OPTN Expedited Placement Workgroup
Meeting Summary
April 29, 2024
Teleconference

Carrie Jadlowiec MD, Chair
Chandrasekar Santhanakrishnan, MD, Vice Chair

Introduction

The OPTN Expedited Placement Workgroup (the Workgroup) met via teleconference on 4/29/2024 to discuss the following agenda items:

1. Welcome and Introduction
2. Orientation: Workgroup Background, Goals, Scope
3. Overview: OPTN Kidney Committee Definition of Hard to Place
4. Literature Review: Expedited Placement Processes

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

1. Welcome and Introduction

Summary of presentation:

OPTN Contractor staff introduced the Chair and Vice Chair of the Workgroup. The group includes representation from the Kidney, Ethics, Operations & Safety, Organ Procurement Organizations, and Transplant Coordinators Committees.

Summary of discussion:

There were no questions or comments.

2. Orientation: Workgroup Background, Goals, Scope

The Workgroup reviewed context, goals, and scope for discussions regarding expedited placement. The Workgroup also discussed collaboration with the OPTN Expeditious Task Force.

Summary of presentation:

OPTN Contractor Staff shared that, in September 2023, the OPTN Board of Directors approved a resolution directing the Kidney Committee to address topics in kidney continuous distribution, including decreasing non-use, decreasing allocation out of sequence, and expedited placement. It was mentioned that the Kidney Committee's focus has evolved, starting to incorporate new goals into their continuous distribution approach, including identifying and discussing efficiency and non-use goals and key research questions; understanding current state of non-use and identify key efficiency/non-use metrics to expand SRTR modeling capabilities; and defining "hard to place" kidneys.

The1 importance of coordination with the OPTN Expeditious Task Force was recognized here, as it has defined its goal and prioritized these efforts. Crossover membership with the Task Force was recognized as a valuable tool for communication. The Task Force is not a traditional policy making group, but will consider the various ideas through protocol development that is expected to lead to more expedited policy development in the end.

The Kidney Expedited Placement Workgroup will focus on the following tasks:

- Literature review to understand the strengths, weaknesses, and lessons learned from expedited placement protocols across organs and transplant systems
- Develop expedited placement variance protocols that will be submitted to the Expeditious Task Force for consideration. Once approved, the Workgroup will receive feedback regarding review, testing and analysis of these protocols.
- Consider, develop, and provide input on potential frameworks for policy and systems implementation of successful expedited placement protocol(s). This is anticipated to facilitate more rapid incorporation of kidney expedited placement pathway into OPTN policy.
    - Potential frameworks should include explicit clinical criteria for organs eligible for expedited placement, explicit criteria for candidates eligible to receive these offers, explicit conditions for the use of expedited placement with specific OPO and transplant hospital responsibilities, and (if the protocol has been used) any additional results regarding its usage
    - Expedited placement variance protocols will be extensively monitored and reviewed for performance and well as unintended impact on pediatric access, potential racial disparities, and potential gender disparities
- Potentially consider other alternate allocation pathways within Continuous Distribution, such as dual kidney.

Summary of Discussion:

A Workgroup member asked whether this group would receive clarity on what the Expeditious Task Force is working on already around expedited placement. The rescue pathway workgroup was acknowledged as also working in the kidney space. Additionally, a video project on educating patients regarding high kidney donor profile index (KDPI) kidney offers is also in development, with feedback sought from the Patient Affairs Committee. A Workgroup member who is also active in the Expeditious Task Force noted that the Task Force aims to put forward a relatively simple first protocol for approval by the Executive Committee, and then expand to test other potential protocols.

A Workgroup member suggested that the Task Force's Rescue Pathway Workgroup be invited to one of these calls to provide an update (once they are beginning to develop ideas) in order to facilitate collaboration and prevent any conflicting or duplicative efforts. It will be helpful to see what their proposed pathways are before then moving on to the Executive Committee for consideration.

A member also suggested looking at scenarios where multiple declines may trigger an alternative pathway for kidney placement.

Next steps:

OPTN Contractor staff will follow calls for the Rescue Pathway Workgroup and invite representatives from this group to speak to the Expedited Placement Workgroup as ideas begin to develop to promote collaboration here.

3. Overview: OPTN Kidney Committee Definition of Hard to Place

The Workgroup received an update on the OPTN Kidney Committee's work to develop a data-based, consensus definition of "hard to place" and "at increased risk of non-use" kidneys, and discussed how this definition can be used in developing a policy for expedited kidney placement.

Summary of presentation:

The Kidney Committee has been working to develop a preliminary, empirically driven, consensus definition of "hard to place." A number of clinical and allocation-based characteristics have been discussed, and the Committee is holding fur further data to continue its discussions. It's proposed preliminary definition of "hard to place" will be shared with the Workgroup for consideration once it is finalized. The Workgroup may then utilize this definition in its development of potential expedited placement variance protocols.

Summary of discussion:

There were no questions or comments.

4. Literature Review: Expedited Placement Processes

Summary of presentation:

OPTN Contractor staff highlighted results of a literature review on expedited placement, including examples of how the U.S., European, and the United Kingdom transplant systems manage expedited kidney, liver, and pancreas allocation schemes. This included:

- UK Initial kidney "Rescue" allocation scheme[1]
    - When 5 centers decline a kidney for donor or organ-related reasons, the kidney is offered to alternative centers who had reported interest in considering these grafts
    - Offers are made in rank order based on the match algorithm (which may lead to increased cold ischemic time of marginal grafts).
- UK Fast Track Kidney allocation scheme[2]
    - Kidneys that meet criteria are offered simultaneously to all centers registered in the Fast Track Allocation Scheme
    - Centers have 45 minutes to respond. Here, kidneys are then allocated to highest ranking center based on allocation algorithm.
- Eurotransplant Recipient Oriented Extended Allocation (REAL)[3]
    - All centers in the region or country where the graft is located are contacted (an "all call")
    - For each center, potential recipients and respective original rankings shown. Centers select up to 3 designated recipients for transplant, After 60 minutes, Eurotransplant offers the organ to the highest ranked candidate
- Eurotransplant Competitive Rescue Allocation (CRA)[4]
    - Utilized when an organ cannot be allocated via REAL, or when allocation time is extremely limited
    - Kidneys in are offered to at least 3 centers. A center that accepts the offer first receives the graft and may choose to transplant any recipient from all compatible candidates on the list. Centers may choose independently to assign the graft according to the match run or predetermined internal rules, with respect urgency, need, or assumed transplanted outcome.

[1] White, et al. (2015). Impact of the new fast track kidney allocation scheme for declined kidneys in the United Kingdom. Clin Transplant, 29(10), 872-881. https://pubmed.ncbi.nlm.nih.gov/26094680/
[2] *Ibid.*
[3] Assfalg, et al. (2023). Rescue Allocation Modes in Eurotransplant Kidney Transplantation: Recipient Oriented Extended Allocation Versus Competitive Rescue Allocation – A Retrospective Multicenter Outcome Analysis. *Transplantation*. https://pubmed.ncbi.nlm.nih.gov/38073036/
[4] *Ibid.*

- US Kidney Accelerated Placement (KAP)[5]
    - Donors were 18+ years of age with a KDPI ≥ 80%, and allocation had reached national sequences (only offered by the Organ Center). KAP offers were initiated electronically, triggered by donor criteria measures. Transplant programs that had accepted and transplanted 1 similar or worse kidney in the prior 2 years received offers, other bypassed. Programs could increase the number of accelerated offers in real time for their patients by acceptance of similarly modeled hard to place organs at local and regional levels
    - Offers are sent sequentially, following match run (with bypasses applied)
- US Expedited Liver Placement[6]
    - Programs are able to opt in candidates to receive expedited offers, with 60% of liver candidates opting in currently
    - Expedited placement is only initiated when primarily liver acceptor declines the organ after OR has begun
    - Bypasses are applied to non-opted in candidates and offers continue to be extended down the match run only to opted in candidates
    - There is a 30-minute window for programs to respond once receiving the expedited offer.
- US Facilitated Pancreas Allocation[7]
    - OPOs and Organ Center are permitted to make facilitated pancreas offers if no pancreas offer has been accepted 3 hours prior to scheduled recovery
    - To qualify for facilitated pancreas offers, the program must have transplanted at least 2 pancreata > 250 nautical miles away. This also includes pancreas transplant as part of multi-organ transplant (including simultaneous kidney-pancreas)
    - Facilitated pancreas bypass button will only apply bypasses to candidates listed for isolated pancreas, and at programs >250 nautical miles
    - Bypasses do not apply within 250 nautical miles or for combined kidney-pancreas candidates

Summary of discussion:

A member asked if the lessons learned from the literature review can be pulled together, utilizing various elements that worked from other countries or studies rather than a "select one model" of those offered. This was acknowledged as exactly the task ahead for this workgroup. Members will review what aspects of the models outlined in the literature review worked well, what aspects created barriers to effective utilization, and lessons learned to determine what can be avoided or remedied.

Members highlighted the literature they were drawn to in their individual review. A member stated that European systems and ischemia times should be examined more. This member also mentioned that biopsy time should be examined. A member said that effective and ineffective practices should be looked at, as well as possible combinations of practices that may be successful.

A member compared liver and kidney placement options, citing the differences in receipt times for biopsy reports. This can also lead to extended cold ischemic time even before travel. This member also

[5] Noreen et al (2022). "Kidney Accelerated Placement Project: Outcomes and Lessons Learned." Am. J. Transplant. 22(1): 210-221. https://pubmed.ncbi.nlm.nih.gov/34582630/

[6] OPTN OPO Committee Expedited Liver Placement Pathway 1 Year Post Policy Implementation Monitoring Report. October 15, 2022.

[7] OPTN Pancreas Committee: 'Facilitated Pancreas Allocation' part of the Eliminate DSA and Region in Pancreas Allocation 2-Year Post-Implementation Monitoring Report. July 10, 2023

said that some organs, even with rescue pathways, may not be transplantable due to medical complexities. They stated that it should be included that transplantable kidney success should be looked at as opposed to all kidneys, some of which are not viable.

A member stated that "hard to place" definitions can include a variety of factors, including center behavior and their willingness to take organs. Ultimately there may need to be a point at which a critical mass of declined offers is recognized before reaching national allocation. Allowing for programs to opt in for expedited offers at this point might allow for more efficient placement and reduced cold time. The opt in was not always seen as effective because many candidates opted in but programs were still not accepting the organs in real time. Qualifying criteria for programs may be necessary to optimize efficiency in this case. Facilitated pancreas was noted as an example here.

The workgroup discussed protocol pumping. A member asked how many non-use kidneys had been pumped, and a member responded that pumps do not always need to be used, though they can be applicable in some situations. A member mentioned that time stamps are helpful for transplant centers. Further, they said that pump and biopsy information is important to kidney transplants. A member said that quality of biopsies can be important for whether an organ is accepted or not. The biopsy itself can be influenced by the quality of the biopsy and the professional reading it as well as the images available to the transplant program considering the offer. A member remarked that pumping and biopsy can also lead to increased non-use, noting that these interventions can lead to greater concern from programs for kidneys that may very well be safe and appropriate for transplant, particularly as similar kidneys that are not pumped or biopsied are transplanted and achieve adequate graft function. A member noted that pumps add logistical challenge and complexity, as they cannot currently be flown for transport.

A member asked about pre- and post-cross-clamp data, while another asked about what defines an aggressive transplant center. OPTN Staff said these are all definitions for consideration within this Workgroup.

In summary, several considerations were identified:

- The impact of cold ischemic time to risk of organ non-use, and the importance of reducing cold ischemic time in allocation. Members recognized that biopsy, pump, and post-clamp information gather can attribute to the accumulation of cold ischemic time. These practices should be re-evaluated for necessity, reliability, and effectiveness against their contribution to non-use. For this reason, early initiation of expedited placement processes may be crucial.
- Some organs may not be safe for transplantation. The expedited placement pathway impact should be evaluated by impact to non-use for transplantable organs
- "Opt in" models may not be as effective. A program's behavior may not align with the program opt in criteria, but there is interest in not "missing" organ offers. For this reason, qualifying criteria may be necessary to optimize efficiency.
- An expedited placement trigger should consider "hard to place" definition in development by the Kidney Transplantation Committee, and incorporate transplant program behavior, risk tolerance, and the number of declines.

Next steps:

Workgroup members were encouraged to continue their study of the literature review and share additional thoughts.

Upcoming Meetings

- May 13, 2024
- May 27, 2024

Attendance

- **Committee Members**
  - Caroline Jadlowiec
  - Chandrasekar Santhanakrishnan
  - Sanjeev Akkina
  - George Surratt
  - Reza Saidi
  - Leigh Ann Burgess
  - Kristin Adams
  - Tania Houle
  - Nancy Rodriguez
  - Jill Wojtowicz
  - Jami Gleason
  - Micah Davis
- **HRSA Representatives**
  - James Bowman
- **SRTR Staff**
  - Bryn Thompson
  - Grace Lyden
  - Jonathan Miller
- **UNOS Staff**
  - Kayla Temple
  - Shandie Covington
  - Kaitlin Swanner
  - Keighly Bradbrook
  - Lauren Motley
  - Thomas Dolan