

## **OPTN Kidney Transplantation Committee**

### **Meeting Summary**

**November 4, 2024**

**Teleconference**

**Jim Kim MD, Chair**

**Arpita Basu, MD, Vice Chair**

### **Introduction**

The OPTN Kidney Transplantation Committee (the Committee) met via teleconference on 11/4/2024 to discuss the following agenda items:

1. Welcome and Objectives
2. Committee Project Planning
3. Discussion: Finalize “Hard to Place” Definition
4. “Hard to Place” Data Request

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

#### **1. Welcome and Objectives**

The Committee Chair and Vice Chair welcomed the Committee members, and OPTN Contractor staff reviewed the meeting objectives.

##### Meeting objectives:

- Review project planning and sequencing
- Determine appropriate “hard to place” thresholds for history of hypertension and donor age
- Discuss “hard to place” data request

##### Summary of discussion:

There were no questions or comments.

#### **2. Committee Project Planning**

The Committee reviewed planning and sequencing of their ongoing project efforts, as well as new project ideas the Committee has discussed.

##### Presentation summary:

The Kidney Committee has several ongoing efforts, including the Continuous Distribution of Kidneys project and the Kidney Expedited Placement project. The Committee has also discussed multiple new projects, such as removal of consent requirements for high kidney donor profile index (KDPI) kidneys, updating KDPI and estimated post-transplant survival scores (EPTS), and developing a model for predicting non-use.

In considering the Continuous Distribution effort, the Committee had reviewed two rounds of simulation modeling, and was finalizing optimization of weights and rating scales with the Massachusetts Institute of Technology (MIT) partners prior to September 2023. The Committee had a few outstanding decisions and discussions related to operational considerations like medical urgency, dual kidney, released organs, and review boards. In September of 2023, the OPTN Board of Directors passed a resolution asking the

Committee to additionally consider leveraging Continuous Distribution to reduce non-use and allocations out of sequence, as well as incorporate an expedited placement pathway for kidneys at increased risk of non-use. In support of these new efficiency goals, the Committee has submitted a request to the Scientific Registry of Transplant Recipients (SRTR) to update modeling capabilities for efficiency and non-use metrics, as well as discussed and developed an expedited placement protocol that the Kidney Expedited Placement Workgroup will transition into a policy effort. Looking ahead, the Committee will continue to work towards finalizing the continuous distribution proposal, including discussing additional efficiency modifications and optimizing for reduced non-use in a continuous distribution framework. The Committee will also finalize operational aspects of continuous distribution, including medical urgency, review boards, dual kidney, released kidney, multi-organ thresholds, and kidney expedited placement.

Per the OPTN Board resolution, Kidney Continuous Distribution must consider some form of expedited placement. The Committee has discussed and supported moving forward with a proposal for expedited placement to operate under the current circles-based allocation system, with necessary modifications for Continuous Distribution-based allocation to be included in the Continuous Distribution proposal. The Committee is currently aiming for August 2025 public comment.

Through November and December, the Kidney Committee will finalize the definition of “hard to place” and review SRTR modeling capabilities, which will be shared with MIT to support later optimization work. The Kidney Expedited Placement Workgroup will review the expedited placement processes developed to date, and discuss transition to nationally applied policy, as well as consider preliminary programming requirements.

January through March 2025, the Kidney Committee will discuss the efficiency modifications to the composite allocation score, including optimization efforts. The Kidney Expedited Placement Workgroup will consider the Kidney Committee’s “hard to place” definition for use as initiation criteria, and continue to work towards finalize the expedited placement policy.

The Kidney Committee will continue to finalize the Continuous Distribution project throughout 2025, including:

- Finalizing composite allocation score optimization and efficiency considerations
- Submit 3<sup>rd</sup> modeling request to the SRTR, with efficiency and non-use inclusive optimized policies and metrics
- Finalize medical urgency and review boards considerations
- Finalize kidney minimum acceptance criteria (KiMAC) modifications in Continuous Distribution
- Finalize operational considerations related to dual kidney and released organs in Continuous Distribution

#### Summary of discussion:

There were no questions or comments.

### **3. Discussion: Finalize “Hard to Place” Definition**

The Committee continued their discussions towards finalizing a preliminary definition of “hard to place” kidneys.

#### Presentation summary:

The Committee initially set out to develop a preliminary, evidence-based definition for kidneys at increased risk of non-use, or “hard to place.” This definition is preliminary in that the Committee will be able to modify and tweak the definition as need for the variety of purposes that such as definition

maybe used for, such as expedited placement. The definition is evidence based in that it is supported by data and literature. The rationale for developing this definition of “hard to place” includes establishing a clear, specific standard to describe which kidneys are “hard to place,” and identifying which organs are at increased risk of non-use. These discussions of characteristics and potential drivers of non-use may also support the Committee’s development of approaches to improve likelihood of transplant and addressing non-use in Continuous Distribution.

Previously, the Committee expressed support for building a predictive model to score kidneys based on the likelihood of non-use. This would require more intensive modeling efforts, including submitting a request to the Scientific Registry of Transplant Recipients (SRTR) to build such a model. This effort would be considered a new project and require Policy Oversight Committee approval. In consideration of this, Committee Leadership recommends continuing to develop the current definition of hard to place, in support of the completion of initial kidney expedited placement and continuous distribution efforts. Iteratively, the Committee can work towards the development of a “difficulty in placement” predictive model. The Chair noted that such a predictive model is outside of the scope of the Committee’s initial goal of defining “hard to place,” and that the Committee’s current efforts towards this definition are in support of finalizing the Continuous Distribution project.

After significant literature and data review, the Committee agreed that a multi-pronged approach may be appropriate, considering clinical indicators, allocation-based indicators, and cold ischemic time. The Committee has noted that such a definition captures risk of non-use over time, for both clinical and logistical reasons. The Committee sought feedback on clinical, logistical, anatomical, and allocation characteristics in public comment.

The Committee identified two primary approaches at their last meeting, including:

- Identified “hard to place” – based on lack of placement (allocation thresholds, cold ischemic time)
- Predicted “hard to place” – based on clinical considerations and known related risks of non-use

The Committee previously looked at an adjusted model to understand and outline the criteria that are independently associated with non-use in context with each other. The Committee narrowed down potential criteria to include:

- 6 hours of cold ischemic time, with consideration for transportation and logistics
- Sequence 100, based on precedent established with SRTR metrics
- Hypertension
- Donor age
- Diabetes greater than or equal to 5 years
- Donation after cardiac death (DCD)
- Biopsy results: glomerulosclerosis >10 percent
- Donor use of continuous renal replacement therapy (CRRT)

Hypertension and donor age were found to be associated with non-use in several articles reviewed by the Kidney Committee earlier this year, utilizing multiple analyses:

- Mohan et al (2018), Factors leading to the discard of deceased donor kidneys in the US, *Kidney Int.*
- Cohen et al. (2019) Predictors of turndown and the impact of late organ acceptance on allograft survival, *Am J Transplant*
- Massie et al (2010), Improving distribution efficiency of hard to place deceased donor kidneys: predicting probability of discard or delay, *Am J Transplant*

- Stewart et al (2017), Diagnosing the decades-long rise in the deceased donor kidney discard rate in the US, Transplantation

In considering distribution of donor age by non-use for 2023, the median donor age for transplanted organs was 40; for non-used organs, the median donor age was 58. In looking at donor age groups, non-use rates were 43.76 percent for donors aged 50-64, and 72.14 percent for donors aged 65 and older. Non-use rates were 37.75 percent for donors aged 50-59, and 63.14 percent for donors aged 60 and older.

Summary of discussion:

One member asked to review the results of the Committee's previous adjusted regression analysis, shown in **Table 1**. The member continued that it makes sense to use the drivers identified in this analysis to determine the characteristics used to define "difficulty in placement." The Chair remarked that this is where the Committee's current list of characteristics were derived from, but that the analysis did not break down hypertension by duration, and donor age was a continuous variable.

OPTN Contractor Staff explained that the bolded variables have been found to be independently and significantly associated with an increased risk of non-use.

One member remarked that a donor age of 60 or 65 make sense, but noted that none of the Committee's identified criteria alone is sufficient to be considered "hard to place" or trigger expedited placement. The member continued that these criteria should be used in combination. The Chair agreed, and noted that this is where the Committee is headed. The Vice Chair agreed, noting that the Committee will submit an additional data request to determine how many characteristics a donor would need to meet to be considered "hard to place." The member agreed, and remarked that donor age 60 is reasonable threshold.

The Chair asked if a broader definition, using lower or wider thresholds is more useful from an Organ Procurement Organization (OPO) perspective. An OPO member responded that a broader definition provides increased flexibility, but that this depends on the processes that the definition is tied to. The member explained that their OPO's definition of "hard to place" is based on donor DCD status, donor age, and KDPI. If that criteria is met, the donor is considered "hard to place" immediately. The member noted that their OPO considered donor age greater than 60 as "hard to place," especially for DCD donors or if the creatinine is 2.5 or higher.

A member noted that it could be helpful to have a higher age threshold just to reduce the overall volume of organs initially qualifying for expedited placement, noting community concerns for allocation out of sequence. The member continued that the Committee could broaden this criteria upon iteration. The member added that organs from donors over 65 are vastly less likely to be placed and transplanted, nearly three to one. The member continued that this is a strong argument for expedited placement for those organs. Another member agreed. The member noted that donor age 60 is also reasonable. The Chair remarked that there is precedent for donor age 60, particularly in the biopsy criteria. The Chair expressed concern that donor age 60 could be potentially too broad of a threshold with a potentially larger donor volume, but otherwise noted that donor age 60 has precedent in other parts of OPTN policy. Another member agreed, noting that this threshold seems to be recognized by OPOs as well.

The Committee supported a donor age threshold of 60 and older. OPTN Contractor Staff noted that the Committee will have an opportunity to revise after reviewing the results of the data request. OPTN

Contractor Staff explained that once the criteria are finalized, the analysis will investigate the volume of donors meeting 2, 3, 4, and 5 of the criteria, as well as rates of non-use across different combinations.

Presentation summary:

In considering donor organ use status by history of hypertension, the data shows that non-use increases as duration of hypertension increases. Specifically, non-use rates were as follows:

- 16.33 percent for donors with no history of hypertension
- 35.41 percent for donors with a 0-5 year history of hypertension
- 48.66 percent for donors with a 6-10 year history of hypertension
- 58.04 percent for donors with a greater than 10 year history of hypertension
- 46.75 percent for donors with a known history of hypertension but unknown duration
- 31.91 percent for donors with an unknown history of hypertension

In looking at hypertension durations combined, non-use rates for donors with a history of hypertension greater than 5 years was 54.21 percent, compared to 19.96 percent for donors with no history of hypertension or a history of hypertension less than 5 years. Non-use rates for donors with a history of hypertension greater than 10 years was 58.04 percent, compared to 22.40 percent for donors with no history of hypertension or a history of hypertension less than 10 years. Donors with an unknown duration of hypertension had a non-use rate of 46.75 percent, and donors with an unknown history of hypertension was 31.91 percent.

Finally, in considering donor organ use status by compliance with hypertension treatment, there is little parity in non-use rate by compliance. Donors compliant with hypertension had a non-use rate of 48.25 percent, compared to 40.78 percent for donors with non-compliance. Donors with unknown compliance had a non-use rate of 44.97 percent.

Summary of discussion:

The Chair remarked that the Committee's previous discussion highlighted unreliability of compliance with hypertension, and thus that the Committee decided not to include compliance in the definition of "hard to place." Another member agreed.

One member offered that a 10 year history of hypertension as a reasonable threshold. The Chair asked what the KDPI calculation uses if hypertension history is unknown. OPTN Contractor Staff noted that the KDPI calculation does not assign a duration, but instead uses a calculated chance of hypertension based on the prevalence of hypertension in the donor population.

A member explained that typically, they tend to be more concerned with a long history of diabetes more than a long history of hypertension. The member continued that a 10 year history of hypertension is not as troubling as a ten year history of diabetes. In considering this, the member expressed support for a higher hypertension threshold. Another member remarked that it is difficult to say, noting that hypertension is typically built into the KDPI calculators and so less considered by their OPO in determining which organs are hard to place.

The Chair remarked that cerebrovascular accident (CVA) as cause of death is currently included in the biopsy criteria, and another member confirmed that the biopsy criteria includes donors aged 50-59 who died of CVA, had a terminal creatinine greater than 1.5, or a history of hypertension. One member pointed out that the expanded criteria donor (ECD) definition did not include diabetes, but noted that it is possible the transplant community did not consider diabetic donors for transplant when the ECD definition was developed.

One member asked if the Committee could use the biopsy criteria as the “hard to place” definition. Another member expressed interest. The member remarked that this could work, although the KDPI threshold may need to be lower. A member asked if the biopsy requirements were developed based on data, or consensus opinion, and expressed support for the alignment. The Chair explained that the biopsy criteria were developed looking at data regarding the characteristics of donors for whom biopsies were performed. The Chair continued that there was variability in biopsy performance, and that this criteria established standardization in biopsy performance.

The Chair remarked that a hypertension history of greater than 5 years would support a broader definition, which would be consistent with the Committee’s choice of a donor age threshold of 60 years and older. The Chair continued that hypertension greater than 10 years is also reasonable. The Chair remarked that hypertension history greater than 5 years captures 54 percent, compared to 58 percent of non-use for hypertension history greater than 10 years. The Vice Chair noted that these criteria will be considered in combination with each other, and so expressed support for hypertension greater than 5 years.

The Committee agreed upon the inclusion of hypertension history greater than 5 years in the definition of “hard to place.”

The Committee’s finalized criteria include:

- 6 hours of cold ischemic time, with consideration for transportation and logistics, based on SRTR data
- Sequence 100, based on precedent established with SRTR metrics
- Hypertension history greater than 5 years
- Donor age 60 or older
- Diabetes greater than or equal to 5 years
- DCD
- Glomerulosclerosis greater than 10 percent
- Donor use of CRRT

#### **4. “Hard to Place” Data Request**

The Committee discussed a final data request based on their developed criteria and characteristics.

##### Presentation summary:

Cohort: All donors with a kidney recovered for transplant in 2023

1. Number and proportion of donors meeting 1, 2, 3, 4, or 5 of the following criteria:
  - a. Donor history of hypertension >
  - b. Donor history of diabetes >5 years
  - c. Donor age
  - d. DCD
  - e. Biopsy with glomerulosclerosis >10 percent
2. Kidney non-use rates for donors meeting 1, 2, 3, 4, or 5 of the above criteria
3. Number and proportion of donors with more than 6 hours of cold ischemic time without placement of one or both kidneys
4. Number and proportion of donors where one or both kidneys are placed at offer number > 100

##### Summary of discussion:

One member remarked that while “offer number greater than 100” has precedent in SRTR data, it is still somewhat arbitrary. The Chair agreed, noting that the Committee’s previous discussions emphasized that sequence number can be a good surrogate for difficulty in placement. The Chair noted that this data request is investigatory, and that the Committee can continue to discuss and finalize upon reviewing results.

The Chair noted that donor use of CRRT is not included in the data request, and OPTN Contractor Staff explained that this is not currently collected in the OPTN Computer System, although it is planned to be added. A member expressed support for future data collection on CRRT. OPTN Contractor Staff shared that the OPTN performed an analysis evaluating donor highlights for mention of donor dialysis or CRRT use, and found it to be relatively rare – about 2 percent of donors. The Chair remarked that, anecdotally, it feels like more donors are on CRRT. A member agreed, but noted that use of CRRT in donor management may be more regional.

The Committee confirmed that the 2023 kidney donor cohort is appropriate and reasonable, and expressed support for the data request as presented.

### **Upcoming Meetings**

November 18, 2024

## Attendance

- **Committee Members**
  - Jim Kim
  - Arpita Basu
  - Christine Hwang
  - Curtis Warfield
  - Eloise Salmon
  - Jason Rolls
  - John Lunz
  - Patrick Gee
  - Tania Houle
  - Toni Bowling
- **HRSA Representatives**
  - James Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
  - Grace Lyden
  - Jon Miller
  - Peter Stock
- **UNOS Staff**
  - Kayla Temple
  - Kaitlin Swanner
  - Houlder Hudgins
  - Lauren Motley
  - Sarah Booker
  - Thomas Dolan