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CLINICAL CONCEPTS

Emergency Medical Services

Implementation of a prehospital whole blood program: Lessons learned

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Abstract

Early blood administration by Emergency Medical Services (EMS) to patients suffering from hemorrhagic shock improves outcomes. Prehospital blood programs represent an invaluable resuscitation capability that directly addresses hemorrhagic shock and mitigates subsequent multiple organ dysfunction syndrome. Prehospital blood programs must be thoughtfully planned, have multiple safeguards, ensure adequate training and credentialing processes, and be responsible stewards of blood resources. According to the 2022 best practices model by Yazer et al, the four key pillars of a successful prehospital program include the following: (1) the rationale for the use and a description of blood products that can be transfused in the prehospital setting, (2) storage of blood products outside the hospital blood bank and how to move them to the patient in the prehospital setting, (3) prehospital transfusion criteria and administration personnel, and (4) documentation of prehospital transfusion and handover to the hospital team. This concepts paper describes our operational experience using these four pillars to make Maryland's inaugural prehospital ground-based low-titer O-positive whole blood program successful. These lessons learned may inform other EMS systems as they establish prehospital blood programs to help improve outcomes and enhance mass casualty response.

1 | BACKGROUND

The legacy concept of the Golden Hour is often too long for the most critically ill and injured patients suffering from hemorrhagic shock.^{1,2} Early blood administration (ideally less than 35 min from injury) in severely injured trauma patients can increase survivability.³

Death from hemorrhagic shock may also occur from nontraumatic conditions, such as gastrointestinal bleeding, peripartum hemorrhage, hemodialysis graft rupture, and coagulopathic conditions.^{4,5} Prehospital patients in hemorrhagic shock who receive blood products in the field from Emergency Medical Services (EMS) have been shown to have improved outcomes.^{6–9} Prehospital blood programs represent an important resuscitation capability, as they directly address hemorrhagic shock, mitigate subsequent multiple organ dysfunction syndrome, and improve outcomes.

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As of September 2023, over 121 EMS systems in the United States carry blood products; most (>70%) use low-titer O-positive whole blood (LTO+WB), and more are expected as access to blood products increases.¹⁰ Best practices for prehospital blood programs include being well-planned and resourced, having multiple safeguards in place, adequate training and credentialing processes, and policies ensuring responsible stewardship of blood resources to minimize or eliminate product waste.¹¹

2 | PROGRAM OVERVIEW

The Maryland Institute for Emergency Medical Services Systems (MIEMSS) coordinates Maryland's statewide EMS system, including treatment protocols, an electronic medical record (EMR) and communications system, and many other functions. Howard County, Maryland, is in the middle of the Baltimore-Washington corridor and has a population of around 325,000. The Howard County Department of Fire and Rescue Services (HCDFRS) provides EMS in Howard County. The department comprises approximately 200 advanced life support and 700 basic life support career and volunteer EMS clinicians and responds to over 30,000 requests annually. We describe the lessons learned from Maryland's inaugural prehospital ground-based LTO+WB program, organized according to the four pillars highlighted in the 2022 best practices documented by Yazer et al, "Trauma, Hemostasis, and Oxygenation Research - Association for the Advancement of Blood and Biotherapies (formerly known as the American Association of Blood Banks) THOR-AABB Working Party Recommendations for a Prehospital Blood Product Transfusion Program." These four pillars include as follows: (1) the rationale for the use and a description of blood products that can be transfused in the prehospital setting; (2) storage of blood products outside the hospital blood bank and how to move them to the patient in the prehospital setting; (3) prehospital transfusion criteria and administration personnel; and (4) documentation of prehospital transfusion and handover to the hospital team.¹²

2.1 | Rationale for blood product use

2.1.1 Choosing low-titer O-positive blood

The hemostatic properties of whole blood (WB) are superior to standard component blood therapy of packed red blood cells, fresh frozen plasma, and platelets, as these components are more diluted, reducing overall oxygen-carrying capacity.¹³ Type O-positive blood is much more commonly available than O-negative, with only 7% of the United States population having an O-negative blood type, compared with 38% who are O-positive.¹⁴

To minimize the possibility of developing hemolytic diseases of the newborn, females of childbearing potential have historically been given O-negative blood in the event they are Rh-negative. The rate of RhDnegative patients who received urgent red blood cell transfusions with O RhD-positive red blood cell concentrates and had anti-D alloimmunization has been reported to be between 11.5 and 30.4%.¹⁵⁻¹⁹ Other studies have calculated the rate of hemolytic diseases of the fetus and newborn following RhD-positive red blood cell concentrates or LTO+WB to injured RhD-negative females of childbearing potential to be between 0.3 and 7%.²⁰⁻²² Newberry et al²³ demonstrated that with San Antonio's population of 1.5 million people, their program risked the alloimmunization of approximately one female of childbearing potential per year. Given Howard County's population of 350,000, the risk of alloimmunization could be extrapolated to approximately one female of childbearing potential per 4.25 years. In addition, the experiences from other prehospital LTO+WB programs have also demonstrated that only a small fraction of the patients will be Rh-negative females of childbearing potential and have described the risk of death from hemorrhage as far greater than the risk of isoimmunization.²⁴⁻²⁶

LTO+WB contains low levels of anti-A and anti-B antibodies, making it safer for administration and less likely to cause a transfusion reaction despite being Rh+.²⁷ The THOR-AABB guidelines reference IgM anti-A and Ant-B levels as <256 as low titer. The blood bank supplying the Howard County LTO+WB program (Inova Blood Services, Sterling, VA) uses a titer level of <128, which is comparable to other programs.²⁸ For example, the US Department of Defense and University of Texas San Antonio Health Sciences Center University Hospital use WB with antibody levels of <256, Cypress Creek (Texas) EMS reports using <150, and the University of Pittsburgh Medical Center uses <50.²⁹⁻³¹ The Food and Drug Administration licenses LTO+WB, an AABB-approved blood product for life-threatening situations when the patient's blood type is unknown. In 2021, MIEMSS enacted a clinical protocol for use by approved EMS agencies that aligns with the THOR-AABB guidelines.³² We reviewed the two prior years' HCD-FRS EMR data using the inclusion criteria identified in this protocol. We determined that approximately 50-75 HCDFRS patients per year could potentially be eligible to receive prehospital blood.

2.2 | Sourcing LTO+WB for prehospital use

Regulatory, administrative, and logistical barriers prevented EMS from receiving blood products from regional health system partners. A regional third-party blood blank with extensive multistate experience supporting EMS programs served as the program's blood supplier.³³ Our EMS system agreed to participate in semiannual blood drives.

2.3 Storage of blood products, deployment procedures, and access to the patient in the prehospital setting

Logistics, storage, and deployment procedures are essential for a safe and sustainable prehospital blood program. We chose a validated portable cold storage system, purpose-built for out-of-hospital blood storage and transportation (Credo, Peli Biothermal; Maple Grove, MN).³⁴,³⁵ Blood is stored continuously in portable coolers, which utilize reusable thermal panels to keep the blood between the required 1° C and 6° C for >24 h while in storage, per regulatory standards.³⁶ Temperature monitoring technology (TracableLIVE®; Webster, TX) provides continuous, real-time, mobile app-based monitoring and mobile device alerting.³⁷ These alerts are transmitted via the cloud in real-time to the smartphones of EMS supervisors on duty, the EMS operations leadership, and the EMS medical director group as push notifications, to allow for immediate recognition and mitigation of any temperature control issues. Colocated with each blood cooler is a kit containing blood administration equipment, including specialized filtered "Y" blood tubing, pressure infuser bags (used primarily for adult patients), the LifeFlow Plus® Volume Infuser (410 Medical; Durham, North Carolina USA), the Qin Flow Warrior Lite® Fluid Warmer (Quality in Flow; New Prague, Minnesota USA).

We mirrored a deployment strategy aligned with other high-acuity, low-occurrence EMS skills (such as Rapid Sequence Induction) in Howard County's EMS system. Limitations in blood product availability allowed for only one unit of LTO+WB to be placed on each of HCD-FRS' three supervisor vehicles. A fourth unit of blood is on the most centrally located EMS supervisor to facilitate immediate resupply if a unit is used. The long-term goal is for each supervisor's vehicle to carry two units of blood. The detailed program information is outlined in the Departmental LTO+WB policy (Appendix S2). This policy was the basis for our LTO+WB program's foundation and operating procedures.

2.4 Budget and finance considerations

The initial cost to equip each EMS supervisor vehicle and station was approximately \$6500 in 2023. Each unit of blood used costs \$550, and administration equipment was approximately \$375. The fluid warmers cost \$4600, and each disposable circuit costs \$87.50. Training costs, including salary support, were funded through existing budget lines and were estimated to be approximately \$225 per each of the 12 EMS supervisors assigned to the field. No salary support was needed for the six EMS supervisors on a daywork schedule, totaling approximately \$2700. Budget reallocations and grant funding enabled blood storage and administration equipment purchase and additional costs, including salaries for personnel training, training supplies, reserve equipment, and ongoing effort support for program administration. Estimated annual program costs are between \$46,250 and \$69,375 (50–75 patients/year × \$925/patient) and depend on blood utilization.

2.5 | Prehospital transfusion criteria and administration personnel training

The prior work by MIEMSS and the Maryland State Police Aviation Command (MSPAC), who provide the air medical transport for the state, laid the foundation for our statewide EMS system's prehospital blood administration protocol (Appendix S1).¹⁸ This protocol was developed following the review of other existing EMS systems' prehospital blood administration protocols and designed to be inclusive of hemorrhagic shock from both traumatic and medical etiologies. Having a prehospital clinical protocol in place, our team was able to focus on the logistical implementation and education of our clinicians. We identified early a need for educational interventions and materials to supplement prehospital clinicians' knowledge, skills, and abilities related to the topics surrounding blood product administration. The THOR network's robust training program served as the basis for the model we used to develop our hybrid asynchronous and in-person training program.

2.6 | Documentation of prehospital transfusion and handover to the hospital

Documentation of prehospital blood administration occurs via the prehospital EMR (ImageTrend Elite®; Lakeville, MN). This documentation aligns with the THOR-AABB recommendations and includes capturing pre- and posttransfusion vital signs, evidence of transfusion reaction, and details (including tracking numbers) of the blood product(s) administered. The EMS supervisor also takes a photo of the unit of blood sticker, which is added to the patient's prehospital record as an additional safeguard. Prehospital records are available in real-time as a PDF to all Maryland hospitals, including their blood banks, through the State's electronic health information exchange "Chesapeake Regional Information System for our Patients" (CRISP) and via the Image Trend Hospital Hub interface.

While enroute to the hospital, the prehospital team notifies the receiving hospital that blood has been administered as part of their standard radio report. Upon transfer of care, the supervisor has a face-to-face conversation with the treating attending physician to communicate the patient received uncross-matched LTO+WB and that the receiving hospital's blood bank should be notified. In addition, a green bracelet (Figure 1) is attached to the patient's wrist, indicating that prehospital blood was administered. The bag(s) of blood administered is given to the receiving hospital so they can be sent for crossmatching. Following the handoff of care, the supervisor notifies the on-call HCDFRS medical director, who follows up with the receiving facility.

Concerns for adverse reactions are immediately communicated to the treating physician and the on-call HCDFRS medical director, who will then contact the supplying blood bank medical director. If LTO+WB is given to a female of childbearing potential, the receiving physician is notified, and it is recommended that the hospital's blood bank be engaged to guide further management. The HCDFRS Office of the Chief Medical Officer follows up on the patient's hospital course and outcome. This information is communicated to the treating EMS clinicians, and the case is reviewed during a monthly case conference. An internal database (Table 1) is maintained for outcome tracking and program quality assurance.

3 | LESSONS LEARNED

 Protocol development: Establishing an EMS protocol for blood product administration should align with best practices and integrate with regional partner agencies and health systems.

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TABLE 1 Howard County Department of Fire and Rescue Services

prehospital blood administration internal tracking database elements.

WHOLE HOWARD FIRE & COUNTY BLOOD RESCUE

FIGURF 1 Howard County Department of Fire and Rescue Services (HCDFRS) blood program bracelet.

Date
HC incident #
MRN
LTO+WB blood unit #
Age
Biologic sex (male or female)
Nature (medical or trauma)
Estimated blood loss (mL)
Field BP Nadir (mmHg)
Field Shock Index
Highest EMS HR (BPM)
Shock Index after first unit administered
Total number of units given (number)
Additional blood given in ED (yes/no)
Nadir hemoglobin (mg/dL)
Blood type (A/B/O) Rh factor (+/–)
Antibodies present yes/no)
Alive upon hospital arrival (yes/no)
Alive at 6 h (yes/no)
Alive at 24 h (yes/no)
Disposition (admitted/transferred/discharged/deceased)
Notes (free text)

Abbreviations: BPM, beats per minute; ED, emergency department; EMS HR, Emergency Medical Services heart rate; HC, Howard County; LTO+WB, low-titer O-positive whole blood.

- 2. Clinical needs assessment: Conducting an early needs assessment and impact analysis is crucial to securing stakeholder engagement, establishing a budget, and planning logistics.
- 3. Education and awareness: Ensuring our regional healthcare workforce colleagues were aware of clinical resources, academic references, and outcomes data from other prehospital WB programs was vital.
- 4. Sourcing blood products: Finding a supplier of LTO+WB was the bottleneck. Once we found this partner, we proactively involved them in our EMS system's blood program planning. This was essential to the execution of clinical, regulatory, contractual, and financial tasks related to the project.
- 5. Health system collaboration: Although our hospital partners could not supply blood for our program, they remained essential part-

ners in our program; specifically, for the continuity and coordination of care and clinical outcomes.

- 6. Blood resource conservation and stewardship: Minimizing waste of expired blood products is morally necessary and logistically essential. We were fortunate to partner with a blood provider who embraced returning blood products on day 14 (within the 35-day expiration window) to allow ample opportunity for redeployment within the healthcare system. Strategies should incorporate the least amount of blood products necessary to cover a geographic region appropriately.
- 7. Establish a budget and secure funding: Building a prehospital blood program requires startup funding to acquire essential equipment and supplies. When using grant funding, it is essential to work closely with procurement, finance, and grant specialists to satisfy all specific requirements and terms. Other additional costs include salaries for personnel training, ongoing effort support for program administration, and ongoing costs for program sustainment.
- 8. Collaboration is key: Planning for a prehospital blood program should incorporate other agencies' best practices and experiences when possible. Project leads allowed us to lay the foreground to engage external stakeholders, including hospitals, mutual aid partners, state and regulatory officials, and community organizations, facilitating effective and transparent communication. For example, in Maryland, state EMS leadership, in partnership with the MSPAC, laid the foundational work for prehospital blood administration. Ensuring our program's interoperability with MSPAC was essential for early success. In another example, collaboration was also necessary among the religious community to address concerns about receiving and administering blood products.
- 9. Building and testing a cold storage chain: A reliable cold storage chain is fundamental for any prehospital program. To ensure our cold storage chain was tested and validated, EMS supervisors carried Credo coolers containing bags of IV fluid for several weeks before the program launch. This allowed us to practice daily changeover procedures, monitor temperature variations, and ensure our ability to maintain a cold storage chain. Once this was mastered, the blood bank provided us with expired blood to continue testing this process. A cellular hotspot was added to each blood bag to ensure continuous communication and avoid a gap in the connectivity of the temperature monitoring system. We welcome the next generation of blood cooler technologies incorporating this functionality.
- 10. Collaboration between medical direction, field operations, and training groups: Program development and implementation necessitated broad internal stakeholder engagement and collaboration. We included representation from HCDFRS's field operations,

education and training, and medical direction leadership. This collaboration allowed for the harmonization and parallel development of policy, operating procedures, and training material. Policies from other blood programs were reviewed, and best practices were identified for inclusion in our program.

- 11. Training and credentialing; program development and implementation: We curated publicly available content from prehospital training programs to develop our prehospital blood administration training curriculum. This was meant to be both clinical and operational. Key concepts included avoiding transport delays to initiate blood administration, awareness of indications and impact, and the procedural processes surrounding blood storage, transport, and administration. This training program also included considerations for individuals with varying religious beliefs on the use of blood. Formative knowledge assessments and technical competencies for clinical procedures were also established, along with evaluation rubrics for credentialing.
- 12. Engage local hospitals, especially nontrauma centers: Critically ill patients may also be brought to community hospitals for stabilization, especially those who have non traumatic etiologies. Therefore, we found it especially helpful to partner with community hospital leadership and develop a list of frequently asked questions, as part of community awareness efforts, that is publicly available on the county's website (https://www.howardcountymd.gov/fire-and-rescue-services/whole-blood-program).
- 13. Anticipate and embrace apprehension from hospital blood banks: Prehospital blood administration programs are evolving, and many hospital blood banks remain minimally familiar with their existence. Administrative safeguards and external regulations surrounding transfusion medicine often result in apprehension and concern from hospital blood banks. Everyone shares the goal of improving patient outcomes and maintaining the highest degree of patient safety. Therefore, collaboration is needed to streamline process development, build case review infrastructure, and track outcomes. If consensus cannot be reached, engaging a third party, such as a state EMS agency, professional organizations, and/or national coalitions, is recommended.

4 | CONCLUSION

Prehospital blood products, including LTO+WB, demonstrate great promise for improving the survival of patients suffering from hemorrhagic shock. This manuscript describes the multifaceted components and lessons learned from our program's implementation. Maryland's statewide approach to EMS protocol development and system organization played a crucial role in removing obstacles to implementation by fostering agreement on key elements. For instance, the prehospital blood administration protocol and all other EMS protocols had to be approved by the State EMS Board and the State Emergency Medical Services Advisory Committee. This approach guaranteed that diverse perspectives from the emergency healthcare system were considered. Despite obtaining widespread support and consensus, it remained

essential to actively involve local hospitals, particularly those not designated as trauma centers. EMS systems in other regions, which may have greater local autonomy, should prioritize allocating sufficient time and resources to garner early stakeholder support during the program planning phases. Given the variability between EMS systems, others will experience their lessons learned. Prehospital blood programs must be integrated into their community's healthcare infrastructure, and include patient-centered, outcome-informed, collaborative relationships. We hope these lessons learned will assist other EMS systems in bringing life-saving prehospital blood administration to their communities.

CONFLICT OF INTEREST STATEMENT

M. J. L. is the noncompensated Chairperson of the nonprofit Stop the Bleed Coalition. M. J. L. and A. M. M. are consultants for Stryker Medical Education. The remaining authors have no conflicts of interest relevant to this article to disclose.

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6 of 6

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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