OPTN Kidney and Pancreas Continuous Distribution Review Boards Workgroup
Meeting Summary
May 22, 2023
Conference Call
Asif Sharfuddin, MD, Chair

Introduction

The Kidney and Pancreas Continuous Distribution Review Boards Workgroup (the Workgroup) met via Citrix GoTo Teleconference on 05/22/23 to discuss the following agenda items:

1. Welcome and Announcements
2. Recap: High Level Overview of Kidney and Pancreas Review Boards in Continuous Distribution
3. Kidney and Pancreas Review Board Framework

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

1. Welcome and Announcements

Staff and the Chair welcomed the Workgroup members to the call.

2. Recap: High Level Overview of Kidney and Pancreas Review Boards in Continuous Distribution

Staff gave a brief overview on the purpose and role of review boards, the scope of the Kidney and Pancreas Review Boards Workgroup, and information about review boards in continuous distribution in general.

Presentation summary:

OPTN heart, liver, and lung review boards quickly review specific, urgent-status patient registrations for candidates on the respective waiting lists. These registrations are generally patients for whom the medical urgency algorithms and system does not appropriately represent, and for whom additional priority is appropriate. Review board members review and submit individual votes to collectively determine whether these listings are appropriate, based on the clinical information provided and the OPTN policies and guidance. This is meant to balance appropriate review and fairness to individual patients with fairness to all other patients, who are appropriately represented by the system. Specific to continuous distribution, review boards allow members to submit an exception request when they think their candidate is not well-represented by the general allocation policies, significantly enhance the flexibility of organ allocation policy, and allow the OPTN and Committees to collect information that can provide insight into where policy modifications may be appropriate.

For now, large volumes of exceptions are not expected for kidney and pancreas review boards immediately post-implementation of continuous distribution, due to small patient populations in these particular attributes and the fact that policy does not currently utilize multi-factorial medical urgency scores for kidney and pancreas. The limited impact to current populations means that it may be necessary and appropriate to start small and potentially modify the structure of the review board in future iterations. Having a review board in place will allow for more flexible implementation and policy development in the future. Staff noted that this is not the final version of the review boards.

Summary of discussion:

There was no discussion.

3. Kidney and Pancreas Review Board Framework

Staff gave a recap of the review board workflow for both kidney and pancreas.

Presentation summary:

There will be two separate review boards: one for kidney and one for pancreas/kidney-pancreas (KP)/islets. Each review board will be chaired by a clinical member of the respective committee. If no clinical member of the OPTN Kidney or Pancreas Transplantation Committee can be found, a clinical member of another OPTN Committee with relevant organ-specific expertise may take on this role. Each review board will also have a Vice-Chair, who will become the next review board Chair.

Staff recapped what was discussed last call, including Chair and Vice-Chair responsibilities, the commitment period, recruitment, and recommended qualifications.

Kidney Review Board

Last call, the Workgroup decided that around 40 members on the review board is appropriate, with a minimum of a third of these reviewers reserved for those with pediatric expertise. Previously, the Workgroup had decided that the only attributes eligible for exception requests in the new review board structure are Safety Net and kidney medical urgency. Safety net cases will be reviewed prospectively, whereas kidney medical urgency cases will be reviewed retrospectively. Staff noted that a loss of pediatric priority due to candidate transfer will be able to be handled administratively and will not need review by the review board.

Staff then recapped the process for submission, voting, and timeline. Some edge cases were explained, including insufficient reviewers (the system will find as many reviewers as possible, with a minimum of two) and insufficient votes (the minimum number of votes is two; if only one vote is submitted, the case will default to an approval). Staff recapped the appeal process. Previously, the Workgroup had decided that a transplant program would have 14 days to appeal a denial of an exception request. The recommended framework for appeal timing was three days, and lung review board uses an appeal timing of five days. Staff noted that a timeline of 14 days means that for denied medical urgency cases, a candidate can have medically urgent status for up to 13 days without being removed from medically urgent status and that this would be within the bounds of policy. The Workgroup was asked to consider if they would like to keep the timeline of 14 days for appeal. Staff then recapped the process for submitting a second appeal.

Membership of the second Appeal Review Body (ARB) is comprised of members from the general review board pool, and membership on the ARB is considered a responsibility of joining the ARB. A portion of the membership of the ARB will be reserved for members with pediatric experience. ARB members will commit for two years, and half of the ARB will rotate off each year. There will be 12 total members on the ARB. Members were asked to consider how many of the 12 should have pediatric experience.

All members of the ARB are assigned to all second appeal cases, except those in which they have a conflict of interest. Cases are reviewed during regularly scheduled calls. Programs may opt to have a representative join the call to present the case, though they are not required to. These representatives will not be present for deliberation and voting. The Kidney Review Board Chair is also the Chair of the ARB and is always a voting member. If the Chair cannot lead the call, the Vice-Chair will lead. If both are unable to lead, another member of the ARB can lead the call. Ties result in an automatic approval. The

ARB will have 14 days to meet, discuss, and vote from case assignment. If the case is not voted on in 14 days, it is approved by default. The minimum number of reviewers and votes is three. If three votes cannot be obtained, the case is approved by default.

Pancreas Review Board

For both organs, the reviewer pool size will not be included in the operational guidelines to allow for flexibility and modification if necessary. The pancreas review board will also have a Chair and a Vice Chair with the same responsibilities as the kidney Chair and Vice Chair. Previously, the Workgroup recommended having about 34-36 members on the review board. Members were asked to consider how many spots should be reserved for pediatric reviewers. It was noted that pediatric pancreas transplant is rare, so pediatric pancreas reviewers are expected to be somewhat rare as well. Pancreas adult cases can be reviewed by adult reviewers and reviewers with pediatric expertise, as the Workgroup noted that these pediatric reviewers are likely to have significant experience with adults as well. Pediatric cases will be reviewed by primarily pediatric specialists, with any gaps filled in with adult reviewers.

For pancreas, exceptions will be reviewed prospectively. The Pancreas committee is exploring a definition and inclusion of a pancreas medical urgency attribute currently. Staff recapped the pathway for submitting an exception request, case timeline, and voting procedures, which closely follow those of kidney. The minimum number of reviewers is two. If two cannot be found, the system will default to an approval. The minimum number of votes is two. If two votes aren't submitted, the system will default to an approval. While the future of the pancreas medical urgency attribute is still under consideration, if the recommendation is that the review of medical urgency cases is retrospective, this Workgroup should consider the timeline that a program has to downgrade their candidate's status or submit an appeal. The current recommendation from the Workgroup is that a program should have 14 days to appeal or remove the candidate from medically urgent status. Staff asked members if they want to shorten this, noting that the same concerns described earlier for kidney apply here.

Staff explained that the pancreas ARB will work the exact same as the Kidney ARB as described above. The total ARB will have 12 members, and the Workgroup was asked to consider how many ARB members should have pediatric experience. The timing and functionality of how the pancreas ARB works is otherwise the same as kidney.

Summary of discussion:

Kidney Appeal Timing

On the question of how long a program should have to appeal a denied case, a member stated that 14 days may be too long for a denied candidate to receive priority that was initially denied. Staff noted that the appeal timeline varies by organ type and organ-specific clinical considerations, however, the other organ systems utilize shorter timelines that are anywhere between one and seven calendar days. The Chair stated that 14 days is too long and suggested either three or five days. A member suggested using three days, as this would typically represent one standard missed dialysis treatment, and that if a candidate is truly medically urgent, the program should make their appeal rapidly.

The Chair asked if three calendar days would afford enough time for programs to gather the appropriate information for the appeal. A member stated that three days seems sufficient especially considering the other organs are able to use three days and have not experienced problems from programs with submission timing. A member explained that if a decision is rendered Friday afternoon, it may be

challenging for programs to gather the information over the weekend. The Chair noted that heart and lung candidates are usually under complete, round-the-clock clinical care by their transplant teams, however, this is not always the case for kidney candidates. Because of this, kidney programs may need additional time to gather the appropriate information for an appeal. The Workgroup reached a consensus to recommend five calendar days for a program to downgrade their candidate or submit an appeal from the denial notification.

Kidney ARB: Pediatric Reviewers

On the question of how many pediatric reviewers should be on the kidney ARB, a member suggested keeping it consistent with the general review board and using a third as the proportion or expanding to a half. The Chair explained that a third would be the minimum, and half makes sense as a maximum. Other members agreed with this.

Pancreas Review Board Pool Size

The Chair stated that the pool size of 34-36 seemed reasonable, and that it could be expanded if necessary. Other members agreed.

Pancreas Pediatric Reviewers

On the question of the proportion of reviewers that should be reserved for members with pediatric expertise, the Chair suggested a third. A member stated that this makes sense and would be consistent with kidney. Another member noted that depending on the definition of "pediatric experience," finding clinicians with the appropriate experience may be difficult. A member explained that the Workgroup should consider that the vast majority of cases will be adult, so deciding on a high proportion may over-represent the pediatrics on the review board and limit the number of adult reviewers. A member asked how many pediatric pancreas transplant programs there are currently. Staff noted that for kidney, there are 102 approved pediatric programs. For pancreas, there are 27 total programs, but it is a bit difficult to discern which are doing pediatric transplants according to the OPTN Bylaws.

A member noted that it is extremely important to advocate for pediatric candidates, however, because it is so rare for a pediatric candidate to receive a pancreas transplant, it may make sense to require five members on the review board have pediatric expertise. This member suggested that the Workgroup may need more information to answer this question. Another member added that the data is complicated by the fact that the pediatric pancreas transplants are usually multivisceral. A member noted that the point of the review board is to have peer review and expertise that matches the cases that will be submitted. Noting that a pediatric case will be very rare, this member agreed with the suggestion to require five reviewers to have pediatric experience. The Chair agreed. A member noted that even finding five people may be difficult. Staff agreed to investigate additional data for members to review next call and also explained that all of these recommendations will be reviewed and discussed by the Kidney and Pancreas Committees, respectively.

Pancreas Appeal Timing

A member suggested being consistent with five days from pancreas to kidney. The Chair agreed with this. A member asked what would happen if a candidate is transplanted at a medically urgent status that is then reviewed and denied. Staff explained that this is up for future discussion for the Workgroup and Committees. In developing the review boards, the Workgroups and Committees are able to build in thresholds and policy language that help determine what happens if a program has too many transplants at denied statuses. The Chair noted that this may warrant review by the OPTN Membership and Professional Standards Committee.

Pancreas ARB: Pediatric Reviewers

On the question of how many slots should be reserved on the pancreas ARB for reviewers with pediatric experience, a member suggested a maximum of five. The Chair suggested three members. A member agreed. Staff noted that this question can be discussed again at a later call.

Upcoming Meeting

- June 13, 2023

Attendance

- **Workgroup Members**
  - Asif Sharfuddin
  - Antonio di Carlo
  - Ajay Israni
  - Dean Kim
  - Namrata Jain
  - Todd Pesavento
- **HRSA Representatives**
  - Jim Bowman
- **UNOS Staff**
  - Joann White
  - Carol Covington
  - James Alcorn
  - Kayla Temple
  - Kieran McMahon
  - Keighly Bradbrook
  - Kim Uccellini
  - Katilin Swanner
  - Krissy Laurie
  - Lauren Motley
  - Lindsay Larkin
  - Sarah Booker
  - Thomas Dolan