

OPTN Policy Oversight Committee

Meeting Summary

July 11, 2022

Conference Call

Nicole Turgeon, MD, FACS, Chair

Jennifer Prinz, RN, BSN, MPH, CPTC, Vice-Chair

Introduction

The Policy Oversight Committee (the Committee) met via Microsoft Teams teleconference on 07/11/2022 to discuss the following agenda items:

1. Public Comment Review
2. New Projects
3. Living Donor Data Collection Update

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

1. Public Comment Review

The Committee reviewed the proposals being presented for public comment between August 3rd and September 23rd.

Data summary:

Proposals for Review:

- **Continuous Distribution Concept Paper (Kidney/Pancreas Committee)**
 - Updates community on progress for the continuous distribution project for kidney and pancreas
- **Update KPD Policy (Kidney Committee)**
 - Minor modifications to KPD policy to provide clarity and alignment with other policies
- **Candidate Waiting Time Affected by eGFR (Minority Affairs/Kidney Committee)**
 - Framework for requesting eGFR waiting time modifications
- **OPO Enhancements to Donor Data and Matching System Clinical Data Collection (OPO Committee)**
 - Updating clinical data captured by the OPTN Donor Data and Matching System to better evaluate organ offers
- **Redefining Provisional Yes (Operations & Safety Committee)**
 - Concept paper addressing inefficiencies in the current allocation system and a proposed new model to improve offer evaluation and acceptance practices
- **Mandatory Offer Filters (Operations & Safety Committee)**
 - Concept paper providing and update and requesting community feedback on the implementation of mandatory offer filters
- **Continuous Distribution Concept Paper (Liver Committee)**
 - Updates community on progress for the continuous distribution project for liver
- **Continued Review of NLRB Policy and Guidance (Liver Committee)**

- Improves NLRB guidance documents for both pediatric and adult liver transplant patients
- **Review of Liver Variances (Liver Committee)**
 - Review liver variances for alignment of expiration upon continuous distribution implementation
- **Update Data Collection for Lung Mortality Models (Lung Committee)**
 - Updating clinical information as a part of Lung Allocation Score (LAS) updates
- **Update Multi-Organ Allocation for Continuous Distribution of Lungs (Lung Committee)**
 - Update lung composite allocation score (CAS) threshold for multi-organ allocation to ensure existing candidates remain eligible
- **Revise Review Board Guidelines, Guidance, and Policy for Continuous Distribution (Lung Committee)**
 - Establish operational guidelines for review boards regarding exception request in continuous distribution
- **Device Recall Retrospective Public Comment (Heart Committee)**
 - Emergency policy approved July 11, 2022 to address proactive assignment of heart candidates with FDA recalled devices
- **Transparency White Paper (Ethics Committee)**
 - Ethical framework to improve transparency of information for patients pursuing transplant evaluation
- **Requirements for VCA Program Inactivation (VCA Committee)**
 - Modify OPTN Bylaws to remove exclusion of VCA programs from requirement to notify their waitlisted patients in the even their program is inactivated

Summary of discussion:

- **Continuous Distribution Concept Paper (Kidney/Pancreas Committee)**
 - The Vice-Chair suggested the paper could improve language surrounding disadvantaged populations.
- **Update KPD Policy (Kidney Committee)**
 - The Vice-Chair noted that not all transplant programs would have access to the benefits from the proposal depending on which KPD exchange they use. A member also inquired why multiple national KPD exchanges exist, and if there should be more transparency in what one program provides over another. The Chair noted that may not necessarily be within the scope of the Committee to consider, but could be feedback for the Kidney Committee. It was also suggested this may tie into the white paper to provide transparency in program selection.
- **Candidate Waiting Time Affected by eGFR (Minority Affairs/Kidney Committee)**
 - No discussion
- **OPO Enhancements to Donor Data and Matching System Clinical Data Collection (OPO Committee)**
 - No discussion
- **Redefining Provisional Yes (Operations & Safety Committee)**
 - The reviewer requested the inclusion of whether organ specific committees had provided input on the proposed framework. Additionally, their group suggested that different time limits for different organs should be considered.
- **Mandatory Offer Filters (Operations & & Safety Committee)**
 - No discussion

- **Continuous Distribution Concept Paper (Liver Committee)**
 - The reviewer inquired how existing variances will be bundled into the new distribution framework, as their group felt that there could be more emphasis on the proposed solution. Staff noted that one of the questions the Liver Committee wanted feedback on in the concept paper was the merging of existing variances into the continuous distribution framework as their committee did not want to be preemptively prescriptive. Additionally, they shared that their committee was especially looking for what the community as a whole felt *should* be included in continuous distribution.
- **Continued Review of NLRB Policy and Guidance (Liver Committee)**
 - The review group suggested more clarity could be given to the individual is responsible for program accepting a split liver (e.g. patient, surgeon, medical support post-transplant). They also suggested that the Lung Committee should be included in the project as one update includes a test of force expiratory volume (FEV). Finally, they wondered if the proposal should be split into two proposals given the density of the updates to the guidelines. Staff responded that given that they both were updates to NLRB documents, it was felt they should be delivered under the same proposal; furthermore, this type of guidance document update was not new and would be expected as one paper for the liver community.
- **Review of Liver Variances (Liver Committee)**
 - The reviewer felt that the consequences of not implementing the proposal were not clearly identified and requested further detail in that area.
- **Update Data Collection for Lung Mortality Models (Lung Committee)**
 - No discussion
- **Update Multi-Organ Allocation for Continuous Distribution of Lungs (Lung Committee)**
 - No discussion
- **Revise Review Board Guidelines, Guidance, and Policy for Continuous Distribution (Lung Committee)**
 - No discussion
- **Device Recall Retrospective Public Comment (Heart Committee)**
 - The reviewer considered that there should be a permanent pathway for potential future device recalls so there does not have to be an emergency action. The group also noted that there is no data surrounding the mortality of the device failures, so there is no clear answer as to what status should be awarded to the candidates impacted. The Heart Committee Vice-Chair responded that the policy was intended to address one discontinued ventricular assist device that had a potentially deadly defect to not restart when batteries are replaced. Additionally, because of the lack of information surrounding these patients and potential complications stemming from device malfunction, their committee felt the status request should be left up to the candidate's physical.

A second member wondered if this should be considered as a variance rather than a policy such that it would have an expiration date. The Chair responded that this was considered an emergency policy because there was a patient safety concern, and, as with all emergency policies, it had an expiration date.
- **Transparency White Paper (Ethics Committee)**
 - No discussion
- **Requirements for VCA Program Inactivation (VCA Committee)**

- A member noted it would be interesting to see the numbers of programs that inactivate to understand how large an impact this policy is expected to have.

With no further discussion, the Committee unanimously voted to recommend all reviewed proposals for public comment (14 yes, 0 no, 0 abstain)

Next steps:

Feedback from the Committee's review will be shared with the sponsoring committees and the proposals will be released for public comment.

2. New Projects

The Committee reviewed one project seeking Committee approval.

Data summary:

- Clarification of OPO Requirements for Deceased Organ Donors with HIV Positive Test Results
 - The project seeks to answer two key questions:
 - What (if any) testing results could be used to classify a deceased donor as not infected with HIV although the donor has at least one positive HIV test?
 - What (if any) clinical judgement or individual protocols would be appropriate and consistent with the requirements to assess suspected false positive results?
 - Correct categorization of HIV+ organs may result in a change in the number of organs allocated via HIV+ match run

Summary of discussion:

A member questioned what the ramifications of a program inadvertently transplanting an HIV+ organ into an HIV- patient after receiving a positive HIV test for the donor, and more broadly, what would be the impact on the OPTN. Staff responded that the language in the final rule only restricts the transplant of "HIV infected" organs, not HIV positive organs. After consulting with federal stakeholders, the sponsoring committee and legal stakeholders agreed that programs should be evaluating whether a donor is HIV infected while using a positive HIV result as supporting evidence for their judgement.

A second member supported the proposal, noting that when any screening test returns with a positive result, the next step to confirm it is to use a test with "a more perfect positive predictive value".

With no further discussion, the Committee unanimously approved the project (14 yes, 0 no, 0 abstain).

The second project seeking approval was not discussed.

Next steps:

The sponsoring committee will consider the Committee's feedback.

3. Living Donor Data Collection

This agenda item was not discussed.

Upcoming Meeting

- August 8, 2022

Attendance

- **Committee Members**
 - Nicole Turgeon
 - Jennifer Prinz
 - Alejandro Diez
 - Andrew Flescher
 - Stevan Gonzalez
 - Jason Huff
 - Kimberly Koontz
 - Scott Lindberg
 - Jondavid Menteeer
 - Gerald Morris
 - Dolamu Olaitan
 - Stephanie Pouch
 - Amond Uwandineke
 - Jesse Schold
 - Peter Stock
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
 - Vanessa Arriola
- **SRTR Staff**
 - Ajay Israni
- **UNOS Staff**
 - James Alcorn
 - Rebecca Brookman
 - Roger Brown
 - Matt Cafarella
 - Cole Fox
 - Courtney Jett
 - Lindsay Larkin
 - Taylor Livelli
 - Isaac Hager
 - Chelsea Haynes
 - Kristina Hogan
 - Lauren Mauk
 - Meghan McDermott
 - Rebecca Murdock
 - Eric Messick
 - Tina Rhoades
 - Laura Schmitt
 - Susie Sprinson
 - Kaitlin Swanner
 - Kayla Temple
 - Susan Tlusty
 - Kim Uccellini
 - Sara Rose Wells

- Joann White