OPTN Operations and Safety Committee
Meeting Summary
December 19, 2024
Conference Call

Kim Koontz, MPH, Chair
Steven Potter, MD, Vice Chair

Introduction

The OPTN Operations and Safety Committee (the Committee) met via WebEx teleconference on 12/19/2024 to discuss the following agenda items:

1. Update: Standardize Practice in the use of Normothermic Regional Perfusion (NRP) in Organ Procurement
2. Project Update: Re-evaluation of Deceased Donor Testing Requirements
3. Review and Discussion: Clarify ABO Determination Post-Transfusion (Membership and Professional Standards Committee Project (MPSC) Project Idea Referral)
4. Closing Remarks

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

1. Update: Standardize Practice in the use of Normothermic Regional Perfusion (NRP) in Organ Procurement

The Committee received an update on progress with the NRP project.

Summary of discussion:

The Committee will move forward with developing a comprehensive guidance document on use of NRP in organ procurement, to release for a special public comment upon completion of the document.

The Chair informed the Committee of the transition from providing an update to the OPTN Executive Committee to developing a comprehensive report for the OPTN Board of Directors (BoD) following the November 7th meeting. This report, encompassing all previously discussed recommendations, was submitted ahead of the BoD's December 2nd meeting. The Executive Committee reviewed the Committee's progress and provided several key pieces of feedback, indicating their overall support for the proposed recommendations. This feedback included a recommendation to refocus their efforts from a request for feedback (RFF) that seeks community input on draft recommendations and instead presenting a finalized guidance document to the public that shares the Committees recommendations with actionable outcomes.

The Committee discussed establishing a timeline as it was recommended to pursue a special public comment period due to the need to finalize the guidance document. The Committee agreed to a special public comment period tentatively scheduled for March to April. To ensure thorough consultation and collaboration, the Committee identified key stakeholders, including the Organ Procurement Organization (OPO), Membership and Professional Standards, Ethics, and other relevant OPTN committees. The Committee's other recommendations related to policy and data collection will be

integrated into ongoing organ procurement organization (OPO) Committee projects, such as the enhanced data collection project focusing on machine perfusion data and the policy review addressing donation after circulatory death (DCD) procedures.

Next steps:

The Committee will continue development of the guidance document and ensure appropriate collaboration with the advised OPTN committees.

2. Project Update: Re-evaluation of Deceased Donor Testing Requirements

The Workgroup Chair presented the work thus far.

Summary of discussion:

The Workgroup Chair advised the Committee of the efforts of the Workgroup in aligning donor testing practices and ensuring OPTN policy is accurate and in line with current clinical guidance. It was explained that the Workgroup began by conducting a thorough review of OPTN Policy 2.8, which addresses general risk assessment and infectious disease testing. Additionally, the Workgroup systematically evaluated organ-specific policies, excluding lung policies, which are being addressed in a separate proposal by the OPTN Lung Committee.

One significant focus area for the group is the introduction of new data collection elements to enhance clarity and accuracy in donor testing. One item they intend to propose is a mechanism to address technical issues such as accurately documenting whether blood typing occurred pre- or post-transfusion.

Next steps:

The Workgroup plans to finalize recommendations over the course of the remaining meetings. Once the recommendations are complete, they will be presented to the Committee for review and consideration.

3. Review and Discussion: Clarify ABO Determination Post-Transfusion (Membership and Professional Standards Committee Project (MPSC) Project Idea Referral)

The Committee discussed a MPSC referral related to discrepancies in ABO determination, especially in cases involving mass transfusions.

Summary of discussion:

The Committee agreed to pursue the project, with particular focus on balancing practical implementation with enhanced safety measures. The Committee will seek additional input from the Histocompatibility Committee and the OPO Committee while engaging in this work when appropriate.

It was highlighted that current policy mandates that OPOs develop protocols to address conflicting or indeterminate primary blood type results, but these requirements are broad and lack specific standards. As a result, variability exists across OPOs in how such cases are managed, creating potential risks for safety and consistency.

A recommendation offered by the MPSC was whether to mandate molecular testing to resolve ABO discrepancies. Some members expressed concern that requiring molecular testing might be impractical, particularly in areas where such resources are not readily available as its accessibility and approval for deceased donation use vary significantly across regions and facilities. Others suggested developing flexible protocols that incorporate molecular testing as an optional, advanced tool when feasible.

Additional issues discussed included the lack of systematic documentation in DonorNet about whether blood transfusions occurred. This omission makes it difficult for transplant centers to understand the

context of ABO results unless explicitly reported by OPOs in free-text fields. Addressing this gap, the Committee identified the need for a standardized data field to indicate whether a transfusion was performed, which aligns with ongoing data collection improvements being developed by the Deceased Donor Testing Requirements Workgroup.

Collaboration with other committees, including the Histocompatibility and OPO committees, was highlighted as essential to refining this project. The Committee plans to share its recommendations with these groups, fostering joint discussions to align policy updates and practical solutions. A joint leadership meeting with the Histocompatibility committee is scheduled for January 2025 to solidify next steps.

Next steps:

The Committee agreed that the ABO determination project is worthwhile but requires careful consideration to balance practical implementation with enhanced safety measures. They will proceed by evaluating current policy, exploring additional data collection mechanisms, and seeking further input from stakeholders before finalizing recommendations.

Upcoming Meetings

- Thursday, January 23, 2025 (Teleconference)

Attendance

- **Committee Members**
  - Kim Koontz
  - Steven Potter
  - Anja DiCesaro
  - Annemarie Lucas
  - Anne Krueger
  - Amanda Bailey
  - Bridget Dewees
  - Elizabeth Shipman
  - Jennifer Smith
  - Jillian Wojtowicz
  - Kaitlyn Fitzgerald
  - Laura Huckstein
  - Norihisa Shigemura
  - Sarah Koohmaraie
  - Mony Fraer
- **SRTR Staff**
  - Avery Cook
- **UNOS Staff**
  - Joann White
  - Kaitlin Swanner
  - Kerrie Masten
  - Laura Schmitt
  - Stryker-Ann Vosteen