

## **OPTN Kidney and Pancreas Continuous Distribution Review Boards Workgroup**

### **Meeting Summary**

**January 24, 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 01/24/23 to discuss the following agenda items:

1. Welcome and Announcements
2. Recap: Decisions So Far
3. Discussion: Review Board Framework

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

#### **1. Welcome and Announcements**

The Chair welcomed the Workgroup members to the call.

#### **2. Recap: Decisions So Far**

Staff gave a brief recap of the Workgroup's decisions to date.

#### Presentation summary:

The Workgroup decided in previous calls that the following attributes where exceptions may be appropriate include Kidney medical urgency, pediatric status, prior living donor status, and kidney after liver safety net, with a recommendation to the OPTN Pancreas Transplantation Committee to further explore the pancreas medical urgency definition. Operational decisions so far include having kidney specialists review kidney-alone cases, and pancreas specialists reviewing pancreas, kidney-pancreas (KP), and islet cases. The members noted that pediatric pancreas specialists should review all pediatric pancreas cases, but in a case where sufficient pediatric pancreas specialists are not available, adult pancreas specialists may review the cases. Pediatric pancreas specialists would also be good candidates to review adult cases as well. Kidney pediatric specialists should review kidney pediatric cases. The Workgroup decided that all cases should be reviewed prospectively, except for a retrospective review for Kidney Medical Urgency.

The Workgroup concluded that the case should close when a majority of votes is achieved or at the end of five days. Reviewers assigned to a case on day zero have until the end of day two to vote, and reviewers who do not vote are replaced on day three. Cases are determined by a simple majority. Reviewers will be notified through email and given a reminder on day two. The Workgroup decided that seven reviewers will be assigned to a case.

Staff explained the background of the Cross-Organ Review Board Framework and explained that deviance from this framework should be justified with an organ-specific clinical rationale.

#### Summary of discussion:

There was no additional discussion.

### 3. Discussion: Review Board Framework

Staff reviewed the process of submitting an exception request and possible outcomes, then asked members to weigh in on the outstanding decision points.

#### Presentation summary:

Staff showed flowcharts explaining and summarizing the prior decisions by the Workgroup.

Staff explained two possible outcomes (Flowchart A) when two new reviewers are assigned to a case where the case has received three yes votes and two no votes:

1. The two new reviewers vote no, and the case is denied as a majority is achieved (four no, three yes).
2. The two new reviewers forget to vote, and the case is approved by the majority of votes received on day five (three yes, two no).

Staff showed an additional flowchart explaining the appeal process (Flowchart B) based on prior Workgroup decisions. The steps are as follows:

1. The program receives case outcome (denied) and rationale is provided.
2. The program decides to appeal case and gather supporting information. Programs have three days to submit an appeal.
3. The program submits an appeal, which restarts the case clock.
4. The appeal is sent back to the previous voting reviewers.
5. On day two, an email reminder is sent to those reviewers that have not yet voted.
6. Reviewers who do not vote are replaced on day three at midnight.
7. When a majority is achieved, the program receives the case outcome and rationale.
8. The program decides to appeal the case again and the process restarts.

The remaining question for the Workgroup to answer is who reviews upon the second appeal?

Staff noted that accounting for edge cases is important in creating a review board. Staff asked members to return to thinking about what should happen in the event of a tie, noting that in the cross-organ framework, the candidate is granted the exception out of concern for fairness and timeliness.

Staff recapped the prior decision of the Workgroup that if no votes are submitted, a candidate should be granted the exception out of a concern for fairness.

The question of the minimum number of votes was re-introduced. The framework suggests a minimum number of two votes, because review boards are intended to be a peer review and ideally, a situation where one person is deciding a case would be avoided. A related question is the minimum number of reviewers assigned to a case. The framework recommends a minimum of two reviewers to align with the suggested minimum number of votes.

Staff asked how long programs should have to submit an appeal. The cross-organ framework recommends three calendar days, giving time to gather information but not extending case timeline too long. Next, the question of the appeal case lifecycle timeline was introduced. The cross-organ framework recommends a five-day timeline to align with the initial case timeline.

The Workgroup was asked to consider who should review the appealed case. The cross-organ framework suggests that the original reviewers review the first appeal to include additional information from the center. The Workgroup needs to decide who should review the case upon second appeal. Some options include Committee leadership, a subset of the Committee forming an appeal review team, or the entire Committee to review the second appeal. Staff noted that the National Liver Review Board

includes an appeal review team of nine reviewers who meet regularly to review the submitted appeals. If quorum is not met, the appeal goes to benefit to the patient. Staff noted some of the pros and cons to this approach. The Workgroup will discuss this question at the next meeting.

#### Summary of discussion:

##### *Flowchart A:*

A member asked what quorum means in this framework. Staff answered that the Workgroup had previously decided that the cases should be decided by a simple majority.

The Chair asked if members felt that scenario two in Flowchart A is reasonable, and members agreed.

##### *Flowchart B:*

Members agreed with the general steps of the appeal process.

##### *In the event of a tie:*

A member stated that in the event of a tie, the candidate should be granted the exception. The Chair agreed. No opposition to this was noted.

##### *If no votes are submitted:*

A member stated that to them, no reviewers is not a reason to grant the exception. This member explained that in a case of no votes, the case should be escalated to the Chair of the appropriate Committee or the OPTN President. A member agreed, stating that other Chairs should be included so that three Chairs would decide the case.

One member noted that this is such an unlikely scenario, and that though they agree this situation should be escalated to additional reviews, the member supported aligning with the cross-organ framework on the basis of how unlikely the scenario is.

A member stated that because this scenario would be so rare, it may be better to go with the cross-organ framework for consistency. A member disagreed, stating that the opinions of this Workgroup should count. The Chair recommended taking this question back to the OPTN Policy Oversight Committee (POC), and a member agreed. Staff clarified the role of the POC in this process, the OPTN Board of Directors' charge of developing continuous distribution, and how the cross-organ framework was developed.

A member stated that someone needs to review the case to decide an outcome and was not in favor of a default acceptance. Others agreed. Staff stated they would contact the POC for more information on the rationale behind the original decision making, and recommended tabling the discussion of what to do when no votes are received until then.

##### *Minimum number of votes:*

Staff asked members to consider what the appropriate minimum number of votes is. A member stated that two votes would be an acceptable minimum. The Chair reminded members of the appeal process and asked if members felt comfortable with approval by only two votes. A member was hesitant about two votes, but stated it may be permissible. Members reached agreement for a minimum of two votes to decide a case.

A member asked if centers receive information about how many reviewers actually voted on the case. Staff answered that the centers receive the number of votes and the vote decisions, for example, three approve and one deny. Also, if the case is denied, a rationale is provided as well.

*Minimum number of reviewers:*

Staff asked if members agreed with the framework recommendation of a minimum of two reviewers assigned to a case. No opposition to a minimum of two reviewers was noted.

*Time to submit an appeal:*

Staff asked if members agreed with the framework recommendation of three calendar days for a program to submit an appeal. A member stated that this seemed unnecessarily short and recommended using business days. A member agreed, noting the potential for the decision to fall on a holiday. A member stated that there is no clear administrative reason to have the timeline be three days and advocated for a seven-day timeline. Another member noted the potential for a three-day timeline to disadvantage a candidate if their program is unable to submit an appeal in that timeframe.

A member asked if there was a maximum number of days that the Workgroup could decide on. Staff answered that it would be important to ensure that the candidate information is up to date and roughly the same as when the original request was submitted. Also, keeping the timeline shorter improves the chances that the original reviewers still have familiarity with the case. The Chair noted the importance of having some cap on the appeal timeline and suggested ten business days. Other members agreed. Staff asked if members would be comfortable with fourteen calendar days instead to align with programming requirements. Members agreed.

*Appeal case timeline:*

No opposition was noted to the framework recommendation of a timeline of five days for the appeal case lifecycle.

**Upcoming Meeting**

- February 14, 2023

## **Attendance**

- **Workgroup Members**
  - Asif Sharfuddin
  - Antonio Di Carlo
  - Ajay Israni
  - Bea Concepcion
  - Dean Kim
  - Michael Marvin
  - Stephen Almond
  - Todd Pesavento
- **UNOS Staff**
  - Alex Carmack
  - Carol Covington
  - Darby Harris
  - James Alcorn
  - Jennifer Musick
  - Kayla Temple
  - Joann White
  - Keighly Bradbrook
  - Lauren Mauk
  - Lauren Motley
  - Lindsay Larkin
  - Sarah Booker
  - Thomas Dolan