OPTN Data Advisory Committee
Meeting Summary
March 10, 2025
Conference Call

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Introduction

The OPTN Data Advisory Committee met via WebEx teleconference on 03/10/2025 to discuss the following agenda items:

1. Welcome, Reminders, and Agenda Review
2. Project check-in: OPTN Lung Transplantation Committee, Modify Lung Donor Data Collection
3. Discuss DAC's role concerning HRSA's Directive on Allocation Out of Sequence (Sent to OPTN on 02/21/2025)
4. Other Committee business
5. Open Forum
6. Closing Remarks

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

1. Welcome, Reminders, and Agenda Review

The Chair welcomed the Committee members and provided an overview of the agenda items. There was a brief review of Committee member tenure extensions, emphasizing the importance of maintaining committee cohesiveness during transitions. Members were reminded to respond to emails regarding their willingness to extend their terms.

2. Project check-in: OPTN Lung Transplantation Committee, Modify Lung Donor Data Collection

The OPTN Lung Transplantation Committee Vice Chair presented information about the Lung Committee's public comment proposal modifying lung donor data collection. The Lung Committee's proposal aims to improve the efficiency of lung allocation by adding specific data elements to donor records, such as peak inspiratory pressure, detailed cigarette smoking history, marijuana smoking history, and vaping history. The discussion highlighted the importance of these data elements and addressed concerns about the burden on OPOs and the accuracy of data collection. This served as the post-public comment check-in about the project with DAC. As such, no DAC endorsement was needed.

Summary of discussion:

No decisions were made as part of this discussion.

The Lung Committee's proposal aims to improve the efficiency of lung allocation by adding specific data elements to donor records, such as peak inspiratory pressure, detailed cigarette smoking history, marijuana smoking history, and vaping history. The Lung Committee's Vice Chair said that these additions were intended to provide lung transplant programs with more granular information to make

informed decisions. The discussion highlighted the importance of these data elements and addressed concerns about the burden on OPOs and the accuracy of data collection.

The Lung Committee's proposal identified several new data elements that OPOs will need to collect and report, including the following:

1. **Peak Inspiratory Pressure (PIP)**: According to the Lung Committee's Vice Chair, this is a ventilator setting that is recorded by the ventilator and already documented by OPOs. The data will be reported alongside arterial blood gases (ABGs). PIP provides insight into the lung compliance and stiffness, which is crucial for lung transplant programs when evaluating donor lungs.

2. **Cigarette Smoking History**: The proposal recommends a more detailed reporting of smoking history. Instead of the binary, greater than or less than 20 pack years, OPOs will report the number of packs per day and the frequency of smoking. The OPTN Computer System will then calculate the pack years, providing a more refined piece of information.

3. **Marijuana Smoking History**: Previously, such information has been inconsistently reported. The proposal calls for standardized reporting of marijuana smoking status, frequency, and method of use. This information is relevant for programs to assess donor suitability and potential post-transplant complications.

4. **Vaping History**: Similar to marijuana smoking, vaping history will be reported in terms of status and frequency. This data is important for evaluating the impact on lung health and transplant outcomes.

The proposal also included modifications to the diagnostic test status reporting. OPOs would categorize tests as complete, pending, or unable to complete, with dropdown menus for common reasons. This change streamlines communication between OPOs and transplant programs, reducing the need for back-and-forth phone calls.

Additionally, the proposal suggested adding the Predicted Total Lung Capacity (PTLC) to the donor data. PTLC, calculated based on gender, age, and height, provides useful information regarding lung size for recipients. Programs would set their own filters for acceptable PTLC ranges, allowing for more precise matching of donor lungs to recipients.

The presentation highlighted the alignment of these proposed changes with OPTN data collection principles, ensuring that all necessary information is available for transplant decision-making. Public comments on the proposal indicated improved data precision, comprehensive history documentation, and streamlined processes with better communication.

Implementation of these changes will require additional staff training and adjustments to existing workflows. OPOs and lung transplant programs would need to educate their staff on the new features and filters in the OPTN system. The proposal aims to enhance the accuracy and granularity of lung donor data, ultimately improving the efficiency and outcomes of lung transplants.

The discussion concluded with a focus on ensuring systematic availability of the new data elements for OPOs and addressing any potential burden. Technical questions were raised about the measurement and reporting of PIP, the frequency and method of marijuana and vaping use, and the impact on SRTR data. The committee emphasized the importance of accurate and comprehensive data collection to support lung transplant programs in making informed decisions.

Next steps:

The Lung Committee will submit the proposal to the OPTN Board of Directors for approval during the Board's 06/2025 meeting.

3. **Discuss DAC's role concerning HRSA's Directive on Allocation Out of Sequence (Sent to OPTN on 02/21/2025)**

The discussion focused on HRSA's Allocation Out of Sequence (AOOS) Directive and the role identified for DAC improving data collection and reporting practices to enhance the efficiency and accuracy of organ allocation processes. The proposed changes to improve data collection, reporting, and education aim to enhance the transparency and accuracy of refusal codes, ultimately contributing to more efficient and equitable organ allocation.

Summary of discussion:

> No final decisions were made as part of this discussion.

The Chair provided an overview of the AOOS Directive. The Directive was issued to the OPTN on 02/21/2025. It calls for urgent review and revision of organ allocation policies to address concerns about the frequency and rationale for the use of out-of-sequence organ offers. The Directive specifically requests DAC to provide detailed recommendations for revising the refusal codes, establishing a training program on the use of the codes, and identifying the most appropriate method(s) for holding OPTN members accountable for their use of such codes.

The AOOS Directive identifies specific activities for DAC to perform in order to improve the organ allocation system overall. The Directive also identifies activities for other OPTN committees to perform to improve organ allocation. The Chair noted that the Committee's project prioritization effort identified some activities that aligned with HRSA's AOOS Directive. The Directive tasks DAC with reviewing and revising the OPTN refusal codes, specifically the codes that are associated with "bypassing" transplant programs in order for an OPO to place a donor organ with a recipient more quickly. The Chair reminded Committee members that DAC was involved with a review and revision of the refusal codes in 2021. The Chair told the members that a copy of the 24-month monitoring report associated with the 2021 project was available on the Committee's SharePoint site.

The Chair continued that the AOOS Directive requires DAC to provide a detailed plan for revising the refusal codes, developing an educational resource about the appropriate use of refusal codes, sharing the educational resource training with OPTN members, and ensuring OPTN members complete the training and attest that they have completed training and understand how the refusal codes are supposed to be used. The AOOS Directive also requires DAC to develop a policy proposal identifying how OPTN members will be held accountable for appropriately using the refusal codes in the future.

In terms of revising the refusal codes, the Chair pointed out that the Committee had already emphasized the need to eliminate the "other/specified" option in refusal codes, as it often lacks useful information. Additionally, the Committee members recommended evaluating all current refusal codes to ensure the intent behind each code is clear and results in consistent understanding and reporting of information. Where appropriate, the Committee indicated an interest in providing additional clarifications of the refusal codes. The importance of timestamps in the data collection process was emphasized to improve the understanding of out-of-sequence offers. The members also discussed broader recommendations, including the need for a regular review of refusal codes to capture any new mechanisms that may arise. The importance of timestamps in understanding the allocation process was highlighted, as well as the need for a strategic educational initiative to improve coding practices.

Key Points of Discussion:

1. **Elimination of "Other/Specified" Refusal Code**: The Committee members agreed that the "other/specified" option often lacks useful information and its use does not contribute to a clear understanding of the reasons for organ offer refusals or AOOS. It was recommended to eliminate this option and replace it with more specific codes that capture the actual reasons for refusal.

2. **Review and Revision of Current Refusal Codes**: A thorough review was proposed of all existing refusal codes to ensure they are systematically reported and provide meaningful data. This includes refining the language used in the codes to enhance clarity and consistency in reporting.

3. **Addition of New Refusal Codes**: The Committee discussed the potential need for new refusal codes to address specific scenarios that are not currently captured. For example, a refusal code for "waiting time exceeds average" was suggested to account for situations where a patient's waiting time justifies expecting a better organ offer.

4. **Timestamp Accuracy**: The importance of accurate timestamps in the allocation process was emphasized. Timestamps help track when refusal codes are entered and when organ offers are made, providing a clearer picture of the allocation timeline. The Committee noted that current data sets often overwrite timestamps, making it difficult to understand the sequence of events.

5. **Strategic Educational Initiative**: The Committee discussed how best to address the Directive's call for a strategic educational initiative to improve coding practices, and perhaps go a step farther in terms of educating OPTN members. The Committee could consider a process for targeting OPOs and transplant centers with high frequencies of out-of-sequence allocations or inconsistent coding practices. The goal is to ensure users understand how to accurately implement refusal codes and improve overall data quality.

6. **Regular Review of Refusal Codes**: Recognizing the dynamic nature of organ allocation, the Committee suggested a regular review of refusal codes to capture any new mechanisms that may arise. For example, it was mentioned that such a review could be conducted biannually to ensure the codes remain relevant and comprehensive.

7. **Attestation Process**: While the Committee acknowledged it would work towards addressing the Directive's request for an attestation process to ensure users are trained on the proper use of refusal codes, there was some skepticism about the effectiveness of attestation requirements, generally. The Committee suggested that implementing a process for auditing OPTN data, as well as collection and reporting practices, is likely to have a more positive and long-term impact on improving OPTN data quality than an attestation process. Members also discussed how focusing on targeted education and training could lead to improved coding practices.

Next steps:

The discussion concluded with an overview of next steps, including the submission of recommendations to the OPTN Executive Committee and HRSA associated with developing training materials and implementing changes in the OPTN Computer System. The Chair acknowledged the importance of the members' collective expertise and encouraged them to share any additional ideas or related matters. The Committee agreed to prioritize the draft of the initial plan response while pausing some other projects.

4. Other Committee business

The Chair reminded the members to respond to emails regarding their willingness to extend their terms, if they are interested in doing so. The Chair emphasized the importance of maintaining committee cohesiveness during transitions.

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 Chair thanked the members for their participation and noted that the Committee is again at the forefront of activity because of the quality of its previous work. Members were encouraged to share ideas about today's topics or other potential Committee work. Members were reminded that the next Committee meeting is scheduled for 04/14/2025.

Upcoming Meetings (Meetings start at 3:00 pm (ET) unless otherwise noted)
- ~~July 8, 2024~~
- ~~August 12, 2024~~
- ~~September 10, 2024 – In-person meeting, Detroit, MI, 8:00 am – 3:00 pm (ET)~~
- ~~October 21, 2024~~
- ~~November 18, 2024~~
- ~~December 4, 2024 10:30 am – 2:30 pm (ET) – HHS Data Collection Directive Meeting~~
- ~~December 9, 2024 11:00 am (ET)~~
- ~~January 12, 2025~~
- ~~February 10, 2025~~
- March 10, 2025
- April 14, 2025
- May 12, 2025
- June 9, 2025

Attendance

- **Committee Members**
  - Jesse Schold
  - Lisa McElroy
  - Rebecca Baranoff
  - Kate Giles
  - Cassie Hertert
  - Michael Ison
  - Paul MacLennan
  - Michael Marvin
  - Christine Maxmeister
  - Nancy McMillan
  - Sumit Mohan
  - Julie Prigoff
  - Meghan Schaub
  - Alicia Skeen
  - Lindsay Smith
  - Allen Wagner
- **HRSA Representatives**
  - Adriana Alvarez
- **SRTR Staff**
  - Avery Cook
  - Ryu Hirose
  - Jon Snyder
- **UNOS Staff**
  - Brooke Chenault
  - Jonathan Chiep
  - Cole Fox
  - Jesse Howell
  - Eric Messick
  - Lauren Mooney
  - Leah Nunez
  - Nadine Rogers
  - Laura Schmitt
  - Sara Rose Wells
- **Other Attendees**
  - Dennis Lyu