OPTN Kidney and Pancreas Transplantation Committees
Kidney-Pancreas Continuous Distribution Workgroup
Meeting Summary
November 19, 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 11/19/2021 to discuss the following agenda items:

1. Review of Project Goals and Approach
2. January 2022 Public Comment Overview: Update on Continuous Distribution of Kidneys and Pancreata
3. Follow Up and Discussion: Incorporating Placement Efficiency into the Continuous Distribution of Kidneys

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

1. 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.

2. January 2022 Public Comment Overview: Update on Continuous Distribution of Kidneys and Pancreata

Staff provided an overview of the Update on the Continuous Distribution of Kidneys and Pancreata request for feedback going out for public comment in January 2022.

Data summary:

The request for feedback will summarize the Workgroup's progress since the initial concept paper, including attributes the Workgroup has decided to include in the continuous distribution framework and the discussions and proposed rating scales for each attribute. This paper will ask for feedback from the community on the proposed attributes and rating scales, as well as through an Analytical Hierarchy Process (AHP). Looking forward, the Workgroup will continue discussing rating scales and begin weighing attributes against each other.

The community can participate in two separate AHP exercises for Kidney and Pancreas/Kidney-pancreas during the January 2022 Public Comment cycle. The results of the community exercise will help inform values-based decisions regarding attribute weights.

Summary of discussion:

The Workgroup had no comments or questions.

3. Follow Up and Discussion: Incorporating Placement Efficiency into the Continuous Distribution of Kidneys

The Committee reviewed a summary of their previous discussions on placement efficiency and the various rating scale options.

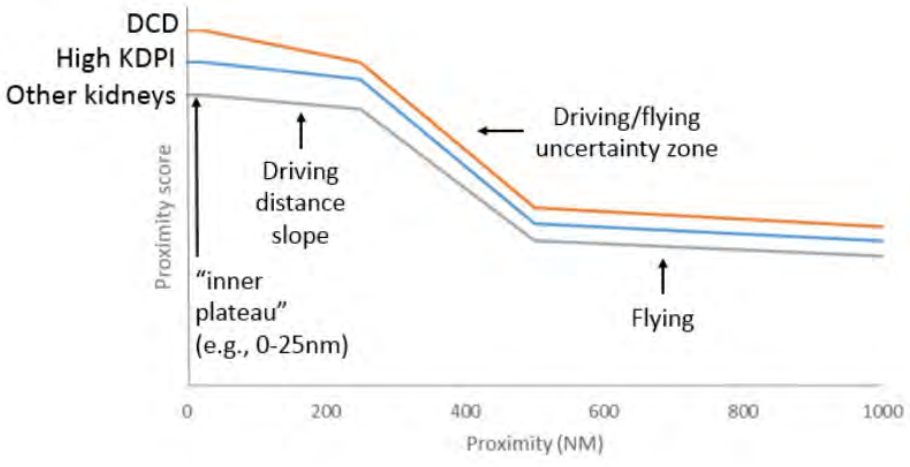
Data summary:

The previous Workgroup meeting's discussions favored the extension of a simple piecewise linear approach, and recognized the following:

- Donor quality is important in kidney allocation – the better the quality of the kidney (such as lower Kidney Donor Profile Index (KDPI)), the less travel distance and efficiency matter since kidney can take more cold time
- Curves in this approach don't need to be parallel
- Weight for placement efficiency can differ for KP and pancreas alone
    - While cold time is important, there are other factors contributing to this attribute, such as the accessibility of local procurement teams
- Considerations for distance include:
    - Cost
    - Driving is preferred to flying; a single flight is preferred to a connecting flight
    - Time of day restricts the availability of flights and impacts costs
- Generally, as distance increases, efficiency decreases.

Option 1: Simple, Piecewise Linear Approach

A linear approach can accommodate differential value judgements on the importance of proximity as a function of organ quality/donor type. The differential value judgements can be reflected through differential weights. Weight can also differ for kidney-pancreas (KP) and pancreas rating scales.



There are several advantages to the piecewise approach:

- Simplicity, transparency, and understandability for the broad community
- Builds and improves upon the current circles-based 250 nautical mile "hybrid" linear proximity point approach
- Can accommodate differential slopes and weights for organs less able to tolerate broader distribution
- Can accommodate the "inner plateau"
- Easy to develop and implement, resulting in a faster development timeline. This can be monitored and reconsidered for adjustment going forward
- Avoids "over-engineering" a rating scale in the context of a low-weight attribute

However, there are some disadvantages. This rating scale is not precise, and is a crude approximation of the association between distance and efficiency. It may also be perceived as too simplistic by some in the community.

Option 2: Mirroring Lung Allocation

The Lung Continuous Distribution model utilized two complimentary rating scales for placement efficiency, one representing travel efficiency and the other placement efficiency.

- The travel efficiency attribute represents the costs associated with travel mode and distance. This rating scale is linear past a steep inner plateau, and was developed from data and evidence on liver transportation. Since lungs and livers are transported very similarly, the use of this data was deemed appropriate.
- The proximity efficiency attribute represents other inefficiencies associated with attempting to place organs to further away candidates. This is an S curve rating scale, which includes an inner plateau and an increasingly steeper slope as distance increases to a certain point of maximum distance, where the slope begins to become more gradual. This rating scale was derived from subject matter expertise and informed by data.

There are several advantages to this approach:

- Precedent with lung continuous distribution models and consistency across the organs
- Separates transportation costs from other proximity-related inefficiencies
- Attempts to reflect driving vs. flying and other inflection points without too much complexity

There are also disadvantages:

- Kidney may not necessarily have a clear infeasibility zone the way lung does, due to ability to tolerate higher cold ischemic times
- Travel cost data is not readily available, and is likely to be a very imperfect and noisy function of distance
- May add significantly to the project timeline to pursue and potential obtain and analyze commercial transport cost data

Policy Monitoring Metrics on Placement Efficiency expected to be available by implementation of Continuous Distribution:

- Shipping distances – mean, median, and distribution; percent local vs. percent non-local; percent expected to require a flight; percent requiring a flight
    - Allocation simulation modelling can be used to forecast the impact of various continuous distribution policy options on these metrics
- Cold ischemic time
- Offer refusals, organ discards, and offers per transplant center

- Organ placement times (first offer to acceptance)
- Geographic disparities by transplant center, donor service area, region; rural vs. urban; socioeconomic status; number of centers near the top of the match run
    - Allocation simulation modelling can be used to forecast the impact of various continuous distribution policy options on these metrics
- Transportation modes, pending new data collection
- Travel times and routes, pending progress on the Global Positioning System (GPS) tracking project

Summary of discussion:

One of the Chairs asked for clarification on the options, noting that the mirroring lung continuous distribution option included two rating scales, and the piecewise linear approach had one rating scale. Staff clarified that if the Workgroup decided to utilize the piecewise linear approach, this would be the only rating scale for placement efficiency, while the lung model would have two attributes with two rating scales. If the placement efficiency category was given a 10 percent weight, under the piecewise linear approach, 10 percent of the composite allocation score would come from placement efficiency. If placement efficiency category was given a 10 percent weight that was equally split under the lung model, then 5 percent of the score would come from travel efficiency and the other 5 percent from proximity efficiency. The Chair asked if the question here is having one approach for placement efficiency, or splitting it into two rating scales. Staff confirmed this, noting that it would be likely that the rating scales for kidney would look differently than those for lung, since kidneys travel differently. Staff added that the Lung Continuous Distribution Workgroup had access to applicable travel cost data, which is not available for kidney transportation. Similarly, the paradigm of an "infeasibility zone" where an organ is rarely shipped past a certain distance may not be applicable to kidney transportation.

One member asked if putting weight on placement efficiency would reintroduce geography disparities, noting that placement efficiency rating scales could introduce bias against patients who live in areas with few commercial flights. A Chair responded that the shape of the rating scale would influence potential disparities. The proposed 250 nautical mile inflection point between the driving and uncertainty zones mimics the current allocation system could move right or left. If moved left, that area would become smaller and could reintroduce narrower distribution and accentuate disparities. If moved to the right, inefficiencies could increase. Having the point at 250 nautical miles takes advantage of the benefits achieved with the circles-based distribution without having kidneys travel long distances needlessly. The Chair concluded that this is an advantage of the linear piecewise approach, which allows inflection points and slope steepness to be altered more dynamically.

A member asked if there was any data available to associate a specific nautical mile distance with cold ischemic time, graft function, or clinical outcomes. One Chair responded that, based on the 6 month report, there is some data available, but that some of this will be better informed by modelling from the Scientific Registry of Transplant Recipients (SRTR). Staff shared that the 250 nautical mile circle used in current allocation was developed with data from the Organ Center's transportation tracking, to see the distances kidneys were driven and flown. From that data, most kidneys that were driven and never flown were within 250 nautical miles of the donor hospital. Staff pointed out that this isn't perfect data, as kidneys placed and transported by the Organ Center are a specific subset, and not representative of all kidneys.

One member pointed out that discussions during the circles-based allocation development favored 250 nautical miles, and didn't necessarily intend to expand distribution too broadly. The member continued that the system is already inefficient with the high volume of offers, and added that giving more points

to patients further away could drive up inefficiency. A Chair agreed, and asked for thoughts on the general shape of the piecewise linear rating scale. The member remarked that this scale may be too flat, but that the lung-model rating scales were potentially too steep at the greater distance. Staff clarified that the steepness of slopes and placement of inflection points are still to be determined based on community and committee input, and that this schematic is intended only to represent the potential scale shape. Different slopes and inflection points can be modelled to predict impact on allocation. Staff noted that the organ center data is what drives the 250 and 500 nautical mile inflection points used to present this rating scale. The member agreed that the piecewise linear model was an acceptable curve shape, with the majority of points within the 250 nautical mile range.

One Chair asked if there was any support or consideration for moving the high KDPI and donor after circulatory death (DCD) rating scales to higher proximity points and increase steepness, so those kidneys are allocated more narrowly geographically. One member agreed, noting these kidneys will be hard to place.

A Chair remarked that travel time is more important than geographic distance, and pointed out that there is a point at which driving time and flying time are equal, at different geographic distances. A member agreed, but added that it can be difficult to predict travel and cold ischemia time, particularly with the variation in flight availability throughout the day. It may be possible to drive a kidney several hours over night and receive it in the morning, while a flight may not be available until that morning, with the earliest flight arrival at noon. The Chair noted that situation reflected the uncertainty zone, and added that there are distances at which driving is simply infeasible, and flying can be more efficient. A red flight and a morning flight are very different in terms of efficiency. The Chair continued that while simplicity is important, distance is not a good surrogate for calculating ischemia time. Another member agreed, and pointed out that a match could be run well before procurement and when that kidney is ready to ship, making travel time difficult to know at time of match run. Another Chair agreed.

One Chair agreed that distance isn't a perfect surrogate, and expressed support for the piecewise linear rating scale shape, with an inflection at 250 nautical miles that is based on data used in the circles-based allocation development. The Chair continued that considering cold time, travel time, and cost that can all involve and relate to inefficiency, distance is most likely the best surrogate available.

Staff shared a timeline for organs transported by plane, noting that there are generally three hours on either end of the actual flight time for organ pick up, check in, cargo boarding, offload, pick up, and driving. Staff continued that driving can be more efficient than flying by a number of hours, and there is a threshold of at least six hours of travel time.

A member asked if it would be possible to work with a logistics company or consultant that could help develop some kind of model. Staff shared that logistics data has been sought out from certain logistics companies, particularly in respect to cost, but that data was challenging to gather and larger not research quality. Staff continued that there are still efforts to consult and gather more logistics data, but that as of now it's not readily available or research quality data. Another member agreed, noting that the data he's seen has been extremely complex. Staff added that data is largely collected for bookkeeping and financial purposes, and that it would be extremely time consuming and difficult to convert that into useable and generalizable data, which could add significantly to the timeline.

A Chair asked if there was any data on how many DCD and high KDPI kidneys were flown and driven, noting that cold time has a greater impact on marginal donor kidneys than on other kidneys, such as low KDPI kidneys. The Chair continued that trying to place marginal donor kidneys within a shorter distance from the donor hospital would be more beneficial to outcomes and placement, and recommended changing the scale based on the type of donor. Staff responded that this framework is designed to be

flexible in that respect, and that the steepness of the scale could be increased for DCD donors, or the weight of placement efficiency increased for DCD donors. Staff continued that, for most kidneys, there is a general sentiment and Final Rule requirement that placement efficiency should not dominate the score, but potentially could be higher for kidneys where utilization is a concern with risk to outcomes from marginality and potential cold time. Changing the weighting for different kinds of donors or kidneys would have an impact on the distribution of transplants and outlooks on practicalities, outcomes, and underutilization.

Staff summarized the discussion, commenting that the Workgroup seems to prefer the linear piecewise approach over the lung-model rating scales, but that there is more to be discussed as far as slope steepness, inflection points, and the interaction of donor quality. The Chair agreed, noting that it wouldn't make sense to break placement efficiency into two attributes for kidney, which doesn't have the same kind of cost data. The Chair added that this concept is advantageous in flexibility for DCD and high KDPI kidneys. Staff shared that the concept of the inner plateau would also need additional discussion, and could be included in the concept paper to request feedback. The Chair remarked that the inner plateau could be difficult with differences in geography across the country, as 50 nautical miles varies in terms of roads, access, and number of donor hospitals. The Chair recommended creating a schematic highlighting the various choices needing to be made, including how far the inner plateau should extend, how different the scale should be for DCD and high KDPI kidneys, the various slopes, and where the inflection points should lie.

A member recommended presenting this concept with information and lessons from the monitoring reports, and whatever other data would be available at that point.

One member asked how the Workgroup should proceed in deciding steepness, inflection points, and relative proximity points from the curve, including weight. Staff shared that the weight, representing the value judgement of placement efficiency vs all the other goals, will be built out by the Workgroups from community feedback, beginning with the AHP exercise. Staff continued that rating scale parameter choices will need a separate deliberative process, with data, subject matter expertise, and consensus development informing discussion and determination of the inflection points and slopes. The member commented that knowing the weight or importance is critical to reconciling and finalizing the shape of the curve, as it makes a difference to the relative complexity necessary. Staff agreed, noting that this comes out to the interaction of the values judgement and data driven aspects of the process, and that other tools such as modelling and the sensitivity tool can help the Workgroup refine and iterate these attributes, scales, and weights. These tools can display sample match runs that can be adjusted by different weights, allowing users to visualize the way candidates are rank ordered with respect to all the different goals and the final rule in mind. Staff continued that many of the questions involved in looking and evaluating different options are related to the degree of engineering and sophistication that should be input for a low-weighted factor. In some cases, these decisions don't need to be finalized yet, and can be discussed further after reviewing the results of the initial AHP.

A Chair pointed out that the Workgroup hasn't fully discussed placement efficiency for pancreas and kidney-pancreas, which are currently allocated with the 250 nautical mile, circles-based system. Another Chair remarked that the shape of this curve could be effective for KP as well, but that public comment would be necessary for determining slopes and inflection points, particularly as pancreata can't travel as far. Staff shared that differences for pancreas and KP could be handled similarly to DCD and high KDPI kidneys, with higher weight but a general shape and cut points in terms of proximity, if there is Organ Center data that can inform similar inflection points.

A Chair noted that the broader sharing within 250 nautical miles has been effective for KP and pancreas allocation, and that a steeper slope may not be necessary than what is currently being done with

proximity points. The Chair agreed that it is difficult to determine the correct slopes without an idea of the general weight.

Next steps:

The AHP exercise will be released with the January 2022 request for feedback to the community, and will provide starting points for weights.

The Workgroup will continue deliberations on weight differences for DCD, high KDPI, KP/Pancreas vs Kidneys, etc. and on inflection points, inner plateau, and long drive and flight decrements.

Looking ahead, the Workgroup will eventually develop an SRTR simulation modelling request of different weights to help evaluate relative gains.

Upcoming Meetings:

- December 17, 2021

Attendance

- **Workgroup Members**
  - Martha Pavlakis
  - Rachel Forbes
  - Jim Kim
  - Oyedolamu Olaitan
  - Aaron Wightman
  - Abigail Martin
  - Alejandro Diez
  - Amy Evenson
  - Arpita Basu
  - Bea Concepcion
  - Dave Weimer
  - Deirdre Sawinski
  - Parul Patel
  - Peter Lalli
  - Rachel Engen
  - Raja Kandaswamy
  - Todd Pesavento
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
  - Raelene Skerda
  - Vanessa Arriola
- **SRTR Staff**
  - Bryn Thompson
  - Jonathan Miller
- **UNOS Staff**
  - Joann White
  - Lindsay Larkin
  - Alison Wilhelm
  - Amanda Robinson
  - Rebecca Brookman
  - Kayla Temple
  - Anne McPherson
  - Ben Wolford
  - Caitlin Shearer
  - Darby Harris
  - Darren Stewart
  - Joel Newman
  - Lauren Motley
  - Rebecca Marino
  - Ross Walton
  - Sarah Booker
- **Other Attendees**
  - Maria Helena Friday
  - PJ Geraghty