OPTN Kidney Transplantation Committee
Meeting Summary
January 19, 2024
Teleconference

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

Introduction

The Kidney Transplantation Committee met via teleconference on 01/19/2024 to discuss the following agenda items:

1. Executive Committee Special Public Comment Proposal: Expedited Placement Variance
2. Investigating Non-Use and Defining Hard to Place: Finalize Preliminary Data Request
3. Investigating Non-Use: Literature Review

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

1. Executive Committee Special Public Comment Proposal: Expedited Placement Variance

The Committee reviewed and discussed the Executive Committee's *Expedited Placement Variance* proposal, which was developed in alignment with the OPTN Expeditious Task Force.

Presentation Summary:

This proposal will modify variance policy to allow for the development, operation, and review of pilot projects to test potential expedited placement allocation policies. These pilots will focus on alternative allocation pathways for hard-to-place organs. Not all pilots or PDSAs tested by the OPTN Task Force will require policy variances.

Variance: A variance is an experimental policy approved by the OPTN. Any variance must comply with the requirements in the OPTN Final Rule and Policy 1.3 Variances. The variance in this specific proposal requires the Executive Committee to approve specific protocols.

Protocol: This proposed variance calls for specific protocols. Each of these protocols will contain instructions to study a particular change in allocation. All of these protocols must meet the requirements dictated by the proposed variance.

Pilots structured as a variance would need to be approved as an open variance by the OPTN Board of Directors and/or the OPTN Executive Committee and go through an special public comment period. These variances would be time-limited studies using an opt-in model. Protocols will be collected from the community, and will be selected based on a framework developed by the OPTN Task Force. The protocols will be accessible to the community outside of OPTN policy. These protocols will be tested to assess which are most effective. There will be an evaluation plan with objective criteria to measure the variance's success, and members will need to submit information as required by the variance.

Each protocol must comply with National Organ Transplantation Act (NOTA) and the OPTN Final Rule, and must include:

1. Criteria for organs eligible for expedited placement.
2. Criteria for candidates eligible to receive expedited placement offers.

3. Conditions for the use of expedited placement.
4. OPO and transplant hospital responsibilities.

The OPTN Final Rule requires that variances have a specified end date. However, the variance can be extended, modified, or terminated early. The Executive Committee is seeking feedback on the length of proposed variance. As currently proposed, the end date of the proposed variance is July 2025.

Variances are governed by the OPTN Final Rule and OPTN Policies. The proposed changes to OPTN variance policy include:

- Clarification regarding the creation of variances.
- Remove requirement to solicit agreement prior to public comment.
- Change frequency of reporting requirements. *Important for short, iterative variances*.

Summary of discussion:

The Chair asked for increased clarity around how these variances will be evaluated, how data will be collected on the variances, and how the variances will be monitored for unintended consequences. Staff noted that the Executive Committee and Task Force agreed transparency is important, and plan to share monitoring reports regarding the variance. The Chair noted that the flexibility provided by the proposed variance will be crucial to testing potential expedited placement pathways. The Chair noted that expedited placement protocols may preference certain populations that may be easier to transplant, and emphasized the importance of ensuring these protocols and related outcomes are closely monitored to ensure disparities do not increase.

2. Investigating Non-Use and Defining Hard to Place: Finalize Preliminary Data Request

The Committee reviewed previous discussions related to investigating non-use and finalized a data request aimed at understanding the current state of non-use and key donor and organ characteristics related to non-use.

Presentation Summary:

The OPTN Board resolution from 9/6 asked the committee to pivot the continuous distribution effort to focus on efficiency, decreasing non-use, decreasing AOOS, and establishing an expedited placement pathway for kidneys at high risk of non-use. The Committee has focused efforts towards understanding and addressing non-use of kidneys, including data and literature review to understand potential drivers of non-use and scope and consensus building efforts to define “hard to place” kidneys across multiple contexts.

The Committee has already discussed several ideas, concepts, focus areas, and pain points regarding non-use, efficiency, and system performance

- Intersectionality of multiple factors, stakeholders, and pain points
- Operational issues are clustered together
- Need to address non-use through alternate approaches, such as expedited placement
- Identifying and defining “hard to place” kidneys, with increased clinical and situational autonomy
- Fundamental limitations of infrastructure
- Defining efficiency in the context of allocation, and making room for necessary variation
- Need for improved metrics to understand logistical impacts
- Shared decision making incorporates greater care teams and requires ample, accessible education

At the December meeting, the Committee dug more deeply into several potential drivers of non-use:

- Donor characteristics and situational patterns of non-use
    - What patterns exist among organs that are not transplanted?
    - How much non-use is due to organ/donor concerns vs logistical concerns?
    - Matching transplanted and not used organs, to understand relative balance of characteristics and logistics
- Allocation logistics – sequential offering, program use of filters
    - How does cold ischemic time affect non-use, particularly in a dynamic sense?
    - How does match run prioritization affect allocation efficiency, cold ischemic time, and non-use?
- Logistical impacts – distance, geography, rural vs. urban, airport proximity
    - If logistics weren't an issue, how many unused organs would have been accepted and transplanted?
- Patient participation, engagement, and notification
    - Increasing likelihood of acceptance for physicians and for patients (education)
    - How are patients informed about offers not accepted on their behalf?
- Impact of OPTN policies, such as "national kidney" requirement, biopsy requirements, etc.

Summary of data request:

Part One of the data request will examine the following metrics over time:

1. Non-use rate
2. Non-use rate by KDPI
    - (0-20%,21-34%,35-85%,86-100%)
    - And broken more granularly (5% KDPI Buckets)
3. Number of deceased kidney donors
4. Number of kidneys transplanted.
5. Number of kidneys recovered for transplant.

Part two of the data request will examine:

1. Distribution of deceased donor and/or kidney characteristics over time and,
2. Non-use rate by deceased donor characteristics

The deceased donor characteristics will include: age (years), race, ethnicity, history of cancer, cigarette use, history of cocaine use, history of drug use, history of hypertension, history of diabetes greater than 5 and 10 years, duration of diabetes, insulin dependence, Hep C, DCD, Height, Weight, Cause of death, Mechanism of death, Blood type, sex, CMV status, Clinical infection, and KDRI.

Part three of the data request will look at characteristics of deceased kidney donors by sequence number (cumulative) to understand if certain type of donors are being allocated much further down the match run. Donors allocated out of sequence will be excluded from the analysis. If time allows, we will perform a sensitivity analysis including and excluding offer filters in the sequence number count. Bypasses will be excluded. Time allowing, recipient characteristics across sequence numbers will also be analyzed.

Summary of discussion:

One member recommended including region, state, and DSA of the donor hospital. The member also recommended considering the inclusion of delays related to late declines, specifically in cases where a program "provisionally accepts" the organ and declines after several hours. The member explained that both late declines from a "provisional yes" and "final acceptance" should be considered. The member noted that late declines can impact a program's ability to accept an organ in a timely manner. The Chair agreed, noting that this is particularly true in local allocation, especially if a program declines for many patients at once. The Chair noted that cold ischemic time would play a role in this as well.

The Chair recommended the inclusion of pump status, biopsy status, and specific biopsy results, such as percentage glomerulosclerosis. The Chair also recommended including anatomy if possible.

One member shared that the SRTR defines a "hard to place" kidney as a kidney placed after sequence 100. The member remarked that it is difficult to define what makes an organ hard to place, and offered that the best method to identifying "hard to place" organs is by sequence number or cold time. The member offered that pre-clamp it may be difficult to determine if an organ is hard to place, but that post-clamp, "hard to place" should be determined by cold ischemic time. The member remarked that logistic regression could provide more insight into attributes that are predictive of increased risk of non-use. Staff shared that the literature review may provide additional insight here.

The Chair remarked that number of turn downs is not always a great predictor or indicator of risk of non-use, particularly if one center has a greater number of patients on the earlier parts of the match run. The Chair offered that number of centers that have declined should also be considered, and remarked that there may be a pattern of characteristics relating to kidneys used further down the match run. The Chair added that there is often a "domino effect," by which centers become less certain and more likely to decline an offer for an organ that has been declined for many other programs. The Chair continued that it is also important to look at organs transplanted far down the match run, noting there may be similarities between those kidneys and kidneys that were not used. Another member agreed, sharing that the Task Force considered the idea of a blinded match run, where a program receives an offer and can see which patients appear on the match, but are unable to see if other programs have declined the offer. The member agreed that offers at high sequence numbers trigger a psychology wherein decision makers evaluate an offer looking for reasons to decline, instead of reasons to transplant.

One member agreed, offering that there may be an opportunity to evaluate kidneys that were declined in the first 100 sequences and then placed, and then look at other metrics such as final cold ischemic time at acceptance. The member remarked that "hard to place" is often defined by a mix of donor characteristics and circumstantial information that is not currently collected in OPTN data, such as logistics. The member continued that flight connection or transportation availability are limiting factors, but there is limited data available. The member continued that sequence placement, time of placement, and cold ischemic time at placement, and then go back and look at donor characteristics to understand those donors and organs. Staff agreed, noting that the Task Force has also considered matching non-used kidneys with similar characteristics to kidneys transplanted further down the match run to see if there were other characteristics, allocation, or logistics that resulted in non-use.

One member also offered that geography of accepting center may also provide insight to logistics. A member recommended a more novel approach of evaluating characteristics for kidneys placed at different sequence number thresholds. The member continued this information, as well as overall transplant rate for programs in an area may provide more meaningful information. Staff asked what those sequence number thresholds should be. One member noted that the first 100 is a good metric, then offered those organs placed within and beyond 250 nautical miles. The member also offered that

highly sensitized patients should be excluded from this analysis. The Chair agreed, recommending excluding 0 mismatch patients as well.

A member offered that pediatric recipients should be looked at differently. Another member pointed out that multi-organ will need to be considered in a pediatric-focused analysis. Others agreed.

One member recommended including time of day that the offer was made.

A member recommended including PHS increased risk status. One member agreed, noting some patients refuse organs that are PHS increased risk.

3. Investigating Non-Use: Literature Review

In preparation for the in-person meeting, the Committee will is asked to participate in a literature review. The Literature Review articles span across 5 topics: Predictors of non-use, drivers, options and solutions, current state of non-use and recent approaches, patient voice and preferences, transportation, biopsy and information presentation. Each Committee member is assigned two articles to review: an email with assignments will be sent out later today and you are encouraged to read and share other articles that you find pertinent as well.

Summary of Discussion:

There were no questions or comments.

Upcoming Meetings

- February 21, 2024 – In-Person, Houston TX
- March 18, 2024

Attendance

- **Committee Members**
  - Jim Kim
  - Arpita Basu
  - Jason Rolls
  - Carrie Jadlowiec
  - Curtis Warfield
  - George Suratt
  - Jesse Cox
  - John Lunz
  - Aparna Sharma
  - Leigh Ann Burgess
  - Steve Almond
  - Tania Houle
  - Sanjeev Akkina
  - Reza F. Saidi
  - Marian Charlton
  - Kristen Adams
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
  - Grace Lyden
  - Jon Miller
  - Peter Stock
- **UNOS Staff**
  - Kayla Temple
  - James Alcorn
  - Kaitlin Swanner
  - Keighly Bradbrook
  - Ben Wolford
  - Carlos Martinez
  - Houlder Hudgins
  - Thomas Dolan
  - Lauren Motley