OPTN Kidney Transplantation Committee
Expedited Placement Workgroup

Meeting Summary
August 5, 2024
Teleconference

Chandrasekar Santhanakrishnan, Chair

Introduction

The OPTN Kidney Transplantation Committee's Expedited Placement Workgroup (the Workgroup) met via teleconference on 08/05/2024 to discuss the following agenda items:

1. Welcome
2. Discussion: Expedited Placement Protocols (Recipient-Oriented Allocation (REAL) System)

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. He set an ambitious goal of finalizing a proposed variance protocol by the end of August.

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

Workgroup Members were reminded that these protocols will not include significant IT programming resources. This is important to keep in mind when considering how the protocols will be implemented effectively and efficiently.

Protocols approved for implementation will be monitored, at a minimum, 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.

To date, only one protocol (developed by the Expeditious Task Force's Rescue Pathways Workgroup), has been approved. There are plans in development for the Rescue Pathways group to provide an update to this Workgroup on a future call.

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, including:

- 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

The Workgroup previously discussed candidate selection and submission, with a desire to prioritize original match run order while using simultaneous offer evaluation for up to three candidates per participating transplant program. Qualifying programs will have the same 60 minutes from final organ offer information to designate and submit these candidates for whom they would accept the offer. After the evaluation, the highest ranking of these selected candidates will receive the organ.

OPO responsibilities were re-capped, noting that pre- and post-clamp activities and timelines may be informed by some of the Kidney Committee's hard-to-place discussion as well.

Specific transplant program and OPO responsibilities and timelines for participation were also briefly reviewed. The Workgroup has discussed the tension between managing the number of programs approved for participation, and how this would impact the number of programs receiving and reviewing offers at once. The Workgroup noted that it is important to avoid burnout for programs evaluating organs that have a low likelihood of receiving for a candidate. Workgroup members agree that it is not feasible to notify all local programs for certain OPOs (with a high concentration of local centers, e.g. the northeast). Many programs receiving offers at once decreases the likelihood of any program receiving the organ in such cases. Concerns regarding transparency of process and feasibility were discussed at length.

Workgroup members reviewed the process map created to step through the expedited placement pathway from OPO and transplant activities and considered outstanding decision points highlighted for discussion. For OPOs, a match run is initiated and the OPO then determines one way or another that a donor meets criteria for expedited placement- this may be after standard allocation to priority classifications. Approved expedited placement programs might be notified that this donor is going to potentially be allocated through an expedited placement pathway. At this point, programs will begin narrowing down to their three potential candidates for an expedited offer of this kidney. As recovery occurs, the OPO will determine whether pump and biopsy is appropriate and initiate those processes. The OPO may need to continue allocation through all priority classification offers. After this point, the approved expedited placement programs would then be notified that they have one hour to review donor information and select up to three potential recipients. During this time, centers will be considering virtual crossmatch results, looking at transportation options to get the kidney from the donor hospital to the program, checking in with their identified candidates to ensure readiness and health. Up to three candidates must be submitted by the end of this hour. The organ would then be offered to the highest priority expedited placement candidate on the match run.

Workgroup members were encouraged to explore the transplant program side of this process chart first. Members were asked to explore:

- For transplant programs: What are the specific transplant program expectations? What is the timeline for the completion of these items in the model being explored?
- For OPOs: What are the specific OPO allocation and notification expectations? What are the timeframes for these responsibilities?

Summary of Discussion:

The Chair shared that the expectations for these programs are not totally dissimilar for a regular kidney offer. The Chair noted that programs generally have an idea of which candidates on their lists who may be an appropriate match for a kidney from a medically complex donor, and OPOs anticipate that programs may have identified several of these patients prior to recovery. Currently, many programs evaluate the match run and inputting refusal codes for candidates who may not be appropriate for the offer, while inputting provisional yes for candidates for whom they would consider accepting the offer. In the case of the draft protocol, these centers would identify their top three candidates and share this information with the OPO. The program would then begin to perform virtual crossmatch.

Members raised concerns about the protocol setting overly prescriptive time requirements for specific evaluation tasks, especially related to identifying appropriate candidates. Workgroup members noted that there is essentially an honor system in place, where programs are obliged to accept the kidney and transplant it into the candidate that you identified. One exception was noted here in instances where a kidney is received, and upon arrival, new findings are discovered that were previously not shared and incompatible with safe transplant for identified recipient(s). Workgroup members suggested that there are very few instances where this happens. Historically in such cases, the OPO worked with centers to reallocate and ship the organ.

One concern was shared regarding OPO offers without complete information. A Workgroup member noted that some OPOs are asking that programs accept an offer pending pump numbers or biopsy results. Rather than noting this as a provisional yes, it had been recorded as an acceptance. This was concerning to Workgroup members whose acceptance as binding - in this case, accepting without all the relevant information. Workgroup members discussed concerns regarding wording here, and the use of accept versus a provisional acceptance.

From the OPO perspective, program overuse of the provisional acceptance code was noted here as well. To OPOs, this indicates that the center is going to accept the organ, given limited concerns resulting from biopsy results or pump numbers. In some cases, even after receipt of unremarkable biopsy findings, centers are declining the kidney. Overuse of provisional yes can mystify a program's commitment to acceptance for a particular organ at any given center for OPOs hoping to ensure placement. Committee members suggested that this type of behavior would not be acceptable in the expedited placement pathway as it could only exacerbate non-use if participating programs do not follow through.

Workgroup members discussed whether pumping should be a prerequisite to qualifying for the expedited placement pathway. Variability in OPOs' willingness to pump kidneys was acknowledged. Pumping was also noted to open up additional questions or requests that could complicate the pathway- how long the organ should be pumped, whether specific flow and resistance are requested, and other questions. There was a suggestion that all donation after circulatory death (DCD) kidneys should be pumped and biopsied to increase utilization. The Workgroup may consider pumping as a pre-requisite to protocol participation. Pros and cons of pumping were discussed, noting that location matters here as well. Pumping a kidney is not always feasible and may delay its travel to an accepting center. Several members noted that pumping not be appropriate for all organs, particularly in instances where pumping could prevent timely transportation.

Members discussed virtual crossmatching as required versus preferred. The time required for a physical crossmatch was seen as adding cold time to these already hard-to-place kidneys, reducing the benefits of expedited placement. There was concern shared that some histocompatibility labs may push back and could impact some participation in some locations. A member recognized that virtual crossmatch is

standard of care in some programs. If there are OPO and centers not doing it, perhaps the question of why should be posed, especially for lower calculated panel reactive antibody (CPRA) candidates. One member remarked on a need for increased uniformity in virtual crossmatching and histocompatibility practices, and others agreed.

A Workgroup member suggested that protocol guidelines should be developed to outline what OPOs and programs should have in place to participate in the protocol. If a transplant center does not have a workflow for considering and accepting expedited offers, then the protocol will be unsuccessful. This document could include virtual crossmatch, pumping requirements, and biopsies with electronic links that allow for easy review by the transplant center. Members remarked that uniformity in the characteristics of these offers and a focus on a select group of kidneys will be more likely to show a successful result. A member remarked that running the protocol in a small group of OPOs and centers would demonstrate the principle of how this can work and may encourage more OPOs to pump kidneys.

In summary of the discussion, the Workgroup outlined the following specific transplant program evaluation expectations:

- The program will determine a general list of candidates that they would consider for expedited placement offers:
    - Important to ensure transparency and objectivity in qualification requirements
    - Important to ensure patients are identified and educated ahead of allocation, to ensure patients understand what to expect and ensure these offers align with their transplant goals
- The program will designate candidates they are willing to transplant based on virtual crossmatch results, and potentially without physical crossmatch results
    - Important to note that some histocompatibility labs may push back; in these instances, the program may need to opt out of the protocol
- The program has completed the evaluation, including virtual crossmatch, wellness check, candidate availability confirmation, etc. before designating the candidate to accept the organ
- The program will accept and transplant the organ for which they have designated the candidate, barring unforeseen circumstances
    - If a program accepts an organ and ultimately has to decline to transplant the patient, the center must provide a more detailed explanation to provide insight into the late decline
        - Important to track instances where a program accepts for one candidate and must transplant into another in order to promote transparency and equity
    - If participating programs are routinely and repeatedly declining, this must be tracked and understood

The Workgroup's conversations next shifted to discuss OPOs expectations.

Whether or not to require pumping was thoroughly discussed by the Workgroup. While recognizing there are instances where pumping would not be beneficial (increasing cold time when a kidney could be en route to center on a plane), it was noted that biopsied and pumped kidneys are easier to place. Pumping, however, should not take precedence over timely transplant. In general, the group was supportive of encouraging pumping, but did not want it to be a rule out or discourage OPOs from wanting to participate in the protocol. The hope is that the protocol data will ultimately reflect that pumping helps in placing these kidneys.

The Workgroup noted that pump data can sometimes be used to delay decision making, as programs request to see more pump numbers, even though cold time continues to accrue. Members suggested a

cap of four hours on pump before acceptance decisions would be required, noting that two hours could generally give a sense of how numbers are trending, and four hours allows for some variation in pump machines.

The timing of biopsy results was also discussed. Great variability was noted in receiving anatomy information depending on the location of the procurement. Workgroup members discussed whether a standard timeframe of having slides and/or a report uploaded for review. This information was seen as essential for the expedited pathway. One Workgroup member on the call noted that they've set a 4-hour window post crossclamp for having biopsy and initial pump numbers available at their OPO. This may be challenging in larger territories.

A Workgroup member asked whether there is value in setting a limit for the time it takes to post an anatomy sheet in the OPTN Computer system. Workgroup members remarked on the value of images of the organ, particularly if pictures are detailed and uniform, including: front, back, ureter, aortic patch. The Workgroup remarked that this could be included in guidelines or expectations, and that organ images could be provided in 2 hours in most cases, though this is at the mercy of the recovering surgeon. A Workgroup member asked if this timeline could be set based upon extraction of the kidney rather than crossclamp time. From there, one would anticipate the information being available within an hour of kidney recovery. There was concern that extraction is fairly subjective in terms of what organs are being recovered and when. Anatomy was seen as a major driver in decision-making, though most programs would be expected to wait for the biopsy before declining the offer.

Workgroup members agreed that OPOs typically work to make this information available to programs as quickly as possible, and that this expediency makes decision making easier and faster. The Workgroup agreed that while it may not be appropriate or feasible to set specific time thresholds, target thresholds could be set as strong recommendations for OPOs participating in expedited placement.

Upcoming Meetings

August 19, 2024
September 16, 2024

Attendance

- **Committee Members**
  - Chandrasekar Santhanakrishnan
  - Tania Houle
  - Caroline Jadlowiec
  - Carrie Thiessen
  - Jason Rolls
  - Kristen Adams
  - Leigh Ann Burgess
  - Micah Davis
  - George Surratt
  - Megan Urbanski
  - Jillian Wojtowicz
- **HRSA Representatives**
  - James Bowman
- **SRTR Staff**
  - Bryn Thompson
  - Jonathan Miller
  - Peter Stock
- **UNOS Staff**
  - Kayla Temple
  - Shandie Covington
  - Kaitlin Swanner
  - Lauren Motley
  - Kieran McMahon
  - Sarah Booker
  - Laura Schmitt