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

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Introduction

The OPTN Data Advisory Committee (DAC) met via WebEx teleconference on 02/10/2025 to discuss the following agenda items:

1. Welcome and agenda review
2. Project check-in: OPTN Pediatric Committee, *Standardize Lost to Follow-up Reporting and Enhance Data Collection on Lost to Follow-up & Transfers of Care*
3. Project check-in: OPTN Kidney Transplantation Committee, *Establish Expedited Placement Policy for Hard-to-Place Kidneys*
4. 2025 DAC Priority Action Items
5. Open Forum
6. Closing Remarks

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

1. Welcome and agenda review

The Chair welcomed the Committee members and provided an overview of the agenda items. The meeting's two primary activities consisted of first check-ins by the OPTN Pediatric Transplantation Committee and the OPTN Kidney Transplantation Committee. The Chair said that the Committee would discuss project priorities if time permitted.

2. Project check-in: OPTN Pediatric Committee, *Standardize Lost to Follow-up Reporting and Enhance Data Collection on Lost to Follow-up & Transfers of Care*

The OPTN Pediatric Transplantation Committee (Pediatric Committee) is proposing a project to standardize the processes related to data submission practices involving an organ transplant recipient whose post-transplant care is transferred to an entity that was not involved with the transplant.

Summary of discussion:

> Decision #1: The Committee endorsed the data collection activities proposed by the OPTN Pediatric Transplantation Committee.

The Pediatric Committee is proposing a project to standardize processes related to the reporting and collection of transfer recipient follow-up data. The Pediatric Committee Vice Chair explained to the DAC members that they want to collect data identifying the reasons associated with 'lost to follow-up' and explore ways of capturing a patient's age at the time of transfer of care. The project seeks to understand the extent of the lost to follow-up problem, not only in pediatrics but also in the adult population. The Vice Chair highlighted the need for standardized definitions and data collection to capture the reasons for lost to follow-up and to explore ways to improve follow-up care for transplant recipients. The

Pediatric Committee is seeking endorsement for this project and plans to submit it for public comment in January 2026.

The Pediatric Committee Vice Chair began by explaining that currently, transplant programs can determine when a patient is considered lost to follow-up, leading to variability in how this status is reported. The Pediatric Committee Vice Chair emphasized the importance of understanding the reasons for lost to follow-up and the barriers to accessing follow-up care for transplant recipients, particularly young adults transitioning from pediatric to adult care.

The DAC members discussed the following key points:

- The importance of defining what constitutes lost to follow-up.
- The need for data to demonstrate the frequency and variability of the problem.
- The potential for combining the "not seen" and "lost to follow-up" categories.
- The possibility of involving patients in the data collection process to capture their experiences and challenges.

A member said that this project is definitely needed. A member asked the Vice Chair of the Pediatric Committee to consider not requiring the addition of another data element for collection if the OPTN Computer System could be programmed to calculate the value being request. The Vice Chair indicated that the request would be kept in mind. Another member provided additional insights and suggestions from the patient perspective. The member shared their personal experience of transferring care between states and highlighted the challenges faced by patients in ensuring continuity of care. The member said that in some circumstances, the recipient may not even realize they would be considered as “lost to follow-up.” The Pediatric Committee Vice Chair acknowledged the importance of including patient input in the project and suggested exploring ways to involve patients and families in determining long-term outcomes.

DAC members expressed support for the project and emphasized the importance of collaboration with other committees to address this issue comprehensively. The Chair called for a voice vote from members. None of the members indicated that they were opposed to the proposed data collection and none of the members abstained.

Next steps:

The DAC Chair and the Pediatric Committee Vice Chair discussed the possibility of creating a separate workgroup with members from different committees to extend the project beyond pediatrics. The Pediatric Committee Vice Chair agreed to keep DAC updated on the progress and to explore opportunities for collaboration. The Pediatric Committee is seeking project approval from the OPTN Policy Oversight Committee on 02/13/2025.

3. Project check-in: OPTN Kidney Transplantation Committee, *Establish Expedited Placement Policy for Hard-to-Place Kidneys*

The Kidney Transplantation Committee Chair presented their project, which aims to develop a standardized, national expedited allocation policy for hard-to-place kidneys. The data collection component of the project would add a new data field on the kidney candidate registration to indicate whether candidates have opted in to receive expedited offers. The Chair explained that this project intends to address the issue of non-use and to allocate kidneys more efficiently. The project is in response to the OPTN Board of Directors directive to the Kidney Committee that the Kidney continuous

distribution allocation framework include an efficiency attribute for reducing the number of kidneys that are not transplanted.

Summary of discussion:

Decision #1: The Committee chose not to endorse the data collection proposed by the OPTN Kidney Transplantation Committee.

The proposal is to create a standardized national expedited allocation policy for hard-to-place kidneys at risk of non-use. A new data field on the kidney candidate registration would be added capture if a candidate has opted in to receive expedited offers. Standardizing the approach for allocating hard-to-place kidneys using defined criteria is crucial. This initiative is in response to a resolution from the OPTN Board of Directors, which directed the OPTN Kidney and Pancreas committees to ensure that the continuous distribution policy addresses non-use, allocation out of sequence, and expedited placement.

The Kidney Committee Chair provided an overview of the project, explaining that programs would opt in their candidates to receive these expedited placement offers. The kidneys that would go through this expedited placement pathway are those at high risk of non-use, and the intent is to allocate these kidneys as quickly as possible. The allocation process would still follow the standard allocation and normal priority classifications until certain triggers are met. These triggers include specific clinical criteria and pre-OR and post-OR characteristics. Once the expedited placement pathway is initiated, candidates who have not opted in would be bypassed, and programs that have not historically accepted these types of offers would also be bypassed. The framework involves simultaneous offers being sent to potential recipients remaining on the match run, with transplant programs having 90 minutes to submit up to three candidates for consideration from the existing match run. The kidney would then be placed with the highest-ranked candidate.

To operationalize this pathway efficiently from a data collection perspective, and where DAC's feedback is needed, the project proposes adding a new data field on the kidney candidate registration to capture whether a candidate has opted in to receive expedited offers.

The Kidney Committee Chair emphasized that this proposal aligns with the OPTN data collection principles for developing transplant donation and allocation policies and tracking compliance with the policy. The policy supports system implementation of the kidney expedited placement allocation policy and ensures that candidates who have opted in are the ones receiving the expedited offers.

The discussion following this presentation raised several concerns and suggestions:

- The need for a clear definition of what constitutes a hard-to-place kidney. The Kidney Committee Chair mentioned that the committee is working on defining specific clinical characteristics, such as KDPI cutoff, sequence number, cold ischemia time, donor age, and medical history (e.g., hypertension, diabetes). During the discussion, the DAC members emphasized the importance of a standardized definition and the potential impact on the allocation system.
- Concerns were raised by Committee members about the operational challenges of implementing this policy, including the variability in practices among OPOs and transplant centers. The importance of considering the following factors was discussed: the use of kidney pumps with the donor organs, how great the distance is between the donor and candidate

hospital and how that translates into travel time, and the ability to perform virtual crossmatches was discussed.

- The potential for gaming the system if the criteria are not well-defined was a significant concern. The Kidney Committee Chair acknowledged this and emphasized the need for a comprehensive analysis of the data to inform the policy.
- The discussion included the idea of bypassing programs that have not historically accepted these types of offers. This raised questions about how center-level behavior would tie into individual patient consent and the need for further discussion on this topic.
- The need for a more comprehensive analysis of the data to inform the policy. The Kidney Committee Chair said that the committee would continue to refine the project and seek further data and analysis.

The Chair asked about how the process being described by the Kidney Committee will interact with the high Kidney Donor Profile Index (KDPI) consent process? The Chair pointed out how important it is to standardize what is meant by 'at a high risk of discard' and also the circumstances under which the proposed expedited placement pathway can be utilized. The Chair also discussed the importance of identifying a compliance mechanism for following up on cases that appear to have occurred outside of the established standards. Better codifying expedited placement will be a step moving forward.

Several Committee members made comments and/or had questions about the project and the proposed data collection. For example, a member stated that how 'hard-to-place' is defined is critical to the project's success; however, the proposed standard criteria are not what would actually be helpful. According to a Committee member, the factors that matter are: Is the kidney on a pump and can the pump be transported?; Can a virtual cross-match be performed or does it need to be a prospective crossmatch?; and What is the distance between the donor and patient hospitals and how quickly can the organ get to the patient's hospital? Another major concern is that historically, OPTN committees have had similar discussions about criteria and a standard refrain has been that opposing points of view will be included in the public comment documents and future presentations, but then those points of view are not shared. The desire to move forward with the protocol or a policy seems more important than getting the policy right. As a result, the member expressed their concern that when the proposal is submitted for public comment there will be no discussion of a criterion for whether the device was on a pump, or discussion of a criterion for the distance between the donor and patient hospitals. A concern was also expressed that transplant programs will opt-in all of their candidates, and then when the transplant programs realize there is no information about a pump or travel distance, the same transplant programs will not accept such offers.

Another Committee member had several questions and concerns about the direction of the project. First, the member suggested that the proposed process would lead to behavioral changes at transplant programs to align with the number of hard-to-place to kidneys rather than actual hard-to-place kidneys. Second, proposing to consent patients to something that has not been defined is problematic. Another Committee member concurred that not having a clear definition is problematic. Third, trying to do this using simultaneous organ offers is going to crush an already overwhelmed allocation system. It will also result in a system biased towards the programs with resources to manage all the components. Fourth, the members also worried that the Kidney Committee has not reviewed the underlying data for out-of-sequence organ allocation. The member recommended that DAC should not endorse the project without being provided the data analysis results, along with recommended changes and how those

changes will be implemented. Also stated that the high KDPI consent framework may not be the most effective or efficient system to use as a model when creating this framework.

After the other members spoke, the Chair pointed out that the members had a lot of questions about the project, such as the need to see more data analysis results and consideration of factors that were not addressed in the presentation. A question was also asked about the proposed process bypassing transplant programs that have been historically unwilling to accept these kinds of donor kidney and what that means for candidates at such programs who have opted-in to accept such kidneys?

SRTR contractor staff discussed the modeling that SRTR could provide about donors and how it might help the Kidney Committee's deliberations regarding what the definition should be for a hard-to-place kidney. SRTR contractor staff added that it might be more productive to work on identifying the data fields that should be collected based on what are the highest predictive factors that predict non-use.

DAC members chose not to endorse the proposed data collection, citing the need for more information and data before endorsing the opt-in data field. Members cited the lack of clarity around what the Committee is actually endorsing. At least two members expressed concern that endorsement of the "opt-in" data element was an endorsement of the entire project which has much larger data-related implications that were not discussed as part of the presentation. A member questioned whether the characteristics identified for determining a hard-to-place kidney will actually be useful for achieving that purpose and suggested other factors for consideration. Another member stated that the Kidney Committee should provide more information about the data analyses that were performed in support of the project and how the results of such analyses supports the Committee's proposed path forward. In total, nine of the 14 Committee members participating in the meeting indicated they did not endorse the project. Two others abstained.

Next steps:

The Kidney Committee Chair said they will refine the project and seek further data analysis, and added that the project will be revisited in future meetings for further discussion and potential endorsement. DAC members expressed the need for more information and data before they would be comfortable endorsing the opt-in data field. They also emphasized the importance of a standardized definition and the potential impact on the allocation system.

4. 2025 DAC Priority Action Items

OPTN contractor staff let the Committee members know that the list of potential projects would be emailed to them. Contractor staff asked the members to identify their top four projects for the Committee to work and then rank the four projects in order of priority.

Next steps:

OPTN contractor staff will email Committee members a spreadsheet with the previously identified projects and information about the projects. Members were asked to indicate on the spreadsheet their four highest-priority projects and email the spreadsheet back to OPTN contractor staff by no later than 02/19/2025.

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 reminder for committee members to prioritize their project ideas and submit their feedback by the specified deadline. The next meeting is scheduled for 03/10/2025.

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
  - Michael Ison
  - Paul MacLennan
  - Michael Marvin
  - Nancy McMillan
  - Sumit Mohan
  - Jennifer Peattie
  - Julie Prigoff
  - Meghan Schaub
  - Lindsay Smith
  - Allen Wagner
- **HRSA Representatives**
  - None
- **SRTR Staff**
  - Ryutaro Hirose
  - Jon Miller
  - Katie Siegert
  - Jon Snyder
- **UNOS Staff**
  - Matt Cafarella
  - Jonathan Chiep
  - Cole Fox
  - Jesse Howell
  - Houlder Hudgins
  - Lindsay Larkin
  - Eric Messick
  - Joel Newman
  - Leah Nunez
  - Laura Oganowski
  - Nadine Rogers
  - Laura Schmitt
  - Kaitlin Swanner
  - Niyati Upadhyay
  - Sara Rose Wells
- **Other Attendees**
  - Neha Bansal
  - Jim Kim