

OPTN Pancreas Transplantation Committee

Meeting Summary

April 18, 2022

Conference Call

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

Introduction

The Pancreas Transplantation Committee (the Committee) met via Citrix GoToMeeting teleconference on 4/18/2022 to discuss the following agenda items:

1. Review/Discussion: Continuous Distribution of Kidneys and Pancreata

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

1. Review/Discussion: Continuous Distribution of Kidneys and Pancreata

The Committee reviewed the following pancreas rating scales for kidney and pancreas continuous distribution and answered some outstanding questions:

- Calculated panel reactive antibodies (CPRA)
- Prior Living Donor (PLD)
- Pediatric
- Waiting Time
- Proximity Efficiency

Summary of discussion:

The follow is a summary of the Committee's discussion:

Calculated panel reactive antibodies (CPRA)

Rating Scale: steep, non-linear scale

A member stated that this rating scale seems very different from the kidney rating scale and inquired if the two scales need to align. Staff explained that this rating scale would be in alignment with the kidney rating scale, as well as the scale for lung.

A member inquired if this rating scale is a place holder or if the shape of the scale is accurate based on data. Staff explained that the idea behind this rating scale is to replace the current kidney CPRA function, which tries to capture non-linearity in a categorical approach. This rating scale would be capturing those differences along a smooth continuum and is non-linear to reflect that an increase of CPRA from 99.9% to 100% is a lot more substantial than an increase from 40% to 50%, so those in need of a boost get that boost. Staff stated that this rating scale is subject to modification and can be evaluated in modeling.

A member mentioned that only extremely highly sensitized patients need that advantage. The member suggested that the scale should be fairly flat until a CPRA of about 99-99.5% and then have an extreme upward slope.

Staff explained that there have been discussions about adding in some extra classifications for those highly sensitized candidates, so what this rating scale does is turn CPRA into a smooth function – those candidates with a CPRA approaching 100% receive even more points. Staff recommended start with this rating scale and if the Committee finds that the scale needs to be steeper, then the Committee can make that modification.

The Chair stated that they thought that CPRA was curvilinear in current allocation. Staff explained that it's a step-wise function in current policy because a certain CPRA range receives the same priority.

The Chair agreed with the concern that the points given to those patients with a CPRA between 50-90% would be a significant advantage that they don't really need and may not be indicative of immunologic reasons consistent with the OPTN Final Rule.

Staff mentioned that they aren't sure how important it is to align CPRA with lung and that it seems this scale is not steep enough for the baseline rating scale. A member agreed and suggested that the curve be really steep after CPRA of 98%.

Members unanimously agreed with the steep, non-linear rating scale for CPRA with the caveat that the scale will be steeper for those extremely highly sensitized candidates.

Prior Living Donors (PLD)

Rating Scale: binary (yes/no) for PLDs of any organ

Members unanimously agreed with the binary rating scale for PLDs.

Pediatric

Rating Scale: binary (yes/no)

A member inquired if this rating scale is solely for those candidates that require a pancreas or a kidney-pancreas (KP). Staff stated that that is correct. The member mentioned that they feel differently about pediatrics when comparing between kidney and KP. Patients that are 19 years old and those that are 17 years old are not very different and the member stated that a step-wise or graded scale would be preferable to the binary scale in that instance.

A member stated that it depends on what the OPTN considers to be pediatric. A member mentioned that they were extrapolating this to when the Committee starts comparing allocation between kidney-alone candidates and those waiting for KP in terms of priority, which the OPTN Multi-Organ Transplantation (MOT) Committee is going to look at. The member stated that, personally, a 16 year old waiting for kidney alone may not have priority in terms of utilization or mortality compared to a 19 year old waiting for a KP.

Staff mentioned that the Committee would need to do their due diligence when determining if there needs to be a smoother approach to age in the pediatric rating scale. Staff also highlighted that, for that reason, age is included in other attributes such as estimated post-transplant survival.

Staff provided the following background in regards to how the definition of pediatric status was decided upon:

- A workgroup of committee leaders met and were asked how to consistently address pediatric candidates
 - Ideally, pediatric status would be determined by age at disease onset, but difficult to measure

- Agreed that pediatric status would be determined by the age when the candidate was registered on the wait list
- National Organ Transplantation Act (NOTA) allows the OPTN to distinguish between adults and pediatrics, and the OPTN can do that more easily with a binary scale than distinguishing between different pediatric candidates.

A member inquired if the Committee thinks that there should be a graduated response for true pediatric. For example, a patient who is aged 10 years old or less should have more priority than a patient who is 16 years old and above and can better monitor their glucose. Staff inquired what evidence the Committee has to make that decision.

A member stated that, when this was discussed at the pediatric committee, it was brought up that not receiving a transplant could effect a pediatric candidate's growth down the line. So, at what age point does not receiving a kidney affect their growth? The member stated that they are thinking about this rating scale when it comes to comparing kidney alone with pancreas adults. The member considered that the age when it's difficult to get pediatric candidates dialyzed (very small pediatric candidates who are less than 20 kilograms are difficult to dialyze) is when they should be receiving a significant amount of extra priority. The member suggested that the Pediatric Committee could help make these determinations.

A member inquired if this rating scale would consider pediatric status as those candidates listed prior to the age 18, not 18 years old on the day of the offer. Staff stated that that's correct.

A member highlighted that this is an extraordinarily small group of patients and if KP pediatric candidates had the same priority as kidney alone pediatric candidates, then the pancreas is going to pull the kidney and give them more priority for that particular donor. The member mentioned that they were envisioning a linear rating scale with 100 percent of points at zero years old and zero percent of points at 18 years old, but also understood that keeping it simple may be the better option.

A member stated that, for the purposes of pancreas alone, this simple rating scale should suffice because the number of pediatric pancreas transplants is so low. The Chair agreed.

Members unanimously agreed with the binary rating scale for pediatrics for the first round of modeling.

Waiting Time

The Committee reviewed that the OPTN Kidney Committee had recommended the no ceiling and no curve rating scale and selected 10 years of qualifying time (when a candidate will receive 100 percent of the points).

The Committee had supported a linear to curve rating scale with no ceiling. The Committee needed to determine the following inflection points:

- What number of years for qualifying time?
- What percentage of the points on the 0-100 scale?

The Chair stated that the whole reason the Committee is using this scale is to counteract the dilution of points and the median wait time for pancreas transplant is 2 years. It seems that these candidates are waiting 9-10 years for other reasons and the Chair wasn't sure that waiting time is so much the factor that drives the organ placement. The Chair stated that they would support 90 percent, or maybe even 80 percent.

A member stated they were curious about how many pancreas candidates are on the waitlist for 6-9 years because it's very unlikely they will receive a pancreas transplant at that point.

A member highlighted that candidates waiting that long is due to sensitization, so hopefully the CPRA points will help with that. The Chair agreed and stated that there are other factors that are contributing to long wait times.

The Chair stated that going closer to the median would help get rid of the weight dilution.

A member agreed and stated that they were surprised that candidates wait 9-10 years for a pancreas, since few will get transplants after waiting that long.

Members voted on the following question: What should the value for X (years of qualifying time) be?

- 5 years (closer to median) – 6 votes
- 7 years (90th percentile) – 1 vote
- 9 years (95th percentile) – 0 votes
- 10 years (between 95th and 99th percentile) – 0 votes

A member stated that it is a very small number of patients who will be waiting 7 years, but the longer they stay on this list the less likely they are to get a transplant. The member expressed that those candidates who wait longer and are still healthy enough for transplant, should be provided a certain number of additional points; however, the member is fine with 5 years qualifying time as well.

Members voted on the following question: What should the value for Y (percentage of points) be?

- 80 percent (second slope less shallow) – 0 votes
- 90 percent – 6 votes
- 95 percent (second slope very shallow) – 1 vote

The Chair explained that this percentage of points is for candidates at the qualifying time and that those above the qualifying waiting time would receive points based on the second slope to get to 100 percent of points.

The Chair stated that since the Committee went back so close to the median for qualifying time, then 90 percent would make sense – for 95 percent, there wouldn't be a significant increase in the priority and, for 80 percent, those candidates would still have 20 points to make once they pass 5 years of waiting time.

A member stated that they would be in favor of 90 or 95 percent. The member mentioned that they would like to see a KP patient receive a KP by 5 years, since the pancreata may not be utilized at that point due to mortality on dialysis. A member expressed that, now understanding this part of the question, they would suggest moving qualifying time to 3 years and choosing 80 for the percentage of points.

A member stated that, if the consensus is 90 percent then that's fine, but they felt that it would be very rare for a pancreas or KP candidate to wait 5 years and would want the majority of points to go to those candidates below 5 years of waiting time.

Proximity Efficiency

Rating Scale: Piecewise linear approach

- KP: 50 nautical mile (NM) inner plateau; 85 percent driving slope
- Pancreas: 50 NM versus 100 NM inner plateau; driving slope to 0% at 250 NM

The Chair stated that the Committee had discussed not awarding points for proximity past 250 NM. Staff inquired if the Committee was envisioning a single rating scale for pancreas and KP. Members confirmed that they would want a single rating scale.

Staff inquired if the Committee would still want 50 NM for the inner plateau. Members confirmed that they preferred an inner plateau of 50 NM.

Staff inquired if the Committee still wanted the driving slope to reach 0 percent at 250 NM. Members thought the concept suited pancreas/KP well.

A member inquired if there is any disadvantage to having the slope completely flat past 250 NM. Staff explained that for this attribute, from a practical perspective, a candidate at 250 NM is going to be treated the same at 2,000 NM or 5,000 NM. The member inquired if the Committee wants to still give some advantage for proximity past 250 NM.

The Chair stated that programs that charter flights it's probably still cheaper for closer charters.

A member stated that the Committee should have a rating scale that is more similar to the kidney rating scale where it drops to 250 NM but it shouldn't be a huge difference between 250 NM and beyond. The member explained that they support this for two reasons: (1) the closer a program is to the donor hospital the cheaper transportation is and (2) whatever the Committee decides on still needs to be negotiated with the OPTN Kidney Committee.

A member inquired if there are regions in the country where there is no pancreas center within 250 NM of a particular donor and then aggressive centers could take that centers local offers, disadvantaging candidates at that center. The Chair stated that there might be, especially in the Midwest or Northwest.

The Chair stated that they would support a gentle slope from 250 NM and beyond. A member stated that the Committee could put 250 NM at 25 or 30 percent of points and then have a gentle slope down to zero percent at the furthest possible distance. Members agreed that that would address some of the potential disparities.

The Chair inquired if there should be further categorizations in distance beyond 250 NM. A member stated that the 'uncertainty zone' outside of 250 NM where programs either drive or fly does not seem to be crystalized for pancreas, since aggressive centers will go whatever distance. The member supported the gentle downwards slope beyond 250 NM to the furthest possible distance. Members agreed that a gentle slope out to the rest of the country, instead of further categorizations, suits pancreas better.

Members agreed on a proximity rating scale for pancreas/KP with an inner plateau of 50 NM, a driving slope dropping to 25 percent at 250 NM, and a gentle slope reaching zero percent at the furthest possible distance.

There were no additional questions or discussion. The meeting was adjourned.

Upcoming Meetings

- May 16, 2022 (teleconference)

Attendance

- **Committee Members**
 - Rachel Forbes
 - Oyedolamu Olaitan
 - Dean Kim
 - Maria Friday
 - Nikole Neidlinger
 - Parul Patel
 - Pradeep Vaitla
 - Ty Dunn
 - Todd Pesavento
- **HRSA Representatives**
 - Marilyn Levi
- **SRTR Staff**
 - Bryn Thompson
 - Jonathan Miller
- **UNOS Staff**
 - Joann White
 - Rebecca Brookman
 - Darren Stewart
 - James Alcorn
 - Lauren Mauk
 - Lauren Motley
 - Sarah Booker