OPTN Kidney and Pancreas Continuous Distribution Review Boards Workgroup
Meeting Summary
November 22, 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 11/22/2022 to discuss the following agenda items:

1. Welcome and Refresher
2. Review: Review Boards Framework Basics
3. Discussion: Review Boards Framework

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

1. Welcome and Refresher

The Chair welcomed the Workgorup members. Staff provided a refresher of the purpose and general function of review boards.

Data summary:

Currently, review board members quickly review specific, urgent-status patient registrations on the OPTN heart, liver, and lung transplant waiting lists. Review board members collectively determine whether these listings are appropriate, based entirely on clinical information that complies with OPTN policies. Kidney and pancreas do not have review boards at the moment, but with the transition to continuous distribution all organs will establish a review board.

Exceptions are rare clinical situations where peers will need to collectively determine whether a candidate should be grandted a different score. The Workgroup will identify candidate-based attributes that transplant centers can request exceptions for.

A framework has been established to ensure consistency for review boards across all organs. The Workgroup is to discuss each aspect of the basisc cross-organ framework to determine what will make the most sense for kidney and pancreas exceptions and review.

Summary of discussion:

There were no questions or comments.

2. Review: Review board and Frameworks Basics

Staff provided a detailed review of general review broad workflows, and an overview of a basic cross-organ review board framework.

Presentation summary:

The basic cross-organ framework recommends that every national program to submit up to 2 representatives to serve on the review board to ensure transparency and equity. Specialty boards and

specialty cases can accommodate cases that need specific reviewers, for example pediactric specialists for pediatrics cases.

The process for submitting an exception request begins with the transplant program, which submits a goal based exception for their candidate. The submission includes the justification narrative supporting their request. The exception request is then reviewd by Organ Center staff who redacts any personally identifying information and the submits the request to the review board. Once submitted to the review board, a 5-calendar day clock starts on the case.

Committees can decide if their specific organ type would require exceptions to be reviewed prospectively or retrospectively. However, the recommendation is an all retrospective or all prospective review for all goals for each organ. If a committee feel this will not work for their specific organ, clinical justification can be given for these to vary on a goal level.

An odd number of review board participants are assigned to each exception case. If they do not vote within three days they will be replaced by a random participant from the review board. If they are not able to vote participants may request that the case be reassigned to another randomly selected participant. Participants can also mark themselves out of office to prevent case assignments. The system emails the participants when the case is assigned, a reminder on day 2, and when a case has been reassigned due to lack of voting.

A case will close when either a for approval or denial is met, or the case reaches the end of the timeline for voting whichever is first. Votes are tallied utilizing the Robert's Rules of Order definition of a majority, simply more than half, to determine the case outcome. In the event of a tie benefit should be given to the candidate and therefore the exception will be approved. The transplant program will receive an email notification with the outcome of the exception case.

If the exception request was denied, the transplant program has the option to submit an appeal with additional information within three days of the denial notification. Once submitted, the five day calendar clock starts again. The first appeal is reviewed by the participats that denied the initial request, the second appeal will go to a reviewing body and the time for appeal should be consistent between the first and second appeal.

During the review, participants may see other requested exceptions for that candidate where a decision has already been determined. Organ Center staff can assign and reassign exception cases, including marking a participant out of office when needed. Participants can see all exception cases they have previously voted on and review redacted comments from other participants. Responsiveness reports help participants and staff assess individual activity on cases.

Summary of discussion:

The Chair asked if a framework was already in place for the term length of a review board member. Staff answered that the framework does not account for this, but current review boards in place have term lengths of a year.

The Chair asked if there are any qualifications requirements for those serving on review boards. Staff responded that this is not currently a requirement for most review boards, but that it is in the best interest of transplant programs to nominate people who are qualified. Staff noted that the review board for lung does have certain qualification requirements, but this is something that is up to the Workgroup to determine. The Chair pointed out that with the review boards handling such rare medical urgency cases that it would make sense to have some sort of qualification requirements to serve on the review board. Another member agreed that it would make sense to have some qualifications around years of practice to qualify as a reviewer.

The Chair asked for clarification on the appeal process, specifically if a case is appealed, whether the first set of reviewers review the appeal first. Staff confirmed this is correct. The Chair then asked which body reviewed the second appeal. Staff answered that current review boards use a subcommittee for the next step in the appeal process, but that the Workgroup must determine who should review the second appeal.

The Chair asked if reviewers are able to view simultaneous exception requests. Staff answered that only cases that have been voted on can be viewed.

A member asked if there will be a centralized dashboard where review board members can declare themselves out of office. Staff responded there is a centralized dashboard where review board members can mark themselves as out of office and schedule future times where they will be unavailable to review cases.

A member asked how many members on a specialty board have to come from that specialty, for example on a pediatric case how many reviewers need to come from a pediatric program. Staff responded that for specialty boards, the pool of reviewers will be entirely from that specialty.

A member pointed out that some institutional knowledge would be helpful for consistency regarding decisions so that similar cases do not result in different outcomes. Staff answered that sometimes similar cases are given different decisions, and while staff does help facilitate review boards, staff does not review or vote on exception cases.

The Chair asked for clarification if the review boards has to meet to collaborate on a decision, or if the case is emailed to the members individually and the reviewers vote individually. Staff responded that when a case is first submitted, the assigned review board members are emailed and vote individually, but the National Liver Review Board (NLRB) does have a conference call for review board members on appeals.

3. Discussion: Review Boards Framework

Staff led the Workgroup in a discussion of review board framework.

Presentation summary:

The purpose of this discussion is on building the operational framework for the review boards. Each topic was introduced, and included a recommendation based on the cross-organ framework developed for review boards in continuous distribution. The recommendations were developed based on feasibility and the experience of other review boards. When discussing each framework topic, the Workgroup was asked to consider what makes the most sense for kidney and pancreas. Staff shared the number of candidates waiting by organ registration as of November 16, 2022:

- Kidney: 89,906
- Pancreas: 864
- Kidney-Pancreas: 1,913

Staff asked if kidney and pancreas should have separate review boards. The cross-organ framework recommendation is one review board for both with pancreas, kidney pancreas, and pancreas islet cases as “specialty cases” that are directed to pancreas reviewers. The rationale for this is the expected case volume, with pancreas and kidney pancreas population being signifcatly smaller than the kidney alone population.

Staff asked the Workgroup how pediatric cases should be handled, by pediatric specialists or by standard review board members, and should pediatric kidney and pancreas review boards be separate.

The framework recommendation is for a separate, pediatric specialty board for kidney and pancreas. Staff noted that for pancreas, non-pediatric pancreas-specific expertise may be needed to ensure appropriate review. The rationale is pediatric patients have a host of different clinical cosiderations. Additionally pancreas cases could also be considered "specialty cases" to ensure an appropriate group of reviewers are pulled because the number of pediatric pancreas cases are so low.

Summary of discussion:

A member stated their concern regarding one kidney and pancreas review board, noting that not all kidney specialitists have experience with pancreases. Another member said they would support having a review board that is exclusively pancreas and a second review board that is exclusively kidney. Staff pointed out that for pancreas-only cases, the pool of reviewers would only be pancreas doctors.

A member asked if there is an estimate available on how many kidney exceptions might be submitted. Staff responded that while the data is not immediately available it could be pulled and analysed, but the volume of medically urgent kidney cases is currently low and there were less than 30 in the one year monitoring report. Another member pointed out that once this review board is established, the number could increase.

The Chair stated that the Workgroup seems to be in an agreement to have one review board, but that could change as they being to discuss other parts of the framework. One member responded they are in favor of two review boards rather than one.

A member recommended having one pediatric review board to handle kidney and pancreas cases since the case load for pediatric pancreas will be so low. Another member stated they would be more comfortable having at least one adult program representative on the pediatric review board to help provide an additional perspective, and the Chair agreed. Another member pointed out that having such a low number of pediatric pancreas cases reinforces the need for a unified review board.

The Chair asked if pediatric cases would go to a separate review board, or are they considered speciality cases for the bigger review board. Staff responded that they could be considered specialty cases. Staff also shared that the lung review board ensures a certain number of pediatric specialists are on the review board for pediatric cases and the remaining spots are filled with adult specialists.

The Chair suggested that many kidney surgeons operate on both adult and pedicatric kidney patients and could possibly serve on both. A member suggested that on at least the initial vote on a case should have reviewers with relevant expertise, but on appeal this could change; a second member agreed.

Staff asked the Workgroup if there was concern over the size of pediatric pancreas review board since there are so few programs and conflict of interest could limit the number of eligible reviewers. One member stated they are not concerned about this for pancreas because the field is so small that there would actually be fewer conflicts. The Chair agreed with the member.

Members agreed with the one review board concept, with specialty cases going to those reviewers with relevant experience for the initial review.

Upcoming Meetings:

- December 6, 2022; 4 p.m.ET
- December 13. 2022; 4 p.m. ET

Attendance

- **Workgrou Members**
  - Asif Sharfuddin
  - Antonio Di Carlo
  - Dean Kim
  - Maria Friday
  - Namrata Jain
  - Reem Raafat
  - Stephen Almond
  - Todd Pesavento
- **UNOS Staff**
  - Alex Carmack
  - Carol Covingotn
  - Darby Harris
  - James Alcorn
  - Jennifer Musick
  - Kayla Temple
  - Keighly Bradbrook
  - Kieran Mcmahon
  - Kirssy Laurie
  - Lauren Motley
  - Lindsay Larkin
  - Sarah Booker