lack of substantive revisions to any of the proposed data collection tools prompted concern among members, who had previously submitted detailed feedback and expected more robust updates.

Key points raised included:

- The lack of transparency regarding why certain data elements were excluded
- The need for mutually exclusive and clearly defined response options
- The importance of piloting the forms to identify potential issues before full implementation

Those attending the meeting expressed disappointment that many of the Committee's and workgroups' earlier recommendations were not incorporated into the revised package. It was noted that HRSA's rationale for excluding certain data elements or maintaining existing structures was either absent or insufficiently explained. This made it difficult to assess whether the OPTN's previous feedback had been meaningfully considered.

The ventilated patient referral form was identified as the area with the greatest disconnect between the OPTN's recommendations and the information appearing in HRSA's 30-day FRN proposal. Members highlighted concerns about the absence of mutually exclusive response options and the continued use of ambiguous fields, which could lead to inconsistent data entry and interpretation. The OPTN's response to the 60-day FRN had addressed these as issues.

Several members emphasized the importance of clear communication regarding timelines, expectations, and rationale for decisions. A member expressed concern that the Committee's input was not being adequately acknowledged or integrated, particularly from the patient perspective. Another member noted that clinicians and program staff rely on predictable timelines to prepare for operational changes, including staffing and training.

A question was raised regarding the timeline for implementing the data collection changes following submission of the OPTN's response to the 30-day FRN. OPTN contractor staff clarified that the 30-day public comment period would close on July 31, 2025, after which the Office of Management and Budget (OMB) would begin its review. HRSA has requested that OMB perform expedited processing, with potential approval expected between August and September. However, development of the data collection systems has not yet begun, and no implementation timeline has been established.

A member asked whether the Committee could reference pilot implementation in its response, given HRSA's mention of piloting the data collections. OPTN contractor staff confirmed that while HRSA is not currently discussing implementation details, the Committee is free to include such considerations in its response. This could help illustrate how certain data fields may lead to errors or subjectivity and inform future development.

A HRSA representative joined the discussion to affirm that all public comments submitted as part of the 60-day notice were reviewed and adjudicated through a robust internal process. It was noted by the HRSA representative that representatives from the Centers for Medicare & Medicaid Services (CMS) were involved with some of HRSA's review and decision-making. While the review and adjudication process are robust, the deliberations and associated decisions are not made public, according to the HRSA representative. The representative also stated that HRSA's review process is designed to weigh all stakeholder responses evenly so that no one stakeholder can have additional, special access as part of the public comment review.

The Committee reiterated its interest in continued dialogue with HRSA and the OPTN Board to ensure transparency and collaboration.

Next steps:

OPTN contractor staff will work with DAC leadership and the MPSC workgroup leader to finalize the draft response to the 30-day FRN. The draft will be circulated to workgroup members for review, with the goal of submitting a final, draft version by 07/18/2025 to OPTN leadership for review. DAC leadership and the MPSC workgroup leader are scheduled to meet with OPTN leadership on 07/22/2025 to review the final, draft response with the objective of OPTN leadership approving the response as the formal OPTN response to the 30-day FRN.

OPTN contractor staff will continue to seek opportunities for dialogue with HRSA regarding the rationale behind data element decisions and the anticipated implementation process. The Committee expressed a strong interest in participating in future discussions with HRSA to ensure that stakeholder feedback is reflected in final policy and system design.

5. Open forum

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

6. Closing remarks

The meeting concluded with a summary of key discussions and next steps. Committee leadership encouraged members to submit additional feedback for inclusion in the OPTN response to the 30-day notice. It was noted that the Committee remains committed to advancing the project ideas members had prioritized early in 2025 alongside responding to external directives. Members were told that materials for their 08/11/2025 meeting will be provided closer to the meeting date.

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

- ~~July 14, 2025, 3:00 – 4:30 pm (ET)~~
- August 11, 2025

- September 8, 2025
- October 20, 2025, 12:00 – 2:00 pm (ET)
- October 27, 2025, 3:00 – 5:00 pm (ET)
- November 10, 2025, 3:00 – 4:30 pm (ET)
- 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
  - Paul MacLennan
  - Christine Maxmeister
  - Nancy McMillan
  - Sumit Mohan
  - Jennifer Peattie
  - Julie Prigoff
  - Alicia Skeen
  - Lindsay Smith
- **HRSA Representatives**
  - Shantel Delgado
  - Brianna Doby
  - Sarah Laskey
- **SRTR Staff**
  - Avery Cook
  - Grace Lyden
  - Maria Masotti
  - Jon Miller
  - Jon Snyder
  - Bryn Thompson
- **UNOS Staff**
  - Lloyd Board
  - Brooke Chenault
  - Jonathan Chiep
  - Marty Crenlon
  - Kaite Favaro
  - Bonnie Felice
  - Cole Fox
  - Jesse Howell
  - Houlder Hudgins
  - Lindsay Larkin
  - Lauren Mooney
  - Carly Rhyne
  - Nadine Rogers
  - Laura Schmitt
  - Sharon Shepherd
  - Niyati Upadhyay
  - Betsy Warnick
  - Tamika Watkins
  - Sara Rose Wells
- **Other Attendees**

- Rachel Miller
- DAC Pre-Waitlist Data Collection Workgroup
    - Leigh Ann Burgess
    - Ashley Cardenas
    - Jennifer Cowger
    - Adrian Lawrence
    - Reem Raafat
- MPSC OPO Performance Monitoring Workgroup
    - Rick Hasz
    - Micah Davis
    - Chad Ezzell
    - Calvin Henry
    - Kyle Herber
    - Cliff Miles