OPTN Kidney and Pancreas Continuous Distribution Review Boards Workgroup
Meeting Summary
November 08, 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 11/08/2022 to discuss the following agenda items:

1. Welcome and Refresher
2. Pancreas Medical Urgency Workgroup Discussion
3. Discussion: Pancreas Medical Urgency Recommendation
4. Data Collection Discussions Exception Request Form
5. Adjourn

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

1. Welcome and Refresher

The Chair welcomed the Workgroup members and briefly reviewed the agenda for the meeting. Staff then updated the Workgroup that the OPTN Histocompatibility Committee confirmed the Workgroup's assumption that exceptions for CPRA and blood type are not needed at this time.

Presentation summary:

Staff reviewed the purpose and scope of the Workgroup:

- Establish review boards for kidney and pancreas with a focus on framework and potential exceptions
- Provide operational guidance for kidney and pancreas review boards
- Provide recommendations to be approved by the OPTN Kidney and Pancreas Committees for the Continuous Distribution proposal slotted for August 2023 Public Comment

Staff reviewed the timeline for the Workgroup and the exceptions the Workgroup has identified. The exceptions identified include:

- Kidney Medical Urgency
- Longevity: KDPI vs EPTS
- Pediatrics, Prior Living Donors, Waiting Time, KAL Safety Net

Summary of discussion: There were no questions or comments.

2. Pancreas Medical Urgency Workgroup Discussion

Staff reviewed work and previous discussions that has taken place for defining medical urgency for pancreas, this was followed by a discussion by the Workgroup.

Presentation summary:

Staff noted that pancreas medical urgency was a pain point the Workgroup had identified in a previous meeting, yet the Workgroup determined at that time more information was needed to confirm a consensus exists to define a medically urgent pancreas candidate. Staff then reviewed the definition of kidney medical urgency, and the qualification requirements to gain kidney medically urgent status.

Staff then reviewed work that was done by the ad hoc Pancreas Medical Urgency Workgroup, which has not convened since 2021. The Pancreas Medical Urgency Workgroup found it difficult to reach a consensus due to little data being available on the subject. The factors they did discuss included:

- Hypoglycemic unawareness
- Type I vs Type II Diabetes
- Cardiac autonomic neuropathy
- Accessibility to technology
- Diabetic ketoacidosis
- Gastroparesis
- Sever hypoglycemic events
- Insulin allergies

Most of the Pancreas Medical Urgency Workgroup's discussion focused on hypoglycemic unawareness and severe hypoglycemic episodes. The mortality rate for severe and prolonged hypoglycemic episodes is estimated to be between 4.9% and 9% , it can occur in young and otherwise healthy patients, and many who experience hypoglycemic events also experience hypoglycemic unawareness. The Pancreas Medical Urgency Workgroup's discussed the frequency of hypoglycemic unawareness episodes and the patient ability to care for diabetes. Severe hypoglycemic events and their connection to hypoglycemic unawareness, and impaired awareness of hypoglycemia defined as Clarke Scale score greater than or equal to 4.

Either the Clarke Scale or Gold Scale can be used to quantify hypoglycemic unawareness. The Gold Scale asks diabetic patients to rate to what degree they know when a hypoglycemic episode is commencing on a scale of 1-7. The Clarke score poses 8 questions indicating awareness or reduced awareness. The Pancreas Medical Urgency Workgroup also had some agreement that continuous glucose monitoring (CGM) may be an important precursor, and critical, to appropriate management. CGM data can be used to indicate severe hypoglycemic events and potentially hypoglycemic unawareness and may also help patients manage their diabetes enough to prevent hypoglycemic events and reduce their hypoglycemic unawareness. There was also agreement that any definition involving CGM must make exception where technology is not available.

<u>Summary of discussion:</u>

A Workgroup member expressed interest in including hypoglycemic unawareness to the definition of medical urgency for pancreas, along with access to dialysis. The member acknowledged this is not perfect, but it is a start and can be approved upon in the future. The member also suggested that CGM could be included, some geographic areas have limited access to specialists, and they should not be held at a disadvantage for this. The member offered having two hypoglycemic episodes that require hospitalization would be a good place to start discussing criteria.

Another member agreed that including hospitalization as part of a rigid definition would be a good thing given how those are easily proven. As far as CGM, the member suggested asking what the patient has access to and what their insurance coverage offers. The member also pointed out that insulin allergies are another important factor to consider.

A member shared that they are struggling to see how any of these factors differ from established reasons for receiving a pancreas transplant, and so discerning medically urgent patients from regular pancreas transplant patients is difficult. A second member responded that for people who are getting a single organ transplant that may be the case, but for patients who are listed for simultaneous kidney-pancreas (SPK) could siphon off pancreases from pancreas-only candidates, or kidneys from kidney alone candidates. The member continued that there should be a distinction between patients who need a transplant and those who are going to die without a transplant. Another member pointed out that mortality may not be the best way to measure urgency since many patients are facing mortality, and the justification for giving additional points to pancreas patients for this exception could be applied to others but is not. The Chair responded that having a rigid definition would provide justification, because a patient with six events every year is facing a different mortality rate than a candidate who has one episode every other year. A member agreed with the Chair's comments and added that this would apply to only handful of their patients over the past several decades.
A few members asked about the availability of data to determine how patients might qualify for this exception, and some members expressed concern over the quality of the data that would be available. A member asked if it would be possible to get data on the one year, three year, and five year waitlist mortality for pancreas only candidates and to see the listed cause of death for those patients in order to help inform the Workgroup's decision. The Chair stated that treatments for diabetic patients has changed drastically over the last decade, which could impact the way the data is collected and analyzed. Staff interjected that this may need to be a formal data request. Staff also pointed out that the Workgroup is building this review board from scratch and can determine what data points need to be submitted and what must be included in the narrative for the exceptions to be considered.

Staff asked if the Workgroup felt it would be more appropriate for the Pancreas Medical Urgency Workgroup to reconvene and allow them to discuss this in more detail. One member pointed out that allowing the Pancreas Medical Urgency Workgroup, and the Pancreas Committee, to determine the criteria would be appropriate, and the Workgroup would then determine whether or not it should be a matter for the review board to consider. A majority of the Workgroup members agreed that this is the best course of action.

Next Steps:

Staff will meet with Pancreas Committee Leadership updating them on the Workgroup's request to reconvene the Pancreas Medical Urgency Workgroup in order to assist in determining how the review board should consider pancreas medical urgency exceptions. Data will also be collected to assist the Workgroup in making this decision.

3. Data Collection Discussion Exception Request Form

Staff provided a brief overview on the role and importance of set guidance for review boards, and introduced topics the Workgroup will be discuss concerning guidance.

Presentation summary:

Lung Committee Leadership had previously shared with the Workgroup the importance guidance and guidelines play in assisting review boards during their decision making process. The Workgroup had previously identified the following attributes as ones for which guidance may be helpful:

- Kidney Medical Urgency – Kidney Medical Urgency Review Subcommittee developed a set of recommendations
- Pediatrics

- Prior Living Donors

Staff noted that many of these topics have already been discussed by the Workgroup, and questions that were raised will be addressed by the appropriate OPTN committees so the Workgroup can make better informed decisions.

Summary of discussion:

Staff asked the Workgroup if they could foresee any other attributes that would need clear guidance as part of the initial implementation of continuous distribution. A member responded that having access to a patient's discharge summaries, if they were admitted for hyperglycemia or hypoglycemia, and a confirmatory evaluation by a center's social worker that these episodes were not brought about by noncompliance.

Upcoming Meetings

- November 22, 2022; 4 p.m. Eastern Time
- December 6, 2022; 4 p.m. Eastern Time
- December 13, 2022; 4 p.m. Eastern Time

Attendance

- **Workgroup Members**
  - Asif Sharfuddin
  - Bea Concepcion
  - Elliot Grodstein
  - Maria Friday
  - Todd Pesavento
  - Raafat Qbeiwi Reem
  - Michael Marvin
- **UNOS Staff**
  - Alex Carmack
  - James Alcorn
  - Jennifer Musick
  - Joann White
  - Kayla Temple
  - Keighly Bradbrook
  - Kieran Mcmahon
  - Kim Uccellini
  - Krissy Laurie
  - Lauren Mauk
  - Lauren Motley
  - Lindsay Larkin
  - Ross Walton
  - Sarah Booker
  - Thomas Dolan