

OPTN Kidney Transplantation Committee Meeting

Meeting Summary

March 18, 2025

Conference Call

Jim Kim, MD, Chair

Arpita Basu, MD, Vice Chair

Introduction

The Kidney Transplantation Committee met via WebEx on March 18, 2025, to discuss the following agenda items:

1. *Monitor Ongoing eGFR Modification Policy Requirements*
2. Update: Kidney Expedited Placement
3. Overview: Kidney Expedited Placement Proposal
4. Discussion: Initiating Kidney Expedited Placement
5. Discussion: Informing Kidney Candidates about Expedited Placement
6. Continuous Distribution Policy Optimization Update

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

1. Monitor Ongoing eGFR Modification Policy Requirements

Summary of discussion:

Decision #1: The Committee will submit a public comment on the MAC's proposal: *Monitor Ongoing eGFR Modification Policy Requirements* to reflect the Committee's discussion.

The Committee received a brief introduction to the Minority Affairs Committee (MAC) policy proposal: *Monitor Ongoing eGFR Modification Policy Requirements*.¹ The proposal is included in the Winter 2025 public comment period and proposes additional requirements for programs to notify candidates of their eligibility and of the outcome of any wait time modification applications submitted for the candidate. Committee members discussed the policy and requested clarification on certain requirements for transplant programs. Contractor staff explained that the patient notification requirements in the policy would be retroactive to January 4, 2024, while the other protocol and documentation requirements would apply after the date of policy enactment. Committee members expressed some concerns with the administrative burden of the proposal and noted many programs may have already documented compliance under the previous policy. Committee members also expressed interest in understanding the volume of patients who have not received proper notification under existing eGFR policy requirements.

Next steps:

The Committee will submit a public comment on the MAC's proposal to reflect the Committee's discussion.

¹ "Monitor ongoing eGFR Modification Policy requirements" <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/monitor-ongoing-egfr-modification-policy-requirements/>

2. Update: Kidney Expedited Placement Project

Summary of discussion:

No decisions were made.

The Chair provided an overview of the Expedited Placement project timeline and reviewed prior feedback received from the Data Advisory Committee (DAC), Policy Oversight Committee (POC), HRSA, and the Executive Committee.

- 10/8: Kidney Committee supported developing a national kidney expedited placement policy
- 2/10: Check-in with the Data Advisory Committee
- 2/11: Received feedback from HRSA
- 2/13: Review by the Policy Oversight Committee for recommendation on project approval
- 2/21: HRSA response to critical comment on allocation out of sequence (AOOS)²
- 3/6: Review by the Executive Committee for project approval

On March 6th, the Executive Committee expressed support for the Expedited Placement project and recommended it proceed as part of the OPTN's broader response to HRSA's AOOS directive.³ The Chair reviewed certain elements in HRSA's directive of particular relevance to Expedited Placement, including the directive's instructions pertaining to batched organ offers, offers, offer modalities and content, and compliance with the OPTN Final Rule.⁴ Committee members agreed that work on Expedited Placement and Continuous Distribution will be important in addressing concerns related to Allocation Out Of Sequence (AOOS). Members agreed consistent definitions around allocation will improve transparency and understanding within the system.

Next steps:

The Expedited Placement Workgroup (EPWG) will continue its work on the policy and seek additional feedback from stakeholder committees. The Kidney Committee is scheduled to vote on the Expedited Placement Policy during its May 2025 meeting, with the goal of including it in the summer 2025 public comment period.

3. Overview: Kidney Expedited Placement Proposal

Summary of discussion:

No decisions were made.

² Dr. Suma Nair, letter to Dr. Rich Formica and Rexanah Wyse Morrisette, February 21, 2025, <https://optn.transplant.hrsa.gov/media/km3fskz1/hrsa-directive-to-optn-on-aos-022125.pdf>.

³ Ibid.

⁴ 42 CFR Part 121

The Expedited Placement Workgroup Chair provided an overview of the Expedited Placement policy, outstanding policy topics, and recent data requests submitted by the Workgroup.⁵ The Chair solicited specific feedback from Committee Members on the following topics:

- 1) Initiation Kidney Expedited Placement
- 2) Informing Kidney candidates about Expedited Placement

4. Initiating Kidney Expedited Placement

Summary of discussion:

Decision #2: Committee members supported standardizing organ procurement organization use of the expedited placement policy.

Decision #3: Committee members agreed there should not be a difference in treatment for pumped vs. non pumped kidneys within the “hard to place” definition and Expedited Placement pathway.

The Chair opened the discussion by emphasizing the need for clear guidance for Organ Procurement Organizations (OPOs) on the initiation of Expedited Placement (EP) to standardize the process and address concerns related to Allocation Out of Sequence (AOOS). Members discussed the practicality of OPOs offering through priority sequences before initiating EP for kidneys meeting the "hard-to-place" definition, with concerns raised about potential delays if the full sequence is followed before EP initiation. Members also discussed the impact on candidates within priority classifications who may potentially not receive certain offers if the organ is allocated through EP. Members posed questions around the number of transplant programs that would receive simultaneous offers under the policy, and the Workgroup Chair noted that discussions on simultaneous offers and sequencing timelines are ongoing.

The Committee considered whether OPOs should be required to use the EP pathway in all cases. While some members supported allowing discretion in exceptional circumstances, such as weather emergencies or transportation challenges, there was general agreement on the need for clear guidelines to ensure standard practices among OPOs. One member supported making EP mandatory for OPOs to achieve this standardization, and noted existing policies already cover exceptional circumstances. Members also discussed the expectation for transplant programs to follow certain protocols to appropriately match candidates. Members discussed the merits of mandatory program level EP offer filters to ensure efficient transplant program acceptance practices, and how offer filters may interact with the large volumes of Provisional Yeses (PY's) often remaining on the match run. The Workgroup will continue refining these policy details in upcoming discussions.

The Chair invited Committee members to provide input on whether additional organ attributes, such as physical abnormalities in low Kidney Donor Profile Index (KDPI) kidneys, or whether or not a kidney is pumped, should be considered when initiating the EP pathway. The Committee discussed whether pumped kidneys should be treated differently under the Expedited Placement (EP) pathway, if pumping data should be required before EP is initiated, or if pumping status should be incorporated into the hard-to-place (HTP) definition. The Committee reviewed previously presented data on the percentage of kidneys pumped over time and the impact of pumping on non-use.

⁵ For overview of policy and recent Workgroup discussions, see OPTN Expedited Placement Workgroup Meeting Summary, March 10, 2024.

Data summary

- The data showed that the percentage of kidneys being pumped has steadily increased, reaching 53% in 2023.
- While the non-use rate for pumped kidneys was initially higher than for non-pumped kidneys from deceased donors, a logistic regression analysis indicated that when accounting for all donor characteristics, pumped kidneys were actually associated with a decreased rate of non-use, with an odds ratio of 0.6.
- Key variables linked to an increased likelihood of non-use were also incorporated into the Hard-to-Place (HTP) model.

Members raised questions about whether the data distinguished between kidneys pumped by OPOs versus those pumped by transplant programs, noting that some kidneys may not require pumping under EP if they are allocated more quickly. Contractor staff confirmed that the analysis presented was based on data entered on the Deceased Donor Registration, which are reported by OPOs.

There was also discussion on whether the Cold Ischemic Time (CIT) threshold should be increased for pumped kidneys in EP, allowing transplant programs to review pump data and account for prolonged preservation time before initiating EP. Some members felt that pumping should not automatically justify additional CIT, while others noted that pump manufacturers recommend waiting some number of hours before assessing pump values.

Members discussed whether all HTP kidneys should be required to be pumped, but concerns were raised that mandating pumping could restrict travel options and conflict with center-specific practices. Opinions also varied on whether kidneys placed on pumps inherently met HTP criteria. Members noted that if EP leads to quicker allocation, some kidneys may not require pumping; while in other instances potential transplant recipients high on the match run may be more likely to accept a kidney if favorable pumped data is provided, avoiding the need to initiate EP.

The Committee concluded the discussion in agreement that due to these complexities and variations, there should not be a difference in treatment of pumped vs. non pumped kidneys within kidneys the “hard to place” definition and Expedited Placement pathway. Still, the Committee emphasized the importance of transplant programs having access to pump data when making allocation decisions. The EP Workgroup will revisit OPO expectations regarding available post-operative details at its next meeting.

5. Informing Kidney Candidates about Expedited Placement

Summary of discussion:

Decision #4: The Committee agreed to pursue revisions to the high KDPI informed consent policy within the EP policy framework, seeking additional PAC and patient representative input in April.

The Committee reviewed previous discussions regarding a patient opt-in approach for Expedited Placement (EP) and discussed the Workgroup’s reasoning for moving away from this approach: namely, wide variation in the types of kidneys that might be offered via expedited placement, and the

administrative burden of an opt-in on transplant programs. Members also noted the overlap between kidneys that would enter the EP pathway and high KDPI (>85%) kidneys, which currently require informed consent under OPTN *Policy 5.3.C Informed Consent for Kidneys Based on KDPI Greater than 85%*.⁶ The Committee reviewed background on the development of the informed consent policy and research findings on the impact of the policy.

Members discussed their concerns with the stigma associated with the current high KDPI informed consent process and emphasized the importance of patient education and shared decision-making. Members discussed whether the current informed consent policy should be revised as part of the EP proposal or whether it would be more appropriate to gather public feedback for a potential follow-up policy.

Some members strongly favored eliminating the high KDPI informed consent requirement, arguing that the KDPI calculation has limitations, and the consent policy discourages organ acceptance, and ultimately does not benefit patients. Many members agreed that the requirement may lead to unnecessary kidney non-use. The Workgroup Chair acknowledged that maintaining a separate consent process for EP could create confusion and that revising both consent requirements together could be beneficial. The Committee discussed broader challenges in explaining high KDPI and EP concepts to patients, emphasizing the need for improved pre-transplant education. Some members suggested incorporating EP language into existing consent forms rather than creating a separate consent process. The Committee agreed to seek further feedback from the Patient Affairs Committee and patient representatives on this topic in upcoming meetings. The Workgroup will continue discussions on how to refine patient education and informed consent policies to support both EP and high KDPI kidney allocation.

6. Continuous Distribution Policy Optimization

The Committee received an update on the Continuous Distribution Policy Optimization project work.

Summary of discussion:

Staff summarized previous efforts, including the Board's 2023 directive to evaluate non-use, the Committee's data request to SRTR to update their simulation models to assess policy impact on non-use, and MIT's subsequent completion of 50,000 policy scenarios to optimize allocation.

Contractor staff reviewed key elements of the Kidney Composite Allocation Score, highlighting how rating scales, weighting, and donor modifiers influence candidate rankings. The Committee revisited its work on DR matching, Estimated Post-Transplant Survival (EPTS), KDPI, qualifying time, and proximity efficiency, considering how adjustments might reduce non-use. MIT's initial optimization work indicated that the previously optimized continuous distribution policy scenarios may increase non-use, particularly for lower KDPI kidneys.

Members discussed whether the model's handling of EPTS/KDPI attributes should be refined, as excessive time is spent allocating older or more complex donors. Members also discussed DR matching, noting past data suggesting it may be more predictive of transplant success than O-ABDR mismatches,

⁶ OPTN policy 5.3.C: *Informed Consent for Kidneys Based on KDPI Greater than 85%*

which is why the Committee had previously opted to proceed with DR matching in continuous distribution instead of ABDR matching.

Next steps:

Moving forward, MIT will further analyze policy variations to identify configurations that balance equity, efficiency, and non-use reduction, with additional refinements to be considered in future meetings.

Upcoming Meeting(s)

- April 21, 2025, 1200 ET
- May 19, 2025, 1200 ET

Attendance

- **Committee Members**
 - Jim Kim
 - Arpita Basu
 - Jason Rolls
 - C.S. Krishnan
 - Tania Houle
 - Prince Anand
 - Marc Melcher
 - Eloise Salmon
 - Aparna Sharma
 - Reza Saidi
 - Christine Hwang
 - John Lunz
 - Leigh Ann Burgess
 - Kristen Adams
- **HRSA Representatives**
 - Sarah Laskey
- **SRTR Staff**
 - Grace Lyden
 - Jon Miller
 - Jodi Smith
 - Bryn Thompson
 - Peter Stock
 - Sommer Gentry
- **UNOS Staff**
 - Kaitlin Swanner
 - Kelley Poff
 - Carly Rhyne
 - Lindsay Larkin
 - Thomas Dolan
 - Ben Wolford
 - Sarah Booker
 - Ross Walton
 - Cole Fox
 - Asma Ali
 - Houlder Hudgins
 - Carly Layman
 - Keighly Bradbrook