

**OPTN Kidney and Pancreas Transplantation Committees  
Kidney-Pancreas Continuous Distribution Workgroup  
Meeting Summary  
October 15, 2021  
Conference Call**

**Rachel Forbes, MD, Chair  
Oyedolamu Olaitan, MD, Vice Chair  
Martha Pavlakis, MD, Chair  
Jim Kim, MD, Vice Chair**

## **Introduction**

The Kidney and Pancreas Transplantation Committee Continuous Distribution Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 10/15/2021 to discuss the following agenda items:

1. Public Comment Overview
2. Review of Project Goals and Approach
3. Overview of Waiting Time in Current OPTN Policy
4. Waiting Time Rating Scale Discussion

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

### **1. Public Comment Overview**

The Workgroup reviewed the feedback gathered in public comment with the release of the first Kidney-Pancreas Continuous Distribution Update Concept Paper.

#### Data summary:

The Concept Paper released for the August 2021 Public Comment period provided an overview of Continuous Distribution, the attributes considered by the Kidney and Pancreas Committees, outlines alignment with the Final Rule and NOTA, and sought community feedback.

Feedback was gathered from 11 regional meetings, eight OPTN Committees, six stakeholders and societies, and four individual comments. Feedback themes included pediatric access, efficiency, kidney donor profile index (KDPI) and estimated post-transplant survival score (EPTS), disparities and disadvantaged patients, multi-organ transplant, patient education, and community engagement.

Ongoing considerations for the Workgroup and Committees include medical urgency for pancreas, impact on disadvantaged populations, ethical implications, and uniformity across organs in project approach for placement efficiency and patient education.

#### Summary of discussion:

The Committee had no comments or questions.

### **2. Review of Project Goals and Approach**

The Workgroup reviewed the goals of the Continuous Distribution project, including the second phase's focus on converting identified attributes into points via rating scales and weights.

Summary of discussion:

The Committee had no comments or questions.

**3. Overview of Waiting Time in Current OPTN Policy**

The Committee reviewed current policy regarding Waiting Time for Kidney, Pancreas, and Pancreas Islet allocation, including qualifying criteria for listing and waiting time points accrual.

Summary of discussion:

A Workgroup Chair noted that the Workgroup will need to discuss how to manage candidates who are listed for pancreas based on needing insulin that need to transition off of insulin when put on dialysis.

One member recommended setting a timeframe for the three islet infusion. The member shared that, in the United Kingdom, two infusions are performed in the first few months, the idea being that more than one infusion is planned for the pancreas islet transplantation. These infusions need to happen in fairly short intervals, which is different than an open ended three islet infusion. The member commented that a candidate who has completed two islet infusion as completion of an islet transplant can return several years later post-graft failure and have significant waiting time and priority for the third infusion. The third infusion in this case, the member pointed out, would not be part of the same transplant or series of infusions and shouldn't be seen as such. Staff remarked that the timeframe is not clarified.

**4. Waiting Time Rating Scale Discussion**

The Committee discussed several options for the Waiting Time attribute rating scale.

Data summary:

Option 1: General Linear Waiting Time Rating Scale

- As waiting time increases, points increase in a linear, direct fashion
- Similar to current kidney waiting list policy, where every additional day of waiting time is equal
- Consideration: weight dilution – most people are in the bottom fraction of the scale, and very few people would receive the maximum points (reflected as the person with the most wait time)
  - The vast majority of kidney candidates fall into the bottom quarter of that scale, resulting in a scale that does not clearly differentiate between candidates

Option 2: No Ceiling

- Choose a threshold (I.E. 10 years) similarly to Option 1, but allow the rating scale to exceed 100 percent linearly for candidates with more than 10 years of waiting time.
- Rating scale line would continue beyond 0-100 range to continue awarding points for differential waiting times, without changing the value judgement
  - If the weighting given to the attribute were 10 percent, those candidates outside of the threshold would have a high amount of points above the threshold, making the weight greater than 10 percent
- This would keep waiting time on a linear scale, but would make weights variable for candidates with more extreme waiting times

Option 3: Ceiling

- As waiting time increases, points increase, up to a cutoff for waiting time (such as 95 percent of patients have a waiting time less than X years)

- Candidates with more time than the ceiling would still only receive 100 percent of the rating scale
- Mathematically simple and keeps a consistent weight on the rating scale, but doesn't distinguish between candidates that have waiting times greater than that ceiling

#### Option 4: Linear to Curve

- Linear scale up to Y amount of waiting time (I.E. 80 percent of candidates have a waiting time less than Y years), with those patients linearly receiving points up to Y points
- After Y, the curve slowly diminishes towards a ceiling, with each additional day worth less than the one before
- This model maintains a 0-100 rating scale and a given weight, and distinguishes between candidates with significant waiting time

#### Summary of discussion:

One member asked, if most of the candidates are at the bottom of the scale, would setting a ceiling really only affect those with extreme wait time? Staff clarified that setting a ceiling would allow for a scale that appropriately considers a distribution of candidates throughout. The member noted that many patients at the bottom of the scale have 1-3 years of waiting time, and commented that there would still be weight dilution for these candidates in a scale with a 10 year ceiling. Staff shared that the distribution of candidates is not a perfect distribution, and remarked that the Workgroup would need to decide where the ceiling should be set. If the ceiling is too high, there will be weight dilution; if the ceiling is too low, too many people will be at the top of scale.

A member expressed concern about setting a ceiling, commenting that these options seem to penalize the rare candidates who have survived more than a decade on dialysis by removing the priority they have for living on dialysis for so long. A Workgroup Chair agreed, expressing that capping waiting time feels inherently wrong. The Chair continued, remarking that candidates who have been on the waiting list for a long time have had other circumstances. Many of these candidates haven't actually been on the waiting list for 20 years, they have been on dialysis and were referred late. The Chair added that the Kidney Allocation System (KAS) recognized and combatted that disadvantage with backdating dialysis, and expressed concern that setting a ceiling will disadvantage those patients again.

A Workgroup Chair asked why there was a 0-100 scale for the Composite Allocation Score (CAS). Staff clarified that each attribute has a 0-100 score established by the rating scale, which is multiplied by a weight. Those weighted attribute scores are aggregated to build a 0-100 score for the CAS. The Chair remarked that weighing attributes against each other is helpful, adding that it's most logical to compare other attributes to one year of waiting time, such that the question is how much of each attribute equates to one year of waiting time.

One Workgroup Chair agreed that there are candidates who should receive additional points for having long waiting times, adding that this also likely includes those patients with high calculated panel reactive antibodies (cPRA). The Chair continued that these patients likely come up on most offers across the country, and remarked that setting a ceiling would make sense from a placement efficiency standpoint, as that example patient would not receive significant benefit from so many offers. The Chair added that it's inefficient for Organ Procurement Organizations (OPOs) to ship blood samples so often for these offers. The Chair also pointed out that waiting time is not a fixed scale, and increases every year. Staff remarked that it is easy to adjust these scales in Continuous Distribution, and that these changes wouldn't necessarily need years of development. Staff shared that, if a ceiling was chosen with a framework similar to 100 points at the maximum time 95 percent of the waiting list falls below, the

policy could include an annual review similar to Kidney Donor Profile Index (KDPI) and Expected Post-Transplant Survival (EPTS). This process captures incremental changes.

Another Chair expressed concern about the ceiling, commenting that it could disadvantage certain candidates. The Chair suggested performing a log transformation, so that rather than capping at 80 or 95 percent of the waiting list, a log transformation could be used. Staff remarked that this would be similar to Option 4 with a curve for the whole rating scale, with the curve steeper in the first few years and flatter after a certain number of years. This would change the concept of each additional day being equal, but it would utilize the whole rating scale and account for outliers.

One member recommended correlating the number of points each candidate receives based on mortality on dialysis, so those candidates who have been on dialysis longer receive greater points compared to those with lower waiting times and less mortality. Staff noted that this would be more like an exponential scale, where the curve is flatter at first and then steeper with increased wait. Staff asked the workgroup the rationale for using waiting time, asking if waiting time is a surrogate for medical urgency or for patient access and fairness. The answer to this should influence the rating scale.

A member agreed that from an efficiency standpoint, a ceiling makes sense, particularly at a local level. The member pointed out that people don't need to be on dialysis to be listed, and so there are many patients who are listed early and have large amounts of waiting time *off* dialysis. The member asked if there was a way to determine which patients have long waiting times due to dialysis or early listing. The member asked the Workgroup if there should be a difference considered for dialysis. Staff noted that it would be possible to compute waiting time differently for candidates on dialysis.

Staff recommended that the Workgroup ask for community input about these concepts in the Update Concept Paper going out in January 2022, and decide that the general trend is a direct relationship, with points increasing as waiting time increases. The Workgroup agreed.

### **Upcoming Meeting**

- November 5, 2021

## Attendance

- **Workgroup Members**
  - Jim Kim
  - Oyedolamu Olaitan
  - Silke Neiderhaus
  - Aaron Wightman
  - Abigail Martin
  - Tarek Alhamad
  - Cathi Murphey
  - Deirdre Sawinski
  - Parul Patel
  - Raja Kandaswamy
  - Caitlin Shearer
  - Aaron Wightman
  - Dave Weimer
  - Grace Lyden
- **HRSA Representatives**
  - Jim Bowman
  - Raelene Skerda
- **SRTR Staff**
  - Ajay Israni
  - Bryn Thompson
  - Jonathan Miller
- **UNOS Staff**
  - Joann White
  - Lindsay Larkin
  - Rebecca Brookman
  - Alison Wilhelm
  - Amanda Robinson
  - Anne McPherson
  - Darby Harris
  - James Alcorn
  - Laura Schmitt
  - Lauren Motley
  - Matt Prentice
  - Ross Walton
  - Sarah Booker
  - Kayla Temple
- **Other Attendees**
  - Maria Helena Friday