OPTN Kidney Transplantation Committee
Meeting Summary
August 16, 2021
Conference Call

Martha Pavlakis, MD, Chair
Jim Kim, MD, Vice Chair

Introduction

The Kidney Transplantation Committee met via teleconference on 08/16/2021 to discuss the following agenda items:

1. Behavioral Research Study
2. Regional Review Project: Request for Feedback
3. Update on Kidney-Pancreas Continuous Distribution Project

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

1. Behavioral Research Study

Staff presented an opportunity to participate in an OPTN research study geared to improve kidney offer decision-making utilizing data analytics.

Summary of discussion:

There were no questions or comments.

2. Regional Review Project: Request for Feedback

Staff presented an update on the Regional Review Project, including several model alternatives to current administrative regions and a request for feedback.

Data summary:

The purpose of the regional review project is to re-evaluate regions, the governance structure associated with regions, and effectives of regions, considering the current and future needs of the nation's donation and transplant community.

Summary of discussion:

The Vice Chair commented on the diversity and difference in opinion within and amongst regions, and pointed out that geography is inherent in transplant, and should remain a part of the transplant governance structure. Another member agreed, adding that OPO policies and practices tend to be regionally similar.

One member noted that current governance structure is somewhat similar to a hybrid model, with OPTN Committees forming communities of interest, and asked how the hybrid model proposed by EY would include OPTN Committees and Committee work. Staff clarified that the hybrid model addresses community engagement beyond committees, adding that the committee structure could remain similar in a restructured, hybrid administrative model. Staff provided an example, noting that the Patient Affairs Committee is a small group relative to the total population of patients being considered and who could

be reached more broadly in a different administrative structure. One member recommended reaching out to patient organizations, such as the National Kidney Foundation and the American Association of Kidney Patients to form a patient group and provide patient perspectives. Staff remarked that there is considerable outreach being done for this request for feedback, particularly around the barriers to participation for patients. The member remarked that many patients are very capable to participate and have knowledge and expertise to contribute, but don't know about opportunities to volunteer with the OPTN and to do so. This information is not necessarily shared broadly.

One member noted that in-person regional meetings provide significant benefits, tangible and intangible. In particular, multi-disciplinary meetings (not just one area of community, but OPOs, transplant centers, histocompatibility labs, etc.) have provided a lot of benefit. Networking, diversity of thought, and discussion are several benefits provided by in-person regional meetings. The member also remarked that there is general confusion over sentiment collection at regional meeting, and the role of the regional councilor at the Board. It's unclear if the regional councilor has to vote with the region as a representative; if that is the case, there needs to be more equity in the size of regions as it relates to representation. Another member agreed, and asked about balancing the size of the region with equity. Staff shared that several options to resize and redraw regions are currently being developed, and that community feedback as of right now reflects the opinion that regions are important, but that they should be redrawn and resized more equitably.

A member pointed out that regions vary by size, population, and equity in transplants, and wondered if the types of transplants performed in a region impact regional differences in equity, particularly multi-organ transplants. The member continued that there is disconnect between the public perception of how organs are allocated and how organs are actually allocated, which should be considered when building an administrative structure, as the general population itself is often the donor population. Staff shared that there is a plan in place to reach out to different populations and to get feedback on all public comment items, including the regional review.

One member noted that creating small groups of like-minded people could create silos that accentuate differences rather than bringing people together on areas of friction. The member remarked that the models decreases the number of representatives on the Board, which could potentially inhibit the goal of increased communication and collaboration. Staff clarified that some of the models reduce the Board size, as the current Board of Directors is relatively large compared to similar organizations.

One member remarked that population size should be considered if regions were to be resized and redrawn, particularly with certain areas of the country being less populated than others. The member continued that the number and types of transplant centers should be considered as well. The Vice Chair agreed, adding that different transplant centers perform transplants at different volumes, and noted that the transplant center type, the organs being transplanted, and the actual population of patients on the waiting list should be taken into consideration. A member pointed out that multi-organ transplant centers impact transplant rates of other populations significantly.

3. Update on Kidney-Pancreas Continuous Distribution Project

The Committee Vice-Chair presented the Continuous Distribution of Kidneys and Pancreata Concept Paper as an update to the Committee on the Continuous Distribution project, and the Committee provided feedback.

<u>Data summary:</u>

The concept paper provides an over of Continuous Distribution and the policy development approach, and summarizes the attributes considered by the Kidney and Pancreas Committees.

Summary of discussion:

A member asked about terminology, and the Vice Chair explained that points based system and continuous distribution are essentially one in the same - under continuous distribution, patients are allocated points for each attribute. Continuous Distribution is the concept for creating the points.

One member asked what mathematical or statistical model will be used to determine the rating scale and weight for each attribute. Staff explained that the Kidney-Pancreas Continuous Distribution Workgroup is developing rating scales on a case by case basis. Some rating scales, such as pediatric or living donor, are binary – you are or you aren't a prior living donor. Other attributes are more complicated, such as calculated panel reactive antibodies (cPRA), and may require a rating scale more complex than just a binary or linear scale. Staff further clarified that exactly how the weights will be derived has yet to be determined, but that the Lung Continuous Distribution utilized a series of pairwise comparisons to assign value and derive weights. However, the approach to deriving weights will be systematic and empirical. The member added that some attributes are more complex, and even some binary attributes may not be fully black and white. There are micro-attributes behind the attributes that shouldn't get lost in the calculations.

The Vice Chair asked the Committee how estimated post transplant survival (EPTS) and the kidney donor profile index (KDPI) should be used in the continuous distribution model. The Vice Chair continued that it is important to consider both multi-organ transplants and pediatric priority in considering continuous distribution, particularly at this stage.

A member asked if the Ad Hoc Multi-Organ Allocation Committee's work will influence continuous distribution directly, or if it's just looking to establish more safety net and safety net protocols. The Vice Chair explained that the current work of the Multi Organ Allocation Committee is to expand eligibility criteria and safety net kidneys for other organs and multi-organ combinations, but will be geared toward equity in multi-organ and single organ allocation. The member agreed that there is a need to expand safety net policy for heart-kidney and lung-kidney allocation. Another member added that multi-organ allocation particularly impacts pediatric patients, as mainly low KDPI organs go to multi-organ transplants as opposed to pediatric or low EPTS kidney-alone patients.

One member remarked that waiting time inversion should be seriously considered, particularly as it can play significantly into placement efficiency. Higher KDPI organs that fall far down the list gain significant cold time, and create inefficiencies at transplant centers receiving these offers amongst many others.

Upcoming Meetings

- September 20 – Teleconference
- October 8 – Virtual "In-Person" Meeting

Attendance

- **Committee Members**
  - Jim Kim
  - Arpita Basu
  - Asif Sharfuddin
  - Beatrice Concepcion
  - Caroline Jadlowiec
  - Elliot Grodstein
  - Erica Simonich
  - Marian Charlton
  - Peter Lalli
  - Precious McCowan
  - Stephen Almond
  - Vincent Casingal
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Ajay Israni
  - Bryn Thompson
  - Jon Miller
  - Nick Salkowski
  - Peter Stock
  - Jodi Smith
- **UNOS Staff**
  - Ross Walton
  - Amanda Robinson
  - Kayla Temple
  - Alison Wilhelm
  - Lauren Motley
  - Anne Paschke
  - Kaitlin Swanner
  - Nicole Benjamin
  - Chelsea Haynes
  - Jennifer Musick
  - Joel Newman
  - Leah Slife
  - Matthew Prentice
  - Melissa Lane
  - Olga Kosachevsky
  - Sara Moriarty
- **Additional Attendees**
  - David Weimer
  - Cathi Murphy