



America's Blood Centers®
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December 13, 2024

Center for Evidence and Practice Improvement
Agency for Healthcare Research and Quality
ATTN: EPC SEADs Coordinator
5600 Fishers Lane
Mail Stop 06E53A
Rockville, MD 20857

Submitted via email: epc@ahrq.hhs.gov

Re: AHRQ Request for Supplemental Evidence and Data Submission on Prehospital EMS Blood Transfusion and Fluid Interventions for Hemorrhagic Shock

Dear EPC SEADs Coordinator:

America's Blood Centers (ABC) is the national organization bringing together community-based, independent blood centers. Our member organizations operate more than 600 blood collection sites providing close to 60 percent of the U.S., and a quarter of the Canadian, blood supply. These blood centers serve more than 150 million people and provide blood products and services to more than 3,500 hospitals and healthcare facilities across North America. All ABC U.S. members are licensed and regulated by the U.S. Food and Drug Administration (FDA).

Blood centers play a unique role in prehospital blood transfusion. Our member centers collect, prepare, and supply the blood required for transfusions. Blood centers must recruit the necessary donors to produce the blood products for transfusion by EMS in addition to the blood products already in use by other providers. As a result, blood centers are particularly interested in minimizing blood wastage and ensuring a sufficient supply of the donors needed for the products generally transfused by EMS. Additionally, many blood centers act as the transfusion service, ensure regulatory compliance, and provide other support services to EMS providing transfusions.

ABC commends the Agency for Healthcare Research and Quality (AHRQ) for commissioning the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Prehospital EMS Blood Transfusion and Fluid Interventions for Hemorrhagic Shock*.

I. ABC prehospital blood utilization surveys demonstrate gradual increase in blood center participation as well as impediments.

AHRQ is seeking completed studies that organizations have sponsored on the topic of prehospital blood transfusion. As part of our advocacy work, ABC is committed to collecting and analyzing valuable information about trends in prehospital blood utilization. To this end, each year over the last three years (2022-2024), ABC has collected and analyzed information about trends in prehospital blood information through a Prehospital Blood Utilization survey of our members.

The results of our surveys show that, since 2022, there has been a slight increase in ABC members' participation in prehospital transfusion programs. In 2022, 18 members reported participating in a prehospital program (10 air service, 7 air and ground services combined, and 1 supplied a hospital-based program). The total number rose to 25 in 2023 (13 air service, 11 air and ground services combined, and 1 supplied a hospital-based program), and in 2024, that number continued to increase with 34 members participating in a prehospital program (14 air service, 18 air and ground services combined, and 2 supplied hospital-based programs).

The number of units collected, processed, and supplied by ABC members to support prehospital programs has dramatically increased from 2022 to 2024. When the survey was first launched in 2022, the total number of products was not separated out by type. Instead, blood center members were asked how many blood product units in total were distributed to a prehospital program. In 2022, the total number of units supplied to prehospital programs was 2,474. This number included low titer O whole blood (LTOWB), O positive and O negative red blood cells (RBC), and AB and A liquid plasma. In 2023, members reported distributing a total of 14,882 units, and in 2024, that number increased to 32,202. The products most often used for prehospital blood programs are LTOWB (5015 units in 2023 and 13,452 units in 2024) and type A liquid plasma (4600 units in 2023 and 10,646 units in 2024).

The reported impediments to implementing and maintaining a prehospital blood program were similar across the ABC membership. The survey revealed that, from 2022 to 2024, little has changed regarding the difficulties blood centers face in contributing to the prehospital transfusion space. The most consistent barrier for blood centers is lack of funding, and operational costs at blood centers are already strained. Those responding to the survey stated that the following would create significant burden to their operations: The difficulty of managing separate inventories, recruiting donors specifically for prehospital blood, the costs of testing (titer testing of whole blood units) and manufacturing (additional blood bag kits needed for whole blood), the cost of providing quality and regulatory oversight, and the overall costs of maintaining a prehospital program by a blood center. Additional barriers that contribute to the reluctance by blood centers to implement a prehospital blood program are the risk of product wastage and the logistical burdens of rotating product between locations to prevent wastage.

II. Clarification is needed on the definition of “Group O Whole Blood.”

Before embarking on funding additional studies, it is worthwhile clarifying what exactly is meant by “Group O whole blood.”

- 1) Leukoreduced vs. Not leukoreduced.
 - a. Programs in Texas and the Mayo Clinic are using non-leukoreduced whole blood which exchanges the benefit of extended shelf life for modestly increased rates of both immediate febrile reaction and higher rates of HLA sensitization. Furthermore, if drawn into a citrate phosphate dextrose adenine (CPDA) anticoagulant solution, there may be an issue in the future, as many/most manufacturers will cease production when switching to DEHP free bag systems.
 - b. If leukoreduced, it is leukoreduced using the “platelet-sparing” filter produced by Terumo Blood and Cell Technologies, which allows many/most of the platelets to be preserved, but at the expense of going into a CPDA anticoagulant with a shorter expiration date of 21 days. One ABC blood center provides this product to air ambulance systems in very remote locations, precluding the cycling out of units and a resultant higher than 50% outdate, which is why they cannot provide O negative as this would severely impact O negative supply for the entire region.
- 2) “Low titer”

- a. While there is now proficiency testing for “low titer” testing, there are many different cutoff values and many different titer methods.
- 3) Age of unit
 - a. While studies at Hoxworth Blood Center have documented durable platelet function as measured on thromboelastography (TEG) out to at least 21 days, there is concern that platelet numbers and function may significantly deteriorate with storage beyond three weeks. Will this be a factor studied in the proposed analyses?
- 4) Rh (D) positive vs. Rh (D) negative
 - a. While most blood collection agencies do not have sufficient group O Rh (D) negative to allow large scale production of Group O Rh (D) negative whole blood, is there a role for Rh (D) negative units once the patient has arrived at the hospital, either components or whole blood?

Finally, a revision of the bag system to use an anticoagulant that would allow storage longer than 21 days that would preserve function of both RBC and platelets is worth further study, especially as new DEHP free bag systems are developed.

ABC appreciates the opportunity to provide additional information to AHRQ to assist in the EPC Program’s review of the evidence for *Prehospital EMS Blood Transfusion and Fluid Interventions for Hemorrhagic Shock*. If you have any questions or require additional information, please contact Justine Coffey, Director of Regulatory Affairs and Public Policy (jcoffey@americasblood.org).

Thank you for your collaborative work to ensure a safe, adequate, and available blood supply.

Sincerely yours,



Kate Fry, MBA, CAE
Chief Executive Officer