

## OPTN Kidney Transplantation Committee Meeting Meeting Summary June 16, 2025 Conference Call

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

#### Introduction

The Kidney Transplantation Committee met via WebEx on June 16, 2025 to discuss the following agenda items:

- 1. VOTE: Kidney Expedited Placement Data Collection
- 2. Review: Kidney Continuous Distribution
- 3. Health Resources and Services Administration (HRSA): Modernization Efforts

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

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

The Committee reviewed the Kidney Expedited Placement Workgroup's (the Workgroup) recommended data changes, in support of the Kidney Expedited Placement proposal. The Committee voted to approve including the recommended data collection in the proposal for public comment.

#### Presentation summary:

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

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

The Workgroup identified the following additional needs:

- Some candidates may not be appropriate to receive expedited offers based on a combination of distance and cold ischemic time
- Some candidates may not be appropriate or willing to receive expedited placement offers overall

The recommended data solution for review 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 will also allow programs to opt

candidates in or out of receiving expedited placement offers overall. These data fields will appear in the candidate waitlist record under a new section for "expedited donor characteristics."

Question	Response Option
Receive expedited kidney offers?	Yes/No
If yes:	
Maximum acceptable distance from the donor hospital (in nautical miles)	[] nautical miles
If maximum distance is greater than 250 nautical miles:	
Maximum acceptable cold ischemic time when distance from donor hospital is greater than 250 nautical miles	[] hours

This data collection also aligns with the Committee's proposed education requirement, which requires programs to inform the candidate of 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. This data element will support shared decision making related to receipt of expedited placement offers, as well as offer management.

The Workgroup recommended the following data definitions:

- Receive expedited kidney offers?:
  - 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.
- Maximum acceptable distance from the donor hospital (in nautical miles):
  - Enter the maximum distance from the donor hospital, in nautical miles, your candidate is willing to accept for an expedited kidney offer.
- Maximum acceptable cold ischemic time when distance from the donor hospital is greater than 250 nautical miles:
  - 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.

## Discussion summary:

One member asked why the distance and cold ischemic time functions wouldn't be subsumed by the expedited offer filters. OPTN contractor staff clarified that these data elements will allow programs to establish candidate-specific filtering, while the expedited placement filters will be generated and applied at a program level. OPTN contractor staff provided additional context, noting that the Workgroup was considering candidates who live a great distance from their transplant program and thus may be more limited in the types of offers they could safely accept.

A member remarked that the expedited placement offer filters should be mandatory, such that programs could not disable them. The member continued that allowing programs to disable the filters will reduce the efficiency of the expedited placement process and minimize benefits to non-use. The member expressed that there should be a pathway for programs to demonstrate shifting acceptance behavior, but that expedited filters should still be mandatory. Another member agreed, noting this is particularly true if the process is intended to reduce the number of offers prior to placement. The Chair noted that this will go out for public comment, and that there maybe a transition period necessary if the filters are made mandatory.

The Committee motioned and moved to a vote, and approved the inclusion of the recommended data collection as part of the Expedited Kidney Placement proposal for Summer 2025 public comment.

## Vote: 13 yes votes, 0 no votes, 0 abstain.

### 2. Review: Kidney Continuous Distribution

The Committee briefly reviewed the Continuous Distribution project, including the timeline of the project's development, previous modeling efforts, and ongoing modeling discussions.

### Presentation summary:

The OPTN Kidney and Pancreas Transplantation Committees have been working to develop Continuous Distribution allocation frameworks. Continuous Distribution aims to shift allocation from a rigid, classification-based framework, to a points-based framework that can more holistically prioritize candidates. Initially, the purpose of Continuous Distribution was to improve equity and flexibility of kidney allocation, removing "hard boundaries" delineated by classifications. The continuous distribution model is composed of weights, rating scales, and donor modifiers, which can be more simply modified without reorganizing classifications.

A patient's composite allocation score is composed of 5 major parts: medical urgency, post-transplant survival, candidate biology, patient access, and placement efficiency. These parts of the score align with the requirements of the OPTN Final Rule. These categories are further broken down into ten attributes, identified by the Kidney Committee:

- Medical Urgency
  - Kidney medical urgency
  - Post-transplant survival
    - DR locus matching
    - Estimated post-transplant survival score (EPTS) and kidney donor profile index (KDPI) matching
- Candidate biology:
  - Blood type
    - Calculated panel reactive antibody (CPRA)
  - Patient access:
    - Prior living donor priority
    - Pediatric priority
    - o Safety net kidney
    - o Waiting time
    - Placement efficiency:
      - o Proximity efficiency

Each attribute is given a rating scale, which determines how candidates are ranked against each other for a given attribute, and a weight, which determines how impactful the attribute is to the candidate's total score. The weight is multiplied by the rating scale score to determine the number of points a candidate receives for a given attribute. Donor modifiers are used to modify the impact of specific attributes based on the donor's characteristics. The total score is the sum of points for each attribute after donor modifiers are applied.

In September 2023, the OPTN Board of Directors approved a resolution asking the Kidney Committee to orient Continuous Distribution efforts towards reducing non-use, reducing allocation out of sequence, and including expedited placement pathways. Since then, the Committee has:

- Evaluated potential drivers of non-use
- Developed an evidence-based definition of "hard to place"
- Developed an expedited placement pathway
- Worked with the Scientific Registry of Transplant Recipients (SRTR) and Massachusetts Institute of Technology (MIT) to improve non-use, allocation out of sequence, and efficiency modeling capabilities

In March of 2024, the Committee submitted a request to the SRTR to assess the feasibility of modeling the impact of allocation policies on kidney utilization. In November 2024, SRTR report identified a collection of submodels that can be used to simulate non-use without any clear deficiencies in other simulated kidney metrics. The SRTR is able to simulate percent of organs not used overall and by KDPI and distance traveled; SRTR modeling does not include AOOS nor cold ischemic time at acceptance.

In March 2025, MIT updated their dashboard with the updated OASIM models. MIT is currently working to model previously optimized policies as well as optimize new policies, incorporating the Committee's non-use goals. MIT's modeling efforts have shown several potential CD policies that meet non-use goals.

The Committee created an initial set of optimized policies (A1-D1) in January of 2023; and then developed a revised set of optimized policies (A2-D2) in October 2023. In order to develop these policies, the Committee defined specific goals for each attribute (such as maintaining high priority for prior living donor candidates, similar to current policy), which were then translated into modeling objectives and constraints.

As MIT works to incorporate non-use modeling capabilities, the MIT team has been able to show that, among 50,000 simulated continuous distribution polices, there are many that may be able to achieve the Committee's goal of reducing non-use, compared to current simulated policy's non-use. The MIT team is continuing to investigate modeling capabilities related to non-use, transportation logistics, and potentially, allocation out of sequence. The Committee will continue working with MIT to optimize and finalize policies utilizing non-use and allocation out of sequence goals.

## Discussion summary:

The Chair remarked that the Committee will continue to review the data in greater detail, particularly as it relates to addressing non-use and allocation out of sequence, and ensuring kidneys are allocated to the proper recipient in an appropriate timeframe.

#### 3. HRSA: Modernization Efforts

The Chair thanked the HRSA representative for joining, and encouraged the Committee to ask any questions they may have, particularly as it comes to Committee work. The HRSA representative thanked the Committee for their time.

The Chair remarked that there have been a number of stops, starts, and redirects for Committee work. The Chair explained that two years ago, the Committee was working steadily on Continuous Distribution, as the organ specific Committees were directed to work towards a more flexible allocation system. The Chair continued that the initial goal was to convert the current system into a continuous distribution system; however, as the discussion evolved, the effort become more focused towards making modifications to improve the system within continuous distribution as well. The Chair added that the Committee has shifted their focus to address specific items, and is now shifting their focus back to Continuous Distribution. The Chair remarked that the Committee would be interested to know if this work is moving in the appropriate direction in terms of alignment with HRSA and community interest. The Chair expressed the Committee's desire to do what is best for patients, trying to transplant as many candidates as possible, and trying to placed organs efficiently as possible.

The HRSA representative remarked that Continuous Distribution of Lungs is informative for a number of reasons, including that in practice, any policy will have unforeseen elements. The HRSA representative continued that when the policy is actually in practice, new considerations apply and postimplementation analysis is important. The HRSA representative explained that this has worked well, and the OPTN Lung Transplantation Committee has made corrections to the framework. The HRSA representative added that historically, allocation out of sequence was not adequately accounted for. The HRSA representative explained that the critical comment arose because of reports of noncompliance. The HRSA representative continued that there were instances of allocation out of sequence in multiple versions of kidney allocation policy, and that understanding the scope of allocation out of sequence has been the most recent wrinkle in what the Committee has been working on. The HRSA representative remarked that the Committee's Continuous Distribution work and Expedited Placement projects are going to intersect with the greater reality of what the OPTN is currently facing. The HRSA representative agreed that it is about serving the greatest number of patients, and noting that over-emphasis on utility leads to problems with other elements required for good policy making. The HRSA representative continued that it is a misunderstanding of the wastage provision in the Final Rule that has lead to an emphasis on utility. The HRSA representative remarked that the OPTN modernization effort aims to center the patients, specifically in making a system that is safe and fair. The HRSA representative remarked that it may not be an uninterrupted policy progression for any Committee, particularly as Committees may be directed or asked to do work to ensure that safety and fairness are maintained. The HRSA representative noted that previous wrinkles in the Committee's timeline may have been based on resource allocation by the OPTN Board of Directors, prioritizing specific projects. The HRSA representative noted that there is generally a three year timeline for policy development Committee consideration to implementation, and this timeline has generally been met.

One member agreed, noting that the transplant system needs to be safe and fair. The member added that part of safety is ensuring the system is timely and response, as the longer patients are on dialysis, the worse their outcomes. The member emphasized the importance of focusing on minimizing patient's dialysis experience. The member remarked that this should be considered in safety and outcomes as a guiding principles.

The Chair remarked that the current allocation system for Kidney is based on KDPI matching and waiting time. The Chair considered whether a larger shift in the allocation system is needed, noting this could be disruptive. The Chair specified inverse waiting time or inverse Kidney Donor Profile Index (KDPI) – Estimated Post-Transplant Survival (EPTS) matching as potential option. The Chair asked if, to address allocation out of sequence, the Committee should consider a larger paradigm shift as opposed to more incremental shifts in policy.

The HRSA representative responded that this would be up to the Committee. The HRSA representative continued that the OPTN is in a situation where there are insufficient organs to meet the need, and as the community discusses gradations in kidney quality and how decisions are made, subject matter expertise and patient and family voices will be required to make that decision. The HRSA representative remarked that isn't a decision HRSA would make, and that HRSA's role is to provide a framework for that discussion and make sure those discussions are compliant with the Final Rule and the National Organ Transplantation Act (NOTA).

One member expressed support for expanded KDPI-EPTS matching, noting this is a matter of efficiency. The member explained that an organ with shorter longevity is not a good match for a patient with long expected survival, nor vice versa. The member remarked that matching is important for reducing morbidity and reducing costs as well. The member continued that the current versions of KDPI and EPTS are sufficient, and may need to be updated to more accurately represent graft and patient survival. The member continued that once that has been done, KDPI-EPTS matching could be expanded to improve the system. The member provided an example, noting that KDPI doesn't account for diabetes management, for example, and thus does not accurately account for related organ damage. The member noted that this is also true for hypertension, and that KDPI does not account for donor use of continuous renal replacement therapy. The member concluded that there is a need to revise the way graft longevity and expected patient survival is evaluated, and then improve how those are matched for parity. The Chair agreed, noting that the current KDPI and EPTS tools have been acknowledged as somewhat crude markers, but still useful, particularly in evaluating modeling. The Chair remarked that there may be a point at which KDPI and EPTS may be less useful in understanding outcomes.

The Chair noted that it has been previously understood that all organs will shift over to Continuous Distribution, and asked if this is understanding is still true. The HRSA representative remarked that this predates their time at HRSA, but that the organs transitioned to circles-based distribution as planning for Continuous Distribution was underway. The HRSA representative explained that the guiding schema from the Ad Hoc Geography Committee, which were generalities, could support continuous distribution. The HRSA representative remarked that the OPTN should always be open to re-evaluation. The HRSA representative noted that accepting an organ with acute kidney injury used to be controversial, and is now a normal practice. The HRSA representative continued that the OPTN has refined measures in a number of different areas, including estimated glomerular filtration rate (eGFR). The HRSA representative remarked the requirement for qualifying eGFR calculations not to use race, and the removal of race and HCV from the Kidney Donor Risk Index (KDRI) calculation. The HRSA representative remarked that donation after circulatory death (DCD) may also see significant advancement, noting that DCD donors are fundamentally different today compared to 5 years ago. The HRSA representative noted that going back and reassessing modeling systems, data quality, and the fundamentals and tools of good policymaking is important.

One member offered a comment in alignment with protection of patients and increasing the number of transplants. The member remarked that there are instances where the program accepts the organ, and the organ performs poorly and then ultimately fails within 6 months or a year. The member continued that these patients don't qualify for primary non-function, and thus reinstatement of waiting time. The member remarked that these instances are also increasing, particularly as the transplant community is transplanting older donors, older DCD donors, and DCD donors with longer warm ischemic times. The member continued that this needs to be considered as the OPTN strives to increase the number of transplants, this will require more protections for patients and for programs. The member offered that potentially there are hard requirements around the types of organs an OPO should *not* recover, in terms of whether an organ is truly transplantable. The member expressed that the transplant community as a whole is learning, and that the goal should be to protect patients and programs, particularly as programs closing results in more patients on dialysis and less access to transplant. The member remarked that this is not helpful for patients nor the health system at large.

The HRSA representative remarked that the transplant community can sometimes focus on what doesn't help in decision making without focusing on the pieces of data that support decision making, or new pieces of data that are valuable. The HRSA representative noted that this is going to be a huge part of making better decisions, particularly as it relates to dialysis time and matching. The HRSA representative referenced an example where a 50 year old patient receives a kidney with a 3 year graft life. If that patient is really suffering on dialysis, that is something that must be considered against the risk that the patient will need to be relisted at 53 and are now highly sensitized or even 51 years old with a catheter or other dependent structures with a poorly functioning graft. The HRSA representative remarked that there need to be checks and balances to ensure utilization is not pushed at the expense

of patients. The HRSA representative commented that it is important to support centers and providers to the extent of protecting patients, not protecting centers.

The member agreed, noting that a closed transplant center results in more dialysis centers. The member continued that ranking transplant centers positions transplant centers against each other. The member commented that the standard for patient survival should be posited against dialysis. The member continued that this is an important mindset shift in transplant.

The HRSA representative commented that transplant is the standard of care, and is considered the gold standard for treating end stage renal disease. The HRSA representative commented that good practices are transmissible, primarily through good data, corrective action, and support programs that are not meeting expectations. The HRSA representative noted that how to provide well for patients is known, and that it is important to ensure those practices are in policy, and that safety and quality reviews effective ensure those practices are in effect. The HRSA representative added that identifying non-compliance with these practices will help programs improve and better care for their patients.

One member described accepting a kidney from a mid-30s DCD donor with around 45 minutes of warm ischemic time who had gone into cardiac arrest prior to being brought to the operating room. The member noted, accepted and effectively transplanted between 24 and 30 hours of cold ischemic time, showed signs of concern on the cortex and in post-operative ultrasound studies. The member shared that the vessels had great flow and there was nothing that could be done surgically to improve function. The member continued that the surgeon who accepted the partner kidney from the same donor had a similar experience. The member explained that these kidneys were accepted because they should have worked, and that it is difficult for the patient to potentially need to be relisted after undergoing transplant. The member continued that there are simply circumstances where a surgeon has to make a judgement call, and may accept a kidney that should function well according to the available information, but that ultimately struggles to function. The member remarked that this is due to the quality of information for this deceased donor, and it impacts the patient.

The HRSA representative noted that this is a good point, remarking that clinical judgement is going to be a function of experience, and experience is sometimes a function of poor outcomes. The HRSA representative expressed hope that the patient and their graft improve. The HRSA representative remarked that delayed graft function is the crudest marker of initial outcomes in transplant, particularly because delayed graft function is a function of the organ, the recipient, and how the transplant operation progressed. The HRSA representative commented that as a system, the transplant community has begun to transplant more candidates who may not have been candidate for transplant five years ago, and that this is a good thing. The HRSA representative added that the transplant community is also transplanting kidneys that would not have been transplanted five years ago as well. The HRSA representative noted that the transplant community is pushing the boundary of what success looks like. The HRSA representative continued that graft failure within 90 days is not success, and that is important to have these conversations with the recipient upfront about the fact that the donor's kidneys would have taken a week or two to function in their own body had the donor not undergone a neurologically devastating trauma. The HRSA representative explained that it is important to update expectations and communicate these expectations and risks to patients. The HRSA representative continued that how these expectations are communicated to payers and patients in terms of the metrics used to judge success are areas of continuing policy evolution.

A member agreed that delayed graft function is a poor metric, and noted that it used to be used against programs. The member remarked that delayed graft function shouldn't be tracked in a program-wide metric, noting that low delayed graft function rates for programs could even be indicative of concern. The HRSA representative noted that it was similar to seeing reduced appendectomy rates.

One member asked about HRSA's efforts to increase living donation. The HRSA representative remarked that the OPTN Living Donor Committee has ongoing work towards improving information for prospective living donor patients. The HRSA representative remarked that the public messaging on living donation has changed over time, and that the focus is now on encouraging programs to be forthright with patients about all the possibilities. The HRSA representative posited the scenario where a seven year old patient may be better served with a living donation than a 60 year old candidate who could potentially wait and received a longevity matched deceased donor kidney. The HRSA representative remarked that the Scientific Registry of Transplant Recipients (SRTR) and the OPTN Living Donor Committee are working to collect more information about potential and prior living donors, which will improve the information ecosystem. This information will allow patients to consider their relative risk based on information of living donors similar to them.

One member thanked the HRSA representative. The member agreed with a previous member's comment, noting that it can be difficult to question the decision to accept a graft that may be performing poorly unexpectedly.

The HRSA representative noted that he has an open door policy, and shared his email with Committee members.

The HRSA representative noted that the Committee had some discussion about the punitive or downside elements of making the most thoughtful decision possible at the time and not having it pan out the way it was expected to. The HRSA representative noted that any policy should incentivize doing right for the patient, and just like appendectomies, it can be the right decision and still have negative patient outcomes. The HRSA representative continued that, as clinicians, the right decision and action is taken, but it doesn't always turn out right. The HRSA representative noted that it is important to make sure policies are oriented towards supporting good decisions, even if the outcomes at an individual level don't match the decision making that went into it. The HRSA representative remarked that good policy can see the decision that was made at the individual level, and make sense of program practices. The HRSA representative thanked the Committee for their work and continued efforts in policy development.

#### **Upcoming Meetings**

• July 21, 2025

#### Attendance

## • Committee Members

- o Jim Kim
- o Arpita Basu
- o C.S. Krishnan
- o Christine Hwang
- o Curtis Warfield
- o Eloise Salmon
- o Jason Rolls
- o Jesse Cox
- o John Lunz
- o Kristen Adams
- o Patrick Gee
- o Prince Anand
- o Toni Bowling

## • HRSA Representatives

- o Ray Lynch
- o Kersten Smith
- SRTR Staff
  - o Bryn Thompson
  - Jodi Smith
  - o Jon Miller

#### • UNOS Staff

- o Kayla Temple
- o Kaitlin Swanner
- Keighly Bradbrook
- o Sarah Booker
- o Ross Walton
- o Thomas Dolan
- o Asma Ali
- o Houlder Hudgins