OPTN Operations and Safety Committee
Donor Testing Requirements Workgroup
Meeting Summary
January 15, 2025
Conference Call

Annemarie Lucas, MHSA, Chair

Introduction

The OPTN Operations and Safety Committee's Donor Testing Requirements Workgroup (the Workgroup) met via WebEx teleconference on 01/15/2025 to discuss the following agenda items:

1. Welcome/Announcements
2. Review of Policy Recommendations
3. Review and Discussion: Data Collection of Pre/Post Transfusion
4. Review and Discussion: Clarify ABO Determination Post-Transfusion

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

1. Welcome/Announcements

The Workgroup reviewed the meeting objectives, which are to review the policy recommendations identified to date, and to review and discuss proposed data collection changes for indicating whether blood testing was completed on samples drawn prior to or following a donor blood transfusion.

Summary of discussion:

No decisions were made.

There were no questions or discussion.

2. Review of Policy Recommendations

The Workgroup members were asked to review the policy recommendations shared via email and provide any feedback.

Summary of discussion:

Decision #1: The Workgroup agreed the policy recommendations should be updated to reflect that total bilirubin remains a testing requirement for deceased liver donors, and direct bilirubin should be removed from the policy.

A member noted that the recommendations state that total bilirubin would be removed for deceased liver donors but that he believed the Workgroup's intent was to remove direct bilirubin and to retain total bilirubin for deceased liver donors. Members agreed that total bilirubin is important to test for deceased liver donors.

Next steps:

Workgroup members will continue to review the policy recommendations and provide any additional feedback via email. OPTN contractor staff will also follow up with Workgroup members for additional feedback on changes to guidance. The recommendations will be reviewed by the Operations and Safety Committee ("OSC") to finalize the policy language. The OSC is aiming to send the proposal out for public comment in summer 2025.

3. Review and Discussion: Data Collection of Pre/Post Transfusion

The Workgroup reviewed potential data collection changes to clarify whether donor blood samples were drawn prior to or after a donor received a blood transfusion.

Data summary:

The proposed data collection would include a new field for organ procurement organizations (OPOs) to indicate if the blood draw for blood typing occurred post transfusion to include blood draw date and time. These fields would be required when blood type is entered and when the blood type is verified. Blood draw date/time and post transfusion fields would be entered each time ABO value is entered or verified. Potentially up to four entries if A or AB is entered and then subtype is entered.

Summary of discussion:

Decision #2: The Workgroup recommended collecting data on the timing of the transfusions as well as information on blood draw date and time.

A member asked if there has been discussion on defining what "post-transfusion" means. From his understanding, a donor is considered "post-transfusion" for determining blood type only if the donor received packed blood cells, versus fresh frozen plasma (FFP). OPTN contractor staff said the Workgroup would need to define post-transfusion and whether it includes all types of transfusions or a subset of transfusion types, with options including whole blood, red blood cells, platelets, plasma, or other types of blood transfusions.

A member said it would be challenging to report blood draw date and time because the amount of draw dates and times for the donor will vary in each case. For ABO determination, if there are blood draws prior to a transfusion from earlier in the donor hospital's stay, the OPO may use those in the determination of blood type.

A member provided a real-world example related to this issue. The member's transplant program performed an ABO-incompatible heart transplant because the ABO determination was not correct. The member said this is a significant patient safety issue as well as a multi-million-dollar liability if it is wrong. Reporting the blood draw date and time is important and perhaps the data collection could be modified to make it easier for OPOs. The member said that transplant programs are concerned about both whole blood and red blood cell transfusions, and when they were administrated, since a transfusion can impact blood typing for more than 6 months following the transfusion.

A member agreed it is vital for transplant programs to have this information and the Workgroup needs to consider how to make this work well in the system. A member said they want the pre-transfusion ABO blood type and they do not need to know the post-transfusion ABO blood type unless it is different from the pre-transfusion ABO, in which cause they would typically default to transplanting the organ in an AB candidate to avoid blood type incompatibility. A member noted there are scenarios where a patient may receive transfusions in one hospital, and then be transferred to another hospital where the

donation takes place, so it may be helpful to provide guidance around these scenarios as well. The member said it is important for the OPO to provide this information if it is available.

A member said that from the OPO perspective there is a "when" component of this – not just when the blood draw date and time took place, but also when the transfusion took place. One of the challenges is there is a lot of "let the OPO determine what the result is" when the system could help OPOs do this. The member recommended requiring the OPO to put the transfusion information into the system and indicate whether the OPO observed discrepancies within that timeline. The member said it is important to put in some checks and balances to mitigate risk as much as possible. The member said he has no way to publish transfusion information in the system except as attachments, which may not be reviewed by transplant programs, so disseminating information about transfusion history should be standardized in the system.

A member of the OPTN Histocompatibility Committee mentioned that her committee recently discussed whether the Histocompatibility Committee should pursue a project regarding molecular ABO testing. The committee noted the lack of definition for "mass transfusion" and that the standard blood type serology used is part of the problem. A buccal swab can be taken from a donor to determine the blood type at a molecular level. The Histocompatibility Committee would like to promote the usage of molecular typing to avoid this type of issue. The member expressed concern about the mock-up for the proposed data collection because it provides no indication about the amount of blood transfused. If there were a list of 30 transfusions or some indication of massive transfusion, that informs providers that there should be extra caution taken around the blood typing. For donors being transferred between different hospitals, that can be very challenging to track. The member expressed concern about making changes with this project that may not be a comprehensive solution, since the volume of blood may be more important, or knowing if the donor was transferred from another hospital and therefore may have received more transfusions than are reported in the system.

A member said that the date and time of blood draw for ABO do not mean anything without the information about transfusions (what was transfused, when, how much, etc.). All OPOs are documenting that information but need a place in the OPTN Computer System for it to land. A member said that transfusions also cannot be defined as "units" as they are not standard across products or institutions.

A member asked if this would replace the requirement for the OPO to upload all information available regarding transfusions. The proposed data collection is more limited than the transfusion records that would be uploaded as attachments. A member agreed it may be challenging to collect all the relevant data in this type of format. The issue could be solved with molecular typing but not every facility is using that technology. The molecular typing can do the ABO subtyping, but it is a newer technology that has not been adopted nationally.

From a data entry burden perspective – a member recommended that the OPO doesn't need to transcribe the blood draw date and time if it is available somewhere else in the system, but it is important to confirm if the blood typing determination is pre- or post- transfusion.

OPTN contractor staff said the system could validate whether blood typing is pre- or post- transfusion based on the data entered, but the Workgroup would need to confirm what data should be used.

The Workgroup discussed the current data collection in the system, which is a field to enter the "number of transfusions during this (terminal) hospitalization," defined as packed red blood cells (PRBC) or whole. OPTN Contractor staff said this data collection could be modified if that better meets the need. The timing of the transfusions would need to be entered in that location for the system to validate if other blood draws were pre or post transfusion.

Next steps:

OPTN contractor staff will consider other options for collecting information on transfusions and bring recommendations back to the Workgroup.

4. Transfusion

The Workgroup reviewed a project idea that was referred from the OPTN Membership and Professional Standards Committee (MPSC) to the OPTN Operations and Safety Committee (OSC) and the OPTN Histocompatibility Committee.

Presentation summary:

The purpose of the proposed project would be to address discrepant ABO results, particularly regarding donors who have undergone mass transfusion. Currently, OPTN *Policy 2.6 Deceased Donor Blood Type Determination and Reporting* requires OPOs to:

- "Include a process to address conflicting or indeterminate primary blood type results in their written protocol" (2.6.A)
- "Document that reporting was completed according to the OPO's protocol and the above requirements" (2.6.C)

However, the policy does not place minimum standards on what these protocols should contain. The solution proposed by the MPSC was to re-evaluate *Policy 2.6* and consider requiring that molecular testing be utilized when blood typing discrepancies occur, especially after mass transfusions

OSC agreed with this referral moving forward as a project, but concern was raised of requiring molecular testing being utilized when blood typing discrepancies occur as access to this testing is not inclusive of all OPOs. OSC Leadership discussed recommendations and next steps with Histocompatibility Committee leadership, and the Histocompatibility Committee agreed to sponsor this project.

The Workgroup was asked to review and discuss OPTN *Policy 2.6* for recommendations to defer to the Histocompatibility Committee for consideration in their project re-evaluating this policy.

Summary of discussion:

The Workgroup discussed that some members of the Histocompatibility Committee are very passionate about pursuing this project, in part because they are familiar with the real-world case described on the meeting.

A member said it would be extremely helpful for the OPTN to provide some guidance on how to develop the written protocol to address conflicting or indeterminate primary blood type results. OPTN contractor staff noted that OSC previously developed guidance on indeterminate blood typing. Staff will share that guidance with the Workgroup so they can consider if updates are needed.

Next steps:

The Workgroup will continue to review *Policy 2.6* and related guidance to provide any recommended changes to the Histocompatibility Committee for consideration.

Upcoming Meeting

- February 19, 2025 (Teleconference)

Attendance

- **Workgroup Members**
  - Annemarie Lucas, Chair
  - Laurine Bow
  - Ashley Cardenas
  - Brychan Clark
  - Vanessa Cowan
  - Lara Danziger-Isakov
  - Dan DiSante
  - Kaitlyn Fitzgerald
  - Christine Hwang
  - Dean Kim
  - Heather Miller Webb
  - Norihisa Shigemura
  - Irma Sison
  - Jessica Yokubeak
  - Chuck Zollinger
- **HRSA Representatives**
  - N/A
- **SRTR Staff**
  - N/A
- **UNOS Staff**
  - Kerrie Masten
  - Cass McCharen
  - Rob McTier
  - Laura Schmitt
  - Kaitlin Swanner
  - Joann White