OPTN Pancreas Transplantation Committee
Meeting Summary
December 12 2022
Conference Call

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

Introduction

The OPTN Pancreas Transplantation Committee (the Committee) met via Citrix GoToMeeting teleconference on 12/12/2022 to discuss the following agenda items:

1. Welcome
2. Kidney-Pancreas Continuous Distribution Attributes: Pediatrics
3. Kidney-Pancreas Continuous Distribution Attributes: Prior Living Donor
4. Kidney-Pancreas Continuous Distribution Attributes: Calculated Panel Reactive Antibody (CPRA)

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

1. Welcome

Staff, the Chair, and the Vice Chair welcomed the Committee and explained the agenda for the meeting. In the next few meetings, the Committee will explore each attribute, review relevant modeling and public comment feedback, and begin to make decisions for the second Scientific Registry of Transplant Recipients (SRTR) modeling request, any changes to rating scales or weights, and any additional data to inform future conversations. Staff reminded members of the upcoming in-person meeting in Houston, TX on January 27, 2023.

2. Kidney-Pancreas Continuous Distribution Attributes: Pediatrics

Presentation Summary:

Staff began by giving brief background information on the Pediatric attribute. Currently, pediatric priority is not included in pancreas allocation policy. The Committee previously decided that pediatric priority should be incorporated into continuous distribution, keeping in mind that pediatric pancreas transplant is a rare event.

Staff also recapped the pediatric rating scale as binary and explained the two scenarios modeled, Combined AHP (pediatric attribute received a 20 percent weight) and All Donor Efficiency (pediatric attribute received a 15.56 percent weight).

Public comment feedback generally showed support for pediatric priority, however, some commenters noted concern for the high weight given to the pediatric attribute in the modeling because it is a rare event.

Staff shared the results of an informal survey sent out to Committee members prior to the meeting, which showed that all respondents indicated that pediatric candidates should be given high priority and appear at the top of or near the top of the match run. Most respondents indicated that the All Donor Efficiency scenario was closer to the goal for the pediatric attribute.

Data Summary:

Organ Allocation Simulation (OASim) results demonstrated:

- Higher transplant rates for pediatric candidates compared to current policy for both modeled scenarios
- Higher median distance from donor hospital for the pediatric age group relative to other age groups, but not a significant change from current policy

Summary of Discussion:

SRTR staff indicated that one reason for higher median transplant distance for pediatric relative to other age groups is due to the small number of centers listing pediatric patients. The Chair asked for the total number of pediatric patients used in the OASim analysis. SRTR staff showed the simulation cohort counts and noted less than ten pediatric pancreas candidates.

SRTR staff noted that a high weight placed on Pediatrics limits the relative weight that can be used for other attributes and suggested having the pediatric attribute only affect match runs on which a pediatric candidate appears. The Chair responded, stating that even if the amount of points available to other attributes would be lower with a high pediatric attribute weight, all attributes will still be proportional, allowing for proper ranking of candidates. The Chair asked for confirmation on this, and SRTR answered that although everything will be proportional, the statistical spread will be impacted. SRTR staff noted that because some variables will group patients together, there may be a need for tiebreakers and candidates will be crowded along the score distribution. The Vice Chair suggested having a higher scale for pediatric patients, such that on match runs where a pediatric candidate appears, the scale is out of 120 points. SRTR staff answered this might be able to be added as a recipient modifier, but needed further SRTR statistician verification. An SRTR statistician noted that adding a recipient modifier may just renormalize the score distribution to one and may not affect match run sorting or the probability of a tie.

A member asked about the average wait time for pediatric pancreas candidates, and SRTR staff answered that they did not have that data accessible, but showed transplant rates per patient-year. Another member asked if the SRTR studied turndown rates for pediatric pancreas patients. SRTR staff responded saying that turndown rates were not included in the OASim analysis, but that the turndown rate is expected to be high for pediatric patients. The Chair asked how kidney was transitioning longevity matching into continuous distribution. SRTR staff answered that this is handled by donor modifiers to exclude some groups, such as pediatric candidates having a score of zero for Kidney Donor Profile Index (KDPI) 35 percent and higher.

The Vice Chair asked for more data on the types of offers pediatric pancreas patients accept to help inform decision making and suggested using a combination of KDPI and age to determine what offers are appropriate to steer to pediatric candidates. SRTR staff answered that statistical conclusions may be difficult because of the low cohort number and asked if the Committee would like to see data about distribution of KDPI and age of recipient. The Vice Chair answered that this data would be helpful along with expert opinions, and the Chair agreed. SRTR staff noted that the goal of a potential modifier would be to push pediatric patients to the top of match runs they are very likely to accept the organ for, but that more investigation is needed for age and KDPI cutoffs. The Vice Chair asked about typical KDPI acceptance for pediatric candidates, and SRTR staff answered that the median KDPI for pediatric kidney recipients was 11 percent and suggested a KDPI cutoff for Kidney-Pancreas (KP) transplants at KDPI 20 percent. The Vice Chair responded, stating that the Committee would like to investigate KDPI, age, weight, and possibly hemoglobin A1C levels for pediatric recipients in better informing decisions about this attribute. Staff asked if this data would be relevant to pediatric candidates listed for KP-alone and pancreas-alone transplants, excluding multi-organ candidates. The Vice Chair affirmed this, and staff

stated that the cohort number for this would be extremely small so the data may be of limited use. SRTR staff agreed and suggested using kidney data to inform this.

A member asked about the age cutoff for the pediatric attribute, and SRTR staff answered that it is a binary attribute with a cut off at age 18. The Vice Chair explained the OPTN Ad Hoc Multi-Organ Transplant (MOT) Committee is investigating this for continuity across organ types. The Vice Chair asked if what the Committee is considering today is the weight, and staff answered that weights were the focus for the discussion of this attribute.

Committee members agreed that pediatric pancreas candidates should receive high priority on the match run.

Staff asked the Vice Chair for clarification on if All Donor Efficiency more closely represented overall goals of all attributes or the goal for the pediatric attribute in particular. The Vice Chair answered that the All Donor Efficiency represented overall goals more and noted that there should be higher priority for children. Another member noted that pediatric centers using their offer filters appropriately to not impact the efficiency of the system is an important consideration.

3. Kidney-Pancreas Continuous Distribution Attributes: Prior Living Donor

Presentation Summary:

Staff gave some background information about the Prior Living Donor (PLD) attribute. Priority for prior living donors is not currently included in pancreas allocation policy, but the Committee previously decided to include priority in the transition to continuous distribution even though pancreas transplant for a PLD is a rare event.

Staff reminded members of the binary rating scale for the PLD attribute and the scenarios modeled. In Combined AHP, PLD received a 20 percent weight and in All Donor Efficiency, PLD received a 15.56 percent weight. Due to small event counts, no OASim results are available for this attribute.

Public comment feedback showed general support for prioritizing PLD, however some concern was shown for the high weight given to the attribute in modeling.

Staff recapped results from the informal survey sent out. Most respondents indicated that prior living donors should receive high priority and respondents indicated a desire to honor the selflessness of a donated organ by reducing candidates' wait time.

Summary of Discussion:

The Chair noted that the concern for the high weight on PLD is the same sort of concern as for pediatrics, and that the Committee may want to align thoughts on PLD with the OPTN Kidney Transplantation Committee. The Vice Chair clarified that the PLD priority would apply irrespective of what organ was donated. One member stated that high priority for PLD makes sense to be in alignment with the broader community's values. The member expressed disappointment with the OPTN Lung Transplantation Committee's decision to not highly prioritize PLD in continuous distribution. The Chair agreed, stating that the transplant community's commitment to living donors should be firm.

A member asked if prior living donors have priority for liver transplant in the current system. Staff responded that kidney is currently the only organ that considers PLD in current policy, but that the other organ-specific Committees will evaluate this attribute as they move to continuous distribution.

The Chair noted that there are similar opinions for PLD as there were for the pediatric attribute. The Committee reached a consensus that PLD should be given high priority.

4. Kidney-Pancreas Continuous Distribution Attributes: Calculated Panel Reactive Antibody (CPRA)

Presentation Summary:

Staff provided background information on the CPRA attribute. Current policy prioritizes candidates with CPRA 80 percent or higher. The Committee agreed on maintaining the priority seen for highly sensitized candidates under current policy. Candidate biology received the highest priority in the pancreas AHP exercise.

Staff recapped the rating scale for CPRA as a steep non-linear curve with a base 100,000. In the Combined AHP scenario, CPRA was given a 15 percent weight, and in the All Donor Efficiency scenario, CPRA was given an 11.67 percent weight.

Public comment feedback demonstrated support for high weight on the CPRA attribute to not disadvantage highly sensitized patients, but to not too highly advantage high CPRA candidates.

In the survey sent to Committee members, most respondents supported achieving similar access for all CPRA groups. Most respondents were highly supportive of ensuring similar access to transplant as in current policy. Respondents demonstrated mixed feedback on increasing transplant rates for the very highly sensitized. Respondents noted that ensuring equity for hard to match candidates and ensuring equity among CPRA groups without disproportionately advantaging high CPRA candidates as goals for this attribute. Most respondents indicated that the All Donor Efficiency scenario was closest to the desired goal for CPRA.

Data Summary:

OASim modeling showed the following results:

- Similar transplant rates for CPRA candidates 0-60 percent across scenarios and as compared to current policy
- For the most highly sensitized candidates (CPRA 99-100 percent), transplant rate is lower across all scenarios and current policy relative to other CPRA groups. However, the Combined AHP scenario showed a moderate increase in transplant rate for this category as compared to current policy, and the All Donor Efficiency scenario showed a slight increase in transplant rate as compared to current policy.
- For CPRA 60-80 percent and 80-98 percent categories, higher transplant rates were seen under the Combined AHP scenario as compared to current policy. Under the All Donor Efficiency scenario, transplant rates were similar or slightly decreased for these middle CPRA groups as compared to current policy.

Summary of Discussion:

SRTR staff noted that the drop in transplant rate in the All Donor Efficiency scenario for CPRA 80-98 percent candidates could be explained by current policy's priority for CPRA 80 percent candidates such that the current transplant rate in that category is driven by the candidates closer to 80 percent CPRA. The SRTR staff member noted that because continuous distribution removes hard boundaries like this, transplant rates are more evenly distributed across smaller CPRA groupings within the 80-98 percent group in the All Donor Efficiency scenario.

SRTR staff noted that because of the lower weight on CPRA in the All Donor Efficiency as compared to the Combined AHP scenario, lower transplant rates across some CPRA groups are expected because higher weight is placed on other attributes. This staff member noted that the Committee can choose to distribute the attribute weights how they see fit.

The Vice Chair asked if a steeper rating scale may address the lower transplant rates seen for CPRA 98-100 percent candidates. The Chair clarified that current policy prioritizes CPRA candidates 80-100 percent, but that as candidates get more and more sensitized, they are harder to match. SRTR staff noted that this is a question of whether to change the weight or the slope as the best way to address the access issues seen by highly sensitized candidates. The Chair asked if OASim will be able to help inform the Committee about the appropriate weight for proximity efficiency and CPRA in tandem. SRTR staff answered that conclusions about tradeoffs are not appropriate from OASim modeling, however, that the SRTR could model any change in rating scale. The Vice Chair noted that increasing attribute weight may push transplant rate up across all CPRA groups, but, that having a steeper slope on the rating scale will increase rate only for those at the highest CPRA. The SRTR provided some details about what the SRTR process is for tweaking rating scale and noted that changing the rating scale may not increase transplant rates for candidates who already receive the maximum amount of points within that scale.

The Chair stated that it makes sense to have equal access and equal transplant rates across CPRA groups as the goal of this attribute, however, you could give high levels of priority to top CPRA candidates and still not match them. The Chair then asked what the goal is for these highly sensitized candidates. SRTR staff explained that in the modeled scenarios, transplant rate for highly sensitized candidates is slightly higher, meaning that continuous distribution is not posing additional access issues.

The Chair stated that the Committee should not be happy with the modeled transplant rate for CPRA 98-100 percent candidates unless it represents a biological limitation. SRTR staff noted that it is possible to increase rates, but that distance traveled will go up to find a match for these candidates. Another SRTR staff member noted that the number of high CPRA candidates in pancreas transplant is low, explaining that the number of high CPRA candidates listed for a KP transplant is probably higher than those who actually are transplanted with a KP (because they are more likely to find and accept a kidney-alone transplant).

The Chair asked if the Committee should be aiming to prioritize highly sensitized candidates even though matching these candidates is hard. A member answered that this should be the goal for the CPRA attribute, noting that because matching a 100 percent CPRA candidate is a rare event, the high priority given to these candidates will not present additional stress to the system. The Chair noted that matching 100 percent CPRA candidates for a KP transplant is especially rare, and the member noted that the question of priority is probably more about the CPRA 99 percent candidates who *may* be able to get an appropriate match with national access. The Chair stated that it may make sense to give similar priority for CPRA 80-98 and 98-100 percent. SRTR staff responded that the CPRA slope can be tweaked based on the intended outcome. OPTN staff also noted that the Massachusetts Institute of Technology's (MIT) tradeoff dashboard (coming soon) may help the Committee make these decisions.

The Committee reached an initial consensus that the 80-98 and 98-100 percent CPRA candidates should have a higher transplant rate than modeling projected. More discussion is needed about what potential changes to the slope formula would achieve this.

The Vice Chair noted that current policy may give too much access to CPRA 80-85 percent and summarized that the Committee favors giving similar access to transplant to all CPRA groups. The Chair noted that equity for all attributes should be the Committee goal. SRTR staff noted that equity interplays with efficiency, and this is important for the Committee to consider.

The Chair asked about the status of offer filters for pancreas. Staff responded that the OPTN Operations and Safety Committee is working on offer filters for kidney, and that expansion to other organs will follow after publishing the proposal.

Initial consensus was reached that as much as possible, equity among CPRA groups should be the goal for the CPRA attribute.

<u>Next Steps:</u>

Committee members will continue their discussion of CPRA in future meetings. The National Academies of Science, Engineering, and Medicine report on the US transplant system will also be discussed in future meetings.

Upcoming Meetings

- January 9, 2023 (Teleconference)
- January 20, 2023 (Teleconference)
- January 27, 2023 (Houston, TX)

Attendance

- **Committee Members**
  - Rachel Forbes
  - Oyedolamu Olaitan
  - Antonio DiCarlo
  - Colleen Jay
  - Diane Cibrik
  - Jessica Yokubeak
  - Mallory Boomsma
  - Maria Friday
  - Muhammad Yaub
  - Pradeep Vaitla
  - Ty Dunn
  - William Asch
  - Todd Pesavento
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
  - Jonathan Miller
  - Raja Kandaswamy
  - Peter Stock
- **UNOS Staff**
  - Carol Covington
  - Joann White
  - Kieran McMahon
  - Krissy Laurie
  - Lauren Mauk
  - Lauren Motley
  - Lindsay Larkin
  - Sarah Booker