OPTN Kidney Transplantation Committee
Expedited Placement Workgroup

Meeting Summary
August 19, 2024
Teleconference

Chandrasekar Santhanakrishnan, Chair

Introduction

The OPTN Kidney Transplantation Committee's Expedited Placement Workgroup (the Workgroup) met via teleconference on 08/19/2024 to discuss the following agenda items:

1. Welcome
2. Discussion: Expedited Placement Protocols

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

1. Welcome

The Chair welcomed Workgroup members and thanked them for making time to participate in these important discussions.

2. Discussion: Expedited Placement Protocols

Committee members received an overview of work to date regarding the variance protocol in development. This Workgroup's variance is loosely based on Eurotransplant's Recipient-Oriented Allocation (REAL) System for expedited placement.

Summary of Presentation:

The expedited placement variance protocol submission template includes:

- Explicit clinical criteria for organs eligible or 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

Expedited placement variance protocols will be monitored for pediatric access, potential racial disparities, and potential gender disparities. An individual monitoring report will be created for each protocol that is approved and tested.

This variance does not include significant IT programming resources, and this must be kept in mind when considering which aspects should be tested.

Feedback from the Rescue Pathways workgroup noted that it is helpful to break down the protocol submission into key elements to be tested within the protocol. The

- Candidate selection and submission
- Prioritization of expedited offers using the original match run
- Simultaneous offer evaluation

- Specific transplant program and OPO responsibilities and timelines
- Pre-clamp and post-clamp criteria

Previously, the Workgroup discussed the following Transplant Program Expectations:

1. Expectation that the program determines a more general list of candidates that they would deem to be appropriate to accept expedited placement offers, ahead of receiving the offers
2. Programs are encouraged to discuss expedited placement and similar offers with these patients, to ensure patients understand their options and may make informed decisions on transplant goals
3. Expectation that program accepts and transplants the organ for which they have designated a candidate
    a. Require that program use more detailed code to describe late decline
    b. Late declines should be monitored, and repeated late decline should result in review and potential removal from protocol
4. Expectation that program designates candidates they are willing to transplant based on virtual crossmatch results
    a. Programs not comfortable with this expectation should opt out of the protocol
5. Expectation that the program has performed general patient screening and notification to ensure wellness, readiness, and due diligence that the patient is interested in accepting the organ
6. Back up candidate prepared to accept the organ?

Summary of Discussion:

The Chair remarked that late decline related review processes should be clarified, and asked which body would be responsible for this process and determining whether a program should no longer partake in the protocol. The Chair noted that it is important not to penalize programs for not accepting organs, although there could be discussions with the program about whether they would continue to opt in. The Chair asked if there would be an appeal process as well. OPTN Contractor staff followed up, asking the Workgroup if there was a threshold or number of late declines that would need to trigger such a process; alternatively, if there are scenarios where late decline may be more appropriate.

One member pointed out that, in initial stages, it may be helpful to understand why programs are declining late before considering a process to hold late declining programs accountable. The member continued that gathering data and information on late declines may be more useful here. Another member agreed, adding that there may need to be additional decline codes to support such analysis. A member agreed.

The Chair remarked that late decline could be logistical, particularly if flight availability is limited and prevents placement with a distant program. The Chair continued that late declines can be attributed to a number of issues, including logistical, clinical, and program behavioral. The Chair added that a center could be late declining due to lack of resources, which may be less common for larger centers that can accommodate greater volumes. The Chair added that it is important to capture the reason for late decline.

Another member agreed, expressing support for improving late decline codes in order to standardize outcomes data, in a protocol but also generally. The member continued that a search function within the decline codes could support increased user compliance and data quality. The Chair agreed. The member remarked that there needs to be a longer list of more detailed codes, and that the method for inputting codes should be more efficient and less burdensome. One member offered that there could be a unique set of decline codes for the pilot group, organized by drop downs, to improve compliance and

analysis. The Chair agreed, noting that the decline codes could be sorted by logistics, center, candidate, and other categories. A member offered that degree of detail may need to be more granular for the protocol, offering the example that "kidney biopsy unacceptable" may not be adequate, particularly if it is due to lack of kidney biopsy performed.

The Workgroup agreed that it is important to collect data to better understand late declines, as opposed to building accountability frameworks.

One member remarked that the Workgroup could easily develop a list of reasons for late decline, such as recipient unstable, recipient testing not complete, and others. The member added that logistics could be included, as well as biopsy results received after organ receipt. One member offered that new biopsy findings could be included. The Chair pointed out that "incomplete data" could be included. The Workgroup discussed the inclusion of crossmatch-related late decline codes, including delayed crossmatch. A member also offered that anatomy findings could be considered.

A member remarked that the OPTN has not yet defined late decline, but that it would be important to have a standardized definition. Another member responded, noting that this would apply to those kidneys that have already gone into expedited placement, and a program has already identified up to three candidates, and then declines the organ. Another member agreed.

One member proposed that "late decline" be defined as when the transplant program has all the information needed to make their decision, and then later declines based on information they had earlier upon acceptance. The member expressed that in these cases, it is difficult for anatomy to be a valid decline reason, because those reports are posted prior to acceptance. Another member responded that discrepancies should still be considered, and others agreed.

The Workgroup discussed the following potential late decline codes: recipient instability or illness; logistics – transportation availability; logistics – transportation issue; discrepant or new biopsy results; delayed crossmatch; and unacceptable new pump parameters.

OPTN Staff asked the Workgroup about a potential expectation for a program to have a back up candidate prepared. One member expressed support for an expectation that programs bring in and prepare a back up candidate, in case the primary candidate is unable to accept the organ unexpectedly. Another member remarked that this could be difficult for blood type B or AB donors, but that it would be helpful for OPOs to be aware upfront that a program does not have a back up and prepare to reallocate if necessary. The member continued that the OPO could ensure there is a back up candidate prepared at another center too, if necessary. Other members agreed.

One member asked how patient education and communication varies with respect to backup or primary offer, specifically whether the patient is notified as back up, or simply made aware of the offer. A member responded that programs should be very transparent with patients about when an offer is primary or back up. Another member agreed, sharing that their program ensures the patient understands the nature of the offer and counsels patients on back up options throughout check in and evaluation. The member shared that often, patients are excited to receive the back up offer.

One member asked if the kidneys allocated via the protocol would be granted waivers. The Chair remarked that this is something that the Workgroup should consider, and expressed that programs that are more willing to take these kidneys and related risk should be granted full waivers. The Chair continued that there has been some countering on this point, as programs will already have the information, but noted that the waivers could support increased acceptance of these organs for more risk-averse programs. The member responded that it is a good point to consider depending on whether a general waiver or a specific waiver is being considered. The member posed a hypothetical scenario

where an OPO would be expected to provide biopsy waivers if access to biopsy images is not available. The member continued that it may not always make sense to grant full waivers to programs who are unsure about accepting the organ due to a number of already known clinical factors. The Chair agreed, and noted that specific waivers, particularly related to biopsy, anatomy, and pump, may be more useful. Other members agreed, particularly noting the importance of waivers where donor or organ information is not clear or readily available at time of organ offer. Another member agreed that there should be sound logic supporting the waiver request. One member expressed support for a pre-established standard or process for granting waivers, particularly considering the medical complexity of the organs that would be allocated via expedited placement.

A member asked if the protocol will need to consider cold ischemic time and transportation over greater distances. OPTN Contractor staff noted that the Workgroup has not finalized this decision yet. The member remarked that transportation poses several new considerations, including the potential for delays or organ loss, at no fault by the transplant program or OPO. The member remarked that the protocol could be geographically limit, which would remove these transportation questions.

Presentation summary:

The Workgroup discussed the following OPO expectations:

- OPOs are strongly recommended to share as much donor information as possible, as quickly as possible
- OPOs are expected to make efforts to pump organs requiring expedited placement
    - This would not be a definitive requirement for participation in the protocol
    - Pumping may not be possible, appropriate, or in the best interest of these organs; in these cases, OPOs are expected to notify programs of pump decision as early as possible
        - Pumping should not take precedence over timely transportation
    - Programs must determine acceptance or decline after 4 hours of pumping
- OPOs are expected to make efforts to ensure biopsy results are available within 6 hours of cross-clamp
    - OPOs are strongly encouraged to share biopsy slide images
- OPOs are expected to make efforts to post anatomy information as soon as possible
- OPOs are expected to take images of the organs and share them to the OPTN Donor Data and Matching System
    - Includes front and back of the kidney, view of the aortic patch
- Expectation or encouragement that OPOs provide waivers for information that is not available or may be discrepant, or transportation?

Summary of discussion:

OPTN Staff asked if there should be an explicit expectation that OPOs are sharing donor information as rapidly as they can. A member remarked that OPOs are already doing this, and are highly motivated to place organs, and so this may not be necessary.

One member remarked that the medical complexity of organs offered through expedited placement may justify pump in most cases, particularly with consideration for donation after cardiac death, high kidney donor profile index (KDPI), and cold ischemic times. The member continued that there may be other kidneys that may not need to be pumped, and so a pump requirement may not be necessary. The member added that OPOs seem to be pumping more frequently as well.

OPTN Contractor Staff asked the Workgroup if there should be a standard time threshold for turning around anatomy and other post-clamp donor and organ information. The Chair offered that a time

threshold should be included, and offered 2 hours after the kidneys have been recovered. The Chair asked if this threshold should be based on cross clamp time, or after full recovery of the kidneys, noting that kidneys tend to be recovered last when other organs are also recovered. Another member remarked that this threshold should be based on the time the kidney is fully recovered, since that is the point at which anatomical evaluation can be started. Others agreed, noting that 1 hour after full recovery would be appropriate.

One member explained that OPOs may not have control over when the anatomy is provided, particularly as the recovering surgeon is responsible for this decision. The member noted that some recovering surgeons wait to evaluate kidney anatomy until the liver is on the pump, and that it is not always possible to have an OPO's recovering surgeons in every organ recovery due to case volume. The member offered that this expectation should not be seen as an absolute requirement. Others agreed.

The Workgroup agreed that OPOs should be encouraged to make efforts to provide the anatomy information within an hour of full kidney recovery.

OPTN Contractor Staff asked the Workgroup about the expectation regarding organ imaging, asking if there were specific images that should be included. The Chair agreed that images of the front and back of the organ and the aortic patch were sufficient, but that this practice needs to be standardized. The Chair added that labeling is also important, so that it is clear which organ is being photographed. One member explained that aortic and donor patch photos are helpful, particularly with consideration for heart disease and other pathologies.

Presentation summary:

The Workgroup discussed additional considerations, including:

- Protocol should leverage retrospectives to evaluate program behavior
    - Potential for intervention to assess reasons for declines, etc. and offer feedback to change and remediate behavior

The Workgroup also considered allocation priority:

- The initial protocol put forth by the OPTN Rescue Pathways Workgroup will require OPOs to make offers to candidates in the following classifications:
    - KDPI 86-100 percent: Classifications 1-19
    - KDPI 75-85 percent: Classifications 1-26
- These classifications include 100 percent Calculated Panel Reactive Antibody (CPRA) candidates, 0-ABDR candidates, prior living donor, medically urgent, 98-99 percent CPRA candidates, and prior liver/heart/lung recipients

Finally, the Workgroup considered notification timeframes:

- Should the protocol include specific notification timeframes?
    - When is it appropriate for OPOs to notify programs about the donor's potential qualification for expedited placement?
    - Are there other key time points where notification may be critical on specific timeframes?

Summary of discussion:

The Chair remarked that these classifications reflect the highest priority classifications and candidates, and agreed that it is important that candidates in these classifications receive these offers prior to initiation of expedited placement. The Chair continued that expedited placement would not begin until

later in allocation anyway. The Chair pointed out that the most highly prioritized candidates are more likely to be worked up and ready to receive an offer due to their priority. Others agreed.

One member pointed out that timing of crossmatch may factor in for the most highly sensitized candidates, particularly because allocation may be pending the ability to send crossmatch materials to the program ahead of recovery so that the center can perform a physical crossmatch. The member continued that this could impact allocation time is the organ is already at risk of non-use. Another member offered that programs hoping to accept for highly sensitized candidates should consider having a back up candidate. Others agreed that it makes sense for programs with highly sensitized candidates to have a back up candidate prepared.

A member emphasized the importance of programs ensuring their back up candidates are available and present at the program, instead of at home waiting, in case transplant of a candidate with a primary offer cannot go forward. The member continued that this should be encouraged, not necessarily required. The member noted that this can make a difference of several hours.

One member noted that the protocol's trigger criteria has not yet been finalized, and that this would be critical to understanding appropriate notification timeframes. The Chair offered that the trigger criteria may align more with the "hard to place" kidney definition that the OPTN Kidney Transplantation Committee is working to build. The Chair continued that it may be more difficult to determine that an organ will be offered via expedited placement prior to recovery. The Chair continued that even if a donor was identified as potentially requiring expedited placement prior to recovery, the OPO would still need to offer through the initial classifications. The Chair continued that expedited placement should be initiated post-recovery, based on the donor data available at that point. Another member agreed, noting that pre-recovery initiation of an expedited placement protocol could be based on a combination of a significant number of declines and concerning clinical criteria prior to recovery. The Chair asked if this would work such that expedited placement would be triggered prior to organ recovery based on sequence number. The member responded that they feel it is important for there to be an expedited placement pathway for pre-clamped kidneys, particularly if there is already difficulty placing the organ prior to recovery. The Chair agreed, noting that there may be scenarios where it is appropriate to initiate expedited placement prior to recovery for kidneys with the greatest difficulty in placement. The Chair continued that the other scenario includes a kidney with some concerning clinical factors, for which post-recovery information ultimately results in triggering expedited placement.

A member remarked that, although the definition of "hard to place" is still being developed, once a kidney has been identified as at increased risk of non-use, the notification and initiation of expedited placement should be immediate.

One member asked what a reasonable timeframe would be for OPOs to move through the expedited placement workflow and send out notifications. A member responded that an hour would be appropriate. Others agreed. One member remarked that everything should be done as quickly as possible, but if a specific timeframe is helpful for standardization, an hour is a reasonable amount of time for OPOs to notify programs that expedited placement will be initiated.

The Workgroup supported a 1 hour notification timeframe for OPOs when expedited placement is initiated post-recovery, and noted that this similarly aligns with the 60 minute evaluation period for programs.

Upcoming Meetings

September 16, 2024

Attendance

- **Committee Members**
  - Chandrasekar Santhanakrishnan
  - Carrie Jadlowiec
  - George Surratt
  - Jason Rolls
  - Jillian Wojtowicz
  - Jim Kim
  - Kristen Adams
  - Leigh Ann Burgess
  - Micah Davis
  - Stacy Sexton
- **HRSA Representatives**
  - James Bowman
- **SRTR Staff**
  - Bryn Thompson
  - Jon Miller
- **UNOS Staff**
  - Kayla Temple
  - Shandie Covington
  - Kaitlin Swanner
  - Ben Wolford
  - Thomas Dolan