

# **Meeting Summary**

# OPTN Pancreas Transplantation Committee Meeting Summary December 13, 2021 Conference Call

# Rachel Forbes, MD, Chair Oyedolamu Olaitan, MD, Vice Chair

#### Introduction

The Pancreas Transplantation Committee (the Committee) met via Citrix GoToMeeting teleconference on 12/13/2021 to discuss the following agenda items:

- 1. IT Update: Multi-Factor Authentication
- 2. Project Update and Discussion: Continuous Distribution of Kidneys and Pancreata
- 3. Project Updates

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

# 1. IT Update: Multi-Factor Authentication

IT staff presented an update on the Multi-Factor Authentication project, including the roll out plan and preparations UNet users can take.

#### Data Summary:

Multi-Factor Authentication will be rolled out in 2022. After implementation, utilizing Authy will be required for everyone logging into UNet.

Users can download and setup an Authy account now to ensure there will be no issues after implementation.

#### Summary of discussion:

There was no discussion.

#### 2. Project Update and Discussion: Continuous Distribution of Kidneys and Pancreata

The Committee reviewed the progress of the continuous distribution of kidneys and pancreata project. There will be a second request for feedback going out for public comment in January 2022 along with the analytic hierarchical process (AHP)/community exercise. There will be two AHP exercises available during public comment; one will be specific to kidney while the other will be specific to pancreas/kidney-pancreas (KP).

After the Kidney and Pancreas Continuous Distribution Workgroup reviews the feedback from their public comment items, they will be moving into phase 3 of the project, which is prioritizing attributes amongst each other.

Staff also updated the Committee that the continuous distribution proposal is now targeted to go to the Board of Directors in June 2023.

## **Summary of discussion:**

The Chair stated that the AHP exercise is pretty easy to complete and will provide important feedback. The Chair encouraged members to participate in the exercise.

Staff stated that the pancreas AHP is ready and that they will be reaching out to Committee leadership to participate and provide feedback.

A member inquired if the Committee will be having an in-person meeting this cycle. Staff explained that, as of right now, there will be an in-person meeting after public comment, so the Committee will have time to review and discuss the feedback received from the request for feedback.

The Chair inquired if the Committee is going to preview the request for feedback before it is released for public comment. Staff explained that it is currently under peer review and being finalized; but, once the request for feedback is finalized, it can be sent to Committee members.

A Scientific Registry for Transplant Recipients (SRTR) representative inquired if phase 3 of the project is the same as phase 2. The Chair explained that phase 2 is creating a rating scale, which would prioritize candidates within one attribute, and phase 3 is weighing the attributes against each other.

There was no further discussion.

## 3. Project Updates

The Committee reviewed updates on the following projects that the Pancreas Committee has representation on:

Ad hoc Multi-Organ Transplantation (MOT) Committee

The MOT Committee was charged with developing allocation policies addressing multiple organ groups and the practice of multi-organ allocation. Additionally, the MOT Committee must ensure that proposed multi-organ policies are aligned with the OPTN Final Rule and the planned transition of each organ allocation system to a continuous distribution framework.

To date, the MOT Committee has:

- o Approved the draft proposal language during their last meeting (November 22)
  - The proposed heart-kidney and lung-kidney language is very similar to what exists for liver-kidney eligibility criteria (Policy 9.9) and safety net prioritization (Policy 8.5)
  - This proposal will be going out for January 2022 public comment cycle
- The Committee will likely be rolling into their next topic of prioritization between kidney multi-organ transplant and single organ transplant candidates.

Reassess Inclusion of Race in estimated glomerular filtration rate (eGFR) Calculations (OPTN Minority Affairs and Kidney Transplantation Committees)

The goal of this project is to prohibit the use of eGFR calculations that include a race-based variable in OPTN policy, so Black kidney candidates' eGFR values will be more reflective of their actual kidney function.

- A proposal is going out for January 2022 public comment. The proposal is recommending:
  - Prohibiting the use of eGFR calculations that include a race-based variable in OPTN policy
  - Defining GFR within OPTN Policy 1.2: Definitions so that any eGFR calculation that does not include a race-based variable may be used

 This requirement for race-neutral calculations intends to increase equity in access to transplantation for Black kidney candidates by more accurately estimating their GFR values

#### Summary of discussion:

The following is a summary of the Committee's discussion for each project update:

Ad hoc Multi-Organ Transplantation (MOT) Committee

The Chair inquired about the timeline for implementation of the heart-kidney and lung-kidney proposal. A member explained that the timeline for implementation will be tied to the implementation of continuous distribution for each organ, since the MOT Committee was created as a part of continuous distribution. The member further explained that they don't think implementation will be as far away as January 2024.

The Chair stated that they thought this effort was in response to a desire for a safety net earlier than when continuous distribution would be implemented. Staff mentioned that they can reach out to the MOT Committee liaison to clarify the implementation timeline.

A member stated that they believe it's useful for programs to have guidelines and standardization across the country. The member inquired if the MOT Committee has reviewed the literature and data about using higher estimated glomerular filtration rate (eGFR) levels. A member explained that the use of higher eGFR level for eligibility criteria and the extension of the safety net had been discussed extensively, especially because kidney disease presents itself differently in heart, lung, and liver candidates. In marginal lung-kidney transplants, kidney failure tends to occur after 12 months due to higher toxicity. In heart-kidney discussions, the MOT Committee discussed using a higher eGFR of 60 for the eligibility criteria. A member further explained that, ultimately, the MOT Committee decided it was best to stay consistent with the current simultaneous liver-kidney (SLK) policy since opinions differed for both heart-kidney and lung-kidney.

A member emphasized that the current level of eGFR is prohibitive and harms candidates that need a kidney alone transplant since more kidneys are being diverted away from the candidate. A member inquired what level of eGFR the member was referring to. The member explained that they were referring to an eGFR level of 45, which they think is still too generous.

A member noted that, staying consistent with SLK policy, an eGFR level of 30 is part of the proposed eligibility criteria for heart-kidney and lung-kidney. The member further explained the safety net extends 12 months after transplant when a candidate's eGFR goes below 20, which corresponds with kidney listing requirements.

A member expressed concern that the safety net is being used in a way it wasn't intended, which the member thought was to offer a safety net to candidates with kidney failure after a liver transplant and eGFRs that just miss the threshold to be eligible. The member stated that they don't believe it is equitable for candidates on the kidney alone list to extend the safety net when a candidate with an eGFR of 100 and end stage renal disease, which had nothing to do with their pre-transplant kidney disease, or a candidate who had bypass surgery can get a kidney ahead of the kidney alone candidate. The member noted that 30% of lung recipients have renal failure within the first year and the end stage renal disease is incredibly high.

A member agreed and highlighted that that was the reasoning behind why the MOT Committee agreed upon staying consistent with the current SLK policy, which kept the safety net at 12 months and an eGFR level of 30. The member also countered that a candidate who had bypass, kidney failure, and is not on

immunosuppression would not receive a heart, lung or liver because the mortality among patients who are on immunosuppression and going on dialysis is worse than those patients not on immunosuppression.

A member mentioned that safety net candidates are prioritized, even though they may not have worse outcomes compared to pediatric candidates or Type I diabetics, and stated that they aren't sure whether safety net candidates should receive such high priority. A member stated that the MOT Committee has had some discussion regarding this prioritization; however, their next step is to discuss priority between MOT and single organ transplant (SOT) kidney candidates. The heart-kidney and lung-kidney proposal is solely the progress the MOT Committee has made thus far and there will be more discussions in the future, meaning safety net candidates might not go ahead of SOT or pediatric kidney candidates.

A SRTR representative mentioned that the MOT Committee has discussed all of these MOT combinations, but has not discussed kidney-pancreas. The SRTR representative explained that, in the current state, is that a kidney will get uncoupled after a heart-kidney, lung-kidney or liver-kidney and go to the pancreas list if KP patient is available to take it. The SRTR representative noted that they hadn't seen this prioritization preserved in either the Kidney & Pancreas Continuous Distribution Workgroup or MOT Committee discussions and highlighted that this prioritization could be in jeopardy.

A member explained that they believe this will be discussed during the next step (prioritizing different MOT combinations and SOT candidates) of the MOT Committee's project.

A SRTR representative also noted that, in keeping this kidney-pancreas priority, they didn't expect pushback from the pediatric community. Pediatric candidates could be prioritized without affecting the uncoupling of the kidney – one kidney would go to the kidney-pancreas pediatric candidate since they would be at the top of the list.

Reassess Inclusion of Race in estimated glomerular filtration rate (eGFR) Calculations

The Chair inquired if there is going to be some retrospective assessment to see if some patients will get an increase in waiting time or if this will just go forward as a new policy. The member stated that the chair of the OPTN Kidney Transplantation Committee looked at the difference between those using the current race-based coefficient and those not using it at their program and found that about 6% of patients would have been listed much earlier if they had not used the race-based coefficient.

There were no further comments. The meeting was adjourned.

#### **Upcoming Meetings**

• January 10<sup>th</sup>, 2022 (teleconference)

#### **Attendance**

# • Committee Members

- o Rachel Forbes
- o Oyedolamu Olaitan
- Silke Niederhaus
- o Antonio Di Carlo
- o Dean Kim
- o Maria Friday
- o Nikole Neidlinger
- o Parul Patel
- o Randeep Kashyap
- o Todd Pesavento

# HRSA Representatives

- o Jim Bowman
- o Marilyn Levi
- o Raelene Skerda

## • SRTR Staff

- o Bryn Thompson
- o Jonathan Miller
- o Peter Stock
- o Raja Kandaswamy

## UNOS Staff

- o Joann White
- o Rebecca Brookman
- o Anne McPherson
- o Amy Putnam
- o Lauren Motley
- o Leah Slife
- o Sarah Booker