OPTN Expedited Placement Workgroup
Meeting Summary
May 13, 2024
Teleconference

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

Introduction

The OPTN Expedited Placement Workgroup (the Workgroup) met via teleconference on 5/13/2024 to discuss the following agenda items:

1. Welcome
2. Literature Review: Expedited Placement Processes
3. Task Force Update: Protocol #1 – Accelerated Placement of Hard to Place Kidneys
4. Discussion: Expedited Placement Protocols

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. Literature Review: Expedited Placement Processes

The Workgroup continued discussions on the expedited placement literature review, including considerations for effective expedited placement pathways.

Summary of presentation:

At the previous meeting, the Workgroup discussed literature and monitoring reports exploring multiple expedited and rescue allocation pathways, including:

- United Kingdom (UK) initial Kidney Rescue allocation scheme and Fast Track Kidney Allocation Scheme[1]
- Eurotransplant Recipient Oriented Extended Allocation (REAL) and Competitive Rescue Allocation (CRA) [2]

[1] White, et al. (2015). Impact of the new fast track kidney allocation scheme for declined kidneys in the United Kingdom. Clin Transplant, 29(10), 872-881. https://pubmed.ncbi.nlm.nih.gov/26094680/
[2] Assfalg, et al. (2023). Rescue Allocation Modes in Eurotransplant Kidney Transplantation: Recipient Oriented Extended Allocation Versus Competitive Rescue Allocation – A Retrospective Multicenter Outcome Analysis. *Transplantation*. https://pubmed.ncbi.nlm.nih.gov/38073036/

- United States Kidney Accelerated Placement (KAP),[3] Expedited Liver Placement,[4] and Facilitated Pancreas Allocation[5]

The Workgroup discussed several considerations:

- Cold ischemic time impacts to risk of non-use, and the importance of reducing cold ischemic time
    - Biopsy, pump, and post-clamp information gathering can contribute to accumulation of CIT – practices should be re-evaluated for necessity, reliability, and effectiveness against contribution to risk of non-use
    - Early initiation of expedited placement processes may be crucial
- Some organs may not be safe for transplant expedited placement pathway impact should be evaluated by impact to non-use for transplantable organs
- "Opt in" models may not be as effective – program behavior may not align with program opt-in
    - Qualifying criteria may be necessary to optimize efficiency
- Expedited placement trigger should consider "hard to place" definition that incorporates center behavior, risk tolerance, and number of declines

Summary of discussion:

One member remarked that definition of "hard to place" used to initiate expedited placement should not include center behavior, as this can vary by program. The member expressed support for initiation expedited placement based on clinical donor and organ characteristics. The member added that post-clamp data may be limited, but should be incorporated, including biopsy, anatomy, and pump parameters.

The member expressed support for the REAL and CRA pathways utilized by the Eurotransplant system, noting that these systems leverage simultaneous offering to reduce allocation time. The member expressed support for an open-offer style expedited placement pathway, similar to the CRA policy, such that the first program to accept the offer receives the organ, noting that this ensures the organ reaches the program that is willing to accept it. The member remarked that the opt-in model, such as that used in the Expedited Liver Placement policy, will help reduce offers to programs that would not accept these organs. The member added that sequential offering, as opposed to simultaneous offering, can help reduce the overall time of allocation. The member noted that cold ischemic times in the Eurotransplant system are generally shorter due to decreased travel distances.

The Chair also expressed support for the REAL model, noting that this model provides increased transparency and equity by leveraging the original match run to determine candidate priority. The Chair pointed out that the REAL model allows programs to indicate which candidate they would accept the organ for based on the most updated information. The Chair also noted that the CRA model is somewhat less transparent, but provides an adequately nimble system of allocation for organs that have not been placed through two different placement pathways – standard allocation and REAL. The Chair explained that, if the organ has not yet been placed via standard or REAL allocation, rapid placement is critical to ensuring use of the organ. The Chair added that, currently, some OPOs utilize a similar model of out of sequence allocation to "rescue" organs that may otherwise not be placed. The Chair explained

[3] Noreen et al (2022). "Kidney Accelerated Placement Project: Outcomes and Lessons Learned." Am. J. Transplant. 22(1): 210-221. https://pubmed.ncbi.nlm.nih.gov/34582630/

[4] OPTN OPO Committee Expedited Liver Placement Pathway 1 Year Post Policy Implementation Monitoring Report. October 15, 2022.

[5] OPTN Pancreas Committee: 'Facilitated Pancreas Allocation' part of the Eliminate DSA and Region in Pancreas Allocation 2-Year Post-Implementation Monitoring Report. July 10, 2023

that these OPOs simply call nearby programs with a reputation for accepting similar organs and make an open offer, and that this process is not particularly transparent.

In considering the Kidney Accelerated Placement study, the Chair noted that prior use of a similar organ does not always guarantee future use of a particular type of organ. The Chair added that clinical characteristics should be considered in context with cold ischemic time as well, and that qualifying criteria should be based on established acceptance behavior.

One member asked if the European Transplant system allows REAL and CRA to be applied for any offer, or only post-clamp offers. The Chair noted that the criteria for initiating REAL is vague, allowing for some clinical discretion but making it unclear if non-standard allocation can begin prior to recovery. Staff clarified that the initiation criteria for REAL includes non-acceptance of a graft from a donor aged 65 or older at least 5 hours post-cross clamp, full center decline from at least five centers for donor or organ related medical reasons, logistics averting prompt transplantation causing an increase in cold ischemic time, impending loss of the organ for transplantation, or a combination of these factors. Staff noted that to initiate CRA, the organ must not have been able to placed through REAL and/or had significant cold ischemic time.

The Chair noted that declines for more than 100 patients or a specific cold ischemic time threshold could work as triggers to initiate expedited placement, but that many programs wait for anatomy, biopsy, and other post-clamp information before making final acceptance or decline decisions. The Chair continued that this contributes to a delay in allocation as that information is gathered and processed, but that most programs are not watching for that information to be shared, and instead evaluate post-clamp information as they receive the primary offer. The Chair continued that expedited placement should also include immediate notification to interested programs that post-clamp information is available to be evaluated. Another member agreed.

One member remarked that reducing cold ischemic time is the most critical element of an expedited placement pathway. The member added that a simpler system may be preferable, noting that the tiered pathways in the Eurotransplant system could be confusing for patients. The member offered that a recovered kidney should enter into expedited placement immediately upon reaching a specific cold ischemic time threshold. The member added that there may be instances where expedited allocation is appropriate prior to cross clamp, and that pathway is less clear.

The Chair recommended that, once all post-clamp information is available, the OPO is able to enter into a REAL-type allocation system where one simultaneous offer is made to qualified transplant programs. From there, the program may choose which candidates it would accept the organ for. The Chair continued that sequential allocation is slow, and does not leverage synchronized evaluation of the organ. Another member agreed, noting that in such a system, less than an hour could also reduce evaluation time frames and so help to reduce cold ischemic time. The Chair commented that 60 minutes to respond seems appropriate. Another member agreed, noting that once all the post-clamp information is posted, programs will have had the opportunity to determine whether to decline the organ outright, and that an hour would allow programs to determine potentially appropriate candidates. The member continued that the center with the highest priority candidate on the match run could receive the primary offer and accept the organ. The member continued that this would provide significantly more transparency than the open offers currently utilized by OPOs, with objective criteria. The member continued that a combination of utilizing the current match run in a REAL system could provide transparency and simplify the expedited process for evaluating programs. The Chair agreed, noting that this system is more flexible and dynamic, particularly in avoiding sequential allocation methods that prevent offers from reaching more appropriate candidates in a timely manner. The Chair explained that currently, their program may receive an offer that would be appropriate for a candidate

further down the match run, but that candidate may not become primary until well after the program is able to feasibly and safely accept and transplant the organ, particularly if there are 30 candidates ahead with an hour for each program to evaluate.

One member shared that one OPO has tried an "open ranked offers" system of out of sequence allocation, where the OPO simultaneously notifies multiple centers with an open offer. The programs will evaluate the offer and mobilize resources in preparation to accept the offer, only to find another program accepted the organ shortly before. The member continued that this process does not adequately consider equity, program resource use, and recipient frustration. The member added that any expedited placement mechanism should particularly consider center resources and recipient frustration. The Chair agreed, noting that it can be resource intensive to run virtual crossmatches and evaluate offers. Another member remarked that a number of potential recipients may be more comfortable with being disappointed in mobilizing for an offer they ultimately did not receive, as long as those patients are made aware ahead of time. The Chair agreed.

A member offered that the counterbalance to a simultaneously offering system is consideration of burden to program resources and ensuring that immediate, rapid, and resource-intensive expedited placement allocation and evaluation is not a constant occurrence. The Chair agreed, noting that it can be frustrating for programs evaluating and preparing to accept these offers to be repeatedly disappointed in not receiving them. The Chair pointed out that many of these evaluation resources should be spent in evaluating these offers anyway, and that this would not necessarily be a new expectation for transplant programs. The Chair explained that programs are supposed to be reviewing the offer, assess the top recipients, understand the quality of the organ, and make preparations as part of offer evaluation. The Chair continued that additional accountability in the form of shortened time intervals or asking programs to indicate which candidates they would accept for may be appropriate.

One member asked if any of the articles discussed burden to resources and whether or not the expedited placement pathway was resource neutral. Staff responded that the UK's Fast Track Allocation Scheme paper noted that using more medically complex kidneys is higher risk, and thus is resource intensive and time consuming with increased risk of morbidity. Staff shared that the Kidney Committee previously reviewed another paper studying simultaneous allocation, and the Kidney Committee discussed how large batches of simultaneous offers can be resource intensive, particularly if the program has invested the resources but ultimately does not receive the organ. A member shared that receiving the offer ahead of recovery significantly eases the burden on programs, but currently, the open offers made by OPOs not notified prior to recovery and the entire evaluation and preparation process needs to occur within the hour. The member continued that typically, these offers are sent out late at night, and often a program's first candidate will be far down the match run. The member explained that this requires contacting the histocompatibility lab, nephrologists, and patients all within a short period of time. The member continued that asking programs to rapidly evaluate and prepare to accept an organ only to not ultimately offer the organ to that program due to a 30 second difference in response timing could lead to significant program and patient burn out.

The Chair agreed, sharing that their program has seen the same thing. The Chair explained that even in contacting the patient to notify them that they may receive an offer and then having to explain it was accepted by a candidate ahead of them can be emotionally taxing for the patient. The Chair added that thorough evaluation does require a lot of resources and that should be considered in a simultaneous offer mechanism.

One member agreed that expedited placement needs to be consistent across OPOs, systematic, transparent, and based on objective criteria. The member recommended considering program performance in determining which programs receive expedited offers. The member offered that the

Offer Filters model outlines center acceptance behaviors. The member continued that the expedited placement pathway could make offers to programs with a proven history of acceptance, plus a small margin to allow centers to change their behavior and accept a more medically complex offer. The member continued that this would ensure the offers are made to those programs that will accept them, and that this will improve efficiency of allocation for OPOs as well as efficiency of evaluation for programs. The Chair agreed, and shared that some OPOs utilize the Recovery and Usage Map (RUM) report to determine which programs to make open offers to. The Chair continued that often, the program who gets to transplant the organ is the program that responds first.

The Chair pointed out that Expedited Liver allocation utilizes an opt in model, instead of qualifying criteria, for programs to receive expedited liver offers. Staff confirmed this, and noted that there was limited uptake and use of this pathway. Staff shared that the OPO Committee commented that this pathway was not adequate due to a high volume of opted in candidates from programs that would not accept such offers and having to sequentially offer to programs that took time to evaluate but ultimately declined. Staff noted that the Liver Expedited Placement pathway less frequently resulted in placement, but that the majority of organs placed in this pathway were ultimately transplanted. The Chair asked if the Expedited Placement pathway still exists. Staff noted that the OPO Committee has not modified the Liver Expedited Placement pathway, and that there is also an increase in out of sequence liver allocation.

One member explained how the Liver Expedited Placement pathway works, noting that the recovery teams are holding cross clamp to get a liver biopsy. Once the liver biopsy is back, holding the rest of the team in the room, there is less than half an hour to make those decisions. The member continued that, in that scenario, the Expedited Liver Placement pathway doesn't move quickly enough to ensure placement. The member shared that their OPO does not use the Expedited Liver Placement pathway, but does establish at least two back-up recipients, including a local back up, in advance of organ recovery. The member added that with such limited time, sequential match run based allocation is less feasible.

The Chair commented that specific and clear expectations for when anatomy is uploaded and biopsy is available for programs to review, as well as a way to notify programs to review, could support more proactive offer review and decision making and help reduce allocation time. The Chair continued that these components also contribute to delays in standard allocation.

Staff summarized the Workgroup's comments:

- Trigger criteria should consider availability of information and aim for early initiation of pathways
- Qualifying criteria optimizes efficiency by offering to those programs that have demonstrated willingness to transplant certain organs
    - Individual cases of prior use does not always guarantee future use
    - Program acceptance behavior should also consider cold ischemic time, and should be considered dynamically
- Reducing time – simultaneous offering with a small timeframe to determine which centers are willing to take the offer
    - Limit timeframe for sequential allocation
    - Important to get offers to programs that will accept the organs quickly
    - Simultaneous offering should not occur until all post-clamp information is available
        - Post-clamp filters for pump and biopsy criteria

        - Program resources should be considered – balancing requested resources, providing accountability, managing volume, and "offer disappointment" risk
- Transparency and Equity – using the original match run, such as with the REAL system, in combination with the most up to date donor information
    - Increased efficiency should balance greater equity and standardization
    - Candidate selection and relative priority on the match run helps support acceptance
        - Once no information is pending, programs could determine which candidates they would accept
        - Recipient verification should be considered – patients should be aware of how these offers may work
- Multiple pathways to account for various situations and points in the allocation process
    - Balance with simplicity and understandability
- Simultaneous notification of post-clamp information – encourage immediate evaluation as information is available not as offer is primary

3. Task Force Update:

The Workgroup received an initial update on the Task Force's Rescue Allocation Pathways Workgroup's first protocol for accelerated placement of hard to place kidneys.

Summary of presentation:

Protocol #1: Accelerated Placement of Hard to Place Kidneys:

- Applies only to offers of deceased donor kidneys with Kidney Donor Profile Index (KDPI) ≥ 75 percent
    - Research shows that kidneys from donors with KDPI ≥ 70 percent are used for transplant less frequently
- Protocol seeks up to 5 OPO participants
    - Varying in characteristics such as geographic location, population density, and medical characteristics of donor population
- Protocol seeks kidney transplant programs with a demonstrated history of KDPI ≥75 percent organs
    - Participating programs may identify 2 candidates for whom they would accept
- For qualifying kidneys, participating OPOs will make offers in the following sequence prior to cross clamp:
    - High priority classifications for kidney transplant candidates
    - Candidates identified by participating programs to be considered for such offers
    - The OPO may then continue to offer the kidneys to remaining potential transplant recipients in the order they appear on the match, or increase the number of simultaneous offers to a set number of recipients at a time
- Proposed evaluation metrics:
    - The number and rate of kidneys from this group of donors used for transplant will be compared before and during the trial period
    - Transplant allocation and usage will be monitored thorough out the trial period. The protocol will be discontinued if adverse effects are observed:
        - Decrease in organ usage
        - Unanticipated rate of early graft loss or delayed graft function

- Intended goals and outcomes: increase likelihood of kidney placement by identifying potential candidates ahead of the match and prioritizing them at an early stage of the placement process
- Observed results previously:
    - A number of OPOs have employed similar strategies for placement of kidneys from high KDPI donors, but the Task Force's Rescue Pathways Workgroup is not aware of any that have used a 75 percent KDPI threshold
        - Many OPOs start with KDPI 85 percent

Summary of discussion:

Upcoming Meetings

- TBD

Attendance

- **Committee Members**
  - Caroline Jadlowiec
  - Chandrasekar Santhanakrishnan
  - Sanjeev Akkina
  - George Surratt
  - Reza Saidi
  - Leigh Ann Burgess
  - Kristin Adams
  - Tania Houle
  - Nancy Rodriguez
  - Jill Wojtowicz
  - Jami Gleason
  - Micah Davis
- **HRSA Representatives**
  - James Bowman
- **SRTR Staff**
  - Bryn Thompson
  - Grace Lyden
  - Jonathan Miller
- **UNOS Staff**
  - Kayla Temple
  - Shandie Covington
  - Kaitlin Swanner
  - Keighly Bradbrook
  - Lauren Motley
  - Thomas Dolan