OPTN Kidney and Pancreas Continuous Distribution Review Boards Workgroup
Meeting Summary
June 13, 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 06/13/23 to discuss the following agenda items:

1. Welcome and Announcements
2. Recap: High Level Overview of Kidney and Pancreas Review Boards in Continuous Distribution
3. Finalization: Exception Requests and Data Collection

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

1. Welcome and Announcements

Staff and the Chair welcomed the Workgroup members to the call.

2. Recap: High Level Overview of Kidney and Pancreas Review Boards in Continuous Distribution

Staff gave a brief overview on the purpose and role of review boards, the scope of the Kidney and Pancreas Review Boards Workgroup, and information about review boards in continuous distribution in general.

Presentation summary:

OPTN heart, liver, and lung review boards quickly review specific, urgent-status patient registrations for candidates on the respective waiting lists. These registrations are generally patients for whom the medical urgency algorithms and system does not appropriately represent, and for whom additional priority is appropriate. 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. This is meant to balance appropriate review and fairness to individual patients with fairness to all other patients, who are appropriately represented by the system. Specific to continuous distribution, review boards allow members to submit an exception request 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 noted that this is not the final version of the review boards.

Summary of discussion:

There was no discussion.

3. Finalization: Exception Requests and Data Collection

Members worked to finalize the process for exception requests in continuous distribution and the associated data collection.

Presentation summary:

Staff first provided an overview of the process of submitting exception requests. Transplant hospitals will submit an exception request which is blinded by the OPTN and submitted to the review board for voting. The review board votes based on narrative submitted by transplant program and the organ-specific candidate information. For prospectively reviewed attributes, candidate score is updated after voting to reflect outcome. For retrospectively reviewed attributes, candidate score is updated at submission to reflect requested score.

Staff then explained specifics of data collection regarding exception requests. When submitting an exception request, programs will need to submit the following information:

- Select which attribute they are submitting an exception for
    - Kidney – Medical Urgency or Safety Net Kidney
    - Pancreas, KP, and/or Islets – Medical Urgency
- Select the percentage of attribute points requested
    - For Kidney and Pancreas, the potential exception request attributes have binary rating scales, and so plan to default to 100%
- Provide a justification narrative
    - This is an open text field in which programs may share a clinical narrative justifying the requested score exception

To finalize the request submission, programs will need to also submit the following:

- Physician name and National Provider Identifier (NPI)
- Email information for any program members who should be updated of the case outcome

Staff demonstrated the system functionality for the current lung continuous distribution review board from the program and reviewer perspectives as an example. Staff then showed a mock up of a possible future user interface in the OPTN computer system specific to kidney and pancreas continuous distribution review boards. Reviewers will be able to see what exception is being requested and how it is being used in the allocation system.

This will require the addition of six new data elements to appear when submitting exception requests, detailed below in **Table 1.**

Table 1: Additional Data Elements for Kidney and Pancreas Continuous Distribution Review Boards

No.	Data Element	Response Option
1	Attribute	(Ki): Medical Urgency, Safety Net Kidney (Pa): Medical Urgency
2	Requested percentage of attribute	(Ki and Pa): will default to 100%
3	Justification narrative	(Ki and Pa): Open text field
4	Transplant physician name	(Ki and Pa): Open text field
5	Transplant physician NPI	(Ki and Pa): Open numeric field, 10 characters
6	Email decision to	(Ki and Pa): three open text fields, allowing for multiple recipients

Staff then provided detail about lung exception requests, noting that lung exception reviewers are currently able to see a significant amount of the candidate's clinical information from the candidate's record on the OPTN computer system upon submission of the exception request. This information provides important clinical context and reduces the burden on the justification narrative. Today, the Workgroup will need to determine what supplemental clinical information should be shared from the candidate's listing to support kidney and pancreas exception request review. Staff shared an example of the information that lung reviewers can see.

Staff then showed a mock-up of the possible system view and what types of information could be available for kidney, kidney-pancreas, and pancreas candidates. For kidney the following information could be shown:

Organ-specific information:

- Medical urgency status
- Inactive reason
- Estimated post-transplant survival (EPTS)
- Total waiting time
- Waiting time qualifying date
- Medically urgent waiting time
- Prior living donor status
- Number of previous kidney transplants
- Number of previous solid organ transplants (kidney-after-liver safety net) if applicable

Clinical information:

- ABO
- Height
- Weight
- HLA
- Calculated panel reactive antibody (CPRA)
- Creatinine clearance

- Glomerular filtration rate (GFR)
- Dialysis status

For pancreas, the following information could be shown:
Organ-specific information:

- Medical urgency status
- Total waiting time
- Waiting time qualifying date
- Any prior kidney transplants and associated information
- Number of previous pancreas transplants

Clinical information:

- ABO
- Height
- Weight
- HLA
- Calculated panel reactive antibody (CPRA)

Kidney-pancreas (KP) candidates can have three different waiting list registrations – one for the combined KP, one for isolated kidney, and one for isolated pancreas. This allows candidates to appear on kidney match runs, pancreas alone match runs, and KP match runs. Some programs may opt for their candidate *not* to have isolated kidney or isolated pancreas registrations. However, all KP candidate registrations will have the following information:

Organ specific-information:

- Medical urgency status
- Total waiting time
- Waiting time qualifying date
- Number of previous kidney transplants
- Number of previous pancreas transplants

Clinical information:

- ABO
- Height
- Weight
- HLA
- Calculated panel reactive antibody (CPRA)
- Other clinical information related to creatinine clearance, GFR, C-peptide use, insulin, and dialysis

Members were asked which of these supplemental data points are necessary for proper review of kidney and pancreas exceptions. Members need to determine if it is appropriate to show both clinical information and organ-specific information.

Summary of discussion:

A member described a situation they had heard about in the lung community, where programs may be submitting exception requests in conflict with policy instead of as a true exception request for a candidate who is not well represented in policy. Another member stated that this is an interesting

concern and should be thought through carefully. Staff stated that there are a couple safeguards in place to prevent this type of situation occurring. First, guidance documents can specify to review board members that the rationale should be based on OPTN policy and clinical information. Second, the OPTN Kidney and Pancreas Transplantation Committee Chairs will be involved in the review board process to be able to provide a level of oversight and monitoring. A member stated that the Committees should keep in mind that clinicians may try to get around policies to benefit their individual candidates, and that the Workgroup should keep in mind this when deciding on the review board structure. The Chair explained that it is reassuring to see that in the current retrospective monitoring of kidney medical urgency cases, most programs are following the guidance and using the intent of the policy in good faith. The Chair continued that the structure of the review board that the Workgroup has settled on has several layers of review, and that monitoring of cases will allow for referral or recommendation of policy modification when necessary, which should help mitigate concerns. Staff noted that the lung review board also meets periodically to discuss how exception requests are going and any concerns that they may have.

The Chair asked if the information the Workgroup would be deciding on is in addition to the clinical narrative the program would be submitting, and staff confirmed that this is the case. A member asked if dialysis access history can be shown to reviewers, and staff showed the current system functionality for programs indicating that their candidate is medically urgent, which asks if a candidate has exhausted or contraindicated dialysis access via all four limbs and peritoneal access as well as transhepatic, translumbar, or other method. However, for programs completing an exception request for medical urgency, a separate form will show up because the candidate will not have met the criteria in policy for medical urgency, and so require an exception. Candidates who meet the criteria laid out in policy for medical urgency will be able to select that and have their candidate granted the status, without going through the exception request process.

The Chair suggested adding candidate age to the kidney data provided to the review board. A member agreed. The Workgroup reached initial consensus to have all kidney organ information provided to members of the review board, noting that the information is helpful for review and not overburdensome to programs. Regarding the clinical kidney information, the Chair suggested that having height and weight may not be super helpful to reviewers. Staff clarified that these are already collected, so they would not represent extra or new data collection. A member stated that height and weight may be useful to a reviewer for seeing the whole picture of a candidate. A member stated that the clinical information should be provided to reviewers in case it is helpful. This member asked if information about heart disease could be added, and staff noted that that is not within current data collection.

For pancreas, the Workgroup reached consensus to show reviewers both clinical and organ-specific information. The Workgroup was also in favor of including candidate age. A member noted that it would be interesting to note the behavior of the center on turn-downs and the relationship between exception requests. This member also suggested collecting time on inactive status and number of offers sent to the candidate. Staff noted that inactive status collection could be taken back to the Pancreas Committee for further discussion. A member stated that offer numbers should not be an element of the review board process.

The Workgroup was in favor of pulling over the kidney-pancreas organ information as well as the clinical information. The Workgroup did not wish to pull over the isolated kidney or pancreas match information (if applicable) because it would not be helpful in a kidney-pancreas review board case. The Workgroup confirmed that candidate age should also be included for kidney-pancreas.

Staff asked if it would be helpful information for review board members to see time at inactive status. A member stated this would be interesting to see and could be useful.

Next steps:

The finalized framework will be presented to the Kidney and Pancreas Committees for review. Because the Workgroup was able to finalize the framework, the Workgroup is not expected to meet again. Staff thanked members for their participation.

Attendance

- **Workgroup Members**
  - Asif Sharfuddin
  - Beatrice Concepcion
  - Ajay Israni
  - Stephen Almond
  - Todd Pesavento
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **UNOS Staff**
  - Joann White
  - Jenn Musick
  - Kayla Temple
  - Kieran McMahon
  - Kaitlin Swanner
  - Krissy Laurie
  - Lauren Motley
  - Lauren Mauk
  - Lindsay Larkin
  - Sarah Booker
  - Thomas Dolan
  - Tamika Watkins