OPTN Kidney and Pancreas Continuous Distribution Review Boards Workgroup
Meeting Summary
May 9, 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 05/09/23 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 Structure
4. Kidney Review Board

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. Check-in: High Level Overview of Kidney and Pancreas Review Boards in Continuous Distribution

Staff gave a brief overview of the Workgroup's decisions to date on kidney and pancreas review boards in 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 Structure

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.

The review board Chair will have several responsibilities, including hearing concerns from reviewers and programs, reaching out to review board members and educating when appropriate, addressing inappropriate reviewer comments, and approve the removal of non-responsive reviewers. The Chair also maintains awareness of cases and trends to determine if new policies may be necessary and acts as a liaison to the Committees. The Chair will also serve as the Chair to the Appeal Review Body (ARB) and lead those conference calls, guiding the conversation and maintaining knowledge of OPTN Policies and Guidance. The Chair acts as a reviewer in the general review board pool and reviews cases as assigned, and is considered one of their program's representatives.

The Vice-Chair will back up the Chair in these responsibilities, but in particular will also be responsible for acting as a reviewer in the general review board pool (and is considered one of their program's representatives), attend the ARB calls and lead them in the case that the Chair is not available, and ais also able to approve the removal of non-responsive reviewers and reach out to review board members and educate where appropriate.

Reviewers will be recruited via open call. Programs may submit nominees if interested in participating. Programs may submit up to 2 reviewers. This would be first come, first served, however, programs who submit nominees after the review board is full will be placed on a waiting list, to be called on if the pool is expanded or a reviewer needs to be replaced. Previously, the Workgroup determined regional representation was not necessary, as this is a national review board and clinical considerations would not change. The following are the recommended review board member qualifications: reviewers should be at least 5 years post-fellowship with direct transplant experience and reviewers should be actively working in transplant at an active transplant program.

Review board membership is a 2-year commitment. Half of the review board will roll off each year and the call for reviewer nominations will happen annually. Upon initiation of the review board, the second half of review board respondents will have a single year term. A remaining decision point is if programs with representatives who have just rolled off be allowed to submit nominees again? Staff noted that members should consider limitations in pediatric expertise.

Summary of discussion:

The Chair asked about the terms for the Chair and Vice-Chair, and staff noted that this was open for Workgroup discussion. A member suggested each position having a one-year term, so that the Vice-Chair would become the Chair their second year on the review board. The Chair agreed with this suggestion, noting that any longer would be a very long term commitment. Another member agreed that a total of two years is a reasonable commitment.

A member suggested only allowing one representative per center to be on the review board and the other representative could be an alternate or a backup. Another member noted that currently for the National Liver Review Board, alternates are permitted. Staff explained that for a national review board in continuous distribution, the hope would be to move away from having primary and alternate reviewers due to some noted difficulties with that setup, including low alternate familiarity with the system. The Chair stated that this is understandable, but having two representatives from a program may bias review board decision making. The Chair recommended having programs submit two candidates, but to only choose one at the most from each program. A member noted that in that case, programs should just be limited to nominating one person to avoid having to come up with selection criteria. Staff agreed that if the concern is having two representatives from one center, programs should be limited to submitting one representative. Other members agreed with this suggestion.

As for the decision point of if programs with representatives who have just rolled off be allowed to submit nominees again, the Chair explained that members should consider if programs should be allowed to submit *any* nominee and if programs should be allowed to submit *the same* nominee who will have just rolled off. The Chair stated that pancreatic pediatric expertise is so limited that there would be concern about limiting the nomination for these reviewers. The Chair noted that they did not see a problem with a program submitting the same or a different reviewer. A member suggested not allowing the same member to serve consecutive terms in the spirit of bringing new voices to the review board. Staff asked if an exception should be made for pediatric pancreas reviewers, and a member noted that this seemed reasonable. Staff explained that one way this could work is by allowing programs to submit the same reviewer, but only choosing them if they are needed to ensure appropriate representation.

A member explained that limiting consecutive terms makes sense for after the review board turnover is established after one year, but that a provision should be made to allow members who served only one year during the first year of operation to serve a consecutive term. A consensus was reached to allow this, and for after the first year of operation, to allow programs to submit the same reviewers, but that these submissions would "go to the back of the line" and only be chosen in the case of ensuring appropriate representation.

4. Kidney Review Board

Staff went through kidney-specific considerations for the Kidney Review Board with members.

<u>Presentation Summary:</u>

For both organs, reviewer pool size will not be included in the operational guidelines to allow for flexibility and modification if necessary. The Kidney Review Board will have about 34-36 members.

- Decision: How many reviewer slots should be recommended to reserve for pediatric expertise?

Staff noted that kidney adult cases are reviewed by kidney adult reviewers and kidney pediatric cases are reviewed by kidney pediatric reviewers. If not enough kidney pediatric reviewers are available, the adult kidney reviewers may review pediatric cases.

- Decision: in the rare event that not enough adult kidney reviewers are available, can pediatric reviewers fill in to vote on pediatric cases?

Case Review

Staff explained that under the kidney review board, exceptions regarding medical urgency will be reviewed retrospectively, whereas all other exceptions will be reviewed prospectively. While the Workgroup had previously discussed providing an exception pathway for pediatric registration, staff

noted that this is expected to be handled administratively through system updates outside of continuous distribution.

Staff then recapped how the review board process works. A transplant program submits an attribute-based exception for their candidate, including the justification narrative supporting their request. The OPTN Contractor staff review the request, redact sensitive patient information, and submit it to the review board. Once submitted, the five calendar day clock begins. Seven reviewers are assigned to each case. If the reviewers do not vote within three days, they will be replaced by another reviewer at random. If they are not able to vote, participants may request that the case be reassigned to another randomly selected reviewer. Participants can also mark themselves out of office.

An exception case will close when a majority approval or denial is met, or the case reaches the end of the timeline of five days, whichever is first. Votes are tallied utilizing Robert's Rules of Order definition of a majority as "simply more than half." The transplant program receives an email notification with the outcome of the case. In the event of a tie, the benefit will be given to the candidate and the exception will be approved.

If the exception request was denied, the transplant program has the option to submit an appeal within 14 days of the denial notification. Once submitted, the five day clock starts again on the case's lifespan. The first appeal is reviewed by the same participants that denied the initial request. The second appeal will go to a reviewing body.

Staff then introduced some edge cases for the Workgroup to consider.

Insufficient Reviewers

If seven reviewers cannot be found, the system will pull as many reviewers as possible, with an absolute minimum of two reviewers.

Insufficient Votes

The minimum number of votes required is two. If only one reviewer (or no reviewers) submit a vote by the end of the case timeline, the case will default to an approval.

Summary of Discussion:

The Chair suggested recommending a minimum of 7-10 slots reserved for reviewers with pediatric expertise. On the question of if not enough adult kidney reviewers are available, if pediatric reviewers can fill in to vote on pediatric cases, a member explained that most pediatric physicians take care of older children and even sometimes patients over 18, and suggested a minimum of 10-12 members as pediatric. The Chair noted that in their experience, sometimes pediatric specialists feel uncomfortable with some of the adult-specific complex clinical considerations. The Chair agreed with at least 10 members as pediatric reviewers. A member noted that by looking at the kidney waitlist, the majority of review board cases would be expected to be adult. Staff noted that members may want to agree on a proportion of slots reserved for pediatric expertise, such as a third. Two members agreed. Members discussed possibly ensuring that at least five out of seven reviewers on a pediatric case would have pediatric expertise. Staff explained that this could not be ensured based on how the system works, but the way to ensure appropriate review would be to have enough pediatric reviewers on the review board. A member stated that a concern is overtaxing the adult reviewers because there are likely to be many more adult cases than pediatric cases. Staff explained that the Workgroup could elect to expand the review board pool and that the number of people in the review board pool can be changed if need be throughout the function of the review board. A member explained that there may be more cases submitted to the review board as programs get used to having that as an option for kidney.

The Chair noted that it is hard to predict, and discussed the different options laid out by members. The Chair asked if 40 members with a proportion of a third reserved for pediatric members seemed reasonable. Members reached an initial consensus to expand the review board pool to 40 members with a minimum of a third of the members in the pool having pediatric expertise.

On the question of if not enough adult kidney reviewers are available, if pediatric reviewers can fill in to vote on adult cases, the Chair stated that this seemed reasonable. A member stated that the cases seen by adult specialists are much different than the cases seen by pediatric specialists. A member agreed. The Chair stated that this should be reasonable because the majority of the reviewers will be adult specialists. Staff noted that if the Workgroup recommends not having members with pediatric expertise fill in for adult reviewers, this may mean a situation where only five or six adult members are assigned to a case. However, this would be an edge case. A member stated that as someone with pediatric expertise, they would feel comfortable reviewing and voting on most adult cases within the scope of the review board. The Chair stated that it seemed reasonable to allow pediatric reviewers to fill in given that the pool has now been expanded to 40 members and that members should have appropriate and sufficient expertise. A member stated that this portion of the review board could be changed if over the course of its operation it is proving problematic.

The Chair noted that if a pediatric member was assigned to a case that they did not feel comfortable reviewing, they could excuse themselves from that case. A member asked how this would work and noted that there may be no way to ensure that members without the proper experience are excusing themselves. This member also noted that it may be problematic if a program finds out that their adult case was denied by a majority of reviewers who had pediatric expertise. Staff noted that programs cannot see who reviews their case and that reviewers can request to be reassigned. A member stated that review board members should be trusted to determine if they do not have adequate expertise to review a case. The Workgroup elected to recommend having pediatric reviewers fill in to vote on adult cases to the OPTN Kidney Transplantation Committee.

A member asked staff to explain how safety net exceptions will work. Staff responded that the exception requests are expected to be based on administrative lapses or transplants that fell just outside the timeline requirements. The member stated that this may prove problematic in volume for heart and lung and should be thought through carefully. Staff noted that some of this can be specified in the guidance documents that will be created for the review board.

Upcoming Meeting

- May 22, 2023

Attendance

- **Workgroup Members**
  - Asif Sharfuddin
  - Antonio di Carlo
  - Ajay Israni
  - Dean Kim
  - Beatrice Concepcion
  - Michael Marvin
  - Reem Raafat
  - Todd Pesavento
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **UNOS Staff**
  - Joann White
  - Carol Covington
  - James Alcorn
  - Kayla Temple
  - Kieran McMahon
  - Krissy Laurie
  - Lauren Motley
  - Lindsay Larkin
  - Sarah Booker
  - Thomas Dolan