OPTN Expedited Placement Workgroup
Meeting Summary
June 10, 2024
Teleconference

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

Introduction

The OPTN Expedited Placement Workgroup (the Workgroup) met via teleconference on 6/10/2024 to discuss the following agenda items:

1. Welcome
2. Recap: Workgroup Goals and Scope
3. Discussion: Expedited Placement Protocol Development

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

1. Welcome and Introduction

The Chair welcomed the Workgroup and thanked them for joining.

Summary of discussion:

There were no questions or comments.

2. Recap: Workgroup Goals and Scope

The Workgroup reviewed their goals and scope in context with the work currently being done in conjunction with the OPTN Expeditious Task Force's Rescue Allocation Pathways Workgroup.

Presentation summary:

The Kidney Expedited Placement Workgroup's scope includes:

- Perform a literature review to understand the strengths, weaknesses, and lessons learned from expedited placement protocols across multiple organs, in various transplant systems
- Develop protocols for consideration by the Rescue Allocation Pathways Workgroup
- Monitor and maintain awareness of all kidney expedited placement protocols, eventually working with the OPTN Kidney Committee, Rescue Pathways Workgroup, and Task Force to develop a kidney expedited placement policy
- Discuss expedited placement in the context of continuous distribution, including systems requirements
- Considers, develops, and provides input on potential frameworks for policy and systems implementation of successful expedited placement protocol(s)
    - Facilitate more rapid incorporation of kidney expedited placement pathway into OPTN policy
- Potentially, consider other alternate allocation pathways in Continuous Distribution, such as dual kidney

Summary of discussion:

There were no questions or comments.

3. Discussion: Expedited Placement Protocol Development

The Workgroup received an overview of the first expedited placement protocol, recently released for public feedback.

Presentation Summary:

The Expedited Placement Variance protocol submission template:

- 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

Expedited placement variance protocols will be monitored for pediatric access, potential racial disparities, and potential gender disparities.

Previously, the Workgroup discussed the following considerations:

- Trigger criteria should aim for early initiation of pathways, incorporate some clinical discretion
- Program qualifying criteria optimizes efficiency
    - Prior use does not guarantee future use – CIT plays a role as well
- Reducing overall allocation time – simultaneous offering, reducing evaluation timeframes
    - Specific timeframes are important to moving allocation along → reduce general delays at all points in allocation
- Transparency and equity – utilize original match run prioritization
    - Candidate selection can help support acceptance
- Multiple pathways could exist to account for various situations and points in allocation
- Offer Evaluation considerations:
    - Notification to all programs of final post-clamp information availability, not just on primary sequential offer
    - "Disappointment factor" – consider balance to program resources, recipient verification and consent
- Outcomes may be worse compared to standard allocation, evaluate in context

Previously, the Workgroup expressed support for modeling an expedited placement protocol similar to the Eurotransplant (ET) Recipient Oriented Allocation model (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 contact for REAL
    - For each center, potential recipients and respective original standard ranking are listed in an online application
    - Centers may select up to 3 designated recipients for transplant, and choice must be entered within 50 minutes after offer
    - When this period has expired, the ET offers the organ to the highest ranked candidate

Summary of discussion:

Guiding Question: which aspects of the REAL model would the Workgroup like to incorporate?

The Vice Chair expressed support for an expedited placement protocol utilizing a requirement for programs to designate and submit up to 3 recipients and a 60-minute simultaneous evaluation. The Vice Chair remarked that 60 minutes is important to ensure allocation is occurring rapidly.

The Vice Chair asked about candidate selection, noting that the Workgroup could consider a requirement for designated recipients to have a low calculated panel reactive antibody (CPRA) score. The Vice Chair explained that this would prevent a situation where a program accepts the organ and ends up not being able to transplant due to a positive crossmatch. The Vice Chair remarked that, with a shortened time frame, it will be important for programs to designate recipients that have a low likelihood of a positive crossmatch. The Chair remarked that this is a good point, and that the protocol should include a clear set of expectations and requirements for programs to complete when submitting and designating potential recipients, including virtual crossmatch performance. The Chair continued that expectations should also include review of key donor information and ensure that programs are able to certainly accept kidneys and transplant them.

One member added that it could be required for OPOs to offer to high CPRA candidates prior to moving to expedited placement, noting that these candidates are unlikely to be a clinical match with other donors and thus are unlikely to receive another offer soon. The member continued that it is important for OPOs to send blood for physical crossmatching for these patients as well, and that this process and offer evaluation for high CPRA candidates should occur well before recovery.

The Chair pointed out that there could be more minor issues where some candidates are moderately sensitized candidates, that have higher level historic donor-specific antibodies that should be avoided. A member agreed, noting that it is important to ensure that the top of the match run candidates, particularly the most highly sensitized, receive those offers prior to expedited placement. The Chair agreed. Staff remarked that this is something the Workgroup is able to denote as part of initiation rules and shared that the first expedited placement protocol evaluated by the OPTN Task Force required OPOs to offer in standard allocation to those highest sensitized candidates.

The Vice Chair suggested that the Workgroup could require that candidates selected and submitted by transplant programs should meet specific CPRA thresholds, such as having a CPRA of 30 percent or lower. The Chair commented that programs vary in their willingness to transplant candidates of varying CPRA ranges based on a virtual crossmatch alone. The Chair continued that such a requirement may unnecessarily curtail clinical decision-making and autonomy. The Chair added that similar efficiency benefits can be gained by programs having clarity in what kinds of candidates they would transplant and ensuring that the protocol is clear in virtual cross match requirements. The Chair offered that the protocol could denote that programs should not submit candidates that they would not be comfortable transplanting based on a virtual crossmatch alone, noting that this requirement is sensible particularly in the context of increased cold ischemic times.

One member asked if the European Transplant system utilizes a guideline on virtual crossmatching and candidate selection. Staff noted that the literature reviewed by the Workgroup does not specifically indicate any requirement for virtual crossmatching; the Chair agreed that this level of detail was not provided in the literature.

The Chair advised that one expectation should be to ensure each candidate submitted by the program has heard of the offer, confirmed no changes in their health and ability to receive a transplant, and has indicated interest in accepting the offer. The Chair noted that the patients need to be comfortable with accepting these offers as well. One member asked if this would occur as a consent form and recommended that this could be coupled with the high Kidney Donor Profile Index (KDPI) form currently required by OPTN policy. The Chair explained that patients who appeared on the high KDPI match runs

have already signed a consent form, and that this consent is prerequisite to being eligible to appear on KDPI 86-100 percent match runs. The Chair added that the patient can still decline the offer, and that programs typically notify the patient of the potential offer prior to the offer becoming primary, if the program thinks it could be an appropriate organ for that candidate. The Chair shared that some patients would decline the offer, particularly if they feel that they could wait to receive a better offer. The Chair noted that this practice varies based on the program. The Chair added that occasionally, patients are simply not available for transplant, due to being out of town or else minor changes in health status. The Chair remarked that waiting until the offer is primary to notify the candidate can contribute to delays in allocation and recommended that patient review of the offer and wellness check should be considered an expectation. One member asked if it would make sense to try to consent patients to being submitted to receive expedited offers, noting that early consent would support shared decision making and patient readiness. The member supported inclusion of patient review and wellness check in offer evaluation expectations, as well as early consent. The Chair agreed, noting that education for different types of donor offers should be included in education for patients. The Chair added that nuances in patient education vary across the country, and that regions with long waiting times may need to strategize patient education. The Chair continued that most programs provide patient education up front. The Chair shared that their program has shorter waiting times and provides patient education upfront; the Chair added that it is rare that their program ends up needing to decline an offer due to patient unavailability or non-interest in a potential graft.

The Vice Chair agreed that early consent from patients about willingness to accept expedited kidney offers could be useful and would align with the expedited model utilized for liver. The Vice Chair continued that this would allow programs to pre-identify certain candidates and assess their relative eligibility to be submitted. The Vice Chair noted that certain candidates may live far from the program, and thus may not be logistically able to accept expedited offers; pre-identifying candidates may help ensure rapid and effective evaluation and candidate selection. The Vice Chair continued that upfront education will also support patients in feeling more comfortable to accept these organs, even if the offer comes late at night. Another member agreed, noting that patient education and consent could support increased efficiency. The member shared that this could also help pre-identify which patients are interested in receiving potentially shorter graft longevity offers in order to cease dialysis dependence sooner.

The Chair shared that their program has noticed that, based on blood type, there are certain patients on the waiting list that may be late-offered hard to place organs more frequently because they are closer to the transplant program and can be transplanted within a reasonable cold ischemic time frame. These candidates also tend to have lower CPRA scores, and thus are expected to be able to accept the organ with lower concern for positive crossmatch. The Chair added that this could be a best practice for programs to consider which candidates may be interested and feasible candidates to receive these types of offers, and that this practice could support program resource management.

The Vice Chair asked if 60 minutes is sufficient for programs to identify multiple patients, ensure the virtual crossmatch is complete and negative for these patients, and contact the patient to determine interest and availability. The Vice Chair remarked that this could be a lot of work for three patients. The Chair agreed and noted that there is balance between program resources and time management, and efficiency. The Chair remarked that extending the evaluation time may increase delays, and that every hour counts for the harder to place organs. The Chair pointed out that making expectations clear for programs will help those programs manage their resources. The Chair added that the program could focus on selecting their highest sequence number patients. Another member pointed out that candidate selection is optional, and that programs could submit less than three candidates.

One member shared that, when their OPO makes aggressive expedited offers, they are able to receive answers from programs in less than 60 minutes about which candidates they would accept the offer for and whether they are willing to take the offer. One member pointed out that identifying potential patients for whom the organ may be appropriate may be able to be done quickly, but that running a virtual crossmatch and communicating with the patient may take more than 60 minutes.

One member noted that there needs to be transparency in determining which programs receive expedited offers. The member shared an example of a nearby OPO offering a kidney as expedited to a program and candidate further down the match run, when their program would have accepted that offer for a higher-ranking candidate. The member shared that this is important for both transparency and ensuring equity.

The Workgroup confirmed that the expedited placement protocol should leverage candidate selection, such that programs can submit up to three eligible candidates. The Workgroup also confirmed that 60 minutes is adequate time for program evaluation and submission of candidates, with specific evaluation requirements. The Workgroup confirmed that the expedited placement protocol should also leverage simultaneous offering, such that programs are notified of final information at the same time and have the same hour to evaluate and designate candidates.

One member asked if this evaluation would be a race, with the program who responds first receiving the offer. Another member responded that this is more of a silent auction model, with the program with the highest-ranking candidate receiving the primary offer at the end of the evaluation time period.

A member noted that this model could result in gaming, where a program submits a higher-ranking candidate, accepts the offer for that candidate, and later declines for that candidate in order to transplant the organ into a lower ranking candidate at their program. The member continued that this would also be allocation out of sequence. The member continued that this should be considered. Staff noted that this is also a possibility in the protocol currently out for public feedback, and that the variance can monitor for this as well. Staff noted that this is something that can be easily monitored, and that the Workgroup could consider reallocation requirements, or potential MPSC referral in a final policy. Another member agreed, noting that recipient replacement should be evaluated the way out of sequence allocation is evaluated. The member continued that reallocation is very difficult once a kidney has been transported to a program, particularly because cold ischemic time may be elevated. The member shared that OPOs typically must rely on program back up to ensure the organ is transplanted in those scenarios. Another member agreed, noting that reallocation efforts often end up in non-use. The Chair remarked that the organs being described in an expedited placement scheme have a high risk of being discarded, and that it is important to ensure that these organs are transplanted. The Chair noted that the scenario described is unlikely, and that monitoring can help ensure late decline in expedited placement is avoided and minimized. The Chair added that variance monitoring will also allow for modification and adjustment to any final policies.

One member asked about waivers, offering that expedited kidney offers could potentially be sent on full waivers. The member continued that at this point, this is the only pathway to place these kidneys, and waivers will encourage programs to accept. A member responded that their OPO has moved more towards trying to place a kidney, and that it would make sense for any kidney in this pathway to be fully waived. The member shared that it's not their OPOs practice to ask for fees for those organs that get transplanted, and that it is always preferred for a n organ to be transplanted.

A member pointed out that the released organ policy could be modified, such that candidates at nearby centers have a chance to accept an organ upon reallocation. The member continued that this could be restricted to only those submitted or selected expedited candidates, noting that the smaller number of

candidates and programs could support increased efficiency and placement in reallocation. The Vice Chair noted that the cold time will already be high, and that other centers may be unlikely to accept an organ that was declined upon arrival. The Vice Chair pointed out that building waivers into this policy will support acceptance and transplant.

One member shared that their OPO does not give full waivers, noting that it does not make sense for an OPO to give biopsy or anatomy waivers when that information is known upfront. The Vice Chair agreed but noted that the waiver question should be resolved to reduce need for reallocation.

A member asked if there is a plan to monitor program resources and efficiency with simultaneous allocation. The member continued that 30 programs scrambling to find patients on their list repeatedly could be resource intensive, especially if there are multiple expedited offers in play. The member recommended assessing efficiency from the program perspective as well. Another member asked if it would be 30 centers receiving the simultaneous offer. The Chair remarked that this has not yet been determined, and that the Workgroup would need to determine how many programs are participating in the initial protocol. The Chair shared that the Workgroup has not yet determined a metric for monitoring program resources but acknowledged that this will be more resource intensive than standard evaluation. The chair noted that programs may need to prioritize evaluating for their highest sequence number patients in order to manage resources and timing. Staff confirmed that the Workgroup has not yet determined how many programs should receive the simultaneous offer at once. Staff continued that the Workgroup could consider multiple parameters to determine this. Staff added that the OPTN Kidney Transplantation Committee has discussed the "disappointment factor" for programs evaluating simultaneous offers but not ultimately receiving the primary offer. Staff remarked that the protocol could potential monitor how many expedited offers a program receives, versus how many of those offers the program is ultimately able to accept and transplant. This would provide insight into how frequently programs are mobilizing resources without receiving a primary offer. One member pointed out that potentially, the protocol could assess the number of person hours represented by these offers, and that this would include the actual cost of mobilizing those resources. One member remarked that each center would need to crossmatch at least 3 candidates, involving the histocompatibility laboratory, and that programs would need to wake up patients, nephrologists, and coordinators. The member continued that this would happen all for a high likelihood of not receiving the final offer. The member remarked that there needs to be a way to monitor and measure the cost to programs and to show that expedited placement is worth this cost.

The Chair offered that programs could instead identify and submit only one patient, and that this could help reduce resources. A member remarked that it should be at least 2 candidates, to ensure each program has a backup patient in the case that unexpected issues prevent transplant of the first candidate. Another member remarked that up to three candidates is fine if that's how many candidates a program decides to identify, and that the bulk of the work and burden is in receiving and evaluating the offer, regardless of which candidate and how many candidates are identified. The member added that designating two candidates over three candidates does not significantly reduce program resources. The member noted that crossmatching three candidates versus two is also not a significant difference in resources and effort. The Chair remarked that the theme of concern for resources and time has been recurrent, and that it may make sense for programs to choose up to three patients, but that programs do not have to designate any candidates.

The Chair noted that, if there is a requirement for a program to have a backup candidate, then the program would need to designate between 2 and 3 candidates for whom they would accept the organ. Another member agreed.

The Workgroup confirmed that programs should be able to submit up to 3 candidates for whom they would accept the offer, noting that the main bulk of program resources are geared toward overall offer evaluation, not necessarily candidate selection.

One member asked how programs will be selected, and if there will be variation in program aggressiveness. Staff noted that the Workgroup still needs to determine this, as well as how many programs would be receiving the expedited placement offer at one time.

One member remarked that this discussion is to support the development of an expedited placement variance protocol. The member noted that there should not be too many programs receiving the expedited placement offer at once, particularly because it may become cumbersome and resource intensive. The member offered that 20 programs may be an appropriate number.

A member remarked that it makes sense for the protocol to be OPO-centric and have OPOs designate a specific number of programs that should be eligible. A member added that this would also provide some flexibility for OPOs in allowing OPOs to nominate additional programs based on their experience and history of acceptance and transplant.

One member asked how many OPOs there are in the country, and another member shared that there were about 52 OPOs actively operating currently. The member considered that it could be calculated how many OPOs should be engaged in order to ensure statistical significance.

A member asked if the Workgroup wants the expedited organ to stay local, in order to be utilized with the shortest amount of cold time. Another member responded that this may not necessarily be true depending on where the OPO is located. The member continued that OPOs in areas without nearby aggressive centers may need to offer the organ to centers further away in order to ensure placement. The member shared that many OPOs utilize SRTR offer acceptance metrics and the recovery and usage map (RUM) report to determine which programs to offer to when offering out of sequence to ensure utilization. A member responded that centers do not have to designate candidates if they would not accept the offer, but that an opt in model allows programs who are interested to designate candidates and indicate that interest.

One member remarked that, for expedited placement to work, it will be important to identify which organs are going through expedited placement, and which programs are considered “aggressive” or more likely to accept at-risk organs. The member continued that identification of which programs receive expedited placement offers needs to be consistent.

The Chair offered that potentially, the Workgroup could look at the offer acceptance metrics released by SRTR. The Chair continued that quartiles above the median could be one threshold. Another member responded that this could be further broken down by KDRI, instead of overall acceptance, to better understand which programs are taking which organs. The Cahir continued that offer acceptance metrics for sequence number over 100 would be good to look at. The Chair also considered including nearby programs with aggressive offer acceptance history. The Chair pointed out that going by sequence number and ensuring the offer is given to the highest-ranking candidate should encourage transparency and equity. One member expressed concern that offer acceptance beyond sequence 100 could be reflective of programs accepting an organ at a lower sequence number and transplanting the organ into a lower ranking, higher sequence number candidate, due to issues with the primary accepting recipient. Another member remarked that kidneys offered past sequence 100 could be arbitrary. The member remarked that every program has an offer acceptance ratio, and that it would make more sense to determine which programs have significantly higher organ acceptance ratios, such as the top 25 percent of programs. The member continued that the Workgroup could make the decision based on the curve of program acceptance behaviors.

A member asked if non-aggressive centers will be excluded from the expedited placement pathway, and asked if this would skew the data from a protocol. Another member agreed, noting that it is important to give programs the opportunity to grow. The Chair agreed, and noted that the aggressive offer can come in, but that if the program would not transplant the organ, the program can decline to designate candidates. The Chair continued that this could still work within the framework developed in this Workgroup. The Vice Chair agreed that it is important to ensure each program has the opportunity to accept expedited placement organs. The Vice Chair shared that the expedited placement pathway for livers utilizes an opt in model, which allows programs to opt in specific candidates. The member expressed that this could encourage early discussion and education with the patient about expedited placement. A member agreed.

One member pointed out that the Kidney Committee is working on a definition for "hard to place," and that this definition could be used to trigger the expedited placement pathway.

The Chair noted that the Workgroup will continue discussion on program selection and identification, as well as initiation rules for the protocol. The Chair remarked that consideration of flight logistics should also be discussed.

Upcoming Meetings

- June 24, 2024
- July 8, 2024
- July 22, 2024

Attendance

- **Committee Members**
  - Caroline Jadlowiec
  - Chandrasekar Santhanakrishnan
  - Anja DiCesaro
  - Carrie Thiessen
  - George Surratt
  - Jami Gleason
  - Jason Rolls
  - Jim Kim
  - Leigh Ann Burgess
  - Megan Urbanski
  - Micah Davis
  - Tania Houle
- **HRSA Representatives**
  - James Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
  - Jon Miller
- **UNOS Staff**
  - Kayla Temple
  - Houlder Hudgins
  - Kaitlin Swanner
  - Lauren Motley
  - Shandie Covington
  - Thomas Dolan