Prehospital Blood Transfusion Initiative Coalition

National EMS Advisory Council
August 9, 2023
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Among the 1504 patients, every 1-minute delay in prehospital resuscitation was associated with 2% increase in the odds of 30d mortality (p=0.03).

Bleeding patients need resuscitation initiated early.
Overview:
Prehospital Blood Transfusion Initiative
Coalition Vision, Strategy and Objectives

Bill Skillman
SVP,
Velico Medical, Inc.
Exsanguination remains the leading cause of preventable deaths among victims of trauma with nearly half of these patients dying in the prehospital setting.\textsuperscript{1,2}

Prehospital blood resuscitation is also clinically indicated for selected patients who hemorrhage from medical conditions (e.g., post-partum hemorrhage, abdominal bleeds) potentially doubling the number of patients who would benefit from field transfusions.

Individuals requiring blood transfusions in the field in most locations in the US do not have access to pre-hospital blood transfusions due to inadequate reimbursement policies and state by state scope of practice limitations.

Vision:
Prehospital blood products available to every medically appropriate bleeding patient;
Appropriate reimbursement to every provider

Mission:
Establish reimbursement coverage, from both government and commercial payors, for prehospital blood transfusions and
Ensure prehospital blood transfusion is included appropriately in the prehospital clinical scope of practice in all states and jurisdictions across the United States.
Build an industry-wide, collaborative initiative including medical groups, EMS trade associations, blood collectors

Elevate Federal awareness of the importance of prehospital transfusion

Drive Congressional support for reimbursement and scope of practice initiatives

Deliver a call to action for CMS and commercial payors

Build nationwide awareness of the critical importance of blood on board emergency vehicles
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The Case For Prehospital Blood Transfusion

John B. Holcomb, MD, FACS
COL (Ret) US Army
Professor of Surgery
University of Alabama at Birmingham and
Uniformed Services University of the Health Sciences, Bethesda MD
• Mil background WW1-WWII
• Crystalloid
• Mil again
• Hospital data
• Prehospital data
  • Funded by DoD
• Endorsement by .....

Overview
By the end of WWII Lyophilized Plasma Resuscitation + WB > 800,000 transfusions

**Figure 159.**—Administration of plasma on beach, only few feet from surf, to survivor of landing craft sunk off coast in first days of invasion of Normandy, June 1944.
Rapid progress in trauma care occurs during a war.

Damage control resuscitation addresses diagnosis and treatment of the entire lethal triad immediately upon admission.

• Stop bleeding
• Hypotensive resuscitation
• Minimize crystalloid
• 1:1:1 or whole blood
• Use plasma as the 1° resuscitation fluid
• Increased platelet use
• Reverse hypothermia and acidosis
• Hemostatic adjuncts
Conclusions

1. The preferred fluids for resuscitation of casualties in hemorrhagic shock, in descending order of preference, are:
   - Whole blood
   - 1:1:1 plasma, RBCs, and platelets
   - 1:1 plasma and RBCs
   - Reconstituted DP, liquid plasma, or thawed plasma alone or RBCs alone
   - Hextend
   - LR or Plasma-Lyte A
Lots of work over a long time by lots of people, Funded by DoD and NIH

Whole Blood vs Components Study
Frozen Blood vs Stored Blood

PROP:P:R
Prospective Randomized Optimum Platelet and Plasma Ratios
• DCR significantly improve outcomes in severely injured bleeding patients.

• After a review of the best available evidence, we recommend the use of a MT/DCR protocol in hospitals that manage such patients and recommend that the protocol target a high ratio of PLAS and PLT to RBC.

• This is best achieved by transfusing equal amounts of RBC, PLAS, and PLT during the early, empiric phase of resuscitation.
Association of Prehospital Blood Product Transfusion During Medical Evacuation of Combat Casualties in Afghanistan With Acute and 30-Day Survival  

JAMA, 2017

Stacy A. Shackelford, MD; Deborah J. del Junco, PhD; Nicole Powell-Dunford, MD; Edward L. Mazuchowski, MD, PhD; Jeffrey T. Howard, PhD; Russ S. Kotwal, MD, MPH; Jennifer Gurney, MD; Frank K. Butler Jr, MD; Kirby Gross, MD; Zsolt T. Stockinger, MD

• “Prehospital blood product transfusion in trauma care remains controversial due to poor-quality evidence and cost”

N = 505
5 vs 19% 24 hr mortality
11 vs 23% 30 day mortality
Prehospital Plasma during Air Medical Transport in Trauma Patients at Risk for Hemorrhagic Shock


NEJM 2018

N = 564 at 9 sites
23% vs 33% 30 day survival, p = 0.02
Diff at 3 hours, Including TBI
But What about Crystalloid?

90 cents versus $500
THE CELLULAR, METABOLIC, AND SYSTEMIC CONSEQUENCES OF
AGGRESSIVE FLUID RESUSCITATION STRATEGIES

Bryan A. Cotton, Jeffrey S. Guy, John A. Morris Jr, and Naji N. Abumrad
Department of General Surgery, Vanderbilt University School of Medicine, Nashville, TN


Although resuscitation guidelines for injured patients favor blood products, crystalloid resuscitation remains a mainstay in prehospital care.

Secondary study of the PROPPR data, N= 680

In regression analyses, each 500 mL of PHC was associated with increased ARDS, INR and PTT, and decreased hematocrit and platelet count (P < 0.05).

Prehospital resuscitation with crystalloid is highly variable across the US and correlates poorly with prehospital hemodynamics and injury characteristics.

Increased PHC volume is associated with greater anemia, coagulopathy, and increased risk of ARDS.
The National Emergency Medical Services Information System (NEMSIS) 2019 dataset was used to characterize prehospital blood product use among trauma patients. (n = 3,059,117)

The American College of Surgeons (ACS) Trauma Quality Programs (TQP) was used to calculate the proportion of ACS-verified trauma centers using whole blood (100% have components immediately available).

Only 208 (0.21%) of all hypotensive trauma patients received any blood product in the pre-hospital setting.

ACS-verified trauma centers transfusing whole blood was 24.5% (123/502) in first quarter of 2020.
Comprehensive, “Why and How to do” a prehospital blood program

Blood bankers, Surgeons, EM physicians, EMS clinicians

- Safety, credentialing, reporting
- Rationale for the use and description of blood products that can be transfused in the prehospital setting,
- Storage of blood products outside of the hospital blood bank
- Prehospital transfusion criteria and administration
- Documentation of prehospital transfusion and hand over to the hospital team.
Conventional teaching has been that females whose RhD (D) type is either unknown or who are D- should receive only D- blood products.

The concern has been that a D- female who is exposed to D+ blood could become alloimmunized to the D antigen with the potential for loss of a future D+ fetus through hemolytic disease of the fetus and newborn.

But D- is a minority of blood available for transfusion

Must balance the death rate after massive transfusion (25%) with the allommunization rate (21%)

Death rate of a fetus after allommunization (4%)

Massively bleeding D- females, or those of unknown D type, should not be denied lifesaving blood
• Performed a national survey using Facebook advertisements in three waves in 2021.

• Asked 4 questions on accepting transfusion with differing probabilities for future fetal harm

• Advertisements were viewed 16,600,430 times by 2,169,805 people with 2,873 surveys initiated and 2256 (79%) fully completed.

• Most females responded “likely” or “neutral” when asked whether they would accept a lifesaving transfusion if the following risk of fetal harm were present:
  • no risk (99%); 1:10,000 risk (92%), 1:100 risk (85%); any risk (83%).

• This national survey suggests that most females would accept lifesaving transfusion even with the risk of future fetal harm.

The females have spoken. A patient-centered national survey on the administration of emergent transfusions with the potential for future fetal harm

Prehospital blood product resuscitation after injury significantly decreases risk of mortality. However, the number of patients who may potentially benefit from this life-saving intervention is currently unknown.

Patients ≥16 years with blunt/penetrating injuries included in National Emergency Medical Services Information System 2019 were identified and classified according to hemodynamic instability.

- 3.7 million adult trauma patients were reviewed and 54,160 met the strictest criteria

Assuming 1 unit of whole blood (or equivalent) is needed per patient, a lower-bound estimate of 54,160 additional whole blood units (0.6% of current collections) will be need for optimal prehospital resuscitation of seriously injured patients
American College of Surgeons Committee on Trauma, the American College of Emergency Physicians, and the National Association of EMS Physicians.

1. Stop all compressible hemorrhage

2. Patients with signs of hemorrhagic shock should receive prehospital blood products whenever available.
   - Establish a prehospital transfusion protocol utilizing a multi-specialty collaborative approach including both field and hospital clinicians.

Berry C, et al. PreHospital Emergency Care, March 2023
Field Experience:
HCESD 48 Fire Department

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Assistant Chief of EMS
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AABB THOR  Working Group
Disclosures

1. No Financial Disclosures

2. I do mention certain products used by HCESD 48 but don’t endorse or receive any financial compensation from them
Harris County ESD 48 Fire Department

- Suburban West Houston
- 55 Square Miles
- Population of 175,000
- 12,000 calls per year
- 6 Ambulances with 1 EMS Supervisor
- Dr. David Reininger, MD Medical Director
- Dr. Jospeh Gill, MD Assoc. Medical Director

Memorial Hermann Busiest Level -1 Trauma Center in the US

29 miles or 45 minutes away with no traffic
• We can’t control the uncontrollable
• The event brought us here, we did not choose the event
• We can however bring order to the chaos
• Provide calm direction and care
• Mitigate the circumstances
• Remember overall we can’t control the cause, we can dictate the solution
• Respond to an Assault
  • Adult male patient around 30 semi-conscious
  • Skin is Cool, ashen and Diaphoretic
    • HR is 130
    • B/P is 60/systolic
• Injuries
  • Large Laceration R. Upper Abdomen, not bleeding
  • Multiple arm defense wounds, both brachial arteries are cut
  • What is your treatment plan, now remember it is 1994!
1990’s Trauma Care
Fast Forward to 2014

- Respond to a Multiple Shooting
  - Adult male patient around 30 semi-conscious
- Skin is Cool, ashen and Diaphoretic
  - HR is 160
  - B/P is 80/systolic and falling
- Injuries
  - Single GSW to the Left Buttocks, transverses lateral to medial and exits left inner thigh
- No active site bleeding
- No Other Injuries
2014’s Trauma Care
2014 The Battle for Pre-Hospital Blood Begins

WHOLE BLOOD IS DANGEROUS?

WHAT ABOUT HEMORRHAGIC SHOCK?
From Medical to Logistics

1. Gain medical direction: Through researching local and military studies, our medical directors felt the medicine and science was sound. Texas is a delegated practice state.

2. Work with regional hospitals and/or the blood bank for stocking blood products. We use Gulf Coast Regional Blood Center, Thank You Dr. Hartwell!!

3. Develop logistics and Maintenance
   - What are you usage levels and guidelines?
   - How do you replace it? (And pay for it)
   - How do you hand off a patient at the ED or for Flight
   - How do you bill for it

4. Convince and partner your local hospitals and trauma centers.

From concept to inception for us was just over a year long project.
Blood Products for Ground EMS

• Used in Military Ops as far back as WWII
• Commonly used later in the Iraq and Afghanistan Theatre,
• Transition to HEMS, Life Flight has utilized for 3 years,
• Request for HCESD 48 use in early 2015
• Deployed for HCESD 48 use in Feb 2016.
• Transitioned to LTO Whole Blood Aug 2017
Three Main Functional Areas of Pre-Hospital Blood

1. Medical
   - Is it the right thing for patient care?
   - Paramedic Scope of Practice?

2. Logistics of Daily Operations
   - Proper care and cooling of stored and deployed Blood
   - Safe Patient administration
   - Good Stewards of the Blood Supply

3. Logistics of managing blood supply
   - Managing donor Side
   - Distribution and supply
   - Maintaining and effective life cycle of the Blood
• **Scope of Practice**
  • Nationally
  • State to State
  • Paramedic Education

• **Medical**
  • Blood Products and Flexibility
  • Patient Delivery
  • Rural Agencies
  • Blood bank and EMS Relationships
  • Female Patients
  • Transfusion Reactions

• **Blood Supply**
  • Availability
  • Cost
  • Flexibility
  • Blood Life Cycle

• **Costs**
  • Capital Costs
  • Blood Costs
  • CMS
  • Commercial Insurance
  • Hospital Replacement
1. Symptomatic bleeding, regardless of cause needs to be treated
2. We initially added medical guidelines to cover these patient’s since we carried blood. What we learned is we treat them 3:1 versus trauma patients
3. GI Bleeds, OB compilations and Bleeding
4. So this raised the question of Female Patients and LTOWB transfusions
First Whole Blood Transfusion
September 2017

• We believe First Whole blood Transfusion (Civilian Ground EMS)
  • Mid 30’s Female with syncopal episode while shopping, 2 weeks post partum
  • Hemodynamically Unstable HR >120, B/P 70/Systolic, MAP 60
  • Patient is pale, Temp 96.5 with POC lactate of 4.7
  • Difficulty catching her breath
  • Vaginal Bleeding x 2 weeks in Hemorrhagic Shock
• Patient Received 1 unit (570ml) of Warmed LTOWB
  • Syncope Resolved
  • Improved Hemodynamics HR 64, B/P 98/Systolic with MAP of 64
  • Skin Color Improved, Temp 97.7
• Commit to change
  • STEMI - Time is muscle
  • Stroke - Time is brain tissue
  • Trauma - Time is blood loss
    • Don’t forget medical causes of bleeding
• STOP the Bleed
• Understand the trauma triad and now diamond
• Be the voice of change
• Be flexible, LTOWB is not always available
• Learn the process and seek assistance from others
• Fight like you train
  • Daily Operation
  • MCI and ASHER
Reimbursement Efforts To Date

Susan N. Leppke, MPH
Senior Director, Public Policy & Strategic Partnerships
Association for the Advancement of Blood and Biotherapies (AABB)
Efforts to Date

• In 2020, worked with the EMS community to explore multiple options for payer coverage and reimbursement.

• Worked with a few organizations on draft language for addition to congressional bills.
  • No movement on bill language.

• In 2023, AABB, ABC, and ARC responded to RFI requests on the Pandemic and All-Hazards Preparedness (PAHPCA) reauthorization
  • Language from comments added to Senate version of PAHPCA bill.
In 2021, AABB proposed a service delivery and payment/reimbursement to the CMS Innovation Center (CMMI).
- Not selected due to the launch of a new CMMI organizational strategy.

EMS Community
- Outcomes and other research
- THOR-AABB Working Party Recommendations for a Prehospital Blood Product Transfusion Program

AABB
- Standards development

ABC
- Scope of practice issues research
Current status of blood programs

Randall Schaefer, DNP, RN, ACNS-BC, CEN
CEO, Schaefer Consulting, LLC
• We don’t really know.
  • No centralized reporting processes

• What we do know:
  • Prehospital blood allowed by HEMS in all 50 states
  • 112 Ground Agencies
    • 37% Fire-Based EMS
    • 42% Third Service
    • 21% Miscellaneous
  • Ground Blood/Blood Products Type
    • 68% LTO+WB
    • 9% LTO-WB
    • 10% PRBC
    • 8% Plasma
    • 5% Unknown
Coalition Discussion

Jon R. Krohmer, MD
EMS SME Consultant
Velico Medical, Inc.
Group Discussion

Barriers, Challenges, Opportunities

Jon Krohmer, MD
Former Director
National Highway Traffic Safety Administration (NHTSA)
Office of EMS

Areas To Be Addressed

Blood Products
Clinical Considerations
Logistics / Financial Considerations
Funding Considerations
Coalition Building
• Whole Blood
• Packed Red Blood Cells
• Plasma
**Clinical Considerations**

**Indications**
- Trauma
- Medical
- OB

**Scope of Practice**
- State / regional / local oversight issues
- Education / Continuing Education

**Administration**
- Right Patient - Right Indications - Right Administration
Supplies Availability and Cost

- Blood Products
  - Hospital Blood Banks
  - Community / Regional Blood Centers
  - Alternatives?
- Storage Capabilities - station and vehicles
  - Product Rotation
  - Administration supplies

Blood Management in the Field

Record-keeping

- Blood Supply side
- EMS side - tracking / temperature recording
- Administration

Getting to the patient
Purchase from the suppliers

Loan from the suppliers

Operating costs of hospital or agency

Reimbursement options - who can bill?

- Federal and state insurers
  - Medicare / Medicaid
  - Private insurers
Prehospital Blood Transfusion Initiative

Coalition

PHTRWG
Steering Committee

PHTRWG
Stakeholder Coalition

- Reimbursement
- Scope of Practice
- Education & Outreach
- Strategic Preparedness
WE WORK FOR HEROES

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PREHOSPITAL BLOOD TRANSFUSION INITIATIVE COALITION