OPTN Expedited Placement Workgroup
Meeting Summary
May 29, 2024
Teleconference

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

Introduction

The OPTN Expedited Placement Workgroup (the Workgroup) met via teleconference on 5/29/2024 to discuss the following agenda items:

1. Welcome
2. Recap: Workgroup Goals and Scope
3. Task Force Update: Expedited Placement Protocol #1
4. Discussion: Protocols for 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 and the Task Force's Rescue Allocations Pathways Workgroup are both working towards the same goal: expedited placement for kidneys

Rescue Allocation Pathways Workgroup and Task Force:

- Developed the Expedited Placement Variance – allows potential expedited placement protocols to be tested in real time prior to implementation as policy
- Reviews, modifies, submits, and monitors protocols under expedited placement variance, working directly with the OPTN Executive Committee

The Kidney Expedited Placement 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 Committee, Rescue Pathways Workgroup, and Task Force to develop a kidney expedited placement policy
- Discusses expedited placement in the context of continuous distribution, including systems requirements

The Kidney Expedited Placement Workgroup's scope also includes:

- Perform a literature review to understand the strengths, weaknesses, and lessons learned from expedited placement protocols across multiple organs, in various transplant systems
- 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. Task Force Update: Expedited Placement Protocol #1

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

Presentation Summary:

These protocols are being operationalized with a Plan-Do-Study-Act (PDSA) philosophy, in which each protocol can be tested, analyzed, evaluated, and iterated upon. This first protocol is intended to be simpler, to encourage community understanding and buy in and ensue that this process is able to achieve increased utilization without adverse impact to outcomes or access to transplant.

Timeline:

- April 2, 2024 – Expedited Placement Variance implemented
- April 18, 2024 – Rescue Allocation Pathways Workgroup initial meeting
- May 2, 2024 – Prioritized protocol
- May 8, 2024 – OPTN Expedited Placement protocol page published
- May 10, 2024 – Rescue Allocation Pathways Workgroup refined protocol
- May 15, 2024 – Notice of protocol sent to community, starting the two-week public feedback period
- May 20, 2024 – Townhall regarding protocol
- June 14, 2024 – Executive Committee to vote on protocol for approval

Currently, the Rescue Allocation Pathways Workgroup plans to implement the protocol within three weeks of Executive Committee approval. To facilitate this, the protocols utilize minimal to no programming.

The protocol is meant to be initiated prior to cross-clamp. Only kidneys recovered from donors with KDPI 75-100 percent at participating OPOs will be eligible. Prior to cross-clamps, participating OPOs will make offers to candidates in high priority classifications, specifically classifications 1-26 for KDPI 75-85 percent kidneys, and classifications 1-19 for KDPI 86-100 percent kidneys. In parallel to these offers, or at least no less than 2 hours prior to recover, the participating OPO will make the expedited offer to the "target programs." The target programs are programs who have decided up front to participate in this protocol and receive these offers. The OPO will notify the target programs to notify them of the donor and scheduled recovery time, to allow programs to evaluate the available donor information.

Once post-recovery information, such as anatomy and biopsy, is available, the OPO will notify the target list programs of the available information. From this notification, the target list programs have half an

hour to submit up to 2 patients for whom the program would accept the offer. In parallel to this, the OPO would continue to offer the organ to any remaining candidates' programs with "provisional yes" indicated in the high priority classifications. If the organs are not accepted in the high priority classifications, the OPO will begin making offers to the target list of candidates, based on the candidate's original ranking on the match run.

The protocol will include up to 5 participating OPOs for the first iteration. OPO selection will consider variation in geographical location, population density, and medical characteristics of the donor population. An interest form will be released ahead of the Executive Committee vote. The Rescue Allocation Pathways Workgroup will review the interest forms and relevant data and make their selections. The OPOs and Rescue Allocation Pathways Workgroup will work together to develop their target program lists. These lists will vary in length and character by OPO, depending on factors like density of programs in the area, transportation capabilities, and other characteristics. The Rescue Allocation Pathways Workgroup has considered different target lists for daytime versus nighttime, based on transportation availability. Program acceptance practices will also be considered.

The participating OPOs and Rescue Allocation Pathways Workgroup will reach out to the list of potential target programs to ensure their interest and communicate expectations. Programs will have the opportunity to opt out of participating, if they choose. The OPO will stay with the same target list for the longevity of that PDSA cycle. The Rescue Allocation Pathway Workgroup noted that it is important, as the protocol progresses, that programs have the opportunity to opt in to receiving expedited offers that they would accept given lower cold ischemic time.

OPOs will meet monthly to review progress and provide status updates. Qualitative interviews may be conducted to gather additional feedback. The variance results will be shared with participating OPOs, the OPTN Committees, and the broader community.

Protocol monitoring will include OPO identified results and aggregated results across all OPOs. Metrics will be shown weekly but may be aggregated to monthly after several months of data has accrued. Metrics will be broken into four sections

- National metrics (involving all OPOs, not just those in the protocol)
- Protocol specific metrics:
    - Usage of the protocol
    - Impacts on efficiency
    - Impacts on equity

There are two types of monitoring: stopping rules and protocol specific reporting.

- Stopping rules – short report examining the proportion of transplants to females, non-white, and pediatric candidates among participating OPOs per policy 5.4.G
    - Timing: weekly
    - Posting to the Task Force SharePoint site
    - Subgroup of the Rescue Allocation Pathways Workgroup will regularly review and provide recommendations to Executive Committee
- Protocol specific monitoring – in-depth monitoring of the success and potential unintended consequences of each protocol
    - Timing: every other week for 2 months and monthly after
    - Posting:
        - Task Force, Kidney and OPO SharePoint sites
        - Presented to Committees upon request

        - Final monitoring report posted to the OPTN website
    - Subgroup of the Rescue Allocation Pathways Workgroup will regularly review and provide recommendations to Executive Committee

If any red flags are raised in the monitoring of stopping rules, the protocol will be stopped immediately.

The monitoring plan is still under review by HRSA and continues to be finalized.

Summary of discussion:

The Chair confirmed that classification 19 and 26 were not related to sequence number, and that the number of candidates in these classifications can vary. Staff noted that the Rescue Allocation Pathways Workgroup is taking feedback on whether these high priority classifications are appropriately captured, ensuring that these candidates receive the organ offer without contributing to significant delays or inefficiencies. Staff shared that the data reviewed by the Rescue Allocations Pathway Workgroup did not show that there was a large volume of patients in these classifications. The Chair agreed that this data may be helpful. The Chair asked what candidate populations are included in classifications 1-26 and 1-19, based on KDPI 35-85 percent and KDPI 86-100 percent, respectively. Staff explained that classifications 1-26 on KDPI 35-85 percent match runs includes high CPRA, 0-ABDR mismatch, prior living donor, medically urgent, and safety net kidney. Staff continued that this includes those classifications considered "top of the match." One member asked why there were fewer high priority classifications for KDPI 86-100. Staff clarified that the same demographic of candidates is captured in classifications 1-19 for donors with KDPI 86-100 percent. The Chair commented that while it is important to ensure these high priority candidates, especially high CPRA candidates, do not miss an opportunity for transplant, some of these candidates would not be expected to accept a high KDPI offer. The Chair expanded, noting that prior living donor and safety net kidney candidates are likely receiving priority on other, lower KDPI match runs, and may not be likely to accept these kidneys that are hard to place due to concerns for graft longevity. The Chair continued that it is important to balance access to transplant opportunities and efficiency. Staff shared that the Rescue Allocation Pathways Workgroup is trying to balance concerns for efficiency – such as receiving a potentially acceptable hard to place kidney offer in a sufficiently early timeframe – with ensuring that high priority patients still have an opportunity to accept these organs and access transplants.

One member asked if participating OPOs are still able to make offers down the initial match run to ensure back up offers behind the target programs. Staff confirmed this, noting that the Rescue Allocation Pathways Workgroup acknowledges the uncertainty of being able to place kidneys through this protocol. Staff shared that the Rescue Allocation Pathways Workgroup is currently providing the guidance that participating OPOs should plan to stay in the protocol when within the protocol; if the target list is exhausted, the OPO may then go back to the match and continue allocation from the last non-protocol decline. Staff continued that it is important for participating OPOs to follow protocol while allocating in protocol, and once the protocol is exhausted, the OPO should continue to ensure the organ is placed.

A member remarked that hopefully, local back up is not necessary, particularly as "target" programs will be required to have two patients prepared to accept the organ offer. The member continued that even in the event of unexpected candidate issues for their first patient, the program should have another candidate that would is willing and ready to accept the organ. The member noted that this process is initiated prior to cross clamp, with acceptance pending anatomy and post-recovery information. The member pointed out that there should be no reasons for late decline. The member continued that, if expedited placement works correctly, OPOs should not need to utilize allocation out of sequence or worry about reallocation. Staff noted that the Rescue Allocation Pathways Workgroup is trying to

preempt all potential scenarios, including the potential that none of the "target list" programs put forward any candidates to accept the organ. The Rescue Allocation Pathways Workgroup wants to ensure there is ample guidance in all cases.

One member asked if the target program list will change for each offer, or if the target list will be the same. Staff explained that the target list is specific to each OPO and would not change based on the match.

The Chair commented that the idea of including all programs that may be interested in participating is good, but that the literature regarding expedited placement has shown that it is still typically more aggressive programs accepting these organs. The Chair recommended that, if many programs are included, it may be helpful to also evaluate more aggressive programs with a history of hard to place kidney acceptance separately, to understand impact to utilization.

Staff shared that the Rescue Allocation Pathways Workgroup plans to review program data based on the previous 6 months of acceptance behavior, waitlist volume, average wait times, and total transplant volume. This information will be combined with how much the OPO is able to grow, based on how many organs the OPO is recovering but not able to place. Staff continued that this will help match OPOs and transplant programs based on capacity for growth.

The Chair asked if the transplant programs are within close geographic proximity to the OPOs. Staff shared that the Rescue Allocation Pathway Workgroup is looking at reasonable travel circles, noting that close geographic could include a direct flight, with consideration for timing. The Chair remarked that there is a narrative that some programs that have not historically transplanted certain types of kidneys but would have accepted the offers with less cold ischemic time; the Chair noted that theoretically, most of these programs would have had an opportunity to use that type of kidney at least within 250 nautical miles. The Chair continued that standard allocation would have provided those programs that opportunity with reasonable cold time. The Chair continued that including all programs is good, but that the data analysis needs to also separately evaluate programs that have proven they utilize and transplant these organs.

The Chair asked when the participating OPOs will be announced, and when the programs would be approached. Staff remarked that OPO selection will not be finalized until the Executive Committee approves the protocol; after this, the Rescue Allocation Pathways Workgroup will select the OPOs and have those OPOs reach out in the weeks following. Currently, the Rescue Allocation Pathways Workgroup is aiming for a July 13 implementation date; this may change.

Staff shared that the OPTN Task Force leadership has been working closely with OPTN Board and Executive Committee leadership, as well as HRSA, to keep all parties updated. Staff also shared that public feedback gathered up to this point has been largely supportive.

One member asked how the Rescue Allocation Pathways Workgroup settled on utilizing only five OPOs, particularly as so many OPOs are working to reduce non-use. Staff shared that the Rescue Allocation Pathways Workgroup is using five to start the protocol with a smaller, more manageable number of OPOs in order to ensure the protocol is both effective and does not have any unintended consequences. This will also ensure the Rescue Allocation Pathways Workgroup can follow up with OPOs qualitatively to ensure this process works well and is effective, without introducing major costs. If the protocol is effective, the idea is to continue to scale the protocol up. Staff shared that the Rescue Allocation Pathways Workgroup aims to remain flexible. Another member pointed out that keeping the protocols small ensures that the protocols can be accomplished quickly and nimbly, to allow for more protocols to be tested and ensure that the finalized expedited placement policy is effective. The member continued

that there was no exclusionary intent, just the intent to accomplish these protocols quickly. A member agreed.

The Chair asked about the selection criteria for the OPOs. Staff shared that the Rescue Allocation Pathways Workgroup has discussed evaluating rural and urban OPOs, and ensuring there is adequate variation in OPOs, including across differences in geography and population.

One member considered the timing of this protocol, at least 2 hours prior to recovery, and shared that there is often significant interest prior to recovery. The member continued that programs don't make final acceptance decisions until the biopsy, anatomy, and pump information is available. The member asked how the Rescue Allocation Pathway Workgroup plans to address this gap in timing and decision making, noting that time is of the essence, especially in reaching out to these programs individually. The member continued that there should be some automation in notification of available donor information and allow that to influence the match run. Staff noted that the Rescue Allocation Pathways Workgroup has discussed the way that a provisional yes may have more meaning from certain programs that an OPO has closer working relationships with the Rescue Allocation Pathways Workgroup has noted that this protocol may be effective simply because the provisional yes holds more meaning and is more effective. Staff continued that this can be studied to understand what will help improve efficiency. The member agreed, noting that it makes sense to utilize minimal programming in the beginning, but that eventually, automation and notification of available and new donor information will be critical. The member added that target list transplant centers will need to commit to their parameters up front, as this will help improve efficiency in allocation and in decision-making when results are available. The member suggested that OPOs could use these parameters to only make offers to programs that have indicated they would accept specific types of offers with specific donor information. The member shared that there are programs that are less aggressive in acceptance, and that honesty in acceptance practices will be critical to improving efficiency. Staff noted that the Rescue Allocation Pathways Workgroup agrees and noted that offer filter use should support this.

A member said that if OPO and program partners can make the commitment to the process, there will be increased success. Another member agreed, noting that this protocol should have some time-saving elements due to pre-cross clamp offering, ensuring programs can notify patients and perform virtual crossmatches. The member continued that this information should be lined up such that the program is able to rapidly make a decision once post-clamp information is available. A member agreed, noting that the best practice of patient communication does not necessarily happen at all programs, and that most programs wait until there are confirmatory results. One member agreed, adding that programs will need to call people at odd hours if transplant occurs as a 24/7 operation.

One member noted that this protocol will lean on many advance decisions to ensure allocation happens quickly. Another member agreed, remarking that kidneys should be treated similarly to other organs, and with the same level of urgency in consideration of kidney offering.

The Chair agreed, and asked if there will be a direct review with participating transplant programs about expectations, particularly with which parts of evaluation need to be complete when submitting patients. The Chair continued that participating programs must have completed their virtual crossmatch and contacted their patients to screen any initial safety or health issues preventing transplant. The Chair continued that it must also be acceptable for programs to decline; if the program is not going to transplant the organ, the program should decline early instead of continuing to show interest while knowing that they are unlikely to be used. The Chair continued that programs don't need to submit any potential recipients if they would not be comfortable transplanting the organ. Staff agreed with both points and noted that this feedback will be shared with the Rescue Allocation Pathways Workgroup.

One member asked if there will be any protections for participating OPOs with respect to metrics. The member asked what may happen for participating OPOs if the protocol did not support increased use and placement. Staff said this is still uncertain, but Staff will follow up. The member added that if the protocol is very effective and other OPOs are excluded, that these other OPOs may be unhappy about this. Staff noted that this is part of why the protocols are intended to be iterative and scalable, such that effectiveness can be evaluated and then the protocol scaled up to include more OPOs. Staff noted that as new OPOs are incorporated in the protocol, these OPOs may be interacting with different variables than others, and iteration and improvement can ensure the finalized expedited placement policy is effective for all OPOs and programs.

4. Discussion: Protocols for Development

The Workgroup briefly reviewed the expedited placement variance protocol submission template, and shared potential concepts to test within an expedited placement protocol.

Presentation summary:

The Expedited Placement Variance protocol submission template includes:

- 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.

Summary of discussion:

The Chair remarked that the Workgroup members seemed interested in the European Recipient-Oriented Allocation (REAL) model, which may require slight manipulation to align with the US allocation framework. The Chair continued that this model is both efficient and transparent and thus may be effective. The Chair shared that the REAL model was similar to the protocol being tested by the Rescue Allocation Pathways Workgroup, but utilized different initiation criteria, such as decline from 5 programs. The Chair continued that the REAL protocol allowed programs to indicate up to 3 recipients. The Chair offered that initiation criteria could include sequence number and timing of offers.

Another member agreed, but expressed concern that a protocol should not give the primary offer based on which center confirms acceptance first, regardless of the match run. The member noted that offering to too many programs at much may result in a lot of wasted program resources, particularly as many programs evaluating simultaneously may lead to program burn out, especially if programs consistently don't receive the final offer. The member offered that organ offer filters may help as well, so that expedited offers are made to programs that are most likely to accept them.

The Chair asked if the REAL framework could be adapted to support those concerns, and the member agreed, but noted that simultaneous offering blocks should be kept to a reasonable number of transplant programs in order to reduce overall burden on programs. The member continued that this should be selective. The Chair noted that this had been brought up in the literature review as well.

One member continued that it is important to understand the intensively competitive environment the OPOs are in, and the pressure OPOs are under to increase recovery and transplant. The member remarked that this context is important to understanding OPO behavior in allocation out of sequence. Another member agreed, noting that this is one of the unintended consequences, particularly when

there is not adequate technology or processes to support the growth of the transplant system at the rate the organ supply is growing. The member shared that each OPO is well intentioned in trying to place organs, but that the new competitive metrics introduce a level of pressure that induces chaos.

The Chair continued that resources are critical to accomplishing growth, noting that there is still a lot of manual work involved in offering and evaluating offers. The Chair continued that there should be room in these protocols for programs to grow and adjust as necessary according to their resources and capacity. The Chair continued that maybe programs could identify one candidate instead of three. Another member agreed, noting that there are likely multiple pathways. The member offered that programs could maintain a subset of their list to keep track of patients that they may consider accepting more aggressive offers for. The member continued that this allows programs to identify and educate these patients prior to receiving these offers, in support of informed shared decision making. The Chair agreed that this is a good strategy, particularly in sorting this list by blood type.

Upcoming Meetings

- June 10, 2024

Attendance

- **Committee Members**
  - Caroline Jadlowiec
  - Chandrasekar Santhanakrishnan
  - Anja DiCesaro
  - Carrie Thiessen
  - Jami Gleason
  - Jason Rolls
  - Jillian Wojtowicz
  - Kristen Adams
  - Leigh Ann Burgess
  - Megan Urbanski
  - Micah Davis
  - Sanjeev Akkina
  - Stacy Sexton
- **HRSA Representatives**
  - James Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Jonathan Miller
  - Peter Stock
- **UNOS Staff**
  - Kayla Temple
  - Jadia Bruckner
  - Kaitlin Swanner
  - Ross Walton
  - Thomas Dolan