

**OPTN Board of Directors  
Meeting Summary  
September 22, 2023  
Webex**

**Dianne LaPointe Rudow, ANP-BC, DNP, FAAN, President  
Richard Formica, MD, Vice President**

## **Introduction**

The Board of Directors met via Webex on 09/22/2023 to discuss the following agenda items and public comment items:

1. Welcome & Announcements
2. Modify Lung Allocation by Blood Type\*
3. Require Reporting of Patient Safety Events (MPSC)
4. Amend Adult Heart Status 2 Mechanical Device Requirements (Heart)
5. Modify Organ Offer Acceptance Limit (OPO)
6. Ethical Considerations of Normothermic Regional Perfusion (Ethics)
7. Summer 2023 Public Comment Items

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

### **1. Welcome & Announcements**

Dianne LaPointe Rudow, Board President, welcomed the Board to their meeting.

### **2. Modify Lung Allocation by Blood Type\***

Marie Budev, Chair of the Lung Transplantation Committee, presented the proposal to Modify Lung Allocation by Blood Type from the Lung Transplantation Committee. The purpose of the proposal is to provide more proportional access to lung transplants for candidates of all blood types and to improve access to lung transplants for blood type O candidates. The Lung Transplantation Committee proposed scaling up the points assigned for blood type, so that blood type O candidates receive a full 5 points. The points assigned to other blood types would be adjusted proportionally. The committee also proposed changing the shape of the blood type rating scale so that blood type has more of an impact on the overall allocation score.

Dr. Budev explained that the Lung Transplantation Committee suggested implementing this proposal on an expedited timeline. The committee's rationale behind the timeline was that blood type O transplants had declined since the implementation of continuous distribution of lungs, even though modeling reviewed when developing the policy suggested that blood type O transplants would increase. The committee suggested a faster timeline because blood type O candidates are waiting longer to receive a transplant and are more medically urgent at the time of transplant.

The Scientific Registry of Transplant Recipients (SRTR) investigated why the modeling did not match the expected outcomes and determined that the modeling had not incorporated incompatible blood type screening rules and as a result, the modeling overestimated blood type O transplants.

Dr. Budev shared the three-month monitoring data that showed a decrease in lung transplants for blood type O candidates, while transplants increased for all other blood types. The Lung Transplantation

Committee also found that due to this modeling error, blood type O candidates now have a higher median medical urgency score at the time of transplant.

For the committee to determine the points for each, the committee multiplied the rating percentage by the weight assigned to blood type in the allocation score. The committee proposed scaling up the ratings so that blood type O candidates receive 5 points for blood type and adjust the ratings for the other blood types accordingly to maintain the overall relationship based on the proportion of incompatible donors. The committee also proposed changing the shape of the rating scale to be a more shallow, nonlinear curve.

Public comment feedback included strong support for the proposed changes to the blood type rating scale, for implementing them as quickly as possible, and for the committee to continue to monitor the policy closely. Some concerns shared during public comment included giving too many points for blood type O related to other blood types, reduction of blood type O lungs to non-blood type O recipients, and blood type O candidates potentially being disadvantaged while the proposal is under development.

#### Summary of discussion:

The Board discussed what precedent this policy sets for policy modifications that may take place in the future. The Board specifically discussed the precedent that this may set for future policy modifications that may warrant an expedited timeline. The Board discussed whether this necessitated reviewing OPTN Bylaws so that going forward, there is a consistent approach when addressing expedited policy needs. They discussed the importance of being able to do what is best for the transplant community, and that acting swiftly is crucial in some situations. Contractor staff agreed to draft potential options for the Board to consider, noting potential pros and cons in creating more stringent criteria for expedited and emergency pathways. The Board agreed that it is important to have a process in place to aid patients in the most efficient and effective way.

#### Vote:

The Board approved the following resolution:

**RESOLVED**, that the changes to Policy 10.1.C.1: Blood Type, as set forth in the materials distributed on September 19, 2023, are hereby approved, effective September 27, 2023.

#### Next Steps:

The OPTN will perform outreach to lung transplant programs with candidates who hold biological disadvantages exception scores. The proposal will be implemented on September 27.

### **3. Require Reporting of Patient Safety Events (MPSC)**

Zoe Stewart Lewis, Chair of the Membership and Professional Standards Committee (MPSC) presented the proposal to Require Reporting of Patient Safety Events. The purpose of the proposal is to align OPTN member reporting requirements with the OPTN's requirement to notify MPSC leadership and HRSA when certain patient safety events are reported.

During public comment, the committee received feedback that:

- The 24-hour reporting timeframe should be extended,
- The near miss definition was adequate,
- The policy should include automate living donor required reporting and extend follow-up past two years after donation, and
- The public agreed with the transportation events that were included in the proposal.

The committee is considering the following post-public comment changes:

- Extension of 24-hour reporting timeframe
- Clarify “sanction” and “other professional body”
- Clarify “did not arrive when expected”
- Include the timeframe “after allocation has begun” for the OPO ABO typing error or discrepancy event

Summary of discussion:

The Board discussed the importance of clearly defining and refining which events should be reported to the MPSC. The Board discussed whether the deadline for members to report an incident within 24 hours was appropriate. One Board member suggested 72-hours, while another suggested 48-hours. There was concern that 24-hours caused too much of a burden on members.

**4. Amend Adult Heart Status 2 Mechanical Device Requirements (Heart)**

Richard Daly, Chair of the Heart Transplantation Committee, presented the proposal to Amend Adult Heart Status 2 Mechanical Device Requirements. The purpose of the proposal is to address community concern regarding the high volume of adult status 2, intra-aortic balloon pump (IABP) candidates whose mortality rates aligned with adult status 3. The proposal from the Heart Transplantation Committee would alter eligibility criteria for adult status 2 temporary mechanical support devices.

Feedback received during public comment showed concern for patients developing arrhythmias and ventricular tachycardia (VT). The community asked the committee to address patients on devices who cannot meet proposed inotropic requirements, and to increase specificity on time on inotropes prior to initial listing and extensions. Other feedback included a concern regarding management of care, the development of a regional review board guidance document addressing concerns about arrhythmias, VT, and the inability to meet inotropic requirements.

Post-public comment changes the committee is considering are:

- Developing a Guidance Document for arrhythmias and VT
- Determining appropriate status for patients who cannot tolerate inotropes
- Defining “time on inotropes” to qualify

Summary of discussion:

The Board discussed patients that do not tolerate inotropes and the potential impacts of this policy. The Board discussed that there will always be patients that will need exceptions and unique situations, but that this policy does address the concerns of the community without having to undergo a large programming effort. Dr. Daly stated that the committee hopes to implement this policy quickly, while they continue to focus on establishing heart continuous distribution policy.

**5. Modify Organ Offer Acceptance Limit (OPO)**

PJ Geraghty, Chair of the Organ Procurement Organization (OPO) Committee, presented the proposal to Modify Organ Offer Acceptance Limit. The purpose of the proposal is to eliminate the scenario where allocation efficiency is diminished when a transplant program holds two primary acceptances for one candidate. The OPO committee proposes modifying OPTN Policy 5.6.C: Organ Offer Acceptance Limit to only allow a transplant hospital to have one organ offer acceptance for each organ type for any one candidate. This policy would not prevent transplant hospitals from receiving additional offers and transplant hospitals would still receive offers and maintain the ability to decline the current primary offer if a better offer occurs.

During public comment, the committee received feedback that the policy should:

- Allow higher status candidates to have concurrent final acceptances,
- Allow two acceptances for DCD donors,
- Consider the effect on pediatric candidates,
- Improve information sharing, and
- Establish a timeframe for acceptance.

Summary of discussion:

The Board discussed rare occurrences when patients are undergoing cross matches and whether the OPO committee has considered an exception for these patients. A Board member raised their concern for the policy and the effect it could have on pediatric candidates, as there is no data on how this policy could affect them. The Board discussed feedback the policy received from other OPTN Committees during public comment.

Board members shared the importance in trusting the expertise of OPOs in these situations, as late turndowns impact multiple patients. Board members reminded the group that is important to look at the policy from a system wide perspective.

**6. Ethical Considerations of Normothermic Regional Perfusion (Ethics)**

Andrew Flescher, Chair of the Ethics Committee, presented the white paper on the Ethical Analysis of Normothermic Regional Perfusion (NRP). The white paper examines the ethical implications of NRP according to the ethical principles of nonmaleficence (do no harm), respect for persons (autonomy), and utility.

Dr. Flescher shared that most comments received during public comment were supportive of the paper, with a variation in whether comments were supportive or opposed to the practice of NRP itself. Themes in public comment included feedback on disclosure, suggestions to differentiate between thoracoabdominal and abdominal NRP, and to ensure there is an understanding on the impact to lungs.

Dr. Flescher shared that the committee would consider the feedback received and whether changes are warranted, while considering the contrasting feedback from the community in support of or against NRP as a practice.

Summary of discussion:

The Board thanked the Ethics Committee for their work on this controversial topic and for presenting it in a thoughtful manner.

**7. Summer 2023 Public Comment Items**

Contractor staff presented the remaining summer 2023 public comment items and the overall sentiment they received during public comment. Comments received on non-sentiment public comment items were also shared with the Board and were broken down by member type. Staff also shared each item's alignment with the strategic plan. These public comment items included:

- Update HLA Equivalency Tables 2023 (Histocompatibility Committee)
- Remove CPRA 99-100% Form for Highly Sensitized Kidney Candidates (Histocompatibility Committee)
- Deceased Donor Support Therapy Data Collection (Operations & Safety Committee)
- Update Guidance on Optimizing VCA Recovery (Vascularized Composite Allograft Transplantation Committee)

- Recognizing Seasonal and Geographically Endemic Infections in Organ Donors: Considerations During Deceased and Living Donor Evaluation (Disease Transmission Advisory Committee)
- Clarification of OPO and Living Donor Recovery Hospital Requirements for Organ Donors with Positive HIV Test Results (Disease Transmission Advisory Committee)
- Concepts for a Collaborative Approach to Living Donor Data Collection (Living Donor Committee)
- Continuous Distribution of Hearts (Heart Transplantation Committee)
- Efficiency and Utilization in Kidney and Pancreas Continuous Distribution (Kidney Transplantation Committee & Pancreas Transplantation Committee)
- Update on Continuous Distribution of Livers and Intestines (Liver & Intestinal Organ Transplantation Committee)

Summary of discussion:

There were no questions or comments from the Board.

The meeting adjourned.

**Upcoming Meetings**

- October 25, 2023
- November 29, 2023
- December 4, 2023

## Attendance

- **Board Members**
  - Alan Langnas
  - Andrea Tietjen
  - Andrew Kao
  - Barry Massa
  - Bryan Whitson
  - Christopher Jones
  - Christopher Woody
  - Colleen McCarthy
  - Daniel Yip
  - Dianne LaPointe Rudow
  - Emily Blumberg
  - Erika Demars
  - Evelyn Hsu
  - George Surratt
  - Ginny McBride
  - Heather Hunt
  - Jennifer Lau
  - Jim Sharrock
  - Julie Spear
  - Kelley Hitchman
  - Kenneth McCurry
  - Laurel Avery
  - Linda Cendales
  - Luis Hidalgo
  - Manish Gandhi
  - Mark Barr
  - Meg Rogers
  - Melissa McQueen
  - Michael Kwan
  - Richard Formica
  - Silas Norman
  - Stuart Sweet
  - Valinda Jones
  - Wendy Garrison
  - Willscott Naugler
- **HRSA Representatives**
  - Adrienne Goodrich Doctor
  - Christopher McLaughlin
  - Frank Holloman
- **UNOS Staff**
  - Alex Carmack
  - Anna Messmer
  - David Klassen
  - Jacqui O'Keefe
  - James Alcorn

- Julie Nolan
- Kaitlin Swanner
- Katrina Gauntt
- Kieran McMahon
- Lauren Mauk
- Liz Robbins Callahan
- Lloyd Ratner
- Maureen McBride
- Morgan Jupe
- Robert Hunter
- Roger Brown
- Sharon Shepherd
- Silas Norman
- Susan Tlusty
- Susie Sprinson
- Tiwan Nicholson
- Tony Ponsiglione
- **Other Attendees**
  - Marie Budev
  - Rocky Daly
  - Zoe Stewart Lewis