

OPTN Kidney and Pancreas Continuous Distribution Review Boards Workgroup

Meeting Summary

January 10, 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 01/10/23 to discuss the following agenda items:

1. Welcome and Announcements
2. 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. Discussion: Review Board Framework

Staff reviewed the purpose of review boards in continuous distribution, and review board framework, then led the Workgroup in discussion of specific framework topics.

Presentation summary:

Staff introduced the question of when a case outcome should be determined and case closed. The framework recommendation is that the case will close when the majority is met or at the end of the case timeline (five days). The rationale behind this recommendation is that closing the case earlier will allow the patient to receive the exception sooner and helps create fairness by closing cases within a reasonable timeframe of five days.

Staff confirmed with the Workgroup that they would like to go with a standard majority, defined as "simply more than half." Members confirmed.

Staff explained the question of what should be done in the case of a tie. The framework recommendation is that the system should default to benefitting the patient.

Staff asked members to consider what should happen if no votes are submitted. The framework recommendation is to default to granting the exception, because it is not the patient's fault that no one reviewed their case.

Next, what is the minimum number of votes required to deny a case? The framework recommendation is that the minimum number of votes should be two, because the review board is intended to be a peer review and should not be decided by one vote. Staff showed possible scenarios to help the members think through this.

Summary of discussion:

Case outcome and case closure:

The Chair asked what would happen if a majority is not met at the end of the fifth day. Staff explained that according to the framework, the case outcome is decided based on the majority of the votes that have been submitted at day five. For example, if at day five, three yes votes and one no vote have been received, the case would be approved. The Chair asked what would happen if a case received three yes, three no, and one no response. Staff explained that according to the framework, the case would still close at five days, but what to do in a tie is up for Workgroup discussion.

A member asked if the five-day waiting time is the standard for liver and lung. Staff responded that this is the standard for lung in continuous distribution, the timeline for liver changes based on the exception.

The Workgroup agreed that the case should close when a majority is met or at the end of the case timeline (five days).

In the event of a tie:

The Chair asked if it would be possible to assign another set of reviewers in the case of a tie, noting the concern that if half of the reviewers voted to deny, there may be a legitimate reason to. A member noted that in the event of a 1:1 tie, it would be hard to justify that as a proper review board. Staff explained that a tie would be rare, but from a programming standpoint, there needs to be an answer for every eventuality.

A member asked if the review board has a Chair because the Chair could act as the deciding vote, and staff answered that the framework does not appoint a Chair to continuous distribution review boards. The Chair suggested having three co-chairs on a review board to avoid one person having an ultimate vote. A member asked for more details on how reviewers who don't respond by day three get replaced, and staff provided clarification.

Staff asked members to elaborate on why they may not want to default to approval in the case of a tie. A member stated that they were in favor of approving a case in a 3:3 tie, but not in a 1:1 tie. Another member agreed. A member disagreed, stating that more "no" votes point to a patient not qualifying for the exception. The Chair suggested finding a way to break the tie, such as adding more people. Staff then asked what members would like to do if those additional votes or non-votes still result in a tie. Staff asked if members felt more comfortable with, in the case of a tie, denying the exception at the end of five days and then the candidate could appeal the denial. A member suggested having a new set of reviewers for the appeal process. The Chair stated that resulting in a tie twice is very unlikely. A member suggested having a separate group of appeal reviewers that only look at appeals.

Members agreed to return to the question of what to do in the event of a tie at a later date.

If no votes are submitted:

The Chair asked why this would occur. Staff answered that this probably would not happen, but from a programming standpoint, there needs to be an answer for this. Members agreed that if no votes are received, the default should be to grant the exception.

Minimum number of votes:

Members suggested a minimum of three, explaining that two votes does not sound sufficient. Staff asked if the minimum is three, what should happen if only two votes are received? Members weighed what should happen in this case. A member suggested using Committee members to review the case because they already have a commitment to the OPTN. The Chair suggested having a "super-user" group to ensure that the minimum number of votes would be met. Staff noted that this would extend case timeline, and asked members to elaborate on why Kidney-Pancreas should deviate from the framework

from a clinical standpoint. Staff noted that consistency among organs is ideal from a patient perspective unless there is a clinical reason to deviate from cross-organ consistency.

The Chair stated that the concern lies within ensuring proper review of cases. A member asked for clarification on why three votes would be selected as the minimum. The Chair explained that three votes seems more fair than two votes and prevents a 1:1 tie. Members discussed a minimum of four votes to align with a quorum and the pros and cons of two votes versus three votes. The Chair suggested programming the system to look for alternate reviewers in this case. Staff explained that they will gather more information on what is possible from an IT standpoint.

A member also suggested having the Chair of the Kidney Committee as the tiebreaker for the second appeal of a case.

Next steps:

Staff will generate a flow chart to explain options to the Workgroup to discuss at the next meeting.

Upcoming Meeting

- January 24, 2023

Attendance

- **Workgroup Members**
 - Asif Sharfuddin
 - Antonio Di Carlo
 - Dean Kim
 - Namrata Jain
 - Reem Raafat
 - Todd Pesavento
- **UNOS Staff**
 - Austin Chapple
 - Carol Covington
 - Darby Harris
 - Jennifer Musick
 - Kayla Temple
 - Joann White
 - Keighly Bradbrook
 - Lauren Mauk
 - Lauren Motley
 - Sarah Booker
 - Thomas Dolan
 - Lindsay Larkin