

Meeting Summary

OPTN Kidney Transplantation Committee Meeting Expedited Placement Workgroup Meeting Summary June 12, 2025 Conference Call Chandrasekar Santhanakrishnan, MD, Chair

Introduction

The Expedited Placement Workgroup met via WebEx on June 12, 2025, to discuss the following agenda items:

- 1. Welcome and Recap
- 2. Discuss Potential Data Collection Changes
- 3. Pre-Recovery Initiation of Expedited Placement

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

1. Welcome and Recap.

No decisions were made.

OPTN Contractor staff welcomed the Workgroup. Since the Workgroup's last meeting, the OPTN Kidney Transplantation Committee voted to send the Workgroup's recommended policy language to public comment.

At their last meeting, the Workgroup discussed potential tools to support programs managing expedited kidney offer volume and the capability for candidates to opt-out of receiving expedited placement offers. The Workgroup's identified needs and recommended data solution was presented to the OPTN Data Advisory Committee for feedback.

The Workgroup will reviewed the recommended data collection, discuss the data standardization checklist, and determine whether to forward the data collection to the Kidney Committee for review and vote to include in the proposal. The Workgroup will also review potential changes to offer acceptance and laterality data entry.

Summary of discussion:

There were no questions or comments.

2. Discussion: Potential Data Collection Changes

The Workgroup reviewed potential data collection changes and worked through the data standardization checklist.

Presentation summary:

Previously, the Workgroup discussed the following:

- Some candidates will not want to receive expedited placement offers based on a combination of distance from the donor hospital and cold ischemic time
 - Goal is to streamline logistics/minimize cold ischemic time for candidates who need to travel farther

- May not differ depending on whether donor is a donation after brain death or circulatory death donor
- Some candidates may have less risk tolerance generally and/or have high priority for kidneys in standard allocation and will not be interested in receiving expedited offers

To address these needs, a proposed data solution will add three new fields to the Kidney Candidate Waitlist record. This data will provide programs with more tools for managing expedited kidney offer volume based on candidate preferences and logistical considerations. This data collection will appear under a new "expedited donor characteristics" section.

OPTN Contractor Staff reviewed the process flow for expedited placement, including initial candidates screening, standard offer filters, expedited placement filters, and screening candidates who have opted out of receiving expedited placement offers.

The following drafted data definitions align with the functional definitions utilized for kidney candidate acceptance criteria:

- <u>Receive expedited kidney offers?</u> Select **Yes** if the candidate is willing to receive expedited kidney offers. Select **No** if the candidate is not willing to consider expedited kidney offers.
- <u>Maximum acceptable distance from the donor hospital (in nautical miles)</u>: Enter the maximum distance from the donor hospital, in nautical miles, your candidate is willing to accept for an expedited kidney offer
- <u>Maximum acceptance cold ischemic time when distance from the donor hospital is greater than</u> <u>250 nautical miles</u>: Enter the donor maximum cold ischemic time at the initiation of expedited placement in hours the candidate can accept for expedited kidney offers for donors at donor hospitals greater than 250 nautical miles away from the transplant program. The cold ischemic time must fall between 0 and 100 hours.

The OPTN Data Advisory Committee's feedback was largely supportive of the recommended data elements and definitions. The OPTN Data Advisory Committee noted alignment with other expedited placement acceptance criteria.

Summary of discussion:

The Chair of the OPTN Kidney Committee noted that this appropriately captures the feedback from the OPTN Data Advisory Committee.

The Workgroup had no questions or comments.

Data standardization checklist:

The proposed data collection aligns with the following the following OPTN Data Collection Principles:

- Develop transplant, donation, and allocation policies
- Fulfill the requirements of the OPTN Final Rule

This data collection supports effective candidate offer management for the kidney expedited placement pathway. This further supports reducing non-use of recovered organs, aligning with:

- CFR 121.6(c) requiring programs to establish and report criteria for organ acceptance
- CFR 121.7(a)(3), which requires that the match run does not include candidates for whom the donor or organ does not meet reported acceptance criteria

The proposed data elements are functional data collection, for the purposes of opting candidates in or out of receiving expedited offers, and managing the types of expedited offers. As such, several questions on the checklist are not relevant.

- Purpose, Relevancy and Face Validity: What is the intent or purpose of collecting these elements? Does the data measure what it intends to measure?
 - These data elements are functional, allowing programs to manage opting candidates in and out of receiving offers, and manage the distance and cold ischemic time of these expedited placement offers
- Availability, Burden, and Interoperability: Is this element widely available for the population of patients for which it is sought to be collected? Are the data easily and readily discovered by a clinical or non-clinical coordinator in the electronic health record?
 - Transplant programs will need to evaluate their waitlists to determine which candidates are willing and appropriate to receive these offers, and which candidates may require distance and cold ischemic time parameters.
 - This may take some time, but the OPTN can provide utilities to help programs managing this task.
- Usability and Conformity: Is the form usable for members? Does the grouping of fields make sense to the users? Are the right fields on the right forms? Is the label, as written, clear to the user with minimal explanation?
 - In order to ensure the candidate-specific screening is applied, this data collection will need to apply to the Candidate Waitlist record.
- Reliability: Is the data element definition sufficiently clear and precise to enable consistent entry?
 - \circ $\;$ The Workgroup supported the drafted functional data definitions.
- Definition: What is the intent or purpose of collecting this specific data element? Is there an industry standard for this definition? What are the acceptable responses or response range for this data element? If a category response, can each response be mutually exclusive? Is this definition suitable for the variety of users providing the data?
 - The drafted data definitions align with similar acceptance criteria data collection
 - o Data elements are non-clinical, and suitable for a variety of users.

Summary of discussion:

The Workgroup expressed support for the drafted data collection and definitions. The Workgroup's recommended data changes will be brought to the OPTN Kidney Committee for a vote at their next meeting for inclusion in the expedited placement proposal.

3. Pre-Recovery Initiation of Expedited Placement

The Workgroup discussed potential system changes to support the logistical initiation of expedited placement prior to recovery of the organs.

Presentation summary:

The policy language voted on by the OPTN Kidney Committee allows OPOs to initiate expedited placement prior to cross clamp for those donors meeting clinical criteria. However, there is also a requirement for OPOs to first confirm acceptance or decline for all candidates in priority classifications before initiating expedited placement. Currently, the system requires OPOs to input the laterality when inputting an organ acceptance, which is not typically determined until the organs are recovered.

The recommended solution is to allow OPOs to input an acceptance pending laterality prior to cross clamp, with the system prompting OPOs to enter the laterality accepted prior to closing the match run. This essentially would add another response option for OPOs entering in an acceptance.

Summary of discussion:

Multiple Workgroup members expressed support for this solution.

OPTN Contractor staff shared that this has come up within the OPTN Multi-Organ Transplantation Committee meetings as well, particularly as the Multi-Organ Transplantation Committee's upcoming proposal relies on prompt reporting of acceptance. This functionality would also support that proposal.

One member asked if the "acceptance pending laterality" would be considered as an acceptance, such that the kidney would then be considered as accepted and thus not available for multi-organ allocation.

OPTN Contractor staff noted that kidney expedited placement would typically follow completion of the multi organ allocation tables, such that they wouldn't conflict, but that there could be potential for conflict if the OPO is initiating expedited placement earlier. A member agreed, but noted that pre-recovery acceptance could potential conflict with multi organ allocation.

One member noted that, in the case both kidneys were accepted pre-recovery pending laterality, and post-recovery information results in decline, those declines should not be considered late declines. The member continued that those declines should not be seen the same way declines for known information are considered late declines. Another member agreed.

One member asked if the expedited offer filters will be mandatory, and how programs will be able to demonstrate shifting acceptance behavior. OPTN Contractor staff clarified that the policy language approved by the OPTN Kidney Committee allows programs to modify or disable their expedited placement offer filters; this is something the Kidney Committee is requesting feedback on in public comment. The member responded that allowing programs to modify or disable their expedited placement filters will significantly reduce efficiency gains. The member continued that programs will disable their filters out of a fear of missing out on offers, even offers that they have not historically accepted and will not accept.

A member commented that one question to consider is potential monitoring to ensure programs are not late declining inappropriately. Another member agreed, noting that this should be part of the monitoring to ensure the system is efficient. The member continued that there may be certain scenarios where programs enter provisional acceptances and then decline late when receiving the offer, and that behavior would be flagged for consideration. The member continued that there may also be monitoring data available from the 6-months post-implementation of default offer filters, and that could be evaluated to determine whether expedited placement filters should be made mandatory. OPTN contractor staff noted that this data report can be shared as it is prepared and available.

Next steps:

The Workgroup's recommended data collection will be sent to the Kidney Committee for consideration and voting to include in the kidney expedited placement proposal.

Upcoming Meeting(s)

• June 9, 2025, 3:00 ET

Attendance

• Workgroup Members

- o Micah Davis
- o Leigh Ann Burgess
- o Tania Houle
- o Jillian Woftowicz
- o Jim Kim
- o Jason Rolls
- o Kristen Adams
- o Anja DiCesaro
- SRTR Staff
 - o Jon Miller
 - o Bryn Thompson
- UNOS Staff
 - Kaitlin Swanner
 - Keighly Bradbrook
 - o Houlder Hudgins
 - o Thomas Dolan
 - o Sarah Booker