

**OPTN/UNOS Operations and Safety Committee ABO Workgroup
Meeting Minutes
June 6, 2019
Conference Call**

**Michael Marvin, MD, Chair
Christopher Curran, CPTC, CPTBS, CTOP, Vice Chair**

Introduction

The Operations and Safety Committee (OSC) ABO Workgroup met via teleconference on June 6, 2019 to discuss the following agenda items:

1. Recap of May 2nd Meeting
2. Discussion: Impact of Massive Transfusion on Blood Type
3. Project Timeline and Schedule
4. Next Steps

The following is a summary of the Operations and Safety Committee ABO Workgroup discussion.

1. Recap of May 2nd Meeting

The Vice Chair provided an overview of the discussion from the May 2nd workgroup meeting.

Summary of Discussion

The Vice Chair summarized the workgroup's last meeting. An SME presented on the alternative testing methods that are currently available.

There was also a review of the Membership and Professional Standards Committee's (MPSC) letter. The recommendations provided by the MPSC was incorporated in the workgroup's established goals. At the end of the meeting the workgroup's established goals and next steps were reviewed and discussed.

It is the goal of the next meeting to have a discussion around the protocols of OPOs in addressing discrepant results. For the guidance document, it will be helpful to discuss the different practices that are being done.

2. Discussion: Impact of Massive Transfusion on Blood Type

The workgroup's SMEs led a discussion with workgroup members on the impact of massive transfusion on blood type.

Summary of Discussion:

An SME began by reviewing the American Association of Blood Banks' (AABB) definition of massive transfusion with members. The patient groups that AABB focuses on are as follows:

- 8-10 red cell units to an average adult patient in less than 24 hours
- Acute administration of 4-5 red cell units in 1 hour
- Exchange transfusion – this usually applies to an infant

The Vice Chair asked members if the project should focus on one set of defined criteria for donors or provide multiple definitions that are being used within the community. A member stated that there are variations between the definitions reviewed and what may be done in practice among the transplant community. There may need to be guidance depending on the facility rather than defining it for people.

Another member stated that AABB provides a reference which organizations tend to struggle with determining the actual meaning. If there is a standard reference, it can be identified as a source for programs that do not have a formal definition.

The Vice Chair continued by stating that the goal is to define at what point should the blood type be questioned after a massive blood transfusion is done. The AABB's definition may not be as conservative as the intent of the guidance document. Another SME agreed that the focus should not be on trying to define what each hospital defines as massive transfusion. The workgroup wishes to address the point where there should be concern that a patient may show changes in their blood type. Depending on the size of the patient and how much blood was transfused, some patients may show a mixed or discrepant blood type. The change may occur before to 10 red cell units for changes to occur. Another SME agreed with this and added that any large volume transfusion can interfere with the blood type.

A member stated that in reference to the pediatric patients and the definition of, "Replacement of > 50% of the total blood volume (TBV) by blood products within three hours", measurements greater than 10 units of blood can result in difficulty in determining ABO results and this should be in consideration when discussing parameters. Another member added that small adult patients should be considered as well.

The Vice Chair stated that a calculation is utilized for determining if a donor is plasma diluted from a serology standpoint and asked if there is a possibility to have a similar calculation when it comes to ABO determination. Is there an algorithm based on a time and blood volume percentage? An SME stated that the AABB guidance that is available takes all of these factors into consideration. The AABB sets standards based on observation and studies. The SME suggested that the workgroup provide a definition for massive transfusion as defined by in the transfusion literature and at the same time make the disclaimer that any out of type or emergency transfusion in a small individual can interfere with their blood type.

A member added that from an OPO perspective and in considering forward and reverse typing, the laboratories being asked to blood type a patient are many of the times serology laboratories where they do blood typing in addition to performing serology. The laboratories are not necessarily blood banks where there is a blood bank medical director who is overseeing the process and can look at the clinical history of the patient.

The Vice Chair reviewed the workgroup's established goals and stated that from a previous discussion, the question came up of whether both forward and reverse typing results should be available to transplant programs. From experience, when typing is received from donor hospitals and HLA labs, it would be hard to illicit these results from donors.

A member stated that this would be hard to illicit but during times where there are discrepant results, what does this exactly mean? The Vice Chair stated that a review and revision of policy language would address this. Would it be feasible for donor hospitals to send both forward and reserve typing results?

An SME stated that if the donor hospital is Clinical Laboratory Improvement Amendments (CLIA) certified, they cannot report an ABO unless the forward and reverse match are concordant. The Vice Chair asked if labs record both results. The SME stated that the labs do record both results and that a copy of their worksheet could be obtained.

The Vice Chair asked members their thoughts on excluding the definition of "Transfusion of >20 units of PRBC units in 24 hours", and utilize the references used by the SME as it pertains to massive blood transfusions in the guidance document. The members agreed with this. The SME agreed and added that the reference is in the AABB technical manual, which explains all of the caveats discussed.

The Vice Chair continued by reviewing the deceased donor blood transfusions data. The data does not include information of when the transfusions occurred – whether it was after ABO blood draws, during the course of management or if it was massive transfusion at the time of admission. There is still uncertainty of how many donors are transfused prior to ABO determination. The information coincides with the MPSC’s recommendation of whether should there be a recording of all blood transfusions that the donor receives during the hospitalization provided as part of the information conveyed to transplant programs. The Vice Chair asked members to keep this in mind to discuss during the next workgroup’s call.

The Vice Chair updated the established goals and reviewed that information with the workgroup members. The revised established goals of the workgroup are as follows:

- Identify alternative methods of ABO typing, including availability and accuracy.
 - Guidance for obtaining pre-transfusion samples
 - Previous hospitalization ABO typing and reliability?
- Create an awareness of the impact massive transfusions can have on blood type determination
 - Has there been any type of change within trauma hospital protocols related to massive blood transfusions?
- Guidance and further defining massive transfusions for members
 - Triggers for further testing?
- Identify time between blood samples, amount of transfusion, and size of the donor that impact a donor returning to their actual blood type.
- Education for the community in whatever form the work group determines will be the most effective
- Indeterminate or Conflicting results
 - Triggers to consider evaluation/investigation of discrepancy
 - Discrepant forward/reverse typing
 - Pediatric donors
 - Blood Bank vs. OPO perspective differences on ABO determination
- Guidance for procedures/protocols for dealing with this
 - Re-test plan or guidance
 - What to do if discrepancy cannot be resolved

The Vice Chair asked the SMEs their thoughts on the reliability of previous hospitalization ABO typing as asked by the MPSC in their letter to the Committee. An SME replied by stating that from a blood banking perspective, transfusions would never rely on a previous ABO typing record. There are many human error points to this documentation. If there is not a current sample, the patient would receive O blood. Another SME agreed with this and stated that they would always review the historical type everytime a new sample is received. The historical type and the new sample are compared but it is not recommended to rely on historical information alone. An SME added that if the historical information and current information do not match, a third source would need to be collected.

A member disagreed on the concept that historical information cannot be relied on. Historical results should not be completely ignored but instead used as another piece of information. In certain circumstances, the historical results can be used. The Vice Chair voiced disagreement with this statement and commented that in a scenario where a patient has had a transfusion and the current results are in question, the historical results should not be the only thing being relied on.

An SME clarified that the historical information would be important to use, but clinical decisions should not be based on this information alone. The Vice Chair agreed with this and added in the context of OPTN policy, members are required to use two sources for ABO determination.

The Committee Chair stated that there is a standard of practice in regards to specimens being used, but this is due to the change in antibodies and sensitization. Blood types do not change. Unless there was a blood marrow transplant, the blood type from ten years ago would be the blood type. In this setting and for the workgroup's purposes, if there is a historical sample, and then a current sample that is consistent with the requirement to having two samples, there should be consideration to using a historic sample if one of the current samples is pre blood transfusion.

Another SME stated that when using an electronic crossmatch process, blood banks cannot solely rely on two historical samples. One sample can be historic but the other sample has to be recent. There is an extremely common error where blood is being drawn by mislabeling. If the sample is mislabeled, and someone is entering the lab numerous times, a sample is always taken to reduce errors. Even though there is an understanding the the blood type does not change, samples are drawn every time a patient comes to confirm and avoid a wrong blood and tube error that could result in an ABO mismatched transfusion.

The SME stated if there is only historical data and no current samples that can be trusted, the recommendation should be to use one of the alternative methods to determine the typing. There is testing that can be done and is reliable that can still be done and should be used when a current sample is in question. The Vice Chair stated that in the case that there is a donor who is transfused and there is a historical sample that could have been typed in error, it can be reverted to an alternate testing methodology to resolve any discrepant results. Rather than label the blood type AB, there should be a recommendation to do additional testing.

A member asked how quickly the alternative testing methods would take. The Vice Chair clarified that according to the SME's presentation during the last workgroup's discussion, it can take about 90 minutes. The testing is based on white cells rather than red cells. The reliability rate of this testing is extremely high. The Vice Chair proposed that there should be mention of using one of the alternative methodologies that does not rely on red blood cells if there is doubt in the results.

The Vice Chair continued to review the established goals and recommended that there should be example scenarios included in the guidance document. For an educational document and in discussing massive transfusions, the information should be more granular. In regards to the MPSC's question about reliance of historical data, this information would be considered, but would not be determined to make clinical decisions.

The Vice Chair asked if there were any resources that discusses whether there is a time when a person would revert back to their original blood type. An SME suggested that the focus should not be solely on massive transfusions as it will already be defined. There should be discussion regarding out of ABO type transfusions. There can be discrepancies and mixed fields that would interfere in some way. Another SME agreed with this and stated that there is not a discreet timeline and instead is a gradual change where mixed fields can be observed early on after a small number of transfusions.

The Vice Chair asked that in a trauma situation, if there is time to draw two samples, and the samples are taken from different times, would this be accurate? An SME stated that most of the time, if there is not a historical sample on file, and a massive transfusion is being performed, the blood bank does require two samples. The Vice Chair stated that the focus will shift away from

massive transfusion and move towards donors that have received transfusions. The workgroup members agreed with this.

The Vice Chair reviewed *OPTN Policy 2.6.A: Deceased Donor Blood Type Determination* with workgroup members. The Vice Chair recommended to revise this policy to address when discrepant results are present, additional testing should be conducted. Whether it is appropriate in policy or the guidance document, there should be steps provided that members could take.

A member asked if policy requires all blood type results to be documented to the recipient when offering the organ. The Vice Chair stated that it is believed that most programs have these results available and can share this information. It is not believed that policy requires OPOs to provide all ABO results performed on DonorNet. The policy language will be reviewed further. The Vice Chair asked workgroup members their thoughts on whether there should be a requirement for alternative testing by molecular DNA based testing? Should this be restrictive or should a requirement be put in?

A member asked if there was mention of labeling as a blood type through PCR methodology is allowed. An SME stated that this was not the case and that it is research use only, but it can be performed through CLIA approved laboratories. The member continued that this would present many limitations and although this information can be put in the guidance document, it should not be included in policy as it has not actually been approved due to this testing still being in research.

An SME stated that in regards to the research use only test, the FDA has stated that these specific tests can not be the sole determinant for clinical decision, but can be used in part of making a clinical decision. The member agreed with this and stated that then this type of methodology would be just be a source of information like the historical blood type.

The Vice Chair stated that this would then present the question of when an OPO comes across two discrepant results, what would be an acceptable substitute and how prescriptive should the policy proposal be? Given the circumstances, any additional testing that could be done to transplant the organs more safely, the workgroup should consider being somewhat prescriptive.

3. Next Steps

The Vice Chair discussed next steps of the ABO project with the workgroup.

Summary of Discussion:

The Vice Chair summarized the next steps of the ABO project with the workgroup. The ABO project form will be revised and submitted to the Policy Oversight Committee (POC), where the project will be reviewed and voted on during the next POC meeting.

The guidance document sections will be divided for workgroup members to begin drafting and policy language changes will be made to be discussed with workgroup members during an upcoming meeting.

The meeting was adjourned.

Upcoming Meeting

- July 9, 2019 (Teleconference)