

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

### **Meeting Summary**

**February 28, 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 02/28/23 to discuss the following agenda items:

1. Welcome and Announcements
2. Check-in: High Level Overview of Kidney and Pancreas Review Boards in Continuous Distribution
3. Discussion: Review Board Pool Size
4. Discussion: Kidney and Pancreas Considerations in a 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. 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 continuous distribution.

##### Presentation summary:

OPTN heart, liver, and lung review boards quickly review specific, urgent-status patient registrations for candidates on the respective waiting lists. 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. Specific to continuous distribution, review boards allow members to raise a flag 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 recapped which attributes the Workgroup had identified as eligible for exceptions: kidney medical urgency, pediatrics, and kidney after liver (KAL) safety net. Prior living donor was discussed by the Workgroup but is currently outside the scope of the creation of this review board.

Staff explained that the general listing trend for kidney medically urgent candidates is about 1-2 candidates per month since the policy was implemented. KAL registrations have been increasing over time, but the number of eligible candidates is consistently around 200-250. For kidney pediatric

patients, as of February 24, 2023, there were around 1,400 patients listed. As of November 16, 2022, there were 51 pediatric pancreas registrations and zero pediatric kidney-pancreas registrations.

Summary of discussion:

The Chair emphasized that the Workgroup's recommendations will be reviewed and possibly modified in the future.

**3. Discussion: Review Board Pool Size**

Staff reviewed some considerations regarding the review board pool size, then asked members to weigh in.

Presentation summary:

Staff explained that, as previously mentioned, the expected case volume is relatively small. Considerations for the review board pool size are as follows:

- The pool needs to be large enough to ensure that reviewers are always available
- The pool should not be too large in order to ensure appropriate engagement
- If needed, the pool size can be adjusted via Committee approval
- Equal opportunity for program and regional representation can be achieved through rotating cohort models and other solutions

The staff recommendation is that a minimum review board pool size should be at least three times the number of reviewers assigned to a case, so a minimum of 21 reviewers.

Summary of discussion:

A member brought up a concern about ensuring adequate pediatric representation. Staff explained that the review board pool is national and not pediatric-specific. A member suggested not mandating specific regional representation as a part of the pool. The Chair explained that in their view, 21 seemed too low and agreed that ensuring equal representation across regions should not be a specific priority. A member asked for clarification on what being in the pool actually entails. Staff explained that for lung, the identified reviewers go into the pool, then, when a case comes up, the OPTN Computer System randomly generates who reviews the case and pulls out reviewers with conflicts of interest and unavailable reviewers.

A member stated that a concern about too large of a pool is that many people in the pool would be inexperienced in reviewing cases. The Chair suggested a pool of 30 reviewers. Other members voiced support for a pool size somewhere in the low-30s. Consensus was reached for a pool size of 33 members with a cohort model and agreed to keep the ability for the Committee to modify the pool size if needed.

Members also agreed to keep a similar nomination process for members of the review board pool as lung currently has. Members discussed which person at a program should be responsible for the nomination of members of the pool.

Then, members discussed their preliminary ideas about possible qualification requirements for reviewers. The Chair noted that it would be preferable to trust the program's nomination of someone who is qualified to review, however, asked members what should be done if a program nominates someone lacking the necessary expertise. A member suggested requiring that reviewers are at least five years post-fellowship and explained that it is a privilege to review these cases, not a right. A different member agreed and noted that the reviewers should have to be performing transplants (as opposed to being primarily research-focused, for example) to serve on the pool. Another member explained that the Workgroup could suggest, but not mandate, that programs nominate their primary transplant

surgeons or physicians. Members reached an initial consensus that five-years post-training with direct transplant experience is a suitable qualification for reviewers. A member asked if the Workgroup could use the qualifications for primary surgeons as outlined in the OPTN Bylaws, however, more junior physicians can apply for this role than the Workgroup would prefer. Members also agreed that the reviewers should be limited to transplant physicians currently active in the field, from an active kidney or pancreas program.

The Chair asked for clarification on how the pool is selected from the larger number of nominations, and staff answered that the cohort model accounts for this.

#### **4. Discussion: Kidney and Pancreas Considerations in a Review Board Framework**

##### Presentation Summary:

Given the considerations outlined in prior Workgroup discussion, it is often appropriate to follow the review board framework developed for cross-organ implementation of continuous distribution and endorsed by the Policy Oversight Committee. The framework is informed by experience, best practices, and lessons learned from other organ groups. Significant consideration was given to legal principles related to fairness, peer review, equity, and clinical input throughout the development of the framework. It also gives consideration of implementation resources and provides provisions for flexibility in key areas. Areas for improvement that have been identified by the Workgroup are being reviewed for modification in future iterations of the framework.

##### Summary of Discussion:

The Chair noted that review board topics have been well-considered by the Workgroup throughout their discussions and asked for an update on the timeline. Staff noted that there is no set end date for the project, but the Workgroup meets next on March 14<sup>th</sup>. A member noted that the decisions made by this Workgroup go back to the OPTN Kidney and Pancreas Committees and through public comment.

##### **Upcoming Meeting**

- March 14, 2023

## Attendance

- **Workgroup Members**
  - Asif Sharfuddin
  - Antonio Di Carlo
  - Ajay Israni
  - Dean Kim
  - Michael Marvin
  - Reem Raafat
  - Todd Pesavento
- **UNOS Staff**
  - Darby Harris
  - James Alcorn
  - Jennifer Musick
  - Kayla Temple
  - Lauren Mauk
  - Lauren Motley
  - Lindsay Larkin
  - Sarah Booker
  - Thomas Dolan