OPTN Kidney Transplantation Committee Meeting
Meeting Summary
May 19, 2025
Conference Call

Jim Kim, MD, Chair
Arpita Basu, MD, Vice Chair

Introduction

The Kidney Transplantation Committee met via WebEx on May 19, 2025 to discuss the following agenda items:

1. Expedited Placement of Kidneys: Review Proposal and Policy Language
2. VOTE: Expedited Placement of Kidneys
3. Open Forum

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

1. Expedited Placement of Kidneys: Review Proposal and Policy Language

The Committee reviewed and discussed the Expedited Placement of Kidneys project, developed by the Expedited Placement Workgroup (the Workgroup).

The purpose of this project is to establish a standardized, national expedited allocation policy for kidneys at risk of non-use. This policy aims to improve the efficient allocation of hard to place kidneys and increase the likelihood of offer acceptance and transplant, thereby reducing kidney nonuse and increasing transparency and equity within the system.

The key components of this policy include:

- Offering to priority classifications ahead of initiating expedited placement
- "Hard to place" criteria for expedited placement initiation
- Initiation of expedited placement and additional filtering
- Simultaneous evaluation period
- OPO and transplant program requirements
- Candidate education requirements

Priority Classifications

Requiring Organ Procurement Organizations (OPOs) to offer to candidates in priority classifications before initiating expedited placement provides guardrails, to ensure candidates with priority receive those offers ahead of an expedited process. These priority classifications include 100 percent calculated panel reactive antibody (CPRA) candidates, prior living donors within 250 nautical miles (NM), pediatric candidates within 250 NM, medically urgent candidates within 250 NM, 0-ABDR mismatch candidates, top 20 percent estimated post-transplant survival (EPTS) candidates, 98-99 percent highly sensitized candidates, and safety net kidney candidates within 250 NM. The OPO would need to confirm acceptance or refusal for each candidate within these classifications before expedited placement can be initiated.

Initiation Criteria

Once acceptance or decline has been confirmed in priority classifications, the OPO may initiate expedited placement when:

- Donor meets at least 2 of the clinical characteristics of "hard to place:"
    - Donor history of hypertension greater than 5 years
    - Donor history of diabetes greater than 5 years
    - Donor age greater than or equal to 60 years
    - Donation after circulatory death (DCD)
    - Biopsy with glomerulosclerosis greater than 10 percent on both kidneys
- **OR**, 6 hours of cold ischemic time have accrued

This "hard to place" criteria was derived from the definition of "hard to place" developed by the Kidney Committee in 2024. The Kidney Expedited Placement Workgroup (the Workgroup) recommended excluding "donor use of continuous renal replacement therapy (CRRT)," as this data is not currently collected and thus its impact cannot be analyzed. This data element is pending Office of Management and Budget (OMB) approval for implementation and could be added later, once data is collected.

Expedited Placement Filtering

When the OPO initiates expedited placement, the OPTN computer system will apply new expedited offer filters based on the "hard to place" donor cohort. Other offer filters will continue to be applied (standard model-identified filters and program-designated filters). If filter criteria are met, these filters will apply to potential transplant recipients (PTRs) with previous Provisional Yes responses. The Workgroup discussed managing offers on a candidate level as well, supporting tooling that allows programs to opt out specific candidates who may not be willing or appropriate to receive expedited offers. Programs would also be able to filter offers for individual candidates based on distance from the donor hospital and cold ischemic time.

The offer filters model will identify expedited placement filters based on a transplant program's acceptance behavior within the last 365 days for donors that meet at least two of the following criteria:

- History of hypertension greater than 5 years
- History of diabetes greater than 5 years
- Age greater than or equal to 60 years
- DCD donor
- Biopsy with glomerulosclerosis greater than or equal to 10 percent for both kidneys

The model identified expedited placement offer filters will be generated and enabled for each transplant program every 6 months, using the following parameters to generate a filter:

- The program declined all kidney offers on at least 20 donors that met the filter criteria
- The program transplanted 0 donors that met the filter criteria, and
- The kidneys that meet the filter criteria were transplanted elsewhere

Expedited placement offer filters will have the same candidate exclusions as standard offer filters. This means that candidates with the following criteria at time of match run *will not* be bypassed by expedited placement offer filters:

- Greater than 90 percent CPRA
- 0-ABDR mismatch
- In medically urgent status, or
- Less than 18 years old

Model identified expedited placement offer filters will be applied to all adult kidney transplant programs. Pediatric alone programs will be able to manually apply model identified expedited placement offer filters. All programs may remove their model identified filters or modify automatic candidate exclusion criteria of their model identified filters.

OPTN contractor staff walked through a flow chart, with clear steps:

1. A kidney match run is generated – candidates are screened from the match run based on blood type, unacceptable antigens, and donor acceptance criteria
2. The OPO sends out standard offers, and standard offer filters are applied
3. The OPO confirms decline from candidates in priority classifications for remaining kidney(s)
4. Once criteria is met, the OPO initiates expedited placement – standard offer filters *and* expedited placement offer filters are applied. Candidates are additionally bypassed if their program has opted them out of receiving expedited placement offers.

Simultaneous Evaluation of Expedited Placement Offers

Once expedited placement filters have been applied, the OPOs will send out offers to the remaining potential transplant recipients on the match. At that time, programs will have one hour to review the offer simultaneously and respond if they have PTRs willing to accept the kidney. Otherwise, programs may decline to respond; a decline to respond will be treated as a decline. Transplant programs interested in accepting must be willing to accept the offer based on virtual crossmatch. At the end of the hour, the OPO will place the kidney(s) with the highest ranked PTR(s) remaining on the match.

Reporting Donor Information

For donors who meet expedited placement criteria by cold ischemic time alone, the OPO must ensure the following information is reported prior to sending expedited kidney offers:

- Anatomical description, including number of blood vessels, ureters, and approximate length of each
- Kidney perfusion information, if performed
- Images of the kidney(s), including front and back of the kidney(s) and view of the aortic patch
- Biopsy results, if performed per *Policy 2.11.A Required Information for Deceased Donors*
- Human Leukocyte Antigen (HLA) source documentation to support virtual crossmatch

For donors who meet the clinical criteria, this information must be reported prior to organ offer acceptance.

The Workgroup discussed whether this information should be required prior to any expedited kidney offers, but noted that it is important to allow OPOs to initiate expedited placement prior to reporting all of this information for kidney(s) meeting the clinical criteria.

Candidate Preferences

The Workgroup recommends replacing the policy requiring informed consent for kidneys with Kidney Donor Profile Index (KDPI) greater than 85 percent with more general candidate education policy. This policy would require kidney transplant programs to provide information to each kidney candidate about the types of offers they may receive, including:

- Potential outcomes associated with accepting kidneys of varying KDPI, compared to potential outcomes associated with extended time on dialysis or extended time waiting for transplant

- Organ offer acceptance criteria used by the transplant program to define acceptable organ offers for the candidate and the candidate's shared role in defining appropriate acceptance criteria
- Priority classifications outlined in Policy 8.6: Expedited Placement of Kidneys, the candidate's likelihood of being prioritized within the priority classifications, and the candidate's likelihood of receiving offers via expedited placement

Programs will need to document these conversations in the candidate medical record.

The Kidney Committee has previously supported replacing the existing informed consent process for kidneys with KDPI 85-100 percent to a more general education policy. This policy language would do this.

Summary of discussion:

One member asked when the "donor use of CRRT" element was to be added to the OPTN computer system, noting that this is a key factor in organ decline and would be a potentially useful criterion for expedited placement. OPTN contractor staff noted that this is currently slated for September 2025, but that the data element has not yet been approved by the OMB, and there is coordination to be done with vendors ahead of implementation.

A member expressed support for virtual crossmatching but noted that certain centers are resistant to utilizing it. The member explained that this may be a point of contention for some programs. The member explained that a flow (physical) crossmatch can take four hours to complete, and so programs relying only on flow crossmatch, as opposed to virtual crossmatch, will not be able to accept expedited placement offers. Another member responded that this pathway is intended to expedited placement and reduce allocation time, and that accommodating programs relying only flow crossmatch could potential result in non-use. The member agreed, but added that there may be histocompatibility members who raise issue with the virtual crossmatch requirement. Another member remarked that most programs have taken up virtual crossmatch to some degree. A member estimated about 30 or 40 percent of programs have not yet taken up virtual crossmatching as a practice, noting that this was still a significant population.

The member explained that there are occasionally scenarios where a potential candidate for an expedited placement organ has an antibody that the lab feels requires a prospective crossmatch. The member remarked that the hope would be that the center would give thought to the time spent crossmatching and how this could contribute to increasing cold ischemic time. The member expressed support for virtual crossmatch and this requirement, but felt it was important to highlight that there may be resistance to this requirement in public comment. The member added that it may be important for programs not utilizing physical crossmatch to decline quickly, or else opt out of receiving expedited offers. The member recommended including education on virtual crossmatching be included in implementation of this proposal.

One member expressed surprise that a proportion of programs have not yet adopted virtual crossmatching practices. Another member shared that the OPTN Histocompatibility Committee presented a webinar on using virtual crossmatching and the data that supports it, but that some programs still have not opted to utilize it.

The Chair shared that this project was presented to the OPTN Histocompatibility Committee recently and received support. The Chair added that educational materials would be helpful, particularly for those centers who are not willing to utilize virtual crossmatch. The Chair noted that most centers have at least some candidates they would be willing to accept an organ for on virtual crossmatch. The Chair

continued that programs would be expected to evaluate their candidates and determine which candidates would be appropriate to receive these offers, and consideration for virtual crossmatching may be part of that. The Chair added that programs and histocompatibility members will have the opportunity to respond to this requirement in public comment.

One member offered that the Kidney Committee could recommend that nephropathologists read the biopsy results, as a best practice. The member remarked that this does not need to be a requirement, but that this recommendation would support more accurate readings of biopsy results. The member spoke to the literature on biopsy, noting that pathologists with less experience in kidney biopsy and kidney transplant biopsy readings may be less reliable. The member added that many programs will then read the biopsy slides themselves or else perform a new biopsy altogether. The member also noted that it could be helpful to recommend that OPOs share slide images to the OPTN Donor Data and Matching System, whenever possible, to support closer evaluation and more accurate assessments of biopsy results. The member noted that this would support increased use of kidneys, as programs may be more comfortable accepting the organ when assessing biopsy results.

2. VOTE: Expedited Placement of Kidneys

Decision #1: The Committee agreed to maintain the policy language allowing programs to modify or remove their expedited placement filters, but ensure the proposal highlights the need for public comment feedback and the Committee's further deliberation on whether the filters should be made mandatory.

Decision #2: The Committee agreed no transition plan was necessary for the *Expedited Placement of Kidneys* proposal.

Decision #3: The Committee approved submitting the *Expedited Placement of Kidneys* proposal to public comment by a vote of 11-0.

The Committee reviewed the proposed policy language changes, and voted to approve sending the expedited placement of kidneys proposal to public comment.

Summary of discussion:

Program Modification and Removal of Expedited Placement Offer Filters

OPTN contractor staff highlighted one area of the policy language, specifically allowing programs to remove or modify their model-identified expedited placement offer filters and/or automatic candidate exclusion criteria for the model-identified expedited placement filters. This policy language matches the language in current offer filters policy, which allows programs to remove or modify their standard model identified filters. Previously, the Workgroup felt strongly that expedited placement offer filters should be mandatory, such that programs *could not* turn off the filters. OPTN contractor staff noted that the public comment proposal will specifically request feedback in this area. OPTN contractor staff asked the Committee if they supported allowing programs to turn off model identified expedited placement filters, allowing those programs to receive and potentially accept those offers. The programs could then also modify automatic candidate exclusions. It was noted that this means allowing more candidates to receive these offers.

The Chair noted that it is important for the expedited placement pathway to significantly reduce allocation and offer evaluation time in order to improve efficiency. The Chair considered one side, noting that ensuring those programs who have not historically accepted these offers receive these offers could improve efficiency; on the other hand, this makes it much more difficult for programs to

demonstrate shifting acceptance behaviors. The Chair considered a phased approach, where programs were notified 6 months ahead of the implementation that the next 6 months of acceptance behavior would impact the filters generated by the Offer Filters model. The Chair agreed that it is important to get public comment feedback on this topic, but asked the Committee how they would prefer to present the proposal.

One member asked if the Committee could leave it open, noting in the policy language that there would be further deliberation by which the Committee decides whether to make this mandatory. The member supported ensuring programs are able to demonstrate shifting acceptance behavior, noting that changes in staffing, particularly amongst surgeons, can rapidly change the kinds of offers a program would consider. The member also supported mandatory expedited placement filters, noting that this is critical to ensure the effectiveness of the pathway. The member remarked that there needs to be a middle path that accommodates both the efficiency and the ability for programs to change acceptance patterns. The Chair agreed, noting that a lot of elements can change program behavior.

A member recommended that programs could modify or remove the expedited placement filters, but only within a certain timeframe. If this causes inefficiency, then the Committee could restructure the pathway to become mandatory. The member supported guardrails in allowing programs to remove their expedited placement filtering. Other members agreed.

The Committee agreed to maintain the policy language allowing programs to modify or remove their expedited placement filters, but ensure the proposal highlights the need for public comment feedback and the Committee's further deliberation on whether the filters should be made mandatory.

One Hour Evaluation

OPTN contractor staff highlighted a section of policy language noting that "transplant hospitals must use virtual crossmatch for final crossmatch."

The Chair asked if the policy language needs to specify that the one hour to evaluate and respond with interest is inclusive of time for virtual crossmatching. The Chair noted that it could also be that programs evaluate and respond within an hour and then run a virtual crossmatch. OPTN contractor staff responded that the current language does not require the virtual crossmatch to occur within the hour evaluation period, but only a response from the transplant program. The organ offer acceptance would remain pending final crossmatch, which would need to be virtual per policy. OPTN contractor staff noted that the language could be modified to more specifically define crossmatch timeframes.

One member spoke to variation across histocompatibility labs, noting that some labs may require more time to run virtual crossmatching. The member remarked that this policy already significantly will save time, it may be okay to leave it open. The Chair agreed, emphasizing there are different practices by program and by lab.

A member commented that most histocompatibility labs should be able to achieve a virtual crossmatch within the one hour timeframe, especially if the program is only interested in accepting for one or two candidates. The member noted that multiple candidates with more complex antibody profiles could take additional time, but one or two candidates should be easily achievable within the hour.

One member noted that it is reasonable to assume that all programs will, or at least should, run virtual crossmatches on at least two patients, in the case there is a last minute candidate issue preventing transplant. The member remarked that local back up is important, especially in reallocating a medically challenging donor kidney. The member agreed that running virtual crossmatches should be feasible within the hour for two candidates. Another member agreed, expressing support for including the virtual crossmatch within the hour time limit, adding that this will ensure defined timelines and clarity

for all aspects of the acceptance process. A member remarked that standard practices should be for programs to notify their histocompatibility labs of the need for virtual crossmatch upon receipt of the offer.

The Committee considered modifications to the policy language to ensure programs are evaluating virtual crossmatch results within the hour one evaluation period.

One member commented that currently, OPTN policy only requires that the crossmatch is done prior to the transplant operation, and that programs can finalize crossmatch reporting while the kidney is in transportation or just in time prior to initiation of transplant. Another member noted that by then, it's been verbally communicated even if not formally reported, in order for the program to finalize acceptance.

A member offered that the language could require the crossmatching assessment be performed within the hour provided. The Chair remarked that the policy language may be appropriate as is, as this is inclusive of current policy and practices. Another member agreed, noting that this language is simpler.

One member asked if there is concern that programs would accept these offers without seeing finalized virtual crossmatch results and then need to late decline due to positive crossmatch. The Committee confirmed. A member offered a requirement that programs have an acceptable virtual crossmatch result within the hour, noting that this puts the onus on the transplant center to accept the organ based on the available results.

The Committee agreed not to modify the proposed policy language, and to ask for public comment feedback on whether the policy language needs additional clarification.

Transition Plan

Per the OPTN Final Rule, for any change to allocation policy, the OPTN shall

OPTN contractor staff remarked that the transition plan is an opportunity to consider whether there are any candidates who may be disproportionately impacted who may need a transition plan, as well as implementation considerations.

Data summary:

32.69 percent of transplanted kidneys in 2024 would have met the proposed expedited placement initiation criteria. The proportion of transplants meeting criteria for expedited placement increased as KDPI increased:

- KDPI 0-20 percent kidneys: 6.37 percent met expedited placement criteria
- KDPI 21-34 percent kidneys: 11.87 percent met expedited placement criteria
- KDPI 35-50 percent kidneys: 21.72 percent met expedited placement criteria
- KDPI 51-85 percent kidneys: 47.92 percent met expedited placement criteria

The vase majority of transplants that qualified for expedited placement went to adults, irrespective of whether those transplants were allocated in sequence or out of sequence. This indicates that expedited placement is likely to impact primarily adult candidates; particularly as most pediatric candidates will be captured in the priority classifications.

On average, expedited placement filters are expected to bypass an additional 5 transplant programs beyond standard offer filters. Standard offer filters will bypass 3.1, and both filter types are expected to bypass 9 programs. This analysis only considers a program as bypassed if *all* candidates on the match run for the program were bypass by the filters; thus this analysis provides a conservative estimate of how many programs will have bypasses input.

The expedited placement filters did not disproportionately filter candidates based on age, sensitization, race/ethnicity, or sex.

Summary of discussion:

The Workgroup agreed that the proposal should seek public comment feedback on whether candidate registrations default to opt in all candidates to receive expedited placement offers, such that programs have to manually opt candidates out. This could involve a phased implementation, such that programs can update candidate records prior to policy implementation. The OPTN could also provide reports or other tools to assist programs in updating their candidate records.

The Committee agreed that public comment feedback is needed to determine whether programs will need to opt candidates in or opt candidates out.

One member remarked that a transition plan is not necessary based on the data, as there is no evidence of inequity in the data surround this policy. The member emphasized the importance of implementing this policy quickly. Other members agreed.

A member asked if there was any pattern for programs not using virtual crossmatch, noting there may be regions of the country disproportionately not using virtual crossmatch that may be impacted. Another member remarked that program variation in use or non-use of virtual crossmatch is random. The member noted that there is data on use of virtual crossmatch overtime, and this could be analyzed.

The Committee agreed that a transition plan was not necessary.

The Committee voted unanimously to approve sending the Kidney Expedited Placement proposal to public comment.

Next steps:

The Kidney Expedited Placement proposal will go to the OPTN Policy Oversight Committee for review. The Policy Oversight Committee will make their recommendations to the OPTN Executive Committee, who will vote to send these items out for public comment this one.

The Workgroup will meet once more to finalize discussions on data collection to support additional tools to manage expedited placement offers at the candidate level. The Workgroup will seek feedback from the OPTN Data Advisory Committee, consider this feedback, and send their recommendations on to the Kidney Committee for review.

OPTN contractor staff will send out policy evaluation plans ahead of public comment for Committee review.

Upcoming Meeting(s)

- June 16, 2025, 1200 ET

Attendance

- **Committee Members**
  - Jim Kim
  - Arpita Basu
  - Christine Hwang
  - Curtis Warfield
  - Eloise Salmon
  - Jason Rolls
  - John Lunz
  - Leigh Ann Burgess
  - Patrick Gee
  - Prince Mohan Anand
  - Toni L. Bowling
- **SRTR Staff**
  - Bryn Thompson
  - Grace Lyden
  - Jodi Smith
  - Jon Miller
  - Peter Stock
- **UNOS Staff**
  - Kaitlin Swanner
  - Carly Rhyne
  - Keighly Bradbrook
  - Ross Walton
  - Thomas Dolan
  - Sarah Booker
  - Carlos Martinez
  - Asma Ali
  - Houlder Hudgins
  - Kayla Temple
- **Other Attendees**
  - Lara Danziger-Isakov