OPTN Expedited Placement Workgroup
Meeting Summary
June 24, 2024
Teleconference

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

Introduction

The OPTN Expedited Placement Workgroup (the Workgroup) met via teleconference on 6/24/2024 to discuss the following agenda items:

1. Welcome
2. Recap: Workgroup Scope and Goals
3. Introduction: Expedited Placement Variance Protocols
4. Discussion: Expedited Placement Protocols (Recipient-Oriented Allocation (REAL) System
5. Adjourn

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

1. Welcome

The Chair welcomed Workgroup members and thanked them for their participation. She noted good progress on this effort and looked forward to continued input and focus on the call.

2. Recap: Workgroup Scope and Goals

The Workgroup received a recap of its overall goals and scope, including how these efforts align and complement work underway in both the OPTN Expeditious Task Force and its Rescue Allocations Pathway workgroup.

Prior to the presentation, the Workgroup briefly reviewed the finalized literature review document. This document will be shared with the OPTN Kidney Transplantation Committee and OPTN Expeditious Task Force.

Summary of presentation:

This Workgroup and the Expeditious Task Force's Rescue Allocations Pathways Workgroup are both working toward the same goal: expedited placement for kidneys.

The Rescue Allocation Pathways Workgroup (and Expeditious Task Force):

- Developed the Expedited Placement Variance, which allows for potential expedited placement protocols to be tested in real time *prior* to implementation as policy
- Reviews, modifies, submits, and monitors protocols under the expedited placement variance, working directly with the OPTN Executive Committee.

This Workgroup:

- Will develop protocols for consideration by the Rescue Allocation Pathways Workgroup
- Will also monitor and maintain awareness of all kidney expedited placement protocols, eventually working with the OPTN Kidney Transplantation Committee, Rescue Allocation

Pathways Workgroup, and Expeditious Task Force to develop a kidney expedited placement policy.
- Discusses expedited placement in the context of continuous distribution, including systems requirements.

Summary of Discussion:

There were no questions or comments.

3. Introduction: Expedited Placement Variance Protocols

The Workgroup received an overview regarding the required elements for an expedited placement variance and key elements to be used in testing and monitoring any proposed protocols. The Workgroup also briefly reviewed their previous discussions.

Summary of presentation:

The template for Expedited Placement Variance protocol submissions includes:

- Explicit clinical criteria for organs eligible for expedited placement
- Explicit criteria for candidates eligible to receive expedited placement offers
- Explicit conditions for the use of expedited placement
- OPO and transplant hospital responsibilities
- If the protocol has been used, any additional results regarding its usage.

All expedited placement variance protocols will be monitored for pediatric access and any potential racial or gender disparities.

Protocols will be tested amongst a smaller group of OPOs and transplant centers. This smaller test group is expected to allow the task force to understand what aspects of expedited placement do and do not work well for a system as big as the United States before formal introduction as a policy.

The Workgroup previously discussed:

- Simultaneous offering to qualifying programs
    - Need to monitor for a "disappointment" factor – how often programs mobilize resources but don't receive the offer
        - Consideration for cost to programs, including in personnel-hours
- Candidate selection

Setting expectations with transplant programs with respect to evaluation and candidate selection (including virtual crossmatch). This acknowledges that programs may have their own levels of comfort with transplanting higher CPRA candidates with only a virtual crossmatch

    - Ensuring verification with potential recipients, confirming no changes in health, etc.
    - Sharing best practices to support offer evaluation resources
- Educating patients about this process ahead of receiving offers.
- Monitoring for instances where programs accept an offer for one candidate but transplant into another candidate within an expedited placement pathway.

Summary of Discussion:

There were no questions or comments.

4. Discussion: Expedited Placement Protocols (Recipient-Oriented Allocation (REAL) System

The Committee received a recap of its discussions before continuing its work on the development of a U.S. protocol that simulates or is similar to Eurotransplant's recipient-oriented allocation model. Such a model would leverage simultaneous offers and candidate selection to maximize the efficiency of a rescue model.

Summary of Presentation:

Previously, this Workgroup expressed support for modeling an expedited placement protocols similar to the Eurotransplant Recipient-Oriented Allocation model (REAL). This model utilizes simultaneous offering and candidate selection to nearby programs to expedite allocation for recovered kidneys. For REAL, all transplant centers in the country or region where the graft is located are contacted. For each center, potential recipients and respective original standard ranking are listed in an online application. These centers may select up to three designated potential recipients for transplant, and this information must be entered within 50 minutes after receiving the offer. When this period has expired, Eurotransplant offers the organ to the highest ranked candidate of the designated potential recipients identified during this exercise.

For the proposed U.S. REAL protocol, the Workgroup had discussed programs submitting up to three candidates. Workgroup members recognized that sunk costs included the overall offer evaluation per donor, balancing program resources and ensuring a backup candidate. Centers could designate less than three candidates if they chose to do so. Programs would have 60 minutes to evaluate the offer and designate their candidates (as opposed to the 50 minutes in Eurotransplant REAL).

The group ended its last call without a decision on:

- How many programs should receive simultaneous offers within the expedited placement pathway. If offers originate within OPOs, should the workgroup designate a certain number of OPOs to participate in the protocol and those OPOs designate a specific number of local programs?
- How is program qualification determined? (SRTR offer acceptance metrics? Recovery and Usage Map (RUM) report) Or should programs be allowed to opt in (and not put forward names if they are not interested in an offer)? The latter would be transparent and give programs a chance to accept these kidneys
- How will OPOs know which programs it may offer to?

Workgroup members were asked to continue discussions to address these questions.

Summary of Discussion:

An SRTR representative suggested that the SRTR offer acceptance metrics sequence number greater than 100 makes sense. Data could be reviewed to determine at what sequence number there is some association with increased risk of non-utilization. The Workgroup Chair noted that in addition to sequence number, cold ischemic time had also been discussed. She questioned whether the SRTR could provide data on whether any of these elements individually or in combination could make the determination of when to move to this protocol easier for OPOs. OPTN Contractor staff noted that the OPTN Kidney Transplantation Committee has previously reviewed program-wide declines, stratified by Kidney Donor Profile Index (KDPI). This data could be helpful in determining a metric or trigger to initiate expedited placement that is more standardized.

A Workgroup member noted concern regarding using a sequence number alone to trigger expedited placement, sharing that geographic location could impact this. In the northeast, there could be 40

different programs considering an offer where in a less densely populated area there may be only two or three. The member suggested that cold ischemic time may be very different for what one OPO must get through to complete 100 offers versus as compared to another in a more rural area. For this reason, cold ischemic time was preferred by this member. It was suggested that offering to the first 100 candidates scattered across many transplant programs in a dense area could literally take 50 hours in a densely populated area. This would only exacerbate turndowns for cold time, especially on an already marginal kidney.

Workgroup members were asked to share their thoughts on whether expedited placement should be initiated prior to crossclamp, or whether crossclamp could be a trigger for expedited placement, especially for high KDPI organ. As the discussion evolved, members discussed the potential for two different versions of the protocol: (1) a pathway for donors with favorable characteristics where sequence number and cold ischemic time trigger expedited placement; and (2) the donor has certain characteristics known to lead to non-use or allocation out of sequence, so the process begins preemptively rather than waiting for the sequence number or cold time trigger.

A member was favorable of this two-pronged approach but noted more transparency with offering out in an open system rather than preselecting centers to receive these expedited offers. The member emphasized the benefit of giving all centers the opportunity to engage in the protocol. Committee members agreed that the protocol will need to be tested in a mix of geographic and regional areas, and some questioned the success of the protocol if local centers were selected and did not accept the expedited organ offers, or if all "aggressive" centers distant to the OPO were selected, bypassing local programs who may have accepted for candidates much further down the list in sequence. Balance will be needed in determining qualifying centers if this is the model that is selected.

The Workgroup also discussed using the 250 nautical mile radius to determine participating centers. Members acknowledged the challenges and complications here of unlocking the full waitlist and having centers designate preferred candidates. The Workgroup considered the potential for multiple rounds of expedited offers, in order to reduce the number of programs evaluating the offers simultaneously. All programs within 250 nautical miles could receive the option to identify up to three candidates appropriate for the kidney offer. The organ would then be allocated to the highest ranked (lowest sequence number of the match run) identified candidate. If no centers put forth potential candidates, the next round of open offers could be made to known "aggressive" programs who meet qualifying criteria regarding their acceptance behaviors using the Recovery and Usage Model (RUM) report.

A member also noted that "aggressive" centers in some areas are exhausting their list of appropriate candidates for these hard to place donors after accepting many of these types of donors. A workgroup member shared that hard to place organs that were accepted and transplanted by these "aggressive" centers a year ago are much more challenging to place now. For this reason, limiting the protocol to a select list of "aggressive" centers may not have the desired outcome. The member recommended casting a wider net to seek program interest without the added cold time. The member noted that allowing programs to consider the offer for anyone on their list, while still using match list rank order for the final determination of primary offer receipt, may create opportunities for other centers to consider these offers in a different way. The RUM report could then be used to monitor changes in behavior, particularly if it could be updated weekly while these protocols are tested.

Workgroup members discussed potential risks of offering first to all programs 250-mile radius before including known "aggressive" centers beyond 250 nautical miles, noting that cold time may then add to challenges when offering these hard to place kidneys to "aggressive" programs, and that this could lead to nonuse. Alternatively, a member expressed concern for placing undue burden on "aggressive" centers that may assess the donor and identify candidates only to find that the kidney(s) was placed

much higher on the match run if the protocol utilized simultaneous offering to all nearby and qualifying programs. The Workgroup Chair noted that this is part of the process, and most aggressive centers are used to the risk versus benefit here related to workload burden. The Workgroup was comfortable with including all programs within 250 nautical miles and some qualifying "aggressive" programs beyond 250 nautical miles in the initial expedited open offer. All of these programs could then submit up to 3 potential candidates as they choose. One member remarked that it is better to offer to "aggressive," more distant programs earlier, and that this allows these programs to opt out of these offers if they choose.

An OPO representative on the Workgroup noted that it will be challenging to identify which kidneys would qualify for expedited placement, particularly early in allocation and prior to cross clamp. The Workgroup agreed that it will be important to start this pilot on a smaller scale, perhaps with high KDPI kidneys and acute kidney injury (AKI) donors. A member remarked that the SRTR models take the blended approach for transplant centers, focusing of how a specific center accepts a specific type of organ for a specific type of candidate. OPOs are held strictly to an expected yield that is completely focused on the donor does not include this blended approach that includes candidate influence. He questioned whether there may be value in marrying these two practices to include a donor yield predicted from the SRTR results for the type of kidneys to be offered to determine what should be anticipated to be accepted by each center. The current data does not fully account for acceptance practices within a program, as it is not clear whether the center may just be the beneficiary of open offers. The member remarked that the raw data is critical here to determine whether programs are accepting these offers at high sequence numbers in standard allocation, or if these programs are also receiving offers out of sequence for these organs. Additionally, the RUM report does not take into account actual clinical characteristics of the candidates for whom these kidneys are accepted. Workgroup members agreed that there is no specific report that captures these elements and connects them to answer this question.

An SRTR representative acknowledged that the protocol would be tested by a smaller number of OPOs, and that these OPOs may already know which programs are "aggressive" and who to call in addition to the programs within the 250 nautical miles. A member responded that transparency is needed for both the transplant community and the public in how OPOs identify target centers for expedited allocation, and that there is not currently transparency in how OPOs determine which programs to make out of sequence allocation offers to. Members agreed that it is important to offer the organs to those programs known to routinely use these harder to place organs in order to ensure successful placement and transplant. A member expressed concern that patients may be disadvantaged because their program did not qualify to receive offers. The Workgroup agreed that transparency and objective qualification based on data are critical.

A Workgroup member noted that expedited placement does not address the root cause of non-use, at least in their region. The member noted that their OPO is able to place kidneys with programs who have expressed interest prior to recovery in only about 11 percent of cases. The member explained that their OPO is constantly having to reallocate, which results in additional cold time and only enhances the difficulties of placement. Members recognized the challenge of developing a protocol where programs are not being excluded, but efficiency of offering is achieved.

Upcoming Meetings

July 8, 2024

Attendance

- **Workgroup Members**
  - Caroline Jadlowiec
  - Chandrasekar Santhanakrishnan
  - Anja DiCesaro
  - George Surratt
  - Jami Gleason
  - Jason Rolls
  - Jillian Wojtowicz
  - Jim Kim
  - Kristen Adams
  - Leigh Ann Burgess
  - Megan Urbanski
  - Micah Davis
  - Sanjeev Akkina
- **HRSA Representatives**
  - James Bowman
- **SRTR Staff**
  - Peter Stock
  - Bryn Thompson
  - Jonathan Miller
- **UNOS Staff**
  - Kayla Temple
  - Kaitlin Swanner
  - Lauren Motley
  - Thomas Dolan
  - Houlder Hudgins