

OPTN Executive Committee

Meeting Summary

March 16, 2023

Webex

Jerry McCauley, MD, MPH, FACP, Chair

Introduction

The OPTN Executive Committee met via teleconference on 03/16/2023 to discuss the following agenda items:

1. Streamline Reporting in the Patient Safety Portal*
2. Expand Intended Incompatible Blood Type (ABOi) Eligibility to All Pediatric Status 1A and 1B Heart and Heart-Lung Candidates*

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

1. Streamline Reporting in the Patient Safety Portal*

Ann-Marie Leary, Assistant Director of Member Quality, presented recommendations from the Membership and Professional Standards Committee (MPSC) to streamline reporting within the patient safety portal. The MPSC recommended the removal of data fields from the Safety Situation Form and the removal of sub-category choices on two fields that are part of the Living Donor Event Form. Both forms are part of the OPTN Patient Safety Reporting Portal. The purpose of removing these select fields and sub-categories is to streamline data collection from safety situation notification forms. Data is currently duplicative to what is collected during the OPTN Safety Review Process; this duplicative collection could result in inappropriate categorization of events as determined from the OPTN Safety Review Process.

These proposed changes were assessed as being immaterial due to the limited impact they would have. The impact analysis demonstrated these changes would not impact OPTN operations, OPTN Policies and Bylaws, OPTN critical processes such as allocation scoring and match functionality), nor would it affect downstream OPTN data flows and products. Historical data collection will not be changed as part of the proposal.

Summary of discussion:

A committee member asked for verification that patient social security numbers would be hidden on these forms, to which Ms. Leary confirmed that only the last four digits would be shown. If a patient's full social security number is ever included in documentation to the MPSC, this information is redacted so no personally identifiable information would be included in these documents. The committee member also asked to clarify that the MPSC does not collect social security numbers for deceased donors. It was clarified that this information is not collected but they do collect social security numbers for candidates in case there is a need to identify a patient and link to an external data source. A committee member added that their OPO does not receive deceased donor social security numbers at all.

Another committee member asked for clarification on whether this just pertained to living donors, or if this was applicable to all donation patient safety forms. Ms. Leary explained that currently, when

someone logs onto the portal, there are three fields they may choose from: patient safety event form, safety event form, and the living donor event option. She clarified that the purpose of this proposed form format is so users can log in and may submit a lab and an event at the same time if they wanted to, and the MPSC will then classify the event on the back end. These changes create more of an open format.

Vote:

The Executive Committee approved the removal of the data fields from the OPTN Patient Safety Reporting as set forth in the distributed materials.

Next Steps:

After the approval of the Executive Committee, these changes will be submitted as part of the OPTN Data System package to the Office of Management and Budget (OMB) at the end of March 2023. Approval for the development work to remove fields to align with OMB approval is expected by spring 2024. Following OMB approval, implemented changes in the OPTN Patient Safety Reporting Portal are targeted for spring 2024.

2. Expand Intended Incompatible Blood Type (ABOi) Eligibility to All Pediatric Status 1A and 1B Heart and Heart-Lung Candidates*

Jondavid Menteer, Vice Chair of the Heart Transplantation Committee, presented the policy on behalf of the Heart Committee. The committee sought approval to implement portions of the Heart Committee's policy to expand intended incompatible blood type (ABOi) to all pediatric status 1A and 1B heart and heart-lung candidates and expand eligibility to all pediatrics registered before turning 18. The Heart Committee sought approval for portions of the ABOi policy proposal to allow ABOi heart and heart-lung offers by increasing the age limit from '2 years old' to '18 years old' and to keep current status 1A and status 1B qualifying requirements. Implementation would happen immediately following approval by the Executive Committee.

The Heart Committee is accelerating the implementation process due to a request from a pediatric heart program for an urgent exception or appeal to allow a pediatric patient to immediately receive ABOi offers. The committee worked quickly and effectively to address patients who may qualify under the proposed policy. The Heart Transplantation Committee will bring remaining aspects of the proposal to the OPTN Board of Directors in June.

Feedback from public comment included support for the proposal, support for increasing the age limit to improve access to donor organs thus leading to improved waiting list mortality rates, and the proposal received support for maintaining transplant program discretion and flexibility for determining appropriate patient care.

Summary of Discussion:

A committee member asked if the Heart Committee had an estimate on how many pediatric candidates could receive ABOi compatible hearts and an estimate on the number of patients who could benefit from this policy. Dr. Richard Daly, Chair of the Heart Transplantation Committee, stated that data suggests there have been 233 transplants over the last five years, which accounts for less than 50 transplants a year. Dr. Menteer stated that as patients get older, the number of insignificant antibodies gets exceedingly small and commented that the number of ABOi heart transplants in general is rare. The number of patients suitable for an ABOi heart transplant is small but waiting times for pediatric hearts can be long. He noted that that doctors could utilize more hearts and give patients a successful outcome is a win-win when you consider there is not much associated risk associated. Data has shown that the

outcomes of such incompatible transplants is the same as the outcomes of compatible heart transplants for patients that are under two years old.

A committee member asked about the experience's children in Canada and the United Kingdom have had from this treatment. Dr. Menteer explained that although the US allowed infant heart transplants across blood types, the allocation system was disadvantageous to secondary blood types and it was rare to achieve an incompatible transplant. The patients who received these hearts received them because there were no compatible recipients available. Dr. Menteer noted that it was not until 10 year post-transplant data became available that the US started to update their policies.

A committee member asked how often ABO titers must be performed in older children, whether this is similar to A2 to B, or whether quarterly titers are necessary to perform. Dr. Menteer responded that currently policy requires patients to demonstrate iso-gluten titers from 1 to 16 without medical manipulation. Dr. Menteer estimated that the frequency of these tests are every thirty days.

A committee member commented that when analyzing public comment feedback, they were surprised that the American Society for Transplant Surgeons (ASTS) posed more questions than answers to this proposal. A committee member commented that they believed this showed ASTS is more of an abdominal society than thoracic. Dr. Menteer did comment that the ABOi procedure is more of a medical procedure than a surgical one. He commented that from a surgical aspect, this procedure is identical to a regular transplant procedure. Dr. Menteer noted that the proposal received positive feedback from pediatric heart societies, including the Pediatric Heart Transplant Society and the Action Network.

A committee member congratulated the chair for the committee's urgency to implement the policy to help the patient in need and commended them for their work.

A representative from HRSA asked if all potential candidates that could potentially be affected by this change would be notified. Dr. Menteer informed them that the Heart Committee has already issued notices to all transplant programs and plan to communicate with these programs more in the coming days. A UNOS staff member confirmed that they planned to reach out to each of the programs individually.

Vote:

The Executive Committee approved the creation of *Policy 6.6.B.i: Eligibility for Intended Incompatible Blood Type Heart Offers*, *6.6.B.ii: Blood Type Matching Priority for Intended Incompatible Blood Type Heart Offers*, and *6.6.B.iii: Reporting Requirements for Recipients of Intended Incompatible Blood Type Hearts*, as well as changes to *Policies 5.3.E: Pediatric Heart Acceptance Criteria to Receive Intended Blood Group Incompatible Hearts*, *6.6.A: Allocation of Hearts by Blood Type*, and *6.6.B: Eligibility for Intended Blood Group Incompatible Offers for Deceased Donor Hearts*. It is further resolved that the OPTN Heart Transplantation Committee shall continue to review its proposal "Modify Heart Policy for Intended Incompatible Blood Type (ABOi) Offers to Pediatric Candidates" and will submit any outstanding recommendations, including adjustments to the policy changes adopted below, to the OPTN Board for review during its June 25, 2023, meeting.

There was no further discussion and the meeting adjourned.

Attendance

- **Committee Members**
 - Annette Jackson
 - Bradley Kornfeld
 - Dianne LaPointe Rudow
 - Gail Stendahl
 - Irene Kim
 - Jeffrey Orłowski
 - Jerry McCauley
 - Jim Sharrock
 - Linda Cendales
 - Lloyd Ratner
 - Matthew Cooper
 - Valinda Jones
- **HRSA Representatives**
 - Adrienne Goodrich-Doctor
 - Christopher McLaughlin
 - Frank Holloman
- **UNOS Staff**
 - Alex Carmack
 - Ann-Marie Leary
 - Anna Messmer
 - David Klassen
 - Eric Messick
 - Jacqui O'Keefe
 - Jason Livingston
 - Kimberly Uccellini
 - Liz Robbins Callahan
 - Maureen McBride
 - Michael Ferguson
 - Morgan Jupe
 - Nadine Hoffman
 - Rebecca Brookman
 - Rebecca Murdock
 - Roger Brown
 - Sara Rose Wells
 - Susan Tlusty
 - Susie Sprinson
 - Tina Rhoades
 - Tony Ponsiglione
- **Other Attendees**
 - Jondavid Menteer
 - Richard Daly