OPTN Expedited Placement Workgroup
Meeting Summary
July 22, 2024
Teleconference

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Introduction

The OPTN Expedited Placement Workgroup (the Workgroup) met via teleconference on 7/22/2024 to discuss the following agenda items:

1. Recap: Workgroup Scope and Goals
2. Discussion: Expedited Placement Protocols (Recipient-Oriented Allocation (REAL) System

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

1. Recap: Workgroup Scope and Goals

A review of this Workgroup's goals and scope was presented for consideration.

Summary of presentation:

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

The Rescue Allocation Pathways Work Group and Task Force:

- Developed the expedited placement variance, allowing potential expedited placement protocols to be tested in real time prior to formal policy development and implementation
- 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 Task Force to develop a kidney expedited placement policy (based on what these groups learn from the test protocols).
- Discusses expedited placement in the context of continuous distribution, including systems requirements.

Previously, the Workgroup has discussed developing an expedited placement protocol based on the Eurotransplant (ET) Recipient-Oriented Allocation Scheme (REAL). A number of questions have been considered in developing this idea, including how to determine which programs should receive placement offers. Discussions over the last few weeks have been focused on how to determine program qualification. A process map had been used to help determine where some decision points like and what such a protocol might look like. Similarly, the Rescue Allocation Pathways Workgroup is having similar conversations regarding the finer details of notification. Communication between these two groups will be important.

On the last call, the general process for allocation was reviewed using the process map. The Workgroup supported high CPRA candidates continuing to receive offers, as the number of offers they may receive would be smaller due to this high sensitivity. From there, programs identified as qualifying for an expedited placement protocol would be notified regarding the donor with clear communication that they may become primary for an expedited placement offer. Once the donor kidneys are recovered, the anatomy and any biopsy information (if completed) are then posted. The standard transplant centers that are involved are notified as are the expedited placement protocol centers so that all are receiving the same information and have ample time to evaluate the donor information as soon as it is available. At this point, if there are any standard allocation programs (e.g. high CPRA patient programs) with provisional yes status, they will need to make a final decision on whether or not to accept and transplant the organ. If not, then the organ would move to expedited placement. These programs would then have an hour to designate up to three potential recipients for the organ. As multiple centers each put up to three candidates forward as their selected potential recipients, rank/sequence number on the match run would then be used to determine which identified candidate(s) would receive the expedited placement offer kidney(s).

Centers who have done the work to put these offers in should make sure that their identified candidate is prepared to take the organ, would expect the offer and would be prepared to receive it. This expedited system would be expected to place these organs in an efficient manner. In looking at the large process map, decision points were identified as well as some evaluation responsibilities for the transplant program. For example, there may be a running list of candidates who would not be willing to receive a Hepatitis B positive donor kidney. These individuals should be screened by the center from such expedited offers for positive donor kidneys. Once anatomy and biopsy are received, the list may be narrowed down further before they begin to determine which virtual crossmatches to run, looking at transportation options, etc. At this time, initial check-ins with potential recipients could be explored. As the expedited placement offer goes live, any final items can be finished in the remaining hour. As outlined, this would not be a required way of considering these offers but rather a sense of what this process might look like. Expedited placement protocols will be tested with a small number of OPOs on a small number of donor organs. Any immediate concerns could be promptly addressed. Major programming changes and automation are not anticipated for these protocols, so it is important to work on a small scale so as not to overwhelm the OPOs or the participating centers. Bypass codes, however, are being developed so that OPOs testing these expedited placement protocols can make it clear why the match run is not be followed and provide data tracking to determine where organs were allocated.

In the interest of transparency, this group had discussed whether the protocol should be opt in or opt out rather than qualifying to participate, perhaps allowing all programs within 250 nautical miles access to expedited placement offers. There was concern, however, that population dense areas like Philadelphia, New York, and Boston with many programs in close proximity could overwhelm OPOs in this manual protocol process. Some of these areas have 40-45 centers in a 250-mile radius.

Summary of Discussion:

Discussion related to this topic was carried into the next agenda item.

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

Workgroup members discussed application of their ideas in developing a proposed protocol for Rescue Allocation Pathways Work Group consideration.

Summary of Discussion:

A Workgroup member asked if a final decision had been made on when expedited placement offers would be triggered. To date, this has not been determined. The Workgroup member noted that the situation may play a role in which centers are activated. They questioned where, if a local program had declined all offers in normal allocation, would this center then be excluded from expedited offers for the same organs. OPTN Contractor Staff noted that this can be discussed, but that the Kidney Committee had been discussing a desire to at least identify some instances based on data where organs are consistently noted as hard to place- what characteristics are consistently present in these organs. To date, the Workgroup has discussed cold ischemic time, sequence number (decline) triggers on the match run, specific clinical characteristics and Kidney Donor Risk Index (KDRI) or Kidney Donor Profile Index (KDPI) as potential characteristics that indicate hard to place organs.

Another Workgroup member recalled discussion of potentially allowing the top five ranking centers locally within the 250-mile circle that already have provisional yes noted on the match run. These centers could each put forward their potential candidates to move through the expedited placement process. If all five of these centers were to decline the kidney(s), then national centers with a demonstrated record for more aggressive offer acceptance could be notified. The member suggested that this maximizes the chance of a kidney being accepted without adding cold ischemic time. Ten centers would require ten phone calls rather than the 40-50 that could be required if all centers in a population dense area (in a 250 nautical mile radius) were required for contact. This would minimize the number of calls while still focusing on sequence numbers on match runs for allocation. It could be triggered post-clamp and activated by cold time accrued.

The Workgroup member recognized that creating an activation trigger based on more clinically complex items such as biopsy results, anatomy, medica history, and others will lead to such a diverse array of opinions on what might constitute legitimate trigger than consensus may not be reached.

Workgroup members then discussed how the five local programs would be selected, especially in a population dense area with many programs in the 250 nautical mile radius. A member suggested that the top five centers with provisional yes acceptances on the match run (e.g. one center has offered 15 provisional yes responses for its candidates on the match run). The member suggested that the top five local centers indicating interest in the donor could then be notified that this offer is now an expedited offer. Programs interested could identify their 2 highest, and the offer will be given to the patient with the highest-ranking sequence number among candidates identified.

Concern was noted that centers may overuse provisional yes on the match run, making identification of the five centers challenging.

Similarly, the trigger point for initiating expedited placement could also be a challenge. As an example, sequence number 100 was offered as the trigger to move to expedited placement. You may have mostly refusals in these first 100 offers with a handful of provisional yeses. A hard numeric threshold may be easier to maintain here. For example, if 75 percent of the first 100 candidates on the match run declined the offer.

A Workgroup member noted that, if cross-clamp has taken place and some local centers have declined for all candidates, but there are still more than 5 provisional yeses, that these centers should be included in the expedited offer. Another member countered, acknowledged that cold time is continuing to accrue, making these already challenging organs even more difficult to place. These centers should be kept in the top 5 on the list due to a level of interest, but these identified centers selected two potential recipients will help move more efficiently toward placement.

A workgroup member recommended using 6 hours as the trigger for expedited placement of more medically complex or marginal kidneys. There was concern shared regarding offering to only five

programs, especially if programs are smaller. It was noted that some smaller programs with a lower number of candidates may appear at higher sequence numbers on the match run and never receive an offer. A member suggested that 14 calls are made for local programs, making open ranked offers on expedited offers to help local programs avoid feeling excluded.

In considering the 6-hour trigger as an option, Workgroup members noted that the timing really depends on location and transportation availability too. In some locations, this would only add to cold time, as the OPO waits for the airport to re-open. The variability in how OPOs are currently handling expedited placement was discussed, and Workgroup members acknowledged that some regions would not be able to manage what works in others. With the many variables at play, a Workgroup member suggested keeping the pilot very simple, perhaps starting with only high KDPI kidneys. There was recognition that criteria may vary for each type of organ (Acute Kidney Injury kidneys, donation after circulatory death, etc.). A suggestion was made to start with high KDPI, noting that these are medically complex donors. Centers would be asked to identify three patients at the time of the initial match offer. From there, certain criteria where expedited placement would be triggered post-cross-clamp. These criteria may differ with cold time based upon the geography of an area. A member suggested that OPOs will need to maintain some discretion because they know that information in addition to sequence number and cold time.

With the protocol pilot, there is a desire to get down to a very focused group in order to collect data regarding the success of the proposed idea. A Workgroup member noted that the allocation pathway should be the same, but the focus should be narrowed to specific clinical characteristics, cold time and or sequence number to test the protocol. This will also offer transparency to the process. This was recognized as the tension point that the Workgroup continues to land on- a desire to make an equitable and transparent protocol while remaining realistic in creating an expedited pathway without full programming and automation. OPOs are limited to how many calls they can make in a limited time while keeping time for consideration the same for all centers to select their potential recipients without markedly increasing cold time.

For the purposes of today's call, the Workgroup considered initiation of the protocol post-clamp. Workgroup members had previously discussed a sequence number trigger and a cold ischemic time of 4-6 hours as alternate triggers. Data reviewed by the group showed the inflection point for non-acceptance starting to change radically at the 6-hour mark. This may vary somewhat from OPO to OPO, so there was a desire to find a median value. A Workgroup member noted a previous discussion suggesting starting at 4 hours post-clamp. Concern was raised by some Workgroup members that this may be too early in the process. The protocol will allow participating OPOs employing this variance to use the appropriate bypass code, avoiding MPSC review for out of sequence allocation.

A member asked how much time an OPO typically needs to collect all the relevant information, including biopsy, anatomy, etc. post-clamp. The member remarked that this information may not be completely available within 6 hours of recovery. Members recognized the level of responsibility for getting this information out to allow for consideration as part of acceptance. Another member suggested that the typical timeframe for having all of these informational elements is 3-5 hours post clamp, noting that timing, such as the middle of the night or weekend, may add time here. Geography may also play a factor. Flight availability in some rural areas and local pathologist availability were cited as big hurdles in the process. During all of this, cold ischemic time continues to accrue.

Workgroup members considered a scenario where provisional yeses or offered, including for a highly sensitive candidate: The OPO is continuing with standard allocation. Something unusual was noted in anatomy. A late decision to biopsy is made. Biopsy results are received 6 hours post-clamp. The Workgroup considered whether existing provisional yes responses should be honored in having the final

opportunity to accept the organ, or if allocation moves to expedited placement anyway. The Workgroup considered that these programs could at that point qualify for expedited placement and have the same hour to identify 2-3 potential recipients. Workgroup members were supportive of these individuals receiving final consideration in this manner, but also sensitive to the potential increase in number of calls OPOs may have to make - only leading to more cold ischemic time.

The Workgroup acknowledged the challenge of using cold time as a trigger, as some kidneys will be known as hard to place even prior to organ recovery. The longer the OPO waits to move to expedited placement, the less chance there is of placement as then cold ischemic time becomes an additional factor. A suggestion was offered that, for high KDPI kidneys, biopsies will be needed. Identifying potential recipients for these kidneys early will be beneficial and may even allow for dual kidney transplant to be considered. Workgroup members acknowledged that a 6-hour turnaround for biopsy results seems excessive, and questioned whether the protocol should be launched in donor service areas where this delay will not be an issue. A member suggested that, for the purposes of the protocol pilot, standards could be put into place requiring that biopsies be read within a few hours, access to local pathology, and electronic biopsy links be available to help streamline national offers. Such inclusion criteria were noted as better demonstrating what is possible.

Next Steps:

Workgroup members were encouraged to consider initiation of the expedited offer protocol pre- versus post-crossclamp prior to the next call.

Upcoming Meetings

August 5, 2024
August 29, 2024

Attendance

- **Committee Members**
  - Chandrasekar Santhanakrishnan
  - Jim Kim
  - Jason Rolls
  - Jami Gleason
  - Carrie Jadlowiec
  - Kristen Adams
  - Tania Houle
  - Jill Wojtowicz
  - Micah Davis
- **HRSA Representatives**
  - James Bowman
- **SRTR Staff**
  - Bryn Thompson
  - Jonathan Miller
- **UNOS Staff**
  - Kayla Temple
  - Thomas Dolan
  - Sarah Booker
  - Houlder Hudgins
  - Kaitlin Swanner
  - Lauren Motley
  - Ross Walton