OPTN Policy Oversight Committee
Meeting Summary
December 8, 2021
Conference Call

Nicole Turgeon MD, FACS, Chair
Jennifer Prinz, RN, BSN, MPH, CPTC, Vice Chair

Introduction

The Policy Oversight Committee (POC) met via Citrix GoToMeeting teleconference on 12/08/2021 to discuss the following agenda items:

1. Continuous Distribution Update
2. January 2022 Public Comment Preview
3. Project Benefit Scoring

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

1. Continuous Distribution Update

The POC received updates regarding the progress of the Kidney and Pancreas Continuous Distribution, as well as Board of Directors approval of the Establish Continuous Distribution of Lungs policy proposal and the Ethical Considerations of Continuous Distribution in Organ Allocation white paper.

Data summary:

The Kidney and Pancreas Continuous Distribution will convert current the current classification-based allocation system into a points-based framework. The upcoming Kidney and Pancreas Continuous Distribution Update will introduce the continuous distribution project to the community and detail the Kidney and Pancreas Committees' progress. To date, the Kidney and Pancreas Continuous Distribution Workgroup has identified attributes related to kidney, pancreas, and kidney-pancreas, and is currently working to convert those attributes into points via rating scales. The Committees will be seeking feedback for these rating scales via public comment and an Analytic Hierarchy Process (AHP) exercise, which will be released to the community during January public comment. The AHP exercise will solicit feedback from the community on weighing attributes against each other. The Workgroup and the Committees will review and utilize the results to help inform decisions on attribute values and weights. The Kidney and Pancreas Committees hope to submit Continuous Distribution proposals to the Board of Directors in June of 2023.

Summary of discussion:

Members were curious about consistency and alignment in continuous distribution frameworks across all organs. The Vice Chair of the Pancreas Committee explained that the Kidney and Pancreas Continuous Distribution Workgroup is following the framework established by the OPTN Lung Committee and modifying for kidney and pancreas, utilizing the same process to convert classifications into points. Staff shared that the development of the Lung Continuous Distribution framework included input from other organ-specific committees and leadership to encourage the development of a basic, consistent framework for use across organs. Staff continued that each organ-specific committee and workgroup will need to be able to justify deviations in framework, such as review board processes or

living donor priority, and that the POC and Executive Committee will play key roles in evaluating these justifications.

One member expressed concern for a consistent maximum score across attributes, noting that certain vulnerable populations need to be considered for each organ that may warrant additional points outside of their goal. The member posed highly sensitized candidates in Kidney allocation as an example, pointing out that a 100 percent calculated panel reactive antibody (CPRA) patient could require additional points outside of the sensitization attribute to ensure priority. Lung allocation may not necessarily consider sensitization or other attributes in the same way, and so may utilize a different maximum score. Staff explained that the flexibility of the continuous distribution framework allows certain attributes to carry different weights and different rating scale shapes to enhance prioritization within a consistent maximum score.

The Chair asked for clarification regarding current Committee and stakeholder representation in the Continuous Distribution discussions. Staff shared that the larger Continuous Distribution conversations include leadership from HRSA, the SRTR, the OPTN and UNOS, the Board of Directors, and representatives from several organ-specific OPTN committees and OPTN Pediatric, Histocompatibility, Ethics, Living Donor, Minority Affairs, and Patient Affairs committees.

2. January 2022 Public Comment Preview

The POC shared feedback on the following proposals:

- Change Calculated Panel Reactive Antibodies (CPRA) Calculation (Histocompatibility Committee)
- Reduce Pediatric Waiting List Mortality (Liver Transplantation Committee)
- Improving the Model for End-Stage Liver Disease (MELD) Calculation (Liver Committee)
- Establish OPTN Requirement for Race-Neutral Estimated Glomerular Filtration Rate (eGFR) Calculation (Minority Affairs and Kidney Committees)
- Establish Minimum Set of Kidney Donor Criteria to Require Biopsy (Kidney Committee)
- Standardize Kidney Pathology Report (Kidney Transplantation Committee)
- Redefining Provisional Yes and the Approach to Organ Offers (Operations and Safety Committee)
- Continuous Distribution of Kidneys Request for Feedback (Kidney Committee)
- Continuous Distribution of Pancreata Request for Feedback (Pancreas Committee)
- Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Transplantation (Ad Hoc Multi-Organ Transplantation Committee)
- Pediatric Candidate Pre-Transplant HIV, HBV, and HCV Testing (Disease Transmission Advisory Committee)
- Ongoing Review of National Liver Review Board Policy and Guidance (Liver Committee)
- Modify Living Donor Exclusion Criteria (Living Donor)
- Vascular Composite Allograft (VCA) Graft Failure Definition (VCA Committee)

Summary of discussion:

The POC organized review and discussion of the proposals into four groups.

Group 1: Change in cPRA Calculation, Reduce Pediatric Waiting List Mortality, Improving MELD Calculation, and Establish OPTN Requirement for Race-Neutral eGFR

Several POC members expressed support for all four projects. The Ethics Committee Vice Chair commented that the *Reduce Pediatric Waiting List Mortality* proposal could improve specificity in

describing the its purpose. The Vice Chair of the Ethics Committee continued that the *Improving MELD Calculation* proposal was specific and well-articulated, mentioning areas for improvement.

Group 2: Minimum Set of Kidney Donor Criteria to Require Biopsy, Standardize Kidney Pathology Report, and Redefining Provisional Yes and the Approach to Organ Offers

POC members expressed concern that the Organ Procurement Organization and pathologist representation in the Biopsy Best Practices Workgroup may not have been fully representative of community resources, and emphasized consideration of potential geographic disparities in access to pathology expertise.

POC members were supportive of the *Redefining Provisional Yes and the Approach to Organ Offers* proposal, with no feedback.

Group 3: Continuous Distribution of Kidneys Request for Feedback, Continuous Distribution of Pancreata Request for Feedback, and Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Transplantation

Members were supportive of both requests for feedback and the multi-organ transplantation proposal. A few members recommended increased specificity and clarity in the feedback requested for both the Kidney and Pancreas Committees' requests for feedback. Members supported continued use of waiting time as a relevant attribute in kidney allocation, and recommended increased discussion regarding Kidney Donor Profile Index (KDPI) and Estimated Post Transplant Survival (EPTS). Another member agreed, and pointed out that KDPI has not been validated for pediatric donors. One member emphasized the importance of including the Minority Affairs and Patient Affairs Committees as stakeholders in the continuous distribution projects. Several members supported the inclusion of kidney failure post-heart or post-lung transplant under candidate biology, similar to kidney failure post-liver transplant.

Members expressed slight concern regarding the limited available data used in the development of the *Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Transplantation* proposal. POC members also requested increased clarity regarding the stakeholders consulted. One member recommended acknowledging participation and input from the Histocompatibility and OPO Committees.

Group 4: Pediatric Candidate Pre-Transplant HIV, HBV, and HCV Testing; Ongoing Review of NLRB Policy and Guidance; Modify Living Donor Exclusion Criteria; and VCA Graft Failure Definition

POC members were supportive of all four proposals. One member shared concerns about vague wording regarding type II diabetes in the *Modify Living Donor Exclusion Criteria* proposal, emphasizing the need to balance living donor safety.

One member recommended the *Pediatric Candidate Pre-Transplant HIV, HBV, and HCV Testing* proposal include organ-specific organizations, such as the American Society of Nephrology (ASN), as stakeholders, as there may be pediatric providers in these societies that are not members of other transplant specific societies.

3. Project Benefit Scoring

Staff presented an update on Committee Project Portfolio Management, including results from the analytic hierarchy process (AHP) exercise on various potential metrics to score and define project value.

<u>Data summary:</u>

Previously, the POC was asked to identify a list of different metrics and attributes to define project value or benefit. These were input to an AHP exercise, where participants were asked to prioritize attributes relative to each other, assigning a weight between 1 and 9.

87 percent of the POC participated in the AHP exercise. Reducing Waitlist Mortality was identified by participants as the most important attribute, followed respectively by vulnerable populations, size of population impacted, OPTN stated priorities, and measurable impact. Project dependency, innovation, data collection, time solution will be in use, and voluntary vs. required were identified by participants as the least important attributes.

While some attributes had high agreement and high alignment, there were several areas where participants had a fair amount of disagreement. There was a larger spread of disagreement between size of population impacted and OPTN stated priorities (low agreement, low alignment).

Summary of discussion:

The Committee had no comments or questions.

Next Steps:

The Committee will continue discussions on prioritizing benefit attributes, to narrow down the set of benefit attributes and work towards consensus for attributes with lower alignment and agreement.

Upcoming Meeting

- January 19, 2022 – Teleconference

Attendance

- **Committee Members**
  - Alden Doyle
  - Alejandro Diez
  - Alex Glazier
  - Andrew Flescher
  - Emily Perito
  - Jennifer Prinz
  - John Lunz
  - Marie Budev
  - Molly McCarthy
  - Nahel Elias
  - Nicole Turgeon
  - Oyedolamu Olaitan
  - Rocky Daly
  - Sandy Amaral
  - Scott Biggins
  - Sumit Mohan
  - Susan Zylicz
  - Valinda Jones
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
  - Vanessa Arriola
- **UNOS Staff**
  - Amber Wilk
  - Amy Putnam
  - Betsy Gans
  - Brian Shepard
  - Chelsea Haynes
  - Courtney Jett
  - Elizabeth Miller
  - Eric Messick
  - James Alcorn
  - Janis Rosenberg
  - Joann White
  - Julie Coriarty
  - Kelley Poff
  - Krissy Laurie
  - Kristina Hogan
  - Leah Slife
  - Lindsay Larkin
  - Matt Cafarella
  - Meghan McDermott
  - Rebecca Brookman
  - Rebecca Murdock
  - Roger Brown

    - Sally Aungier
    - Sarah Payamps
    - Susan Tlusty
    - Susie Sprinson
    - Tina Rhoades
- **Other Attendees**
    - Ian Jamieson