

OPTN Policy Oversight Committee

Meeting Summary

July 27, 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 Citrix GoToMeeting teleconference on 07/27/2022 to discuss the following agenda items:

1. Public Comment Review
2. New Project: Clarification of OPO Requirements for Deceased Organ Donors with HIV Positive Test Results
3. New Project: Review and Update OPTN Histocompatibility Guidance and Policy with Current Practice
4. Living Donor Data Collection

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

1. Public Comment Review

The Committee reviewed the proposals slated for the August 3rd to September 28th public comment cycle and voted on whether to recommend them to the Executive Committee for release.

Data summary:

The Committee reviewed the following proposals:

- **Kidney/Pancreas Continuous Distribution Concept Paper (Kidney, Pancreas)**
 - Concept paper updating the community on kidney and pancreas continuous distribution project
- **Update KPD Policy (Kidney)**
 - Minor modifications to Kidney Paired Donation (KPD) policy to provide clarity, align with other policies, and improve efficiency
- **Update Candidate Waiting time Affected by eGFR (Minority Affairs, Kidney)**
 - Framework for requesting eGFR waiting time modifications for Black kidney candidates impacted by race-inclusive eGFR calculations
- **Enhancements to Donor Data and Matching System Clinical Data Collection (OPO)**
 - Updates clinical data collection to better capture info used during donor and organ evaluation
- **Redefining Provisional Yes (Ops & Safety)**
 - Concept paper on addressing inefficiency and increased allocation time through improving provisional yes system and organ offer acceptances
- **Optimizing the Usage of Offer Filters (Ops & Safety)**
 - Concept paper providing update and seeking community feedback on potential options to increase utilization and system benefit of kidney offer filters

- **Liver Continuous Distribution Concept Paper (Liver)**
 - Concept paper updating community on liver continuous distribution project
- **Continued Review of NLRB Policy and Guidance (Liver)**
 - Improving NLRB guidance documents, including for pediatric liver transplant candidates with cystic fibrosis & adult liver transplant candidates with hepatic adenomas and Budd Chiari syndrome
- **Review of Liver Variances (Liver)**
 - Review liver variances for alignment of expiration upon continuous distribution implementation
- **Phase 2: LAS Refinements & Clean Up (Lung)**
 - Updating clinical information as part of LAS clean up – reviewing data collection for currency
- **CAS Threshold for MOT (Lung)**
 - Update lung composite allocation score (CAS) threshold for multi-organ allocation (lung-liver, -kidney, & -heart) to ensure qualifying candidates maintain eligibility
- **Lung Review Board Guidance (Lung)**
 - Establish operational guidelines for review boards regarding exception requests to components of CAS
- **Heart Device Recall – Retrospective Public Comment (Heart)**
 - Emergency Policy approved July 11th to address proactive assignment of heart candidates with Food and Drug Administration (FDA) recalled heart device
- **Transparency in Program Selection (Ethics)**
 - Ethical framework to improve transparency of information for patients pursuing transplant evaluation
- **Requirements for VCA Program Inactivation (VCA)**
 - Modifies Bylaws to remove exclusion of VCA programs from requirement to notify their waitlisted patients in the event their transplant program is placed under inactive status

Summary of discussion:

- **Kidney/Pancreas Continuous Distribution Concept Paper (Kidney, Pancreas)**
 - It was suggested by a review group member that the OPO Committee should be involved for their insight on how the removal of region and direct service area (DSA) impacted allocation
 - The review group felt that the language surrounding disadvantaged populations should be more specific to indicate how points would be distributed to these candidates
- **Update KPD Policy (Kidney)**
 - It was noted that some programs may not be impacted by this change depending on which KPD exchange they utilize
 - A member wondered why there were multiple KPD exchanges, to which the Chair responded that that may not be within the scope of the Committee to consider, but could be useful feedback for the Kidney Committee to consider for the future
- **Update Candidate Waiting time Affected by eGFR (Minority Affairs, Kidney)**
 - There were no comments on this proposal and was recommended by the review group
- **Enhancements to Donor Data and Matching System Clinical Data Collection (OPO)**
 - There were no comments on this proposal and was recommended by the review group
- **Redefining Provisional Yes (Ops & Safety)**

- The review group considered that organ-specific committees could be involved for the review of allocation within different organ groups
- A member also suggested there could be different time limits for different organ groups
- **Optimizing the Usage of Offer Filters (Ops & Safety)**
 - There were no comments on this proposal and was recommended by the review group
- **Liver Continuous Distribution Concept Paper (Liver)**
 - Review group members wondered how existing variances would be addressed within the new allocation framework
 - Staff responded that a key question for the community in the concept paper is how present variances should be incorporated into continuous distribution (become policy, extend variance, etc.)
- **Continued Review of NLRB Policy and Guidance (Liver)**
 - The review group wondered if, due to the amount of content contained within this proposal, it would be better considered as two separate proposals
 - Staff noted these updates have traditionally been within one proposal and the community expects them to be delivered this way
 - They requested further clarification on how patients would be educated on the possibility of accepting a split liver
 - The Lung Committee should review the inclusion of the pulmonary function test to ensure it is being used appropriately
- **Review of Liver Variances (Liver)**
 - The review group requested further clarification on the need for this proposal, noting that with its present justification, it seemed like it came from “an administrative standpoint”
- **Phase 2: LAS Refinements & Clean Up (Lung)**
 - There were no comments on this proposal and was recommended by the review group
- **CAS Threshold for MOT (Lung)**
 - There were no comments on this proposal and was recommended by the review group
- **Lung Review Board Guidance (Lung)**
 - There were no comments on this proposal and was recommended by the review group
- **Heart Device Recall – Retrospective Public Comment (Heart)**
 - The review group recommended this policy be considered as a pathway for future recalls so that the emergency pathway does not need to be used
 - They requested more evidence on how this recall affects heart candidates in terms of waitlist mortality
 - The Vice-Chair from the Heart Committee noted that the lack of data is due to it being an emergent issue that is being addressed proactively for candidates
 - This policy creates a way to increase the rate of transplant for the candidates impacted by the recall without requiring programs to admit these patients to justify a higher status
 - The sentiment from the Heart Committee was that they believed most surgeons would request status 3 or status 2
 - Staff replied to a question about the time frame of the policy that emergency policies remain in effect for one year, at which point their continued need is re-evaluated
- **Transparency in Program Selection (Ethics)**
 - The review group suggested adding a question of whether there could potentially be negative impacts caused by increased evaluation transparency

- A member wondered if the white paper should include the issue of candidates not being notified when they are passed on the list for an organ
 - The Vice-Chair responded that it was not considered for this white paper, but would like to consider it for a future proposal or white paper
- **Requirements for VCA Program Inactivation (VCA)**
 - The review group requested specific questions for public comment that could garner feedback on the implications if this requirement is not instated
 - A member requested the numbers of candidates impacted by this policy change

Next steps:

The Committee unanimously voted to recommend all projects to the Executive Committee (14 yes, 0 no, 0 abstain)

2. New Project: Clarification of OPO Requirements for Deceased Organ Donors with HIV Positive Test Results

This project was presented by the Vice-Chair of the Ad Hoc Disease Transmission and Advisory Committee (DTAC).

Data summary:

This project will clarify OPTN Policy on deceased donation from HIV positive donors and answer the following 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 result?
- What (if any) clinical judgement or individual protocols would be appropriate and consistent with requirements to assess suspected false positive results?

Summary of discussion:

A member wondered what the legal ramifications would be if a program followed OPTN Policy and transplanted an HIV positive organ into an HIV negative recipient. The DTAC Vice-Chair replied that conversations have taken place with the National Institute of Health (NIH), Centers for Disease Control (CDC), FDA, and Health Resources and Services Administration (HRSA) to determine what the minimum acceptable standard would be. Staff added that the language in the Final Rule prohibit the transplant of HIV infected organs into HIV-negative individuals, rather than HIV-positive organs into HIV-negative individuals.

A member supported the project, noting that in the event there is ever indeterminate results, you can always use a more definitive test afterwards.

With no further discussion, the project was approved with 14 yes, 0 no, 0 abstain.

Next steps:

DTAC will continue to appraise the Committee of their progress.

3. New Project: Review and Update OPTN Guidance and Policy with Current Practice

This agenda item was not discussed.

4. 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
 - Kimberly Koontz
 - Jason Huff
 - Scott Lindberg
 - Jondavid Menteeer
 - Gerald Morris
 - Dolamu Olaitan
 - Stephanie Pouch
 - Jesse Schold
 - Peter Stock
- **HRSA Representatives**
 - Vanessa Arriola
 - Jim Bowman
 - Marilyn Levi
 - Amond Uwadineke
- **SRTR Staff**
 - Ajay Israni
- **UNOS Staff**
 - James Alcorn
 - Rebecca Brookman
 - Roger Brown
 - Matt Cafarella
 - Cole Fox
 - Isaac Hager
 - Chelsea Haynes
 - Kristina Hogan
 - Lindsay Larkin
 - Taylor Livelli
 - Courtney Jett
 - Lauren Mauk
 - Meghan McDermott
 - Eric Messick
 - Rebecca Murdock
 - Tina Rhoades
 - Laura Schmitt
 - Susie Sprinson
 - Kaitlin Swanner
 - Kayla Temple
 - Susan Tlusty
 - Kimberly Uccellini
 - Sara Rose Wells

- Joann White