OPTN Kidney and Pancreas Continuous Distribution Review Boards Workgroup
Meeting Summary
December 13, 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 12/13/2022 to discuss the following agenda items:

1. Welcome and Announcements
2. Review: Purpose of Review Boards and Framework
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. Staff explained some changes to the meeting schedule for the Workgroup.

Summary of discussion:

The Workgroup had no questions or comments.

2. Review: Purpose of Review Boards and Framework

Staff reviewed the purpose of review boards in continuous distribution, and review board framework.

Presentation summary

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 on clinical information that complies with OPTN policies.

With the transition to continuous distribution each organ group will establish a review board. These review boards will review exceptions to collectively determine whether a candidate should be granted a different score. A framework has been established to ensure consistency for review boards across organs. The Workgroup will discuss each aspect of the basic cross-organ framework to determine what will make the most sense for kidney and pancreas exceptions and review.

Summary of discussion:

The Workgroup had no questions or comments.

3. Discussion: Review Board Framework

Staff led the Workgroup in discussion of specific framework topics.

Presentation summary:

Staff reviewed and compared prospective and retrospective review of exception requests. Prospective cases are reviewed prior to the candidate receiving the benefit, while retrospective cases are reviewed

after the candidate receives the benefit or is in the process of receiving the benefit. Staff reminded the Workgroup that in their previous discussions it was determined that most cases would be reviewed prospectively. However, as one Workgroup member pointed out in the previous meeting, there may still be a need for retrospective review for patients who have no access to dialysis or other truly immediate life-threatening scenarios.

Staff examined the timetables for reviewing an exception case. The recommended framework provides a maximum time of five calendar days to end of the case timeline, and three days for reviewers to vote before they are replaced. This means that the patient waits a maximum of 5 days for the case to be reviewed.

Staff reviewed the notification process for review board members. The framework establishes that notifications are sent by email when the case is assigned, a reminder email on day two, and when the case is reassigned.

Staff then reviewed the number of reviewers serving on the review board for each assigned case to review. The framework recommendation is seven reviewers assigned to a case, with a recommended range of five to nine. An odd number is preferred to prevent ties. Having more reviewers for each case would allow for more diverse representation of perspectives and experience, yet it would take longer to reach a majority. Fewer reviewers would allow for a shorter review time but also fewer perspectives.

Last, staff briefly reviewed the recommended framework that would allow each program to submit up to two representatives for each organ type. This number should allow for equal representation regardless of program size, and also allows for equally trained representatives with an equal chance to review cases. Staff noted that qualifications for reviewers will be discussed in a future meeting. Staff stated that lung allows their reviewers to serve a specific term within a cohort.

Summary of discussion:

Prospective versus retrospective review:

The Chair stated that having no access to dialysis can be life threatening, especially during the three-day waiting period the review board examines the case. The Chair asked if there were other scenarios that would need a retrospective rather than a prospective review.

A member stated that while they could not think of a clinical reason, there are times when staff may not be available to review a case and grant and exception within the set period. In those situations, it may be necessary to give transplant hospitals the option to file for a retrospective review. Staff noted that all reviews could be prospective except for those that fall under the medical urgency attribute, which has a clinical need to be reviewed retrospectively. Staff shared that the Heart Committee currently has a subcommittee to examine cases where a patient is transplanted at an unapproved and later denied status, and that this Subcommittee works with the Membership and Professional Standards Committee. The Workgroup agreed that cases should be reviewed prospectively, with the exception of some medical urgency cases where a total loss of dialysis access is proven.

Staff noted that currently, Waitlist does not differentiate between different types of loss of dialysis access, and that this would require a change to the data collected for medical urgency. Staff added that, under the current framework and system, all medically urgent cases would need to be reviewed prospectively or retrospectively.

The Workgroup reviewed the definition of Kidney Medical Urgency. A member shard that one study found that exhausting these dialysis access does not always mean the patient has met the medically urgent threshold, and perhaps these cases should all be reviewed prospectively.

The Chair asked if it is possible to break up the medically urgent cases into categories; one that would that is extremely medically urgent and one that is not. Staff noted that the technology system would have to be built out in order to achieve this, and the current framework does not do this type of categorical sorting. Another staff member said the current framework does not allow for some medically urgent cases to be reviewed retrospectively while the others are reviewed prospectively.

A member asked if pediatric medical urgency cases would be reviewed separately from adult cases, as these patients are subject to uniquely pediatric issues. Staff stated that in previous conversations the Workgroup has expressed interest in minimum number of pediatric specialists reviewing pediatric cases.

The Workgroup reached a consensus for retrospective review for medically urgent kidney cases, and prospectively review of all other exception requests.

Review timeline:

The Chair 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 Chair asked for some clarity regarding holiday schedules when a reviewer is unavailable. Staff responded the case would be sent to another reviewer that is not listed as out of office.

A member asked if the timeframe could be monitored to add or subtract the number of days to review, and then to change the number of days based on what that report would show. Staff responded that it is possible to monitor this, and the number of days could be changed if that's needed.

Reviewer Notification:

The Chair asked if it was possible to receive a text message notification rather than an email. Staff answered that this idea has been brought up before and that possibility is being examined. Another member suggested a notification similar to the notification when an organ becomes available would also make sense, and that emails are too often seen and then forgotten.

Number of reviewers:

A member asked if the pool size for available reviewers had been determined yet. Staff responded this is something the Workgroup has not yet determined. The Chair express concern that with a larger number of reviewers and a smaller pool reviewers would be on a case too often.

The Chair stated that nine reviewers may be too much of a stretch, and five seems too small, and that seven seems like the correct number. Another member agreed with the number seven. The Workgroup reached a consensus for seven reviewers for all cases.

Program Participants:

A member asked for clarity on the cohort model that lung uses. Staff responded that each program nominates two people, but not every program nominates at the same time.

The Chair stated that by nominating two people from each program that the pool could be as large as 400. Staff confirmed this to be true, but only if the Workgroup decides every program gets to have representation in the pool at the same time. Another member expressed they aren't as concerned with their program always having representation in the pool if there are only a handful of cases per month and the pool is large. The Chair asked the member if they are suggesting one participant per program; the member responded they were suggesting this because of the administrative issues that arise with a pool that large and to promote engagement. Staff responded that the pool size is determined by the Workgroup and does not mean the pool is going to be 400 reviewers, it could be 100 or 70 or any appropriate number the Workgroup decides on.

The Chair stated they support the idea of two per program and determining when and how programs can nominate to determine pool size can be discussed later. The Workgroup agreed to discuss this more in the future before determining a consensus.

Upcoming Meeting

- January 10, 2023

Attendance

- **Workgroup Members**
  - Asif Sharfuddin
  - Antonio Di Carlo
  - Beatrice Concepcion
  - Maria Friday
  - Namrata Jain
  - Stephen Almond
  - Todd Pesavento
- **UNOS Staff**
  - Alex Carmack
  - James Alcorn
  - Kayla Temple
  - Kieran Mcmahon
  - Lauren Mauk
  - Lauren Motley
  - Sarah Booker