

## **OPTN Policy Oversight Committee**

### **Meeting Summary**

**January 19, 2022**

**Conference Call**

**Nicole Turgeon, MD, FACS, Chair**

**Jennifer Prinz, RN, BSN, MPS, CPTC, Vice Chair**

### **Introduction**

The Policy Oversight Committee (the Committee) met via Citrix GoToMeeting teleconference on 01/19/2022 to discuss the following agenda items:

1. Public Comment Review
2. Technical Implementation Budget
3. Project Benefit Attribute Scoring Results

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

#### **1. Public Comment Review**

The Committee reviewed proposals eligible for public comment during the winter 2022 public comment cycle. Following this review, they submitted a recommendation to the Executive Committee as to whether the proposal should be released for public comment.

#### Data summary:

IT implementation resources estimates were reviewed by the Committee.

The Committee reviewed the proposals being submitted for public comment with the following focus questions:

- Does the proposal address the purpose of the project?
- Is there a sufficient foundation in evidence for the solution?
- Were identified or necessary stakeholders sufficiently engaged?
- Does the proposal sufficiently explain the reasoning and the solution?
- Are there any questions for community feedback that should be included, but are not already identified in the proposal?

The following proposals, identified with their sponsoring committee, were reviewed in order:

- Change CPRA Calculation (OPTN Histocompatibility Committee)
- Improving Liver Allocation: MELD, PELD, Status 1A, and Status 1B (OPTN Liver and Intestine Committee)
- Reassessing the Inclusion of Race in eGFR Equation Proposal (OPTN Minority Affairs/Kidney Committees)
- Minimum Criteria Appropriate for Kidney Biopsy (OPTN Kidney Committee)
- Standardized Kidney Biopsy Reporting and Data Collection (OPTN Kidney Committee)
- Redesign Regional Maps (OPTN Executive Committee)
- Update on the Continuous Distribution of Kidneys and Pancreata (OPTN Kidney and Pancreas Committees)

- Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation (OPTN ad hoc Multi-Organ Transplant Committee)
- Pediatric Candidate Pre-Transplant HIV, HBV, and HCV Testing (OPTN Disease Transmission Advisory and Pediatric Committees)
- Ongoing Review of NLRB Diagnoses (OPTN Liver Committee)
- Modify Living Donor Exclusion Criteria (OPTN Living Donor Committee)
- VCA Graft Failure Definition (OPTN Vascularized Composite Allograft Committee)

Summary of discussion:

- Change CPRA Calculation
  - This proposal identifies inequity in the current Calculated Panel Reactive Antibodies (CPRA) calculation and will better reflect candidate sensitization. The group reviewing this proposal was supportive of this proposal. They noted there were only minor areas of constructive feedback on the project form, and met all five of the criteria outlined by the Chair. Additionally they identified that the proposal would increase equity in allocation, as the current CPRA calculation disadvantages black candidates, as well as women.
- Improving Liver Allocation: MELD, PELD, Status 1A, Status 1B
  - This proposal adds a sex variable to the Model of End-Stage Liver Disease (MELD) calculation, which will provide points to candidates who identify as female. The group was supportive of this, adding that it too answered the five focus questions with no further explanations required.
- Reassessing the Inclusion of Race in eGFR Equation Proposal
  - This proposal requires programs to use an estimated Glomerular Filtration Rate (eGFR) that does not include a race based variable. The group lead stated that the current system exacerbates inequity in transplant by deferring wait time for similarly sick candidates black candidates in comparison to white candidates.
- Minimum Criteria Appropriate for Kidney Biopsy
  - This proposal identifies a minimum standard for when a procurement biopsy must be performed. The group lead noted there was a question surrounding whether Organ Procurement Organizations (OPOs) would have the right to refuse biopsies on kidneys that did not meet this criteria, and responded that this was already existing practice. Additionally there was a second question as to whether all OPOs had access to pathology and biopsy capability at all times, and replied that, in their experience, nearly all did with a small handful of exceptions. A member agreed with this analysis, stating that access to renal pathology was not universal.
- Standardized Kidney Biopsy Reporting and Data Collection
  - This proposal identifies a standardized set of information to be reported from procurement kidney biopsies. The group lead mentioned that, from their experience, there were organizations who exist to read biopsies for a number of OPOs. They wondered if their feedback had been solicited for this proposal.
- Redesign Regional Maps
  - This request for feedback seeks community feedback surrounding how and if they OPTN should redesign their regional maps. There was no discussion surrounding this item.
- Update on the Continuous Distribution of Kidneys and Pancreata
  - This request for feedback seeks community input on how candidate's qualities should contribute to their composite allocation score. The group lead noted that there was a

comment on how much the public comment feedback would contribute to the actual weighting of candidate attributes. There was also feedback from their group that the existing medical urgency classification would need to be considered as, in the continuous distribution framework, it would not exist in a separate elevated category. Additionally, there was a question surrounding the Human Leukocyte Antigen (HLA) matching for pancreas that was not answered by the sponsoring committees. Finally, the group requested further clarification surrounding the HLA matching for kidneys. They concluded by stating that the focus questions were all addressed by the sponsoring committees. A member requested staff respond to how the questions posed for public comment differed from those posed by the paired Analytic Hierarchy Process (AHP) exercise. Staff responded that specific questions for public comment were posed in the proposal, whereas the AHP exercise assessed how the community prioritized different characteristics.

- Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney
  - This proposal defines eligibility criteria for heart-kidney and lung-kidney multi-organ transplants. The reviewer said there were some comments on the clarity of the criteria, but added that this was similar to the feedback received when the liver-kidney policy was proposed. Furthermore, there were comments that this policy should be continued to be studied through and after implementation to ensure it is performing as intended. A member mentioned that they felt that the criteria for a lung-kidney transplant, a Lung Allocation Score (LAS) of 28, was easier to meet than the heart-kidney criteria, adult statuses 1 to 3. They went on to say that there was strong support from the Heart Committee that adult status 4 should be included with this criteria. A member from the sponsoring committee noted that that will be a specific question for public comment feedback, and they could be open to including adult status 4.
- Pediatric Candidate Pre-Transplant HIV, HBV, and HCV Testing
  - This proposal adjusts the timing requirements for pre-transplant HIV, HBV, and HCV testing for pediatric candidates. The reviewing group was in support of this proposal. The lead noted that there was good involvement with stakeholder organizations. They added that there was inconsistency in the proposal on the age cutoff, with some areas saying 10 years old, and other saying 11 years old. Furthermore, there was a comment that this proposal is primarily motivated by low-weight candidates, rather than young candidates, and there should be a contingency for low-weight pediatrics older than the age cutoff.
- Ongoing Review of NLRB Diagnoses
  - This proposal updates National Liver Review Board (NLRB) guidance documents on hepatocellular carcinoma (HCC), ischemic cholangiopathy, and polycystic liver disease. The review group was similarly in support of this proposal, and agree with the updates to the guidance due to the possibility of increased Donor after Cardiac Death (DCD) donors.
- Modify Living Donor Exclusion Criteria
  - This proposal evaluates the current living donor exclusion criteria to reassess some absolute contraindications to living donation. The review group was in support of this proposal, noting that living donor guidance had not been updated since 2014. Additionally, they felt there was strong data to support the proposed changes. They review group had one comment that the proposal did not address minor malignancy in the transplant organ, and provided the example of a small renal cell cancer that can be removed on the back table.

- VCA Graft Failure Definition
  - This proposal updates the definition of graft failure and the associated data collection to include VCA graft removal. The review group strongly supported the proposed changes. They did inquire whether it would be possible to include the timeframe for anticipated removal at the time of delisting in a blanket statement (e.g. 1 year, 2 years, 5 years, etc.).

The Committee voted unanimously in favor of recommending all items to the Executive Committee for public comment (16 yes, 0 no, 0 abstain). There were no concerns raised about the purview or legal authority of the OPTN for these public comment items by committee members or attendees.

Next steps:

The Executive Committee will review the recommendations from the Committee at their January 20<sup>th</sup> meeting. Items the Executive Committee approves for public comment are planned to be released on January 27<sup>th</sup>.

**2. Technical Implementation Budget**

The Committee discussed the forecasted workload for OPTN policy work as it impacts technical implementation. With the projected policy work for the next five years, there is a disparate amount of resources available to implement those policies. The current OPTN technical implementation budget by Board cycle is 15,000 hours.

Data summary:

The Committee reviewed the anticipated hours required for implementation for all known committee priority proposals in each board cycle for the next five years. It was noted that some of the estimates may be less refined for anticipated proposals in the more distant future, as the projects are currently less developed.

Two questions were posed to the Committee in this review:

- 1) What critical work can be accomplished at the current resource level?
- 2) What changes need to occur to allow for a larger volume of work?

Summary of discussion:

A member started off the discussion by stating that many of the issues with hours are driven by the implementation of continuous distribution. In a time when projects to implement an entirely new allocation system are moving forward, it is natural that any other sizeable project will begin to stretch the budget. They concluded that they were in favor of requesting more resources, as the current budget did not make the policy development process efficient or feasible, and suggested that these additional resources could be requested specifically for continuous distribution. Another member added that, even with continuous distribution budgeted into its own category, there still may be a shortage of hours between the strategic policy priorities, contract requirements, approved proposals, and the possibility for new proposals to appear. This was supported by a third member, who noted that continuous distribution should not come at the expense of every other policy proposal.

However, a member did inquire whether, if the resource budget for policy project implementations were to be expanded, would the budget for other necessary work shrink. The UNOS Executive Director responded that there is likely no area in which the budget could draw from, so a resource increase

would likely come from an increase in membership costs. He did add that, if continuous distribution is a bubble in terms of implementation hours required, there were reserves that the organization could draw upon that may fund a portion of this work. A member responded to this, asking if there were a way continuous distribution could be rearranged, or delayed, such that budgeting would be less of a concern. The UNOS Executive Director stated that this likely would not be possible, and even if it were, as stated earlier, there are a large number of policy proposals that could already stretch the implementation budget. Furthermore, he suggested that if the Committee does approach the Finance Committee with a proposed budget increase, the Committee should approach them with oversight plans to ensure that every project has been vetted thoroughly against a new budget.

A member expressed concerns that, with this increased oversight, UNOS implementation hours would become a driving force to determine which policy proposals should be considered. UNOS developing the prioritization of projects, they stated, would strip the committees of some of their autonomy to work on projects they considered important. The UNOS Executive Director replied that this was not the intent of the budget or portfolio assessment, and that they want any solution on how to manage the portfolio of work in terms of budget and prioritization to come from the Policy Oversight Committee, rather than the Finance Committee or UNOS staff. However, the solution the Committee develops should not be to consider a budget increase without developing framework to consider each proposal in the context of a 20,000 hour budget, to make a shared commitment to develop the evaluation processes that POC will use to prioritize and stay within budget.

It was also proposed that, within the executive and POC updates on the OPTN regional meetings, a section could be dedicated for feedback on how the community felt on a fee increase. This was supported by a number of members.

One member suggested that it would be useful to have tools available to estimate project hours more accurately from when proposals are initially reviewed by the POC. They identified the wide range of hour estimates as an area that the Committee could potentially improve upon, noting that tools could help better identify how much of the budget that project will take up. This was supported by the UNOS Executive Director, who added that a tool similar to this is in development for use by the POC. One member suggested ensuring this information was also available to the policy development committees when developing their proposals.

Another member mentioned for consideration that they felt continuous distribution likely would not be a bubble, as it would a framework that is constantly being updated, especially across different organ types. They added that they felt that committees could do better considering how their work fits within strategic policy priorities when developing proposals to take to the Committee.

Another member asked that the implementation hours be contextualized for the committee, so they are able to understand the sense of scale of potential impact to the OPTN fee for the various implementation budgets considered.

#### Next steps:

The Committee leadership will develop a proposal with potential technical implementation budget increases and the cost associated with each one.

### **3. Project Benefit Attribute Scoring Results**

The Committee was briefly reminded about the results from their project benefit attribute survey. There was not enough time for discussion on this item. This item will be discussed at an upcoming meeting.

## **Upcoming Meeting**

- February 9, 2022

## Attendance

- **Committee Members**
  - Nicole Turgeon
  - Jennifer Prinz
  - Sandra Amaral
  - Scott Biggins
  - Marie Budev
  - Lara Danziger-Isakov
  - Alden Doyle
  - Andrew Flescher
  - PJ Geraghty
  - Alexandra Glazier
  - Valinda Jones
  - Jim Kim
  - John Lunz
  - Nahel Elias
  - Sumit Mohan
  - Oyedolamu Olaitan
  - Emily Perito
  - Natalie Santiago Blackwell
  - Zoe Stewart Lewis
  - Susan Zylicz
- **HRSA Representatives**
  - Marilyn Levi
  - Shannon Taitt
- **SRTR Staff**
  - Ryutaro Hirose
- **UNOS Staff**
  - James Alcorn
  - Sally Aungier
  - Lloyd Board
  - Rebecca Brookman
  - Roger Brown
  - Matthew Cafarella
  - Carrie Caumont
  - Amelia Devereaux
  - Amber Fritz
  - Betsy Gans
  - Isaac Hager
  - Kristina Hogan
  - Robert Hunter
  - Cole Fox
  - Courtney Jett
  - Lindsay Larkin
  - Krissy Laurie
  - Lauren Mauk
  - Meghan McDermott

- Eric Messick
- Elizabeth Miller
- Rebecca Murdock
- Kelley Poff
- Amy Putnam
- Tina Rhoades
- Janis Rosenberg
- Laura Schmitt
- Brian Shepard
- Sharon Shepherd
- Leah Slife
- Susie Sprinson
- Darren Stewart
- Kaitlin Swanner
- Kayla Temple
- Susan Tlusty
- Kimberly Uccellini
- Joann White