OPTN Kidney & Pancreas Continuous Distribution Review Boards Workgroup
Meeting Summary
September 09, 2022
Conference Call

Asif Sharfuddin, MD, Chair

Introduction

The Kidney & Pancreas Continuous Distribution Review Boards Workgroup (the Workgroup) met via Citrix GoTo teleconference on 09/09/2022 to discuss the following agenda items:

1. Review Boards
2. Overview of Project Timeline
3. Closing Remarks

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

1. Review Boards

Staff reviewed the purpose and scope of this Workgroup to establish review boards for kidney and pancreas, and identifying exceptions that can be requested in continuous distribution. The Workgroup will focus on the review board framework and potential exceptions, as well as provide operational guidance for kidney and pancreas review boards. The recommendation the Workgroup develops will be sent to the OPTN Kidney Transplantation Committee and the OPTN Pancreas Transplantation Committee for their approval. The approved recommendations will be incorporated into the main Kidney and Pancreas Continuous Distribution proposal currently scheduled for August 2023 Public Comment.

The current Chair for the OPTN Lung Transplantation Committee, and the immediate past Chair for the OPTN Lung Transplantation Committee, joined the Workgroup to share their experiences with establishing a continuous distribution framework for lung allocation. The past Chair of the Lung Committee pointed out the clinical differences between lung and kidney and pancreas, noting that lung had an established review board prior to implementing continuous distribution that had to be adjusted rather than established. Prior to continuous distribution, lung allocation was based on lung composite allocation score. There were many clinically relevant factors that were not part of the lung allocation score that many felt needed to be addressed in continuous distribution. The National Lung Review Board would consider these factors and adjust a patient's lung allocation score accordingly. Moving into continuous distribution, some of those factors became attributes, yet there were still clinical factors that would require exceptions for certain patients. The National Lung Review Board now reviews those factors. The Lung Committee had to determine where the points the review board could award would come from. The Lung Committee also used this as an opportunity to reevaluate how the review board operates and its oversight.

The Chair of the Lung Committee suggested the Workgroup consider where the issues with the current allocation of kidney and pancreas exist. This will help the Workgroup in establishing the exceptions that the review boards will consider. The Lung Committee Chair also suggested that there may be some automatic exceptions, those should also be considered to help reduce the workload of the review boards. Diversifying the geographic makeup, size of centers, and specialties of review board participants

is critical to ensure all considerations are examined. The lung review board focuses more on wait list mortality and medical urgency points than on other attributes, because most of those must be done after a match run. The Lung Committee Chair recommended the Workgroup concentrate on the areas where people could be asking for exceptions.

The past Chair of the Lung Committee explained the importance of providing good guidance to the community on how to submit exceptions requests. Educating the community on the importance on submitting literature that can help explain why the exceptions are important and why their patient isn't being well represented in the system.

The Lung Committee Chair pointed out that the Workgroup also needs to consider what happens when an exception is denied. The Workgroup should consider how many times someone can file an exception to the review board, and at what point can they take a denied exception to the larger committee.

Staff provided an overview of the project timeline and the purpose of review boards. Currently, review board members quickly review specific, urgent-status patient registrations on OPTN heart, liver, and lung transplant waiting list. Review board members collectively determine whether these listings are appropriate, based entirely on clinical information that complies with OPTN polices. Kidney and pancreas do not currently have review boards. With the transition to continuous distribution, all organ systems will establish a review board to address exceptions. Exceptions are rare clinical situations where peers will need to collectively determine whether a candidate should be granted a different score and if the allocation score is accurately representing that candidate or not. If not, the Review Board will need to determine an appropriate score for that candidate. This Workgroup will identify candidate-based attributes for which transplant centers can request exceptions. A recommended framework has been established to ensure consistency for review boards across organs.

Staff then reviewed the framework of review boards and how the framework helps to create consistency for review boards across all organs while recognizing that every organ will have its own unique issues and needs. Every program can submit up to two representatives to serve on the review board to ensure transparency and equity. Specialty boards can accommodate cases that need specific reviewers. For example, for a case involving a pediatric patient a separate review board with only pediatric specialists could review that case.

Transplant programs will submit a goal-based exception for their candidate, including the justification narrative supporting their request. The Organ Center staff reviews the request, remove any personal health information, and they submit the request to the review board. Once the request is submitted to the review board, the review board has five calendar days to review the case. It is up to the specific organ committee to decide if case review should be prospective or retrospective. The review board then considers the case. There will always be an odd number of reviewers for each case. If a reviewer does not vote on a case within three days, then a random reviewer is assigned the case. If the review board member is not able to vote, they may request the case be reassigned to another randomly selected reviewer. Review board members do have the ability to mark themselves as out of office to prevent case assignments when they know they will be unavailable. The system sends emails to the review board members when the case is assigned, a reminder on the second day, and to alert the review board member that the exception case has been reassigned due to lack of voting. An exception case will close when either a simple majority votes to approve or deny the case, or when the case reaches the end of the five days, whichever comes first. Votes are tallied utilizing the Roberts Rules of Order definition of more-than-half to determine the case outcome of approved or denied. In the event of a tie, benefit is 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 is denied, the transplant program has the option to submit an appeal within 3 days of the denial notification. Once the appeal is submitted using the same process of the original submission the five-day clock starts again. First appeal is reviewed by the participants that denied the initial request. The second appeal will go to a reviewing body, which could be another cohort of the review board or the committee, as determined by the Kidney and Pancreas Committees. The timeline for appeal would remain consistent between the first and second appeal. During the review, reviewers have access to other exception cases for that candidate where a decision has already been determined. Reviewers can see all exception cases they have previously voted on as well. Organ Center staff can assign and reassign exception cases, including marking a participant out of office when needed. Responsiveness reports help participant and staff assess individual activity on cases, and this helps determine if an issue with a consistently inactive reviewer needs to be addressed.

Summary of discussion:

The past Chair of the OPTN Lung Transplantation Committee asked how exceptions are currently handled if there is no review board in place. Staff answered that there are already exceptions in place, and the way patients are scored is different than lung. This includes things like waiting time modification policy and a process for medical urgency, which involves a Medical Urgency Subcommittee that retroactively reviews medical urgency documentation.

A Workgroup member asked if there have been any thoughts given to pediatric patients on dialysis that have vascular access and complications from dialysis, can they be included? The Workgroup Chair responded that this is the type of thing the workgroup needs to consider.

A Workgroup member asked if the review board is going to work locally, on a regional basis, or is going to operate on a national level. The past Chair of the OPTN Lung Committee stated that this is something the Workgroup is going to have to establish, but doing reviews regionally creates inconsistency in what gets approved and denied. However, a national review board ends up taking a lot of time because there are so many exceptions that are filed. Staff responded that this is one of the many factors this Workgroup must consider, but a national review approach seems to be the current line of thinking for continuous distribution. The Workgroup will need to determine what works best for kidney and pancreas.

A member asked if the attributes are going to be individual factors that are incorporated into a composite score, as many attributes interact. Staff answered that there are rating scales and weights for each attribute. The rating scale is how each specific attribute is scored, and the weight is how important an attribute is in comparison to other attributes. This is what the kidney and pancreas are currently considering, and the Workgroup is considering what parts of those attributes might not be covered.

A member asked if the results from the Pancreas Committee workgroup that was established to formulate a definition of medical urgency for pancreas would be included in the attributes. Staff responded that while there was a dedicated workgroup for that effort, the decision was made to establish continuous distribution first and then establish a definition for medical urgency for pancreas. Staff also pointed out that medical urgency for pancreas might be an area for the review board to consider.

A member asked how many reviewers are assigned for a case involving liver. Staff responded that five reviewers are selected for liver cases, but the National Liver Review Board currently uses a super majority when voting.

A member asked if review board members operate collectively or individually when reviewing cases. Staff responded that they operate individually, it is up to each reviewer to participate and vote on their own.

A member asked if reviewers can see the history of exceptions filed by center rather than by candidate. Staff responded that a reviewer can not look at other candidates who have requested similar exceptions, or by center, a reviewer can only see the case history based on the specific candidate.

A member asked what the benefit for applying a case prospectively is when it comes to kidney and pancreas. Staff responded that it really depends on the organ and how it impacts the patient. The member then stated that it might not have any benefit for kidney and pancreas. Staff noted that this is something for the Workgroup to consider.

A member asked for clarity on the number of reviewers from each center. Staff noted that, for the Lung Review Board, each center can have two, and they get put into a pool of all reviewers that are selected per case. The member asked how the reviewers are selected. Staff responded that reviewers who might have a conflict of interest, have an out of office status, or have had a high caseload recently would be filtered out. A member pointed out that some kidney programs also do pancreas, and asked whether would there have to be two separate review boards for pancreas and kidney-pancreas. Staff responded that it is up to the Workgroup to determine if there should be two or multiple review boards based on organ, multi organ, and specialty.

The Chair asked what the qualifications are to participate on the Lung Review Board. Staff responded, that the Lung Review Board did make a requirement based on experience, but ultimately that will be up to the Workgroup to consider.

2. Overview of Project Timeline

Staff provided a timeline for the project.

Summary of discussion:

The Workgroup had no questions or comments.

3. Closing Remarks

Staff announced that beginning in October, the Workgroup will meet on the second and fourth Tuesdays of every month at 4 PM.

Summary of discussion:

The Workgroup had no questions or comments.

Upcoming Meeting

- September 27, 2022

Attendance

- **Workgroup Members**
  - Asif Sharfuddin
  - Dean Kim
  - Elliot Grodstein
  - Michael Marvin
  - Raafat Qbeiwi Reem
- **UNOS Staff**
  - Alex Carmack
  - Jennifer Musick
  - Kayla Temple
  - Keighly Bradbrook
  - Kim Uccellini
  - Lauren Mauk
  - Lauren Motley
  - Lindsay Larkin
  - Sara Booker
  - Taylor Livelli
  - Rebecca Brookman
- **Other Attendees**
  - Erika Lease
  - Marie Budev