

**OPTN Operations and Safety Committee
ABO Workgroup
July 16, 2019
Conference Call**

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Introduction

The ABO Workgroup met via Citrix GoToTraining teleconference on 07/16/2019 to discuss the following agenda items:

1. Recap of 6/6/19 Meeting
2. Discussion: OPO Processes and Best Practices
3. Project Timeline and Schedule

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

1. Recap of 6/6/19 Meeting

An overview of last week's Workgroup call.

Summary of discussion:

The Workgroup had a discussion on the impact of massive transfusion on blood type determination. With the help of Subject Matter Experts (SMEs), the workgroup agreed to use the American Association of Blood Bank's definition for the purposes of their guidance document. The workgroup learned that it does not take a massive transfusion to impact a patient's blood type. The Workgroup also reviewed the established goals of their subcommittee that will serve as the framework for the guidance document.

Next steps:

The Workgroup will continue to develop their guidance document.

2. Discussion: OPO Processes and Best Practices

The Workgroup discussed OPO processes for managing ABO discrepancies. Individuals from one OPO agreed to share their best practices for facing discrepancy challenges.

Summary of discussion:

The individuals from the OPO shared three areas where they found challenges with ABO discrepancies. These areas are hemodiluted samples, massive transfusion protocols, and indeterminate results. Their OPO is still attempting to define a massive transfusion protocol within their system. Currently they are utilizing 10 units in 24 hours. They are also looking to establish more safe protocols for situations in which lab results do not match.

A Workgroup member pointed out the importance of understanding that there can be differences in the quality of serology and ABO hemodilution samples. This member asked if the OPO had looked at molecular or DNA typing as part of their process. They reported that they do molecular typing for every donor, but that this test is not considered a validated source. They also noted that they cannot solely consider molecular typing results as it is not approved by the Food and Drug Administration (FDA). It was also reported that the OPO's turnaround time is longer than desired for this type of testing. Another member reported that her hospital can turn these results around in an hour and a half. She called for

clarification on the utilization of molecular typing. This member supported molecular testing becoming more of a norm for ABO typing due to its accuracy.

A member asked about the OPO's use their massive transfusion definition on pediatric patients. The OPO member reported that they have been challenged with figuring out when a patient's blood type will be compromised in pediatric situations. The same member asked how wait times until retest were determined. The OPO reported that this was based on total plasma, blood volume, volume of the infusion, and time.

The OPO member noted that the absence of FDA approval of molecular typing could contribute to less overall confidence in lab results. Another member countered that her experiences with molecular testing have been accurate and reliable. She reported feeling confident in molecular testing, but agreed that policies surrounding this type of testing should be developed. This workgroup member reported that molecular testing is fairly new and not yet mainstream, but believes it has potential to become FDA approved and more widely utilized.

The Workgroup discussed how labs have differing requirements for forward and reverse typing. The need for consistent and thorough protocols was highlighted. A Workgroup member reported that upon receipt of an undetermined lab result, his organization redraws fresh blood samples the following day and sends them to three separate labs. He acknowledged that this might not be the best method, as this gives OPOs the opportunity to simply pick the best result.

A Workgroup member reviewed the current policy language for *Policy 2.6.A: Deceased Donor Blood Type Determination*. He highlighted the absence of any language that mentioned protocols surrounding indeterminate results. He suggested a modification that would include forward and reverse typing along with a requirement for a process when discrepant results are found. Other workgroup members supported the call for discrepant results processes. There was also support for education surrounding forward and reverse typing, as many professionals from the transplant center perspective do not have knowledge on this topic. The workgroup reported that a section of their guidance document should focus on defining forward and reverse typing as it relates to how ABO typing is determined.

Next steps:

The workgroup will divide up sections of the guidance document in order to begin writing draft language.

3. Project Timeline and Schedule

The Workgroup discussed their plan for the next call.

Summary of discussion:

The Workgroup planned to gather volunteers to begin drafting guidance document language.

Next steps:

The Workgroup's goal is to have the document go for public comment on October 24th, 2019.

Upcoming Meeting

- August 1, 2019