OPTN Kidney and Pancreas Continuous Distribution Review Boards Workgroup
Meeting Summary
October 25, 2022
Conference Call

Asif Sharfuddin, MD, Chair

Introduction

The Kidney and Pancreas Continuous Distribution Review Boards Workgroup (the Workgroup) met via Citrix GoTo Teleconference on 10/25/2022 to discuss the following agenda items:

1. Welcome and Refresher
2. Recap: Exceptions, Attributes, and Clinical Guidance
3. Discussion: Exceptions, Attributes, and Clinical Guidance Continues
4. Data Collection Discussions: Exception Request Form
5. Adjourn

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

1. Welcome and Refresher

The Chair welcomed the Workgroup members. Staff then provided a brief review of the scope and purpose of the Workgroup

Presentation Summary:

The Review Boards Workgroup will establish a review board for kidney and pancreas and identify exceptions that can be requested in continuous distribution. The focus will be on the review board framework and potential exceptions, and provide operation guidance for kidney and pancreas review boards. The Workgroup will develop recommendations, these will be sent to the OPTN Kidney and the OPTN Pancreas Committees to approve. The approved recommendations will be incorporated into the Continuous Distribution proposal, which is currently slotted for the August 2023 Public Comment Cycle.

Summary of discussion:

No questions or comments.

2. Recap: Exceptions, Attributes, and Clinical Guidance

Staff reviewed exceptions, attributes, and clinical guidance that were previously discussed, as well as, those that need further deliberations.

Presentation Summary:

Exceptions are attribute-based, candidate-specific and submitted or known prior to the time of the match run.

- Attribute-based exceptions are more tangible, consistent, and flexible.
- Exceptions are to shift a candidate's position on the rating scale and grant a candidate more points for that specific attribute.
- Exceptions do not change the weight of the attribute nor the importance of that attribute relative to other attributes

- Attribute-based exceptions align with donor factors which are also attribute-based
- Goals are less tangible, less objective and consistent, and less flexible in implementation

The key takeaways from a prior meeting with OPTN Lung Committee Leadership were reviewed. Lung Committee leadership shared that it is important to identify pain points in the current system, particularly areas where patients are not well represented, and determine what aspects could be considered more straightforward and common exceptions.

Attributes the Workgroup has previously discussed are:

- Kidney Medical Urgency
- Longevity
- Pediatrics
- Prior Living Donors
- Kidney after liver (KAL) Safety Net

Attributes that still need to be discussed are waiting time, proximity efficiency, and organ registration. Staff then provided a brief review of the kidney and pancreas rating scales.

Summary of discussion:

No questions or comments.

3. Discussion: Exceptions, Attributes, and Clinical Guidance Continues

Staff provided a review of kidney and pancreas waiting time, proximity efficiency, and organ registration prior to leading a discussion of these attributes.

Presentation summary:

The kidney waiting time attribute is a linear rating scale with no limit, it exceeds 100% beyond 10 years. Current policy can backdate waiting time for a candidate due to administrative mistakes or unforeseen circumstances according to *OPTN Policy 3.7.A*.

The pancreas waiting time attribute is a linear curve rating scale with an inflection point at 90% and 5 years, with a shallower line beyond 5 years to the maximum waiting time.

The kidney proximity efficiency attribute is determined by the distance to the donor hospital. This is a piecewise linear rating scale with a 50 nautical mile (NM) inner plateau, 85 percent at 250 NM, 25 percent at 500 NM, and zero at 5181 NM. Proximity efficiency is calculated at the time of the match run.

The pancreas proximity efficiency attribute is also determined by the distance to the donor hospital. This is a piecewise linear rating scale with a 50 NM inner plateau, 25 percent at 250 NM, and zero at 5181NM.

Pancreas organ registration is an attribute that is intended to allow for appropriate prioritization of pancreas islets. The rating scale is binary with a whole pancreas or kidney and pancreas (KP) candidate receiving one point, and a pancreas islet only receiving zero points. With donor modifiers, whole pancreas and KP are prioritized over islets for donors 45 years and younger and donors with a body mass index (BMI) equal to or less than 30. It is important to note programs will not be able to request and exception to donor modifiers as they are donor specific. Organ registration, though candidate-specific and known prior to the time of a match run, could not necessarily be an exception due to the nature of the attribute.

Summary of discussion:

Kidney Waiting Time Modification Discussion:

Staff asked if this could be a review board process. A member stated they could envision a scenario involving primary graft non function and a center forgetting to, or not knowing they had the ability to, reinstate the candidate's waiting time; this could be a legitimate exception for a review board to consider.

Another member asked if there is a time limit for asking for the wait time reinstated due to primary nonfunction, or does a center have to wait until the patient is ready to be retransplanted before asking for the wait time. Staff answered that there is no time limit for applying for a wait time modification graft failure, but the actual failure must occur within ninety days.

The Chair state they feel that this should not be review board process for first time candidates, and the current wait time modification process under that scenario should remain in place and be incorporated into continuous distribution. The Chair suggested allowing wait time modification if there is an administrative error or delay.

A member offered a scenario where a patient should have been but was not listed prior to turning 18 years old; should that patient have their waiting time modified so they could be listed as a pediatric candidate. Staff answered this was discussed when the Workgroup considered the pediatric attribute and this would go through a review board process.

The Chair asked how frequently wait time modifications are requested. Staff responded that there are a handful of these requests a year.

Staff pointed out that the Workgroup can develop guidance that states this review is only for administrative lapses and primary graft nonfunction, and that centers must prove there was an intent to list or that the candidate should have the time given back. A member agreed.

Staff stated there seems to be a consensus around this issue on keeping wait time modification, but there does not appear to be any strong opinions on whether or not this is a review board process or a waiting time subcommittee. The Chair agreed on keeping the process the way it is but tracking it. A member asked who exactly would be tracking and considering this. Staff answered that this is a decision for the Workgroup to determine. A member said they do not have a strong opinion on if this should go to a review board or some other body.

A member state they believe that those who petition to have their waiting time enacted due to oversight of the program because of natural disaster or other structural problems, because they were not referred prior to the initiation of dialysis due to poor resources at the centers or poor access to medical care should not be considered. The member feels this should be done at the policy level and not by a review board or administrative body. The Chair agreed, and said that the OPTN Kidney and the OPTN Minority Affairs Committee should handle this on a policy level and that the Workgroup is considering very specific scenarios.

The Workgroup agreed that for waiting time modification, especially for primary graft nonfunction there should be an exception.

Pancreas Waiting Time:

The workgroup agreed that exceptions for waiting time modifications for pancreas patients should exist under the same scenarios as kidney patients.

Kidney Proximity Efficiency:

The Workgroup was in agreement that this is not something where an exception can be considered because it is not known before the time of the match run.

Pancreas Proximity Efficiency:

The Workgroup was in agreement that this is not something where an exception can be considered because it is not known before the time of the match run.

Pancreas Organ Registration:

The Chair stated they do not believe an exception could be submitted for this attribute. A member ask for clarification that this is purely a donor factor, staff confirmed.

4. Data Collection Discussions: Exception Request Form

Staff lead a discussion regarding pain points that have not yet been considered and areas within the transplant process where patients may not be well represented.

Presentation summary:

Staff used Medically Urgent Pancreas Candidates as an example. Currently, this is a placeholder attribute, because there is no definition of medical urgency for pancreas candidates. The attribute has a binary scale, and a review board determines if a candidate qualifies.

Summary of discussion:

A member said that medically urgency pancreas is a good example because often times KP candidates are prioritized even over pediatric candidates, and that is difficult to explain without the medical urgency component. Another member stated that they strongly support having a medically urgent pathway in the review board framework

A member asked for an example of a medically urgent pancreas case. Another member responded that having hypoglycemic unawareness that causes seizures, or someone who lives alone and has no one to help with frequent bouts of diabetic ketoacidosis. The Chair added at the medical reasons should certainly qualify, but the social scenarios may not. A member asked if there is data to support this, and if there is data that shows patients are waiting for long amounts of time for a pancreas on average to justify a medically urgent prioritization. The member also encouraged the Workgroup to not lose sight of pediatric renal transplantation. The Chair responded that the data the member asked for may not exist, but that the role of the Workgroup is to determine if there is an exception that might exist. A member said that this could go wrong and that the definition of medically urgent needs to be held to high standard and they are not sure if the candidates that were described in those scenarios would die if they do not get a pancreas and prioritizing those people may disadvantage others on the list. The Chair did agree a clear definition of medical urgency for pancreas with a high standard needs to be put in place. Another member also agreed.

A member asked if there was a set of criteria that everyone could agree on would qualify a pancreas candidate as medically urgent. The Chair responded that answering this might be outside the Workgroup's scope, and they should only consider if such a criteria should exist.

A member asked if there are enough patients on the list for pancreas alone to prevent discard. Another member answered that there are not many pancreas alone candidates, but there are certainly enough pancreas after kidney candidates to prevent discard.

A member pointed out that the number of people who would apply for medical urgency for pancreas would be quite small.

Staff noted that the OPTN Pancreas Committee had a subcommittee in 2020 and 2021 that met to discuss this attribute and came up with a list of criteria for pancreas medical urgency. Staff suggested inviting the Chair of the OPTN Pancreas Committee to the Workgroup's next call to get their perspective on the matter. A member agreed and said that during that process there was support from the Pancreas Committee but not from others working on continuous distribution. The Chair asked staff to invite the Pancreas Committee Chair to the next call.

A member asked about the possibility of considering type two diabetic patients who don't meet the body mass index (BMI) requirements who could petition an exception because of their body type rather than their BMI. The Chair agreed that this sounds like it could be an exception.

Another member said that a pain point is pediatric candidates who have to compete with multi organ transplant candidates. The member also said that high quality organs going to patients who have a lower post-transplant survival rate than pediatric candidates is another pain point brought about by the proliferation of medical urgency for multi organ candidates. A member stated that this came from a goal of reducing waitlist mortality. The Chair appreciated the comments but said this probably falls outside the scope of the Workgroup.

The Chair asked if there are surgical consideration for pediatric candidates that has not yet been considered. A member responded that there are some aspects for transplantation with smaller, younger, transplant candidates and their medical urgency. Another member agreed with this because of the surgical complexities that are part of those transplantations. The Chair asked if the current medical urgent definitions apply to both adult and pediatric patients, staff confirmed. A member said there should be a separate pediatric criteria. The Chair pointed out that this is something for the OPTN Kidney and OPTN Pediatric Committees to work on. Another member asked how multi organ transplants impact this. A member responded that this seems more like a policy consideration rather than a Workgroup consideration. Staff noted that guidelines for pediatric patients could also be considered by the Workgroup.

5. Adjourn

The Chair and Staff thanked the Workgroup for the discussion.

Upcoming Meeting

- November 8, 2022; 4 p.m. Eastern Time

Attendance

- **Workgroup Members**
  - Asif Sharfuddin
  - Beatrice Concepcion
  - Dean Kim
  - Elliot Grodstein
  - Maria Helena Friday
  - Reem Raafat
  - Stephen Almond
  - Todd Pesavento
- **UNOS Staff**
  - Alex Carmack
  - Carol Covington
  - Jennifer Musick
  - Joann White
  - Kayla Temple
  - Keighly Bradbrook
  - Kieran Mcmahon
  - Kim Uccellini
  - Lauren Motley
  - Lindsay Larkin
  - Sarah Booker
  - Thomas Dolan