OPTN Expedited Placement Workgroup
Meeting Summary
July 8, 2024
Teleconference

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Introduction

The OPTN Expedited Placement Workgroup (the Workgroup) met via teleconference on 7/8/2024 to discuss the following agenda items:

1. Recap: Workgroup Scope and Goals
2. Overview: Recovery and Usage Maps
3. Discussion: Expedited Placement Protocols (Recipient-Oriented Allocation (REAL) System
4. Adjourn

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

1. 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.

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.

A literature review has been completed by the Workgroup in an effort to understand strengths, weaknesses, and lessons learned from expedited placement protocols across multiple organs and in various transplant systems. As discussions continue, the Workgroup will:

- Develop expedited placement variance protocols for submission to the Expeditious Task Force's Rescue Allocation Pathways Workgroup
- Receive updates on its own and other expedited kidney placement variance protocols that are being reviewed, tested and analyzed by the Rescue Allocation Pathways Workgroup
- Consider, develop, and provide input on potential frameworks for policy and systems implementation of successful expedited placement protocol(s) to facilitate more rapid incorporation of a successful kidney expedited placement pathway into OPTN policy.
- Explore other alternative allocation pathways in Continuous Distribution, such as dual kidney allocation.

The Workgroup has been focused on developing an expedited placement protocol. TO date, it has favored basing this protocol on Eurotransplant's Recipient-Oriented Allocation Scheme (REAL). As part of these discussions, the Workgroup has considered a number of questions in the protocol development. A recent focus of these discussions is how to determine which programs should receive expedited placement offers- How is program qualification determined and how will OPOs know which programs they may offer the qualifying kidneys to in lieu of offering in sequence down the match run. These discussions have included:

- SRTR Offer Acceptance Metrics, including for "hard to place" organs
- Recovery and Usage Maps (RUM) report
- Program opt in or opt out, including:
    - All programs within 250 nautical miles and some programs outside of 250 nautical miles known as accepting "hard to place" organs
    - Geographical considerations related to the huge variation in the number of programs within 250 nautical miles of an OPO (e.g. New York or Boston versus Omaha)

Summary of Discussion:

There were no questions or comments.

2. Overview: Recovery and Usage Maps (RUM) Report

OPTN Contractor staff shared an overview with Workgroup members regarding how the Recovery and Usage Map (RUM) report works.

Summary of presentation:

The RUM report is a national report that is updated weekly and available to all transplant programs and OPOs. It is located in the data services portal. The report itself is an interactive Tableau dashboard that consists of two maps (recovery and usage) as well as a landing page that provides the user with an overview of some different national metrics per organ (raw number of deceased donor organs recovered and deceased donor transplants as an example).

The recovery map displays donor data for organs recovered in each donor service area (DSA). This information can be stratified by the user and filtered on different donor characteristics, infectious disease testing, donor body mass index (BMI) as well as organ specific filters. For example, when kidney is opened in the report, the organ specific filters include kidney donor profile index (KDPI) and terminal creatinine. Similarly, if you open for lung, the filters include terminal PO_2 and whether bronchoscopy was performed. This information can all be filtered on recovery date. The map visualization can be modified to review organs transplanted, donor volume, discard rate, utilization rate, SRTR observed vs expected yield, and DSA population. This information can be reviewed for a specific recovery date or a date span for all 50 states and Puerto Rico.

The usage map is the second map in the RUM report. Any filters selected in the recovery map will carry over into the usage map, but the filters can be reset at any time. The usage map displays the volume of transplants performed by transplant hospitals. This is also based on the same donor characteristics (infectious disease, donor BMI, etc.). The coloring used in this map is based on distance groups and nautical miles. When the user hovers over a particular center, you will see the number of transplant completed broken down by distance from center to donor hospital (e.g. 0-50 nautical miles, >50-150 nautical miles, >150 to 250 nautical miles, >250-500 nautical miles, >500-1000 nautical miles, >1000 nautical miles) for the selected date range. This can be toggled between the usage map and a bar chart that reflects the number of transplants across all centers. This information can also be reviewed by region.

The RUM report also includes a documentation tab that includes general information and definitions related to the tool and its use. This includes some information specific to the COVID-19 filters that are a part of the infectious disease results.

Summary of discussion:

A Workgroup member asked if the usage map could be filtered for a specific donor. The RUM report was used to demonstrate for a high and then a low KDPI donor, one who was HBV negative and a second that was HBV positive.

A member noted that larger centers appear to skew to more local donors based upon the coloring on the map. They did not question the data, but wondered what this explains in terms of center behavior.

Workgroup members asked if it was possible to filter by those centers who are not accepting medically complex donors. For the purposes of this Workgroup, it was recognized that identifying these centers could be helpful to target for implementing the protocol for testing. This could potentially be achieved by adjusting the filters accordingly. For example, screening for KDPI 86-100 with a specific terminal creatinine would identify which centers are accepting most of these organs. In this case, the process of elimination would address the Workgroup member's question. The usage map would identify which centers have a pattern of accepting these types of organs over the last two years.

Members of the Workgroup acknowledged appreciation for the report's usefulness in placing medically complex kidneys but noted that additional data points would be helpful, including glomerulosclerosis percentage, warm ischemic time, and pediatrics donors by weight, and en bloc kidneys were suggested as additions that would be very helpful in locating aggressive centers willing to accept these "hard to place" kidneys.

A member suggested that using the distance piece here may help, looking at programs that used more organs from locations beyond their 250 nautical mile circle may indicate that they are more aggressive. This comment was recognized, but the inclusion of more donor specific data points was seen as a more valuable addition here in working to place specific "hard to place" organs efficiently based on past behavior. OPTN Contractor staff noted that these additional datapoint could be looked at in a data report once they are more defined. The additional programming needed to update the RUM report as part of this proposed protocol was noted as a challenge, as the desire here is to move expeditiously to test ideas to find a solution and utilize more kidneys. The data request may be a shorter-term solution to identifying centers to participate in the protocol.

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

The Workgroup received a recap of its work to date on protocol development and then continued its discussions related to protocol development

Summary of presentation:

Previously, the Workgroup expressed support for modeling its Expedited Placement Protocol similar to Eurotransplant's Recipient-Oriented Allocation Scheme (REAL). REAL utilizes simultaneous offering and candidate selection to nearby programs to expedite allocation for recovered kidneys:

- All transplant centers in the country or region where the graft is located are contacted for REAL
- For each center, potential recipients and respective original standard ranking are listed in an online application
- Centers may select up to three designated recipients for transplant, and choice must be entered within 50 minutes after offer
- When this period has expired, the recipient is identified by selecting the submitted candidate with the highest ranking on the original match run

The Workgroup has discussed keeping the simultaneous offering to qualifying programs, but monitoring for the "disappointment" factor- how often are programs mobilizing resources (man hours in offer evaluation and related cost to programs) but not receiving the organ.

Workgroup members have discussed candidate selection and setting expectations with transplant programs related to evaluation and candidate selection (e.g. use of virtual crossmatch).

- Programs may have their own levels of comfort with transplanting higher CPRA candidates with only a virtual crossmatch
- Ensure verification with potential recipient, confirming that there are no changes in health or availability that would impede acceptance
- Sharing best practices to support offer evaluation resources

Patient education for participation was also discussed, noting that patients should be notified and education regarding the protocol ahead of beginning to receive organ offers.

Key monitoring points were discussed by the Workgroup, including examining instances where a program may accept for one candidate and transplant into another, late declines after expedited placement is executed, and solving for these issues.

During its most recent call, the Workgroup discussed how many programs should be eligible to receive expedited placement offers as part of the protocol and how many programs should receive an expedited offer at a time. For the number of programs receiving expedited placement offers as part of the protocol. There are, at most, two kidneys being allocated from a single donor. The larger the number of programs to receive an expedited placement offer, the less efficient is the use of program resources. With an increased likelihood of not receiving the organ, programs may experience burnout in protocol participation.

Program qualification was also discussed previously, including how program qualification to receive expedited offers will be determined. The SRTR offer acceptance metrics and RUM report may serve as resources, or program could be allowed to opt in or opt out. Members had recognized the regional variations impacting the number of programs within 250 nautical miles from OPO to OPO. High population areas on the East Coast may have 20-40 centers in this range, where there would be far fewer in less populated areas in the Midwest.

A visualization of the process had been recommended to help provide the Workgroup with some clarity. OPTN Contractor staff developed a workflow map of OPO and transplant program process and actions to help guide the discussion, outlining all the various steps from offer to transplant. Staff walked Workgroup members through the process flow map, including decision points to be determined by the

Workgroup and potential challenges to be considered that may impact allocation (e.g. flight versus driving by courier to receive organ).

The Workgroup was encouraged to explore one of the following during this call:

- Which programs should be qualified as participating in the expedited placement protocol?
- How many programs should receive the expedited offer at once?
- What is the trigger point to initiate expedited placement?

Summary of discussion:

A member asked the Workgroup where they thought the most challenging or critical decision points to be resolved reside on this chart. From a transplant program perspective, one member noted how this will be automated regarding the offer and timing of acceptance, as programs are monitored. The Workgroup member questioned whether the OPTN Donor Data and Matching System would flag programs for expedited placement notification. It was recognized that a bypass code would be needed for centers not participating in the protocol. Additionally, there was some concern regarding OPOs manually calling programs (especially if there was a large number) and tracking the one hour for OPOs to consider the offer and name up to three potential recipients.

OPTN Contractor staff noted that if policy changes were approved after successful testing of a protocol, programming would be implemented to efficiently manage the questions posed regarding bypass and offer acceptance. The protocols, however, are meant to be tested quickly by a trial group and may not include full programming. This is why keeping the protocol to a small and manageable scale is important. Some Workgroup members did raise concerns about operationalizing the protocols without programming to aid both the OPOs and the transplant programs in offering and accepting organs. The protocol will go out for a brief public comment period, and this could be offered but it will be good to keep in mind that programming options will most likely be limited here.

Workgroup members acknowledged that out of sequence placements to aggressive programs are already occurring and continued with discussion regarding operationalizing the protocol- specifically what may trigger moving to expedited placement for the protocol. A Workgroup member noted that there will be pre-recovery and post-recovery characteristics that will drive this process and that opening this discussion up to the full committee will likely spur lengthy conversation. With the complexities here, a simple path forward was suggested. A member noted using a certain sequence number as the trigger might be the most practical route forward here, suggesting a sequence number trigger be identified for moving to expedited placement pre-cross clamp. For post-cross clamp expedited placement allocation, cold time accrued was suggested as a trigger.

Conversation shifted to operationalizing the protocols itself. Workgroup members talked about the 250 nautical mile boundary as a potential means for identifying participating programs. Centers could opt in or opt out of receiving expedited placement offers. The challenge of high numbers of centers within the boundary in high population density areas (e.g. the Northeast) were acknowledged. There was concern that centers may dislike this approach, as they scramble resources in the middle of the night to meet the one-hour limit to offer up to three potential candidates with the knowledge that they most likely will not receive the organ. Members discussed the possibility of a sliding scale, where denser population areas get to select more potential patients for the expedited placement protocol offers. There was also some discussion about extending the time window to two hours for pre-cross clamp and reducing it to 45 minutes for post-cross clamp.

The Workgroup walked through a conceptual offer in the Northeast:

- Approximately 40-45 centers fall within donor hospital's 250 nautical mile radius

- OPO offers to 5 high CPRA zero mismatch candidates
- There are no medically urgent candidates
- There are no prior living donor candidates
- OPO hits the expedited placement trigger on the match run, and must now notify all 40-45 centers in the 250 nautical mile radius to request up to 3 potential candidates
  - A standardized message could be placed in the Donor Highlights to note expedited placement is now initiated and centers within 250 nautical miles are qualified to submit these potential candidates within the next hour.
- Without programming, OPO would be responsible for calling these 40-45 programs as anatomy and biopsy results become available.
  - This could be achieved with an automated message to programs, but this programming may not be available while the protocol is operating within the variance
  - This is important because it would be unrealistic to think that the OPO could contact all of these programs, keep track of timing of offers to make sure that all have a fair opportunity to review. This also doesn't account for unanswered calls and waiting for return calls.

The Workgroup agreed that some automation would be critical to maintain fairness within the protocol. Recognizing that some programs will decline for all, this will reduce the number of centers vying for the kidney(s). A member questioned whether perhaps the top 5 centers with the highest ranked candidates could be the only ones the OPO would need to contact with follow up details such as biopsy results, pump numbers, etc. Another member noted that, while this calling of the top 5 centers may work for pre-cross clamp offers, it would not be appropriate for expedited offers initiated post-cross clamp. In the case of pre-cross clamp offers, everything should be available in the OPTN Donor Data and Matching System and they will only need to check on pump, biopsy, and anatomy when it becomes available. If it is a post-cross clamp offer, the decision time will have to be shortened. If the OPO is only appealing to 5 centers at a time and they all decline, another round will have to be pursued. This will lead to increased cold time on an already hard to place kidney. The Workgroup acknowledged the smaller size of Europe and the smaller number of transplant programs. These differences here make for challenges in applying this model to the U.S. The Workgroup acknowledged these concerns about offering the kidneys to so many programs both practically and workload wise.

Workgroup members revisited the idea of programs qualifying to participate based on their past acceptance behavior. While recognizing the "fear of missing out" that may lead some programs to want to participate in a protocol, the idea of potential losing time while offering to programs who have not historically accepted these types of kidneys was recognized. There was concern that classifying kidney acceptance by looking only at KDPI was not an accurate depiction, as it did not include anatomy and biopsy, which would also impact decision making. KDPI alone does not provide an accurate look at why an organ might not have been accepted or utilized.

In closing, Workgroup members acknowledged the challenge for large number of centers to have the ability to work quick to determine their highest sequenced candidates on the match run for whom they would accept these organs and submit this information within an hour based on characteristics of these "hard to place" kidneys.

Upcoming Meetings

July 22, 2024
August 5, 2024
August 29, 2024

Attendance

- **Committee Members**
  - Jim Kim
  - George Surratt
  - Jason Rolls
  - Leigh Ann Burgess
  - Kristen Adams
  - Tania Houle
  - Jill Wojtowicz
  - Carrie Theissen
  - Megan Urbanski
- **HRSA Representatives**
  - James Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
  - Jonathan Miller
- **UNOS Staff**
  - Kayla Temple
  - Shandie Covington
  - Thomas Dolan
  - Houlder Hudgins
  - Ross Walton
  - Kieran McMahon
  - Taylor Burton