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## Removing the barriers to prehospital blood: A roadmap to success

Randall M. Schaefer, DNP, Eric A. Bank, AS, Jon R. Krohmer, MD, Andrew Haskell, PhD, Audra L. Taylor, MS, Donald H. Jenkins, MD, and John B. Holcomb, MD, *New Braunfels, Texas*

**ABSTRACT:** This review describes the necessity, evolution, and current state of prehospital blood programs in the United States. Less than 1% of 9-1-1 ground emergency medical service agencies have been able to successfully implement prehospital blood transfusions as part of a resuscitation strategy for patients in hemorrhagic shock despite estimates that annually between 54,000 and 900,000 patients may benefit from its use. The use of prehospital blood transfusions as a tool for managing hemorrhagic shock has barriers to overcome to ensure it becomes widely available to patients throughout the United States. Barriers include (1) current state Emergency Medical Services clinicians' scope of practice limitations; (2) program costs and reimbursement of blood products; (3) no centralized data collection process for prehospital hemorrhagic shock and patient outcomes; (4) collaboration between prehospital agencies, blood suppliers, and hospital clinicians and transfusion service activities. The following article identifies barriers and a proposed roadmap to reduce death due to prehospital hemorrhage. (*J Trauma Acute Care Surg.* 2024;97: S138–S144. Copyright © 2024 The Author(s). Published by Wolters Kluwer Health, Inc. on behalf of the American Association for the Surgery of Trauma.)

**KEY WORDS:** Blood; emergency medical services; hemorrhagic shock; prehospital.

The National Academy of Science, Engineering, and Medicine report “A National Trauma Care System: Integrating Military and Civilian Trauma Systems to Achieve Zero Preventable Deaths After Injury” (2016) challenged the US government to meet a national goal of Zero Preventable Deaths After Injury.<sup>1</sup> The National Highway Traffic Safety Administration (NHTSA) has also called for a strategy for zero preventable roadway deaths.<sup>2</sup> Despite efforts to implement improved standards of prehospital care, trauma remains the leading cause of death in people aged 1 year to 44 years, with hemorrhage being the most prominent reason for those preventable deaths.<sup>3</sup> Based on hemodynamic instability upon hospital arrival, studies estimate that annually, between 54,000 and 900,000 patients may benefit from prehospital blood transfusions (PHBT).<sup>4</sup> The following article describes the evolution and current implementation of PHBTs in the United States, identifies four important barriers to wider adoption, and a proposed roadmap to reduce death due to prehospital hemorrhage.

One essential battlefield tool that has yet to be widely adopted in civilian practice is the early use of blood transfusions by 9-1-1 ground emergency medical services (EMS). Through

the battle-proven lessons of military medicine, recent conflicts have demonstrated that the early use of blood products near the point of injury or while en route to a medical treatment facility has decreased mortality and increased survivability.<sup>5</sup> These results have been replicated in the civilian studies, showing decreased death rates when blood products are transfused within minutes of injury.<sup>6,7</sup>

Blood products have been used by civilian helicopter emergency medical services (HEMS) and ground agencies during interfacility critical care transports since the 1980s with New York becoming the last state to approve HEMS use.<sup>8</sup> In 2014, prehospital advocates in Houston, Texas asked the question, “If the military medics can safely transfuse prehospital blood products at the point of injury, and in an aircraft in a war zone, why can't we deliver blood products to critically injured trauma patients by ground EMS in the US?” After deliberate and careful coordination between the local Level I Trauma Center, the EMS agency, and the regional blood supplier, a pilot project placing packed red blood cells (PRBCs) and liquid plasma (LP) on ground ambulances was launched in Houston, Texas in 2016. With support from local rural hospitals directly providing the PRBCs from their hospital inventory, a small number of EMS agencies outside of Texas become early adopters (Fig. 1) (J. Jarrell, personal communications, July 25, 2023).

A balanced resuscitation of PRBCs, plasma, and platelets in a (1:1:1) ratio is the gold standard in the hospital setting during massive transfusion protocols.<sup>9,10</sup> Using a 1:1:1 transfusion strategy in the prehospital setting is not practical or sustainable due to logistics, various expiration dates of the three blood components, cold chain and platelet storage requirements, product availability, and associated costs. In 2017, the American Association of Blood Banks, now known as the Association for the Advancement of Blood and Biotherapies (AABB), approved Low Titer O Positive Whole Blood (LTO + WB) as an Emergency Release Blood Product, making it feasible for EMS agencies to implement prehospital blood programs with a product that provided all the components in one bag and reducing concerns about the logistics and costs of managing multiple blood product.<sup>11</sup> This transition

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From the Schaefer Consulting, LLC (R.M.S.), New Braunfels; Harris County Emergency Services District 48 (E.A.B.), Katy, Texas; Department of Emergency Medicine (J.R.K.), College of Human Medicine, Michigan State University, Michigan; Oak Ridge Institute for Science and Education Fellow, Biomedical and Advanced Research and Development Authority (A.H.), Washington, District of Columbia; South Texas Blood & Tissue, BioBridge Global (A.L.T.), San Antonio, Texas; Department of Surgery (D.H.J.), University of Texas Health San Antonio, San Antonio, Texas; and Division of Trauma and Acute Care Surgery, Department of Surgery (J.B.H.), University of Alabama at Birmingham, Birmingham, Alabama.

Address for correspondence: Randall M. Schaefer, DNP, 28742 Sierra Drive, New Braunfels, TX 78132; email: randi.schaefer@schaeferconsulting.net.

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**Figure 1.** 9-1-1 ground emergency medical service prehospital blood agencies from 2016 to 2018.

allowed for a conversion of the Houston Blood Ground Program to the use of LTOWB in 2017 and a scaled-up response in South Texas starting in late 2018.<sup>12</sup>

According to the 2020 National Association of State Emergency Medical Services Officials (NASEMSO) Assessment, there are approximately 11,450 ground EMS agencies that provide 9-1-1 response with transport to an acute care hospital.<sup>13</sup> As of October 2023, it is estimated that 121 ground agencies in 24 states have successfully implemented PHBT as part of a comprehensive prehospital damage-control resuscitation strategy (Fig. 2). While the numbers are growing, this only accounts for less than 1.00% of 9-1-1 EMS agencies in the United States using this proven lifesaving intervention. Texas ( $n = 42$ ), North Carolina ( $n = 13$ ), and Virginia ( $n = 9$ ) have the highest implementation rates. California has one ground EMS agency using PHBT, an Army installation that only serves Ft. Hunter-Liggett and falls under military clinical protocols with an active-duty service member EMS Medical Director.<sup>14</sup> Not included in the NASEMSO data set are Office of the EMS Medical Director Vehicles, Physician Response Vehicles, or Law Enforcement Agencies (to include Tactical EMS teams). However, they are rapidly adding PHBT capabilities to their teams. Since there is not a comprehensive registry that meshes prehospital

blood transfusion with clinical outcomes, these numbers were obtained through the authors' personal knowledge, social media content, previous surveys, and Internet searches (Table 1). Despite Level I data supporting PHBT as an effective lifesaving intervention, the implementation has been slow and limited to geographic clusters in the United States. Suburban and rural agencies have adopted PHBT at a faster rate than their urban counterparts for a variety of reasons, largely financial and perceived minimal benefit given faster transport times to hospitals. Despite data showing that mortality in patients with torso penetrating trauma increases within 15 minutes after injury, challenges remain in metropolitan adoption.<sup>15</sup> Data are emerging that PHBTs, when part of an advanced resuscitative care bundle, are essential in decreasing in-hospital mortality in fast-paced urban systems.<sup>16</sup> While the initial implementation emphasis was focused on penetrating and blunt trauma, the use of prehospital blood for medical and non-trauma hemorrhagic shock accounts for 40% to 60% of patients in urban, suburban, and rural areas.<sup>17,18</sup>

Of the 1% of agencies carrying blood products, most use LTOWB (73%) (Fig. 3). In geographical regions where LTOWB is unavailable, PRBCs and LP are used individually or concurrently. One region in North Carolina will use either LTO + WB, LTO-WB, LP, or PRBCs depending on the availability of



**Figure 2.** 9-1-1 ground emergency medical services prehospital blood agencies as of October 2023.

**TABLE 1.** Type of 9-1-1 Ground Response With Prehospital Blood Capabilities

	Total Agencies (N = 121)
Third-service EMS*	52
Fire-based EMS**	43
Hospital-based EMS†	10
Office of the EMS medical director/physician response vehicle‡	8
Privately owned EMS§	5
Law enforcement¶	3

\*Municipal/government EMS service (not within fire or police services).  
 \*\*Municipal/government operated within the fire department.  
 †Owned and/or operated by a hospital to provide 9-1-1 response.  
 ‡EMS medical direction response vehicles within a service entity, operating at the physician level.  
 §Nongovernment entity providing 9-1-1 response (may be for-profit, not-for-profit, or volunteer).  
 ¶Paramedic level providers within a law enforcement agency.

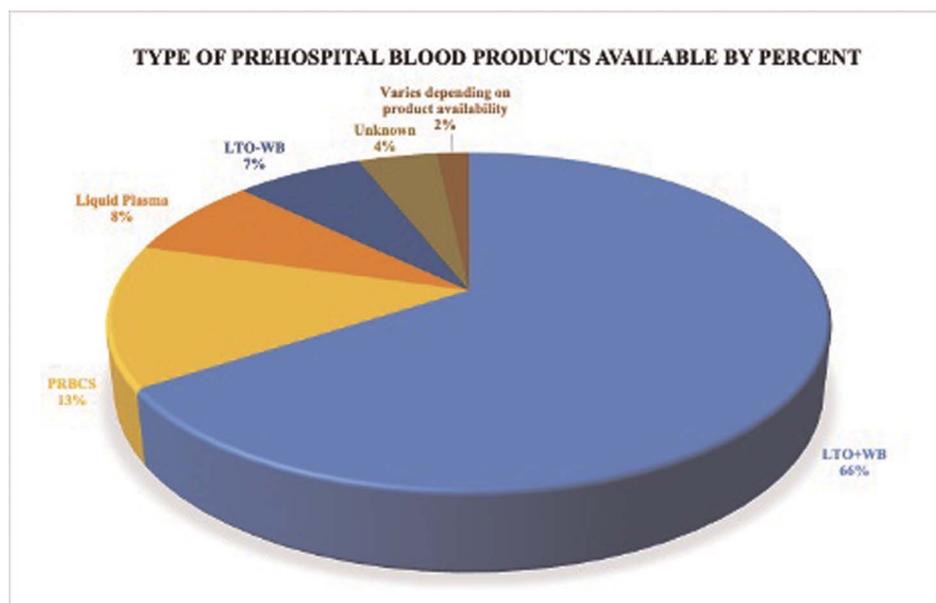
products provided by their Regional Trauma Center (C. Warren, personal communication, July 25, 2023).

**PREHOSPITAL BLOOD PRODUCT SUPPLY**

There are no national databases linking patients receiving PHBT to hospital outcomes, so accurate national data are difficult to report. Few research articles have described best practices and models for optimal prehospital blood management. To understand management of PHBT programs, prehospital agencies need a firm understanding of the blood industry roles (and vice versa).<sup>19</sup> For the purposes of this article, a blood supplier is responsible for donor collection, manufacturing, and distributing blood products to hospitals or other locations. A hospital transfusion service ensures that blood products within its organization are managed and transfused within regulatory guidance to include required compatibility testing ensuring that additional

considerations are met and have active participation in the resolution of transfusion reactions. As of October 2023, prehospital blood has been primarily sourced by independent regional blood suppliers or provided directly from a hospital's transfusion service. Program management depends on the types of products available for sale or from where the blood products are sourced. The following models are variously used throughout the country:

1. The Blood Supplier and EMS agency have a direct vendor/customer contract. This accounts for approximately 60% of programs. The following represent the variations in these types of contracts:
  - a. Blood products are sold to an EMS agency with no Return Privileges. Products are discarded upon expiration. The EMS agency pays for all used and unused blood products.
  - b. EMS has the blood products for an agreed-upon timeframe, generally between 5 and 21 days. This timeframe depends on the product type and the preservative used in the collection bag. The following represent the final dispositions of the unused blood products in the EMS systems.
    - i. After ensuring proper cold chain storage, the EMS agency can return it to the Blood Supplier for an account credit. It is then sold to a hospital and used as a short-date product. This is known as a "Rotation Model." It allows lower-use sites to send blood products to hospitals where they are more likely to be used before product expiration.<sup>12</sup>
    - ii. LTOWB is returned to the Blood Supplier and separated into components as appropriate.
  - c. Law enforcement tactical EMS teams will pick up the product(s) from a Blood Supplier for the specific duration of a mission and return it if unused.
2. A local (Level III/IV) or regional hospital (Level I/Level II) transfusion service provides the EMS agency blood products from its internal inventory.<sup>20,21</sup> Blood products that remain



**Figure 3.** Type of blood products provided to 9-1-1 ground emergency medical services agencies from blood suppliers or hospitals.

within identified criteria can be returned to the hospital's transfusion service before expiration.

3. In rural areas or where it is not practical for the Blood Supplier or EMS to do a direct delivery or exchange, a Blood Supplier can take it to a local hospital or another location they already serve and hold it until the EMS agency can pick it up. The blood products do not come from the hospital inventory. This method helps decrease the shipping and courier costs associated with moving blood products around the area (J Cook & David Long, personal communication, July 25, 2023).

## REMOVING THE BARRIERS TO IMPLEMENTATION

The civilian adoption of PHBT as a tool for managing hemorrhagic shock still has barriers to overcome to ensure it becomes widely available to patients throughout the US. Barriers include (1) current state EMS clinicians' scope of practice limitations; (2) program costs and reimbursement for blood products; (3) no centralized data collection process for prehospital hemorrhagic shock and patient outcomes; (4) collaboration between prehospital agencies, blood suppliers, and hospital clinicians and transfusion services. The following identifies barriers and a proposed roadmap to reduce death due to prehospital hemorrhage.

### STATE SCOPE OF PRACTICE LIMITATIONS

In the United States, the National EMS Paramedic Scope of Practice model is funded by the Department of Transportation, NHTSA, Office of EMS and the Department of Health and Human Services Health Resources Services Administration EMS for Children (EMSC) program under contract to the NASEMSO to serve as a guideline and template for states.<sup>22</sup> It is up to each state to define the scope of practice specifically for those clinicians in that state. While some states allow paramedics to monitor a blood transfusion already started, many prohibit the initiation without a registered nurse or physician present.

As innovators in PHBT, Texas and Florida, did not have this barrier due to its Delegated Practice Model that does not rely on State approval or National EMS Guidelines and defers medical authority to the local EMS Medical Director. States have taken various approaches to overcome Scope of Practice challenges. Georgia has implemented a pilot program incorporating the initiation of PHBTs as a Post-Licensure Skill.<sup>20</sup> Colorado approved a PHBT waiver program (S. Branney, personal correspondence, August 2023). Delaware received approval from state EMS leaders to develop an Operational Plan for Prehospital Blood Administration.<sup>23</sup> Pennsylvania received approval to allow paramedics to initiate transfusions.<sup>24</sup> Other states are in the process of various methods of approval of PHBT. With no centralized reporting processes existing to track scope of practice for specific clinical interventions, it is difficult to identify and track which model works best.

Support from professional practice organizations such as the National Association of EMS Physicians, the American College of Emergency Physicians, and the American College of Surgeons Committee on Trauma is critical and they have recently recognized the ability of paramedics to initiate a PHBT in-

dependently safely, rapidly, and effectively without on-scene physician or registered nurse oversight.<sup>25</sup>

## PROGRAM COSTS AND REIMBURSEMENT OF BLOOD PRODUCTS

Medicare currently reimburses ambulance services through bundled payments under a fee schedule, which varies in amount based on service level such as Basic Life Support or Advanced Life Support.<sup>26</sup> This model is followed by most private healthcare insurers nationally. The payment rates for the existing service levels are insufficient to cover adding the cost of blood transfusions in the field. The average market cost of a unit of PRBCs is \$200 to \$250, LP \$80 to \$100, and LTOWB is \$500 to \$600. Exact costs are difficult to obtain due to the use of non-disclosure agreements in the industry. With the initial capital investment of blood coolers or refrigerators, fluid warming equipment, rapid infusion devices, vascular access, and consumables, the average per-patient cost of a PHBT can be upwards of \$1000 depending on the product type and quantity used.<sup>27</sup> This cost is in addition to the other concurrent lifesaving interventions (i.e. hemorrhage control devices or advanced airway management devices). One urban EMS system reports that a complete "blood bundle" using PRBCs costs approximately \$900 (pediatric) and \$1,200 (adult) (B Salmeron, Prehospital Blood Transfusion Initiative Coalition Kick Off Meeting, November 13, 2023).

Ground agencies successfully implementing PHBT programs have utilized various methods to offset the initial start-up and ongoing costs. This includes federal and state special grant funding, county or city government support through budget allocation for programs, philanthropic foundation grants, incentive programs with blood suppliers, and ongoing hospital collaborations. Preapproved air and ground specialty critical care interfacility transports can successfully obtain reimbursement of blood transfusion related costs from insurance agencies. However, ground EMS and other agencies using blood products for 9-1-1 scene response internally absorb the operating costs to provide this high-quality care to their local communities. In systems where blood products are purchased and do not have return privileges or rotation hospital participation, this can add a significant budget burden. One midsized system reports non-reimbursable blood product costs of upwards of \$80,000 per year (D. Long, personal correspondence, December 2023). This approach is not sustainable and severely limits program adoption.

Agencies that already struggle to meet existing operation costs and ever-increasing budget constraints, such as those in underserved areas and at-risk populations, will not be able to access funding mechanisms to initiate and sustain a PHBT program. This disparity propagates the difference in outcomes seen between racial groups. Establishing programs and getting reimbursement coverage from government and commercial payers is imperative to ensuring the appropriate nationwide implementation of PHBT programs.

## DATA COLLECTION PROCESS FOR PREHOSPITAL HEMORRHAGIC SHOCK MANAGEMENT AND ASSOCIATED PATIENT OUTCOMES

Regional, state, and national data collection systems are already in place for cardiac, stroke, and in hospital trauma patients. No cohesive or collaborative processes are available for

understanding the management and outcomes of patients experiencing prehospital hemorrhagic shock.

The current mechanisms for understanding the impact of PHBT fall to the individual EMS agencies and their local hospital's ability to support research. This process is burdensome because many midsize and smaller EMS agencies cannot support staffing dedicated to data collection and analysis beyond local quality improvement/quality assurance programs. Emergency medical service agencies rely on hospitals' voluntary reporting of patient data and outcomes to them, which has vast degrees of successful collaboration across the country. Conversely, because of HIPAA concerns, trauma centers often have issues integrating prehospital data from multiple agencies into their Trauma Registries. Further challenges include that a substantial number of trauma patients in the country are cared for at non-trauma designated hospitals.<sup>28</sup>

Agencies with PHBT programs should actively engage with their local trauma centers to have their data recorded into a Trauma Registry. While this process facilitates and informs trauma care, it leaves a significant information gap on the emerging uses of PHBT for treating nontrauma patients experiencing hemorrhagic shock. Hospitals will need to consider methods to capture and report on these critical patient populations like peripartum, postpartum, or gastrointestinal bleeding.

The National Emergency Medical Services Information System (NEMSIS) is the voluntary national EMS data collection standard and provides the basis for reporting and recording clinical care in the prehospital setting. Although the data elements exist to report blood product use in the field, there needs to be more consistency among states and agencies in the level of detail reported for PHBT programs.<sup>29</sup> As PHBT programs become more common, additional clarification will be necessary for clinicians to report these interventions appropriately. For trauma patients, the NEMSIS data should be linked with the American College of Surgeons Trauma Quality Improvement System data registry, which will require additional federal funding.

### **COLLABORATION BETWEEN PREHOSPITAL AGENCIES, BLOOD SUPPLIERS, AND HOSPITAL CLINICIANS AND TRANSFUSION SERVICE ACTIVITIES**

Unlike cardiac or stroke prehospital lifesaving interventions, EMS agencies must wholly rely on support from the blood industry and/or hospitals to gain reliable access to blood products. When an agency attempts to start a PHBT program, they must first determine which of the methods best aligns with their local blood supplier. In many EMS systems, PHBT may be a low-frequency, high-impact intervention. As EMS strives to be good stewards of the blood supply, this will require active engagement by the blood supplier, hospital clinicians, and transfusion service to minimize discarding of products due to expiration. Systems using a blood product rotation model as described earlier have low discard rates due to blood product expiration (1–2%), assisted prehospital agencies in making PHBT programs affordable, and have allowed for expansion of programs.<sup>12,20,21</sup> Prehospital blood transfusion is associated with patients arriving at the hospital more stable and requiring

fewer hospital resources over time, including blood products, which yields cost savings to the hospital.<sup>30</sup>

Understanding the system impact of collaboration, the AABB is updating its 2018 “Standards for Out-of-Hospital Transfusion Administration Service” to include prehospital care to ensure maximum participation from blood suppliers and hospital transfusion services.<sup>31</sup> In addition to the leading transfusion accreditation agency providing compliance guidance, blood supplier associations, such as America's Blood Centers and Blood Centers of America, support their membership establishing collaborative PHBT programs.<sup>32</sup>

In urban areas, patients likely to benefit from this potentially lifesaving intervention are victims of increasing levels of violence. Penetrating trauma disproportionately affects people of color and people in lower-income areas.<sup>33</sup> Ground EMS is the primary response method to these incidents in densely populated areas, yet PHBT programs are not yet widely available. Preventable death due to hemorrhage is not limited to urban areas. With increasing closures of rural hospitals across the United States, EMS serves as the lifeline to get patients transported further distances to reach the appropriate level of care, and a PHBT will likely improve their survival.<sup>34</sup>

No “one size fits all” PHBT implementation model works across the county. Best practices indicate that regionally based programs meet each of these environments' unique needs. Collaborative efforts among stakeholders will enable broad participation by all emergency service models in all geographic settings to provide equal access to this lifesaving intervention. The goal is to give all hemorrhaging patients a blood transfusion where they need it, and when they need it, regardless of their ability to pay or socio-economic status.

Coalitions of prehospital blood advocates at a national level, such as the Prehospital Blood Transfusion Initiative Coalition ([www.prehospitaltransfusion.org](http://www.prehospitaltransfusion.org)), can provide a unifying voice of all interested stakeholders to ensure that disparities and inequities of prehospital care are highlighted to Federal agencies.

### **PHBT INNOVATION AND SUPPORTING NATIONAL READINESS AND RESPONSE**

Military conflict always results in advancements in medicine, and PHBT is one of those. Waiting for the next conflict for innovation and advancements is not acceptable when >30,000 of people are dying every year from prehospital hemorrhage in the United States. In a best-case scenario, much like the widespread access to hemorrhage control devices, PHBTs would be available to every citizen in the country through EMS, Law Enforcement, or other First Responders. However, some barriers will not be overcome due to the sheer geographic size of the United States, as well as the numbers and diversity of agency types. Alternative solutions are needed where current PHBT programs are not feasible.

Blood and pharmaceutical products that combat hemorrhagic shock must be low-cost, shelf-stable, and do not have strict cold-chain storage requirements. Advancing the concepts of bioengineered artificial RBC substitutes, dried plasma, platelets, and fibrinogen or synthetic whole blood that can be dried for long-term storage are envisioned for prehospital treatment of traumatic hemorrhage when cold-stored liquid blood products

are unavailable or undesirable.<sup>35,36</sup> These new products need to be developed, not only for the military, but also for civilian use. The same barriers to adoption as described for currently available blood products will remain without active and early engagement from all stakeholders.

Innovation is not only required to address the everyday causes of prehospital bleeding but will also support an enhanced national strategic preparedness plan when blood donors are not widely available, supply chains are disrupted, and strict cold chain management is not available during a national emergency. Management and availability of the blood supply is a national strategic health and safety issue. Rapid delivery of blood products to the scene, especially in rural or remote locations, is vital. The Department of Justice recently weighed the importance of blood availability at the scene after a mass shooting event.<sup>37</sup> A coordinated regional response of providing blood products to the scene within an hour of the elementary school shooting in Uvalde, Texas, was facilitated by the fact that several EMS agencies already have a robust network of PHBT programs in place.<sup>38</sup>

The successful scaling up of efforts during disasters and massive casualty incidents happen when the fundamental practices and principles of PHBT are used daily within a well-developed trauma system.<sup>39</sup> Unless changes in the availability of this lifesaving therapy are made, the health and safety of the country remain unnecessarily impeded.

## RECOMMENDATIONS FOR THE NEXT 5 YEARS TO 10 YEARS

As the field looks to the future, we think that several concepts need to be clearly articulated.

- (1) Prehospital agencies that want to include prehospital blood in clinical treatment protocols should be empowered to allow practice changes.
- (2) Blood suppliers must actively engage in innovative ways to modify current business practices to increase donor pools and manage currently available products that allow for the expansion of PHBT programs and disaster response. The success of Heroes In Arms program in San Antonio, Texas, which includes female donors, provides a template for others to follow.<sup>40</sup> Other hospitals and blood suppliers have adjusted donor scheduling and product-type collections to meet the flexible needs of EMS agencies (D. Hermelin, personal correspondence, November 7, 2023). When dedicated and prescreened donor pools exist, transitioning from tested cold stored products to untested fresh whole blood can be done during local or national disasters. The formation of “walking blood banks” should be used as a bridging measure until regular supply chains can be resumed. This is of the utmost importance in rural settings where blood deserts exist.<sup>41–43</sup>
- (3) Regional or state-level trauma systems must regularly engage with blood suppliers, hospitals, and EMS agencies so that when a disaster occurs, the response is a scaling up of routine activities. Blood suppliers should be included in local and state disaster planning and exercises.

Historically, during crisis events, blood suppliers focus on sending blood products to the hospital and managing the short-

term surges in donor collections. A paradigm shift is needed to encourage Blood Supplies to actively push blood products directly to the incident through the utilization of ground and helicopter EMS assets.<sup>44</sup>

- (4) To support all the above and sustain PHBT programs, commercial and government payers must approve reimbursement for this lifesaving intervention.

These four interventions, if implemented will serve to improve the survival of all patients suffering hemorrhagic shock, regardless of etiology.

## CONCLUSION

Enhancement of prehospital capabilities and clinical practice is needed to help achieve the national goal of zero prehospital preventable deaths due to hemorrhage. The use of PHBT for hemorrhagic shock requires a coordinated effort that transcends therapeutic interventions for treating and managing other injury and disease processes. Emergency medical services and other agencies wholly rely on collaboration with blood suppliers and hospitals to successfully implement PHBT programs. Federal, state, and local jurisdictions need to expand the paramedic scope of practice to include the initiation of blood products. Establishing reimbursement for this lifesaving intervention from government and commercial payers will stimulate implementation and sustainment. Collaboration at local, regional, and state levels between blood suppliers, EMS agencies, and hospitals is imperative for logistical, clinical, fiscal, and data collection needs. The availability and rapid deployment of blood products is a national healthcare and safety issue, especially during disasters and massive casualty incidents. Preventable death due to prehospital hemorrhage is substantial and impacts all persons across the country. By being innovative and scaling up the implementation of PHBTs across the county, we can prevent the deaths of countless patients with this lifesaving intervention.

## AUTHORSHIP

All authors have contributed significantly to and take public responsibility for its design, data acquisition, analysis, and interpretation of the data.

## DISCLOSURE

Conflicts of Interest: Author Disclosure forms have been supplied and are provided as Supplemental Digital Content (<http://links.lww.com/TA/D778>).

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