OPTN Kidney Transplantation Committee
Expedited Placement Workgroup

Meeting Summary
December 9, 2024
Teleconference

Chandrasekar Santhanakrishnan, Chair

Introduction

The OPTN Kidney Transplantation Committee's Expedited Placement Workgroup (the Workgroup) met via teleconference on 12/9/2024 to discuss the following agenda items:

1. Review: Project Timelines
2. Review: Kidney Expedited Placement Process
3. Discussion: Workflow Options

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

1. Review: Project Timelines

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:

There were no questions or comments.

2. Review: Kidney Expedited Placement Process

The Workgroup reviewed previously discussed potential frameworks for a kidney expedited placement process.

Presentation summary:

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:

The Workgroup had no questions or comments.

3. Discussion: Workflow Options

The Workgroup discussed several potential workflow considerations, evaluating for potential efficiency benefits and usefulness.

Presentation summary:

The Workgroup has defined several potential issues driving the need for an expedited placement process, including limited program evaluation prior to becoming primary, offer volume, late offers, post-recovery information leading to late decline, etc. There are several workflow and policy levers for consideration in addressing these drivers, including expanded notification, candidate opt-in, offer filters modifications, program qualification and waitlist inversion.

Expanded Notification

The Workgroup has discussed leveraging simultaneous evaluation and candidate selection in the expedited placement process. This would require simultaneous notification of multiple programs, which can be difficult to achieve via standard phone-call notification practices.

One option could be expanded, expedited-specific notification workflow, such that OPOs are able to notify multiple programs simultaneously of an expedited offer. Previously, the Workgroup discussed a 90 minute evaluation period timeframe with this requirement. The Workgroup also discussed specific evaluation requirements within the 90 minute period, including virtual crossmatching, candidate availability, etc.

Summary of discussion:

One member remarked that this workflow component would be extremely helpful, and would critically ensure programs all receive the offer at the same time. The member explained that, currently, OPOs making similar offers must do so over the phone, which requires at least a few minutes per phone call; with consideration for offering to multiple programs, this results in an extended allocation process. The member continued that this process can result in difficulty tracking evaluation times; a simultaneous offer process would ensure timeliness and fairness for all programs receiving offers. Another member agreed, adding that this kind of tooling would be necessary to implement simultaneous offering appropriately.

A member noted that, in discussing expedited placement with transplant program colleagues, there is some concern about the amount of work required in the evaluation period. The member asked transplant program members for their thoughts on performing full evaluation processes without ultimately receiving the organ. Another member responded, noting that this is dependent on the program and their current processes. The member explained that their program is already going through a similar process when considering aggressive offers. The member continued that this risk is part of the workflow, and that programs will find that evaluation efforts may not always yield an offer, and that it may be that not every program is then interested in considering expedited placement offers. The member added that expedited offers would be occurring due to donor and organ characteristics that have made the organ at risk of non-use, and that the critical component is timely allocation. The member continued that potential disappointment is a trade-off to ensuring use for some organs.

One member shared that, currently, their local OPO will make aggressive, “rescue” offers to about ten programs, and that this process does not always result in their program receiving the final offer. The member explained that programs need to assess their current capabilities and capacity for assessing expedited offers, and that this will require a separate workflow and increased resources. The member added that programs must be prepared in order for expedited placement to be successful, and that not every program may be prepared or appropriate to receive expedited offers.

Presentation summary:

Candidate Opt-In

Previously, the Workgroup discussed a potential expectation that programs maintain a pre-identified list of potential candidates who may be appropriate to accept expedited offers. One workflow option could allow programs to indicate which candidates they would like to opt in for expedited kidney offers. This could potentially encourage candidates consideration and evaluation to be performed upfront. This would operate similarly to the expedited liver and dual kidney model. However, expedited liver and dual kidney say much higher volumes of candidates opted in, than accepting those offers. The Workgroup is asked to consider, if utilizing this workflow, whether there should be a limit to the number of candidates that a program may opt in.

Summary of discussion:

One member expressed support for a candidate-specific opt-in functionality, so that programs are able to indicate which candidates they would accept these offers for and are prepared to evaluate on behalf of these candidates. Another member agreed.

A member asked if candidates would be made aware, or otherwise consent to being opted-in for expedited offers. The member noted that transparency for patients is important. OPTN contractor staff noted that the Workgroup has discussed this, and has emphasized the importance of ensuring patients understand the expedited placement process, what these offers are, and how they may work so that they are able to make informed decisions. The Workgroup has previously noted it's important to not be overly prescriptive in how programs inform patients, as patient populations and relevant needs may vary widely, and programs will know how to best serve their patients.

OPTN contractor staff noted that previously, the Workgroup discussed a recommendation that programs maintain a shortlist of candidates that may be appropriate to accept these kinds of offers; this functionality would incorporate this into the workflow. OPTN contractor staff asked if there are concerns about programs having to decide whether to opt a candidate in or not. A member responded that it is important to for each program to have a documented workflow, so that all patients generally have the same experience and have their needs met. The member explained that this could look like some programs deciding only to include patients who live near enough to the program to easily transport themselves to the program in a timely manner, or similar sets of guidelines decided by clinicians at the program. The member continued that programs should simply define their process and adhere to it, but that these considerations could include geography and distance, whether the patient is on hemodialysis, sensitization and comfort with virtual crossmatch, and more. Another member agreed, noting tha t programs need to be able to work through the list based on each organ as well.

OPTN contractor staff asked the Workgroup whether such a workflow should limit the number or amount of candidates from a single center that can be opted in to receive these offers.

One member asked if there was any discussion on transparency of inclusion criteria for patients. OPTN Contractor staff noted that this is something the Workgroup can note, and that there may be a level of clinical decision making that varies for each candidate based on their clinical needs and logistical considerations. One member agreed, and noted that there is already an additional consent requirement for high KDPI kidneys, and so that process may feed into this. The member continued that there is standard criteria for offers such a dual kidney, as well as hepatitis C, but otherwise, all potential donor offers are screened and evaluated for the candidates on the match run on a case by case basis. The member added that when an offer is not accepted for a candidate, there are clear reasons why, and those reasons are input into the system.

Presentation summary:

Offer Filters Modifications

One workflow option could be to update the offer filters system such that programs are able to set expedited placement-specific filters. For example, a program would be able to set a higher or lower cold ischemic time threshold when considering an expedited offer.

Another option would modify the offer filters application within the expedited placement allocation, such that offer filters bypasses could overwrite provisional yes responses once bypass criteria has been met. For example, if biopsy results come back or the cold ischemic time threshold is above a program's threshold, the system would overwrite a program's previous provisional yes. This would only adapt the offer filters bypass rules once expedited placement has been initiated.

Summary of discussion:

One member remarked that both modifications may be necessary, particularly if a program is not as responsive and donor information has changed. The member asked if the filter would be specific to expedited offers, such that a program could filter for certain types of donors with expedited offers. OPTN contractor staff confirmed this, and noted that the main question here is whether there is a need to filter expedited offers differently than standard offers, and if this would be critical to a successful expedited placement system. A member responded that there wouldn't be a major benefit to having additional filters specific to expedited offers, at least for their program, and that their criteria would largely remain the same. The member asked if there are programs that would have different filtering criteria for expedited offers compared to standard offers.

OPTN contractor staff noted that the second option would allow program's existing filters to become more effective, responsive, and dynamic with new information.

One member asked how this would work if a program chooses not to use offer filters at all. OPTN contractor staff explained that currently, the system is operating within "default offer filters" framework, so programs have the option to not use recommended filters. If no filters are active, then there simple would be no filter to apply bypasses over provisional yes responses. OPTN contractor staff explained that the functionality of Option 2 mainly would allow the system to apply filters more closely based on real-time information.

A member expressed support for option 2, noting that it is important for programs to utilize the filters in order to achieve the efficiency benefits, especially if those programs would not accept those offers. Another member responded that having an opt-in would help reduce this, as well as a requirement for programs to demonstrate that they are capable of assessing and accepting expedited offers in a timely manner. OPTN contractor staff noted that the Workgroup has emphasized the importance of these pieces working in conjunction.

Presentation summary:

Program Qualification

With simultaneous evaluation, the Workgroup identified tension between managing the number of programs evaluating an offer and ensuring programs have access to offers. Previous discussions have highlighted ensuring smaller programs have a chance to become more aggressive, while also considering impacts of large offers and evaluation on program resources. One workflow option could be to establish program qualification criteria, based on donor-specific acceptance history. This could leverage offer filters to bypass programs who would not be expected to accept the organ. These filters could include additional margins or "buffers," to allow programs who may be interested in becoming more aggressive to receive and consider these offers. Thus, program qualification criteria could be potentially less strict for programs within 250 nautical miles (NM) of the donor hospital, compared to programs outside of 250 NM.

Summary of discussion:

One member emphasized that the expedited placement pathway should serve both equity and efficiency. The member offered that the expedited offer could made to the top few programs within 250 nautical miles, for those programs to identify 2 or 3 patients for whom they would accept the offer. The member continued that this would ensure there is local participation, irrespective of center size, and thus equity would be served. The member continued that, in order to ensure the kidneys are transplanted, so the top local centers declined, then the organ could be offered to more aggressive transplant programs outside of 250 nautical miles, based on their previous acceptance history. The

member explained that this serves equity by ensuring local centers have a chance at the organ, and then there is a mechanism to ensure the kidneys are ultimately placed.

OPTN contractor staff noted that whatever model was used to establish program qualification criteria would need to have some threshold delineated to determine which programs would be considered as likely to accept expedited offers. Staff explained that this rule could be made more or less stringent, so that a program may qualify to receive an expedited offer from within 250 NM that they may not qualify to receive from outside of 250 NM. Staff asked the Workgroup if it made sense to incorporate some level of program qualification criteria for programs within 250 NM, particularly when considering transplant-program dense areas like New York or Philadelphia. Staff continued that, for programs inside of 250 NM, they could be receiving offers slightly outside of the realm of what they normally transplant, but not necessarily receiving every expedited offer. OPTN Contractor staff presented an example, such that a program may receive expedited offers for donors similar to those they have previously transplanted, as well as donors who may be slightly older, have slightly longer histories of hypertension or diabetes, etc. OPTN Contractor staff explained that this could help the system reduce offer overwhelm and ensure offers are made to those programs likely to accept them.

A member noted that this system is predicated on knowing programs' acceptance and transplant behavior, and asked how granular this data is, and how easy it is to understand this behavior. The member continued that a more readily available figure, such as offer acceptance ratios, may be more helpful, although these are not currently donor specific. The member continued that offer acceptance ratios are decent proxies for program aggressiveness. OPTN contractor staff noted that acceptance behavior is an important aspect of the offer filters model, and that this model could be similarly leveraged for expedited placement. OPTN contractor staff continued that the offer filters model is relatively specific and effective at recommending filters such that programs only filter out offers they would not accept. OPTN contractor staff noted that offer acceptance ratios are less granular.

One member asked how frequently offer acceptance history used to determine expedited offer eligibility would be updated. OPTN contractor staff noted that this is something the Workgroup could discuss and make a final recommendation on; currently, default offer filters are updating every 6 months.

A member asked if this is something that patients could be made aware of at time of evaluation. OPTN contractor staff noted that the Workgroup could discuss this, and that programs may have different processes to ensure transparency regarding filtering and screening practices. OPTN contractor staff noted that offer acceptance ratios provide some information related to general aggressiveness, which may be meaningful for patients.

One member remarked median time to transplant is the most useful metric for patients, but that many patients don't know how to access SRTR's information. The member continued that it could be helpful for the OPTN to find ways to ensure patients are informed of how quickly they can expect to be transplanted at a given center. The member added that programs need to be held accountable for how they're working to consider these offers and make them work for their patients. The member noted that program behavior within the expedited allocation pathway will ultimately translate into their median time to transplant.

Attendance

- **Committee Members**
    - Anja DiCesaro
    - Carrie Jadlowiec

- George Suratt
- Jami Gleason
- Jason Rolls
- Jillian Wojtowicz
- Leigh Ann Burgess
- Megan Urbanski
- Micah Davis
- Tania Houle

- **HRSA Representatives**
  - Sarah Laskey
- **SRTR Staff**
  - Bryn Thompson
  - Jonathan Miller
- **UNOS Staff**
  - Kayla Temple
  - Kaitlin Swanner
  - Lauren Motley