OPTN Kidney Transplantation Committee
Expedited Placement Workgroup

Meeting Summary
November 4, 2024
Teleconference

Chandrasekar Santhanakrishnan, Chair

Introduction

The OPTN Kidney Transplantation Committee's Expedited Placement Workgroup (the Workgroup) met via teleconference on 11/4/2024 to discuss the following agenda items:

1. Welcome and Announcements
2. Updates: Expedited Placement Variance
3. Project Planning
4. Review: Kidney Expedited Placement Process

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

1. Welcome

The Chair welcomed Workgroup members and thanked them for making time to participate in these important discussions.

Summary of discussion:

There were no questions or comments.

2. Expedited Placement Variance Updates and Project Planning

The Workgroup reviewed the work to date on expedited placement across the OPTN, and received an update on the status of expedited placement development.

Presentation summary:

Through 2024, there were three groups discussing and considering expedited placement:

- Task Force Rescue Allocation Pathways Workgroup – focused on testing potential expedited placement pathways on a small scale through the Expedited Placement Variance
- OPTN Ethics Committee – developing an ethical analysis of expedited placement
- Kidney Expedited Placement Workgroup – sponsored by the Kidney Committee
    - Supported expedited placement variance work, and positioned to push forward final expedited placement policy
    - Performed literature review evaluating multiple types of expedited placement
    - Maintained awareness of protocols to be tested within the variance
    - Developed a protocol for consideration by the Task Force

In September 2024, the Health Resources and Services Administration (HRSA) received a critical comment, and asked the OPTN to pause work on the Expedited Placement Variance. However, OPTN Leadership has expressed continued interest in expedited placement.

At their October 8th meeting, the Kidney Committee expressed support for pursing a national kidney expedited placement policy. The kidney expedited placement project would be separate from and precede Continuous Distribution, and operate in the current kidney allocation system.

The kidney expedited placement project would aim for a Summer 2025 public comment cycle. The Kidney Expedited Placement Workgroup will be meet once a month to address outstanding questions and develop an expedited placement process. The Workgroup may have additional meeting ad hoc. Outstanding items include:

- Overall process review for national policy consideration
- Initiation criteria – informed by Kidney Committee's definition of "hard to place"
- Which programs receive expedited offers, and how many?
- Programming and notification requirements
- "Rounds" of expedited allocation
- Dual kidney and released kidney impacts

Summary of discussion:

The Chair remarked that it makes sense for the Workgroup to build on the work they have already done, and that the goal remains the same: to expedited placement for "hard to place" kidneys. The Chair noted that the Workgroup still has several crucial conversations, and will need to ensure that the expedited placement process built is equitable, transparent, and in line with the final rule. The Chair continued that the definition of "hard to place" developed by the OPTN Kidney Transplantation Committee will help to inform when expedited placement is initiated. The Chair added that requirements for pre-expedited placement allocation through priority classifications will also be important. The Chair continued that it will also be important for the Workgroup to finalize and establish expectations for both OPOs and programs within the expedited placement framework.

One member expressed support for expedited placement efforts, but highlighted the need for programs to seriously evaluate and make decision on pre-recovery offers. The member continued that expedited placement would be necessary in far fewer instances if the programs were seriously reviewing offers and accepting organs prior to recovery. The member added that programs should be held accountable for having evaluated all donor and organ information if they have a primary offer going into organ recovery, and should not be declining the offer for information known well before recovery. The member shared that their OPO receives a lot of resistance from programs in evaluating primary, pre-recovery offers seriously. The member continued that this contributes to cold ischemic time build up, which contributes to increased difficulty in placement. The member explained that the expedited placement pathway is important to ensure placement for those truly medically complex kidneys, but upfront accountability and manageability for programs evaluating offers would reduce the need for expedited placement or allocation out of sequence for potentially less medically complex, more likely to be transplanted organs. The Chair agreed, noting that there can occasionally be surprises in organ anatomy or biopsy results, but that otherwise programs should be accountable in these situations. The Chair added that strong back-ups are also important to ensuring organ placement, and that these mechanisms can support reduced non-use. The member responded that the OPTN Computer System should have accountability mechanisms programmed in, such that OPOs can define the primary offer holder, which would support data collection related to late decline and potentially accountability mechanisms later on. The member continued that it is reasonable for programs to decline for anatomy, biopsy, or pump information known after recovery, but that declining post-recovery for pre-recovery information is unacceptable.

The Chair shared that, from a surgeon perspective, it can be easy to initially express interest for a late night offer, and then let the offer sit with minimal reconsideration until recovery. The Chair remarked

that their OPO has their own definition of “hard to place” kidneys, for which they expect programs to crossmatch patients early on if the program has interest in the organs, or else code out. The Chair continued that this has helped their program make decisions on which candidates they would consider the organ for ahead of recovery, ensuring that the candidates who the program has input a provisional yes for are those candidates that may be a good match.

One member remarked that OPOs are under a tremendous amount of pressure under the new performance metrics to increase the number of organs both recovered and transplanted. The member expressed support for offer acceptance ratio monitoring, noting the benefits of transplant program accountability. The member offered that this could be further broken down in to overall offer acceptance ratio and late declines. The member continued that there could also be further conversation on whether the Offer Acceptance Ratio (OAR) thresholds are aggressive enough.

The Chair asked if there was any granular data on late declines, or declines submitted after recovery for information known prior to recovery. The Chair noted that decline codes in the past few years have become more specific, and that this could support improved data quality on late declines. OPTN Contractor Staff noted that the OPTN Operations and Safety Committee looked at this when discussing provisional yes, but that this is tough because formal acceptances are not typically input for kidneys until after recovery due to laterality choice. A member responded that this could be challenging particularly when a case last beyond changing offer call. The member explained that one surgeon could be comfortable with a particular offer, while another surgeon may not be. The member continued that, in that instance, its possible the latter surgeon would code out for a different reason, such as anatomy, to avoid being held accountable for declining for pre-recovery information. The member noted that if only one program coded out for anatomy, this would flag as anomaly or potential late decline.

OPTN Contractor Staff noted that these discussion make sense, but are operating outside of the scope of expedited placement. OPTN Contractor Staff continued that the Workgroup’s discussions and key points are noted, and that the Workgroup may be able to consider potential accountability mechanisms within an expedited placement pathway.

One member remarked that it is important to understand potential drivers of the need for expedited placement as well, such that the expedited placement process is able to address and resolve root issues preventing kidney placement. The member continued that, for now, it makes sense to focus on the expedited placement pathway itself, but keep in mind these aspects of inefficiency that the expedited placement pathway may address. The member also noted that default offer filters implementation should also be considered as expedited placement is considered, and could help to address late decline concerns as well.

3. Review: Kidney Expedited Placement Process

The Workgroup reviewed their discussions to date in developing an expedited placement process, and

Presentation summary:

The goal of today’s discussion is to identify areas of the kidney expedited placement process as currently discussed that may warrant further discussion or modification in order to support a national expedited placement policy. The Workgroup is also asked to consider the specific programming requirements.

The Workgroup has discussed a kidney expedited placement process based on the Eurotranplant’s Recipient Oriented Allocation System (REAL). The process as the Workgroup has developed summarily:

- Leverages a different offering and evaluation method to expedite placement
    - Potentially, leverages different notification capabilities to support this

    - Candidate submission
    - Simultaneous offer evaluation
- Relies on data and initial match run order in efforts to maintain equity
    - Potentially, leverages qualifying criteria to offer only to those programs with history of acceptance
- Potentially, establishes a higher threshold of expectations for programs and OPOs
    - Specifically related to donor information sharing (IE photo requirements), virtual crossmatch, etc.

The Workgroup has discussed the following elements as part of the Kidney Expedited Placement process:

- Candidate selection and submission:
    - Programs may submit up to 3 candidates for whom they would accept an offer
- Prioritization of offers using the original match run
    - The highest ranked candidate submitted will receive the organ
- Simultaneous offer evaluation
    - Programs receiving expedited placement offers will have the same 60 minutes from final organ information posted to designate and submit candidates
- Data driven initiation criteria, based on the “hard to place” definition
    - Definition still in development by the OPTN Kidney Transplantation Committee
- Program qualification to receive expedited kidney offers
    - Workgroup defined tension between managing the number of programs receiving expedited placement offers at once and ensuring programs have access to those offers
- Organ Procurement Organizations (OPOs) must offer kidneys through several initial classifications prior to moving to expedited placement
    - 100 percent calculated panel reactive antibody (CPRA) candidates, 0-aBDR, prior living donor, medically urgent, 98-99 percent CPRA, and prior liver/heart/lung recipients
- Specific OPO expectations, responsibilities, and timelines:
    - OPOs encouraged to share as much donor information as possible, as quickly as possible
    - OPOs are expected to make efforts to pump organs requiring expedited placement
        - Pumping may not be possible, appropriate, or in the best interest of the organ – pumping should not take precedence over timely transportation
    - OPOs are expected to make efforts to ensure biopsy results are available within 6 hours of cross-clamp
    - OPOs are expected to make efforts to post anatomy sheet as soon as possible
    - OPOs are expected to take images of the organs and share them to Donor Net
        - Front and back of kidney, view of aortic patch
    - OPOs should notify programs about a donor’s potential qualification for expedited placement within an hour of initiating EP, if possible
- Specific transplant program expectations, responsibilities, and timelines
    - Program pre-determines a more general list of candidates that they would deem to be appropriate to accept EP offers
        - Considers clinical factors, but also candidate ability to get to the program quickly, etc.
    - Programs are encouraged to discuss EP and similar offers with these patients, to ensure patients understand their options and may make informed decisions on transplant goals
        - Aligns with high KDPI consent modifications/patient education attestation

        - Should there be policy updates associated with EP policy to ensure programs are educating patients on EP process
    - Expectation that program accepts and transplant the organ for which they have designated a candidate
        - Programs must use more detailed codes to describe late declines
        - Late declines should be monitored
    - Expectation that program designates candidates they are willing to transplant based on virtual crossmatch results
    - Expectation that program has performed general patient screening and notification to ensure wellness, readiness, and due diligence that the patient is interested in accepting the organ
    - Expectation that program has back up candidate prepared to accept the organ

Summary of discussion:

One member considered the number of candidates a program could select, and recommended that programs should select at least two candidates, in order to ensure the accepting program has a back-up candidate in the case of last minute issues. The member continued that programs will be financially responsible for the organs they accept, and so it is also in the program's best interest ensure there is a back up. The member continued that thus, it may not be necessary to require programs to have a back up, given that programs will want to mitigate their own risk naturally. The member added that it is important for OPOs to ensure strong back up options, including potentially candidates at other centers, particularly centers with high acceptance rates for the specific donor or organ type. The member continued that those centers could act as back up if all local centers decline the expedited offer.

A member shared that, even for centers with robust waiting lists, it may difficult for programs to identify two candidates who are potential good matches, especially with rarer blood types. The member continued that a requirement to submit multiple candidates could prevent smaller centers from participating in expedited placement. The Chair agreed, and noted that it may not be necessary to require a program to submit two candidates, especially in the case of rarer blood types. The Chair remarked that up to two or three candidates would be sufficient, allowing programs to cap the number of candidates they submit. Another member responded that, if their program could not identify a second back up candidate, that their program would simply not accept the organ. The member presented a scenario where a program accepts an aggressively offered organ for a candidate who ends up testing positive for covid, noting that the chances of finding another center who is interested in accepting the organ are much lower with additional cold time and transportation considerations. The member continued that the program would also be financially responsible for an organ that does not ultimately end up transplanted. One member responded that the expedited placement process should leave it up to the programs to decide whether to take on that risk. A member agreed, noting that programs should always be able to opt out or decline the offer. The member continued that as long as OPOs offer to a certain number of centers within 250 nautical miles or else exhaust all programs within 250 nautical miles in that first round of expedited placement, then equity will be served.

One member presented a scenario where an OPO makes the expedited placement offer to the highest ranking centers within 250 nautical miles, and if all three centers decline, the OPO can expand their offering to include aggressive centers outside of 250 nautical miles who may be more likely to accept and transplant the organ. The Chair expressed reluctance regarding such a process, noting that this may not be sufficiently transparent and objective. The member responded that this process would need to be based on historic acceptance data, such as that found in the Recovery and Usage Map (RUM) reports.

The member emphasized the importance of transparency and equity, and that the expedited placement processes and program qualification criteria should be based on program performance.

The Chair asked how long the nearby programs would be given to evaluate the offer, and the member remarked that 60 minutes would still be adequate. The member continued that programs will need to evaluate for all candidates on the list to determine the most appropriate matches, and so half an hour is insufficient. The Chair agreed. Another member asked if this includes time for crossmatching, and the member responded that programs would largely be expected to utilize virtual crossmatch. The member explained that expedited placement processes will need to rely heavily on programs' use of virtual crossmatching.

A member walked through the process, noting that the program would evaluate through their candidates, and that it would take at least 15 minutes to determine which candidates to crossmatch. The member continued that this process assumes that the lab would be able to return crossmatch results within half an hour. Another member responded that, in instances of receiving aggressive offers, they will quickly look through the match run and identify which patients are at least initially appropriate juts based on basic donor and patient information, and have their lab run virtual crossmatch on that larger list of names. The member continued that while this is happening, their team will more deeply evaluate the patient charts and call the patients to determine patient wellness and availability. The member noted that it is critical to have these processes running in parallel, in order to maintain time advantages. Another member remarked that their program maintains a shortlist of candidates who have been pre-identified as potentially good matches for "hard to place" and aggressive offers. The member continued that even with this, one hour is a tight turn around for virtual crossmatches, especially if a candidate is more sensitized. The Chair remarked that, for an expedited placement process, the intent is to quickly find a well suited patient, and that it may be that programs will need to consider lower CPRA patients. The Chair continued that programs will always have the option to decline or opt out of expedited placement offers, but that the expectation should be that programs are able to identify patients quickly. The Chair remarked that adding time for crossmatch and screening could work against ensuring rapid placement.

One member remarked that it does feel like virtual crossmatches can be more time consuming than expected, especially considering the virtual aspect. A member agreed, and noted that this process will already replace serial offering with simultaneous offering. The member continued that 90 minutes, as opposed to 60 minutes, is not a significant trade-off when ten or more programs are evaluating at a time. Another member agreed. The member continued that, if considering this process in multiple rounds, the first round could be focused on a greater number of nearby and local centers, to ensure equity, and then apply more stringent program qualification criteria in making offers beyond 250 nautical miles if all local programs decline. The member continued that 90 minutes is not a significant increase in cold ischemic time, and hopefully would not prevent acceptance beyond 250 nautical miles.

A member remarked that programs often don't call their recipient until they receive the primary offer, noting that it is too cumbersome to continue to call the same recipient with multiple back up offers to determine candidate available. The member asked if this process will require programs to confirm candidate availability, and if this is a reasonable expectation when so many offers may remain a back up offer that does not ultimately result in transplant for that recipient. OPTN Contractor Staff noted that this is a key consideration for the Workgroup, and that this "disappointment factor" of programs evaluating intensively for an organ they ultimately do not receive should be considered, both in the context of candidate outreach and program resources. Another member remarked that this is something all programs occasionally deal with, and noted that programs struggle with being disappointed in not receiving primary offers after significant evaluation. The member also noted that

patients don't like being called multiple times for offers that they do not become primary for, although some patients are better at accepting the back-up offer availability checks as a fact of life, and that while it is inconvenient, back up offers are also unavoidable. The member continued that it may be helpful to obtain patient feedback as part of this deliberation. Another member agreed, noting that back up offers are part of allocation, and that programs are somewhat used to having candidates be first back up. The member continued that this discussion relates to medically complex kidneys that were not initially accepted, and that candidate selection means that programs will be able to determine which candidates to call based on their relative match run priority and medical compatibility as well. The member continued that each program may function differently in how they handle this process. The member remarked that, ideally, the candidates that are submitted by the program are those that you have identified as good matches and ultimately candidates for whom the program would accept and transplant the organ.

One member asked if expedited placement variances will occur simultaneous with this process, and another member iterated that the expedited placement variance work has been put on hold, and that this policy would work to standard expedited placement across OPOs. The member continued that this policy would provide transparency and equity in expedited placement protocols.

A member recommended that programs notify patients that these expedited placement offers are essentially back up offers, as opposed to formal offers, to reduce confusion and disappointment. Another member agreed, noting that this is a good recommendation. The member remarked that it is not necessary for the policy to be overly prescriptive, and that each program will know best how to work with their patients.

One member discussed the primary offer, asking at which point the program with the highest ranked candidate would need to finalize their decision. The member noted that, if that program does not accept the primary offer, the OPO would need to continue allocation according to the match order of submitted candidates. The member continued that this will be important to preventing gaming, such that a program accepts the organ for one patient and transplants it into another. Another member remarked that there is a released organ policy, but that there should be a strong mechanism to ensure that an organ released after expedited allocation can be transplanted. The member continued that there could be increased accountability for programs releasing these organs. The Chair noted that the current released organ policy may not be appropriate post-expedited allocation, and asked if the Workgroup would support continued expedited placement allocation or instead consider center back up. The Chair added that flexibility in policy will be important in such cases. The Chair continued that monitoring will be important, and that a pattern of overuse of center back up should be followed up with, but that there are fair reasons a program may need to release an organ accepted for a specific patient, such as sudden covid positivity. The Chair noted that returning to the match run to re-allocate the released organ may not be effective, nor align with expedited placement philosophy. A member agreed, noting that the Workgroup should focus on getting to the contingencies before discussing the contingencies.

A member reviewed the process the Workgroup has delineated thus far, noting that programs have to submit a certain number of candidates; if the program is not able to transplant into the candidate they accepted it for, then the OPO would need to offer to the next highest ranking candidate. Another member commented that the Workgroup only noted programs would submit up to three candidates, although the Workgroup has recommended the program have a secondary back up candidate at least, in order to ensure transplant.

One member offered a center-based model of expedited placement where the top three programs are given the offer at a center level. The programs would have 90 minutes to evaluate, and from there the top ranking program will accept the organ and have the responsibility of ensuring its transplant. The

member continued that this is simpler, and that it would not be necessary to stipulate number of patients. The Chair remarked that this could result in programs monopolizing the expedited placement process, and that this would not ensure equity for candidates. The Chair noted that this would be very efficient, but could shortchange candidates at smaller centers who may be open to accepting these organs. The Chair continued that this pathway should not be built to favor larger centers.

A member expressed support for increasing the evaluation time from 60 minutes to 90 minutes, noting that this is a minimal amount of time with consideration for simultaneous evaluation and to ensure the kidney is used. A member pointed out that, with 90 minutes for evaluation, the program may be better able to perform patient health checks and reduce the odds that the organ has to be released due to patient issues.

One member asked how many programs the OPO would make the initial expedited offer to. The member continued that previously, the Workgroup had discussed all programs within the 250 nautical mile circle, but that this would be a very high volume of offers for OPOs in transplant-dense areas. The member continued that the Workgroup would need to consider how many programs should receive the initial expedited placement offer. The Chair offered that it may be easier to consider it in terms of patient numbers, noting that 20 patients could represent 20 centers but may represent only 2 or 3 programs. The Chair continued that this could align with match run order but accelerate evaluation. The member responded that if this was the case, then maybe it should be three programs evaluating and submitting three candidates each, resulting in 9 patients within 250 nautical miles.

The Workgroup will continue their discussions towards developing an expedited placement pathway.

Upcoming Meetings

- TBD

Attendance

- **Committee Members**
  - Chandrasekar Santhanakrishnan
  - Anja DiCesaro
  - Carrie Thiessen
  - Jami Gleason
  - Jason Rolls
  - Jillian Wojtowicz
  - Jim Kim
  - Stacy Sexton
  - Tania Houle
- **HRSA Representatives**
  - James Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
  - Jonathan Miller
- **UNOS Staff**
  - Kayla Temple
  - Houlder Hudgins
  - Lauren Motley
  - Sarah Booker
  - Thomas Dolan