

**OPTN Policy Oversight Committee
Meeting Summary
July 19, 2023
Conference Call**

**Jennifer Prinz, BSN, MPH, Chair
Erika Lease, MD, FCCP, Vice Chair**

Introduction

The OPTN Policy Oversight Committee met via Citrix GoToMeeting teleconference on 07/19/2023 to discuss the following agenda items:

1. Public Comment Review and Recommendations to Executive Committee

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

1. Public Comment Review and Recommendations to Executive Committee

The Committee reviewed fourteen items and recommended whether they should move forward to public comment. Members were all given different proposals to review and provide feedback on whether the proposal is ready to move on to public comment.

Summary of discussion:

Voting results:

Modify Organ Offer Acceptance Limit: 11 yes; 5 no; 0 abstain

Ethical Analysis of Normothermic Regional Perfusion: 14 yes; 2 no; 2 abstain

Amend Adult Heart Status 2 Mechanical Device Requirements: 16 yes; 0 no; 0 abstain

Concepts for a Collaborative Approach to Living Donor Data Collection: 13 yes; 0 no; 0 abstain

Continuous Distribution of Livers and Intestines Committee Update: 18 yes; 0 no; 0 abstain

Collect Donor CRRT, Dialysis, and ECMO Interventions Data: 15 yes; 0 no; 0 abstain

Require Reporting of Patient Safety Events: 14 yes; 0 no; 0 abstain

Update Human Leukocyte Antigen (HLA) Equivalency Tables 2023: 16 yes; 0 no; 0 abstain

Remove CPRA 99-100% Form for Highly Sensitized Kidney Candidates: 14 yes; 0 no; 0 abstain

Improve Donor Evaluation for Endemic Diseases Guidance Document Revisions: 14 yes; 0 no; 0 abstain

Clarification of OPO Requirements for Deceased Donor Organs with HIV Positive Test Results Concept Paper: 13 yes; 0 no; 0 abstain

Update Guidance on Optimizing Vascularized Composite Allograft (VCA) Recovery from Deceased Donors: 13 yes; 0 no; 0 abstain

Continuous Distribution of Kidneys and Pancreata Committee Update: 13 yes; 0 no; 0 abstain

Modify Organ Offer Acceptance Limit (OPO):

- Purpose of the project is to reduce the limit for simultaneous organ offer acceptances for a single candidate (per organ type) from two to one.
- Feedback highlighted the importance of the project for late turndown issues; however, reviewers had some difficulties in comprehending the second part of the proposal. Overall, though they felt that the proposal addresses the main purpose of the project and should progress to public comment.
- The Vice-Chair for the Liver and Intestines Committee brought up their objections with the proposal, stating that the LI Committee discussed it and unanimously opposes it. They cited two issues with the proposal: one, that it does not keep the patients' interest at the forefront by only allowing one organ acceptance and two, with abdominal transplantation there is often less clarity on when an organ procurement will happen, so by accepting two offers, centers can go with whichever organ is procured first, typically around 48 hours after initial acceptance. The member claims that if only one acceptance is allowed, a patient could be waiting up to 2 days and might pass before the organ is even procured. They recommend the proposal only enforce this for patients with a MELD score that is 35 or higher. The LI Committee was encouraged by the POC Chair to share this sentiment in public comment.
- The Vice-Chair for the Lung Transplantation Committee also brought up concerns, stating that the Lung Committee unanimously opposed this proposal as well. They asked for clarification on whether all of the options listed in the proposal for changes applied to all of the organ types or only to certain ones, such as liver and/or lung. It was confirmed that the proposed changes apply to all organ types but concurred that there is greater specificity on liver.

Ethical Analysis of Normothermic Regional Perfusion (Ethics Committee):

- Purpose of the white paper is to analyze the implications of normothermic regional perfusion (NRP) according to the principles of nonmaleficence (do no harm), respect for persons, and utility.
- Feedback included a commendation to the Ethics Committee for writing a balanced and robust white paper on an incredibly difficult topic. A member asked whether the paper clearly indicates that it was not a consensus document, but rather that it is ethical commentary, to which some POC members responded yes. One member responded in the negative, stating that once the paper is out for public comment, it becomes a consensus document. This member cited a particular sentence that speaks to whether cerebral perfusion is restored during NRP as potentially harmful to NRP's perception. They also cited concerns that the language is too prescriptive in nature and could discourage further development of NRP. The Chair of the Ethics Committee added their thoughts to the discussion, referencing some parts of the paper that state NRP donation should proceed with caution, but not that it should be halted even with lingering questions remaining. Additionally, they reaffirmed the questions that the Ethics Committee asks the community during public comment.
A member addressed the question of whether this document is ready to proceed to public comment, referencing their participation in the NRP Workgroup as well, stating that the policy process was respected and due diligence done, in their opinion, and that it is now up to the transplant community to provide their comments about the white paper.

Amend Adult Heart Status 2 Mechanical Device Requirements (Heart Committee):

- Purpose is to modify adult heart allocation policy by requiring certain proof of inotrope failures within 7 days prior to the use of an Intra-Aortic Balloon Pump (IABP) in order to gain status 2.
- Feedback highlighted that from a clinical perspective the policy seems straightforward, a question on which groups might be disadvantaged by a policy change was raised however, as that data seemed to be lacking in the proposal. The Vice-Chair of the Heart Committee spoke to the decision behind not automatically dropping patients with IABPs to status 3 from status 2 lies in the fact that there are some who still need to remain status 2. They emphasized that the goal of the policy is to create a more rigorous inclusion criteria for status 2.

Concepts for a Collaborative Approach to Living Donor Data Collection (Living Donor Committee):

- Purpose is to gather feedback and comments on the viability and feasibility of a larger living donor data collection effort, a joint effort between the OPTN and SRTR as well.
- Feedback indicated that this is an important step towards gathering much needed data and information about living donation.

Continuous Distribution of Livers and Intestines Committee Update (Liver and Intestines Committee):

- Purpose is to update the community on the liver continuous distribution work and supplement the values prioritization exercise.
- Feedback included comments stating that the update meets standards to proceed to public comment, and whether the Pediatric Transplantation Committee had any involvement as a stakeholder. The Vice Chair of the LI Committee confirmed their engagement with the Pediatric Committee during this process.

Collect Donor CRRT, Dialysis, and ECMO Interventions Data (Operations and Safety Committee):

- Purpose is to create a multi-option field within the OPTN Donor Data and Matching System that standardizes the reporting of donor continuous renal replacement therapy (CRRT), dialysis, and extra-corporeal membrane oxygenation (ECMO) interventions.
- Feedback highlighted that this proposal was straightforward and clear cut, as well as being greatly needed from the OPO perspective.

Require Reporting of Patient Safety Events (Membership and Professional Standards Committee):

- Purpose is to require additional reporting of patient safety events, including near misses.
- Feedback deemed this an important topic, and members are looking forward to seeing the public and other OPTN Committees engage on this during public comment.

Update Human Leukocyte Antigen (HLA) Equivalency Tables 2023 (Histocompatibility Committee):

- Purpose is to increase the efficiency of unacceptable antigen screening for sensitized candidates by increasing the granularity of HLA typing and unacceptable antigen options in the OPTN Computer System.
- Feedback noted that though there were no questions for the community included in the proposal, this is a regular annual update and so none were required.

Remove CPRA 99-100% Form for Highly Sensitized Kidney Candidates (Histocompatibility Committee):

- Feedback noted that this would streamline and speed up the process of patients gaining allocation priority as soon as an unacceptable antigen is entered into the system, increasing equity in allocation.

Improve Donor Evaluation for Endemic Diseases Guidance Document Revisions (Disease Transmission Advisory Committee):

- Purpose is to update and consolidate guidance documents on the OPTN website for endemic diseases.
- Feedback was positive, mentioning the importance of this document in providing guidance for deceased and living donation as well as for recipients in regards to 6 different endemic diseases.

Clarification of OPO Requirements for Deceased Donor Organs with HIV Positive Test Results Concept Paper (Disease Transmission Advisory Committee):

- Purpose is to clarify OPTN policy on deceased donation of from HIV positive donors and ask for community feedback on a variety of pertinent questions.
- Feedback indicated that the proposal is clear in its intent, seeking guidance on how to manage such cases where a donor is HIV positive. The paper attempts to address and provide an algorithm on how to manage these instances.

Update Guidance on Optimizing Vascularized Composite Allograft (VCA) Recovery from Deceased Donors (VCA Committee):

- Purpose is to provide guidance for OPOs and transplant programs on VCA recovery from deceased donors.
- Feedback mentioned that this is straightforward and provides helpful guidance on the VCA recovery process.

Continuous Distribution of Kidneys and Pancreata Committee Update (Kidney Committee; Pancreas Committee):

- Purpose is to provide an update on where the Kidney and Pancreas committees currently are in the continuous distribution process, including attribute decisions, modeling results, and the rating scales.
- Feedback stated that this was well written and a solid update, with a wealth of information.

Continuous Distribution of Hearts Concept Paper (Heart Committee):

- Purpose is to update the community on progress made with heart continuous distribution work identifying attributes relating to heart allocation.
- Feedback finds that it is a thorough paper and educational. A member mentioned they were a little disappointed in the layout of the second portion as there were changes mentioned that would greatly alter heart allocation policy, but this member felt these were obscured in the later parts of the paper as whole and the concept paper would benefit more from highlighting these changes. Another member indicated that there might need to be more clarification of the metrics for determining success of certain attributes.

Next steps:

The Committee will present its recommendations to the Executive Committee at their next meeting for final approval for public comment.

Upcoming Meetings

- August 10, 2023
- September 14, 2023

Attendance

- **Committee Members**
 - Arpita Basu
 - Christine Brenner
 - Erika Lease
 - JD Menteer
 - Jennifer Prinz
 - Jerry Morris
 - Jesse Schold
 - Lisa Stocks
 - Lori Markham
 - Molly McCarthy
 - Peter Stock
 - Rachel Engen
 - Sanjay Kulkarni
 - Stephanie Pouch
 - Stevan Gonzalez
 - Ty Dunn
 - Scott Lindberg
 - Shimul Shah
- **HRSA Representatives**
 - Daniel Thompson
 - Jim Bowman
 - Shelley Grant
 - Vanessa Arriola
- **SRTR Staff**
 - Ajay Israni
 - Jon Snyder
- **UNOS Staff**
 - Alex Carmack
 - Cole Fox
 - Courtney Jett
 - Joann White
 - Kayla Balfour
 - Kayla Temple
 - Kelley Poff
 - Kieran McMahon
 - Krissy Laurie
 - Kristina Hogan
 - Lauren Mauk
 - Laura Schmitt
 - Lindsey Larkin
 - Matt Cafarella
 - Moran Jupe
 - Rebecca Brookman
 - Rebecca Murdock
 - Robert Hunter

- Roger Brown
- Stryker-Ann Vosteen
- Taylor Livelli
- Betsy Gans
- **Other Attendees**
 - Ginny McBride (Board member)