OPTN Kidney and Pancreas Continuous Distribution Review Boards Workgroup
Meeting Summary
December 6, 2022
Conference Call

Asif Sharfuddin, MD, Chair

Introduction

The Kidney and Pancreas Continuous Distribution Review Boards Workgroup (the Workgroup) met via GoTo Teleconference on 12/06/2022 to discuss the following agenda items:

1. Review: Exception Process Walkthrough
2. Discussion: Review Board Framework

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

1. Review: Exception Process Walkthrough

Staff reviewed the purpose of review boards in continuous distribution, review board framework, and exceptions.

Presentation summary

Current review board members quickly review specific, urgent status patient registrations on the OPTN heart, liver, and lung transplant waiting lists. Collectively they determine whether these listings are appropriate based entirely on clinical information that complies with OPTN policies.

Currently, kidney and pancreas do not have review boards. With the transition to continuous distribution, all organ systems will establish a review board. The Workgroup is tasked with determining what exceptions to allow. Exceptions are rare clinical situation where peers will need to collectively determine whether a candidate should be granted a different score. The Workgroup will identify candidate-based attributes for transplant centers to request exceptions.

Summary of discussion:

The Workgroup had no questions or comments.

2. Discussion: Review Board Framework

Staff led the Workgroup in discussion of specific framework topics.

Presentation summary:

This discussion is centered around building the operation framework for the Review Board. Each topic will be introduced, and include a recommendation based on the cross-organ framework developed for review boards in continuous distribution. The recommendations developed based on feasibility and experience in other review boards. Each framework topic should be discussed based on what will best serve the kidney and pancreas transplant community and candidate populations.

The Workgroup has previously decided that each organ type should be evaluated by reviewers of that specialty. Pediatric cases should be adjudicated by pediatric reviewers, and pediatric cases should also

be separated by organ type. The question remains who should vote on pediatric kidney-pancreas cases - should it the reviewers of these cases be only pediatric specialists?

Between 2017 and 2021, 22 transplant hospitals listed a pediatric candidate for either pancreas alone or kidney-pancreas. Currently, 14 transplant hospitals have a pediatric pancreas candidate currently listed and one transplant hospital has a pediatric kidney-pancreas candidate listed. This leaves a very small pool of people who could possibly review these cases and increases the likelihood of a conflict of interest.

Another topic for the Workgroup to consider is how exceptions should be reviewed, prospectively or retrospectively. Prospective allows for cases to be reviewed and approved prior to candidate receiving the benefit of the exception. Retrospective cases are reviewed and approved or denied while the candidate receives the benefit of the exception.

Summary of discussion:

The Chair began the discussion by reminding the Workgroup they had previously discussed and agreed that pediatric cases should be handled by pediatric specialists, and one member had pointed out that it might be beneficial to keep one adult specialist on each case and other members had agreed with this idea. The Chair then asked if it would be possible to delineate between cases that might need an adult reviewer and cases that would need only pediatric specialists.

Staff responded by noting that one part of the framework the Workgroup needs to address is what to do when there are not enough pediatric pancreas doctors available for review. The solution could be to put as many pediatric reviewers on the case as possible and then fill the rest of the spots with adult reviewers, or only the pediatric specialists available at the time could review the case. It would also be possible to have pediatric specialists outside of the pancreas specialty review a case.

A member responded that in this scenario it would make sense to fill the remaining spots on the board with adult pancreas specialists, as at the very least this keeps all the reviewers within the same organ specialty. The Chair agreed with this idea, pointing out that, although they may not have pediatric experience, adult specialist would have enough background knowledge of the exceptions to understand the case and how the exception would impact the patient. The Chair continued that pediatric pancreas cases are rare and likely not as urgent, and as such the timeline for reaching a decision could be extended in order to find enough reviewers and give them an appropriate amount of time to review the case.

Another member stated, that while they do not disagree with this idea, there are certain diseases and disorders within pediatric populations that an adult specialist may not be familiar with. The member is concerned that in certain cases having too many adult reviewers might disadvantage a pediatric patient. The member offered that it may be more appropriate to have pediatric kidney specialists reviewing the cases because they have faculty knowledge on pediatric diseases. The Chair agreed with this concern but pointed out that having the majority of the reviewers as pediatric specialists should prevent this from happening as long as all reviewers do their due diligence in reviewing the case.

Staff asked the Workgroup at what point would they be uncomfortable with adult specialists reviewing pediatric pancreas cases. Keeping in mind that ideally all seven reviewers would be pediatric specialists, and as a group they have established that one adult reviewer is acceptable, how many adult reviewers is too many?

The Chair responded that one or two adult specialists is acceptable but beyond that, it does not feel like a fair review. Another member agreed.

Staff then asked how the Workgroup felt about pediatric kidney specialists reviewing pancreas cases.

The member who had originally offered this idea stated they are not advocating for it, especially with pediatric kidney-pancreas patients having a low number of candidates, but they did want the Workgroup to consider this as a possibility.

The Chair asked if other review boards, such as liver, ever let adult specialists review pediatric cases. Another member, who had served on the national liver review board (NLRB), responded that currently adult specialists do not review pediatric cases, but they used to when the NLRB first started. Staff responded that the Lung Committee had similar concerns when establishing their review board, and ultimately determined that adult specialists could review pediatric cases, but each pediatric case must have a certain number of pediatric specialists.

Staff noted that if the Workgroup wants to go in a similar direction as the Lung Committee did, they would need to decide who reviews a case when not enough pediatric reviewers are available. The Chair responded that they are comfortable with adult reviewers examining cases in order to meet the necessary quorum for the case. A member agreed, noting that the transplant hospital submits a narrative explaining the need for the exception and an adult specialist would be able to read that and appreciate the validity of the exception or not. A second member agreed while highlighting how rare pediatric pancreas exceptions are and how small the pediatric pancreas field is, it would make sense to have adult specialists reviewing those cases when needed. Another member suggested that adolescent pediatric patients could have their case reviewed by all adult reviewers. The Workgroup achieved consensus around allowing adult specialists to review pediatric cases when needed.

Staff asked the Workgroup how comfortable they are with pediatric specialists reviewing adult cases. One member pointed out that on the surgical side of pancreas, most surgeons are doing pediatric and adult because pediatric is so rare, so it really does not make a difference. Another member said that while they would be comfortable with pediatric specialists reviewing adult cases, it probably will not be needed since the field is much larger. The Chair said pediatric specialists would still be knowledgeable enough for both kidney and pancreas that they could review adult cases. Multiple members agreed.

Staff asked the Workgroup for their thoughts regarding prospective and retrospective review. A member voiced their support for prospective review rather than retrospective review. Another member agreed, elaborating that rarely are the cases urgent to the point of imminent death, which is the biggest advantage to retrospective review. Other members agreed with prospective review.

A member asked how members are notified and when precisely does the clock start. Staff explained that the day the exception case is sent to the reviewers is considered day zero, reviewers are notified via email and have three days to vote before they are replaced. A member asked about the possibility of receiving a text message rather than an email. Staff responded that is a good idea and made note of it.

A member shared they would like to shorten the review timeline for kidney medical urgency to three or four days, because losing dialysis for so many days could become a life-threatening issue.

Upcoming Meeting

- December 13, 2022

Attendance

- **Workgroup Members**
  - Asif Sharfuddin
  - Dean Kim
  - Elliot Grodstein
  - Maria Friday
  - Michael Marvin
  - Namrata Jain
  - Stephen Almond
  - Todd Pesavento
- **UNOS Staff**
  - Alex Carmack
  - Carol Covington
  - Darby Harris
  - Jennifer Musick
  - Joann White
  - Kayla Temple
  - Keighly Bradbrook
  - Kieran Mcmahon
  - Krissy Laurie
  - Lauren Motley
  - Lauren Mauk
  - Lindsay Larkin
  - Sarah Booker
  - Thomas Dolan