



***State of Delaware
Department of Health and Social Services
Division of Public Health
Office of Emergency Medical Services***

State of Delaware Pre-Hospital Blood Administration Pilot

A handwritten signature in black ink, reading "Robert A. Rosenbaum, MD." The signature is written in a cursive style.

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State of Delaware Emergency Medical Services

State of Delaware Pre-Hospital Blood Administration

Operational Plan Project: EMS Initiation of Pre-Hospital Blood

Administration in Adult Patients

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State EMS Medical Director

A collaborative, unified effort by the Office of Emergency Medical Services, New Castle County EMS, and Sussex County EMS.

1. Background Information

High Performance EMS Systems throughout the United States have begun to carry whole blood for administration by paramedics. These agencies have initiated treatment of hemorrhagic shock with transfusion of whole blood.

Blood is recognized as the treatment of choice for trauma patients. This is a departure from prior practice of utilization of large boluses of clear IV fluids (saline or lactated ringers) for volume replacement which have been shown to dilute blood and clotting factors. This dilution can, in fact, increase hemorrhage and lead to worse outcomes. Attempts to utilize synthetic blood substitutes have been unsuccessful. Use of fractionated blood products, while having some utility in hospital settings, would not be a practical solution in the EMS environment.

EMS agencies in Delaware have developed a comprehensive plan to begin to carry a supply of whole blood and administer blood safely to patients above the age of 15. Planning and development of this concept began in July of 2021. They modeled their plans, equipment, supplies and protocols from existing plans completed and utilized by similar EMS agencies elsewhere in the U.S. The Office of EMS supports, this plan, authorized administration of whole blood as a pilot project and presented the concept for acknowledgement of the Board of Medical Licensure and Discipline with inclusion of a new standing order for administration of whole blood by paramedics.

2. Subjective Impact

Whole blood would be utilized to treat patients in hemorrhagic shock. Parameters would include mechanism to suggest blood loss (typically penetrating trauma), low blood pressures (including patients with significant traumatic head injury), tachycardia, and shock index elevation. Blood would be carried by EMS supervisors and these supervisors are immediately dispatched to many of the events which where patients are expected to require blood such as shootings, stabbings, or high-speed motor vehicle crashes.

Projections for initial blood utilization were based on an existing protocol used to treat patients with hemorrhagic shock. This protocol included the use of the medication tranexamic acid (TXA) for patients meeting similar criteria as those listed above. TXA is a medication administered to assist the physiologic response of the body attempting to form clots at bleeding sites. TXA had a more

restrictive application and was used less often than blood could be used in the future. EMS protocols have recently been modified to capture additional patients who may benefit from TXA and to give TXA at an increased dose based on Tactical Combat Casualty Care (TCCC) guidelines (<https://pubmed.ncbi.nlm.nih.gov/32969002/>). Based on these historic use projections of TXA and allowing for the possibility of slightly more liberal application of a protocol to administer blood, projections for blood use are roughly 200 patients per year statewide. This is based on numbers of patients per month being “TXA eligible” including 10-15 per month in New Castle County and 2 to 4 per month in Sussex County.

3. Goals of Project

The patient population most heavily impacted by this potentially life saving treatment will be victims of violence. Penetrating trauma disproportionately affects people of color and people in lower income areas who also are likely to receive disparate levels of health care in other areas. (<https://www.cdc.gov/vitalsigns/firearm-deaths/index.html>) The city of Wilmington alone has seen fatalities from gunshot wounds increase over the past 8 years with over 20 and exceeding 30 fatal shootings per year. The number of victims of gunshot wounds in Wilmington has reached 3-4 per week on average. Increasing levels of violence are being seen throughout the state and patients in all three counties would benefit from the use of blood in the field. (<https://sac.delaware.gov/wp-content/uploads/sites/64/2021/11/Crime-in-DE-2020-Main-Report.pdf>)

Beyond victims of violence, patients injured in high force blunt trauma, crush injuries or amputations also experience major blood loss. The addition of treatment of medically related hemorrhage such as massive bleeding in the gastrointestinal tract or treatment of shock from acute rupture of aortic aneurysms are areas where treatment may expand in the future. Receiving timely blood replacement can correct the effects of hemorrhage and improve morbidity and mortality. The potential impact on historically underserved communities in both urban and rural areas creates an opportunity for the use of whole blood in the treatment of trauma to be one way to address an issue of healthcare equity for patients with disparities based on race, income, or location.

Blood is a perishable commodity often in short supply. Avoiding waste of blood products has been a priority for the EMS agencies planning this process with a goal of “zero-waste” of blood products. While EMS has units of blood in their possession, the blood will be kept in specially designed coolers with temperature monitoring that are utilized for the safe handling and transport of blood products. These coolers have multiple mechanisms to alert providers and supervisors if the temperature is moving out of range so this can be addressed before the blood is unusable including audible alarms and Bluetooth/app based notification systems for Smart Phones. EMS agencies will maintain a relatively low amount of whole blood on hand with expectations of use based on historical data. This will minimize risk of expiration of blood prior to a unit being able to be administered. Even with these precautions, there is an expected low rate of unused blood. Counties are working with partner agencies to find meaningful uses for units of whole blood that cannot be administered to patients. These may include law enforcement training, education, equipment verification, research, or other uses. Utilizing the practices and safeguards listed above, which are modeled off other systems with EMS blood programs, we anticipate a very low rate of blood units which are not administered and that agencies will have multiple pathways to find value for units which cannot be administered.

4. Proposed Solutions

Delaware EMS agencies have developed an operational plan for the administration of whole blood to patients with evidence of hemorrhagic shock. This follows the initiative of other high performing EMS agencies in the United States. The Delaware Office of EMS supports this initiative, has developed medical protocols for blood administration and has secured the acknowledgement of the Delaware Board of Medical Licensure and Discipline for paramedics to perform this skill.

Two County EMS agencies are prepared to move forward rapidly (Sussex and New Castle) with Kent County and Delaware State Police Aviation interested in following to eventually provide this care statewide through all pre-hospital EMS agencies.

Participating County EMS agencies have purchased the equipment needed to safely maintain and administer blood. These agencies have worked with the Blood Bank of Delmarva and have developed a plan for delivery and resupply of blood with final agreements completed. The operational components include temperature monitored storage for the blood, appropriate documentation, and communication to receiving hospitals at patient transfer.

5. Target Measures

- Number of patients treated with whole blood
- Indication for treatment
 - May include vital sign abnormalities, paramedic impression, nature of injury
- Patient demographics
- Destination Interventions
- Change in condition during EMS transport
- Attempts will be made to obtain details on hospital treatment and outcome
 - at the hospital may include additional blood products and need for operative intervention
 - Outcomes of survival to discharge versus mortality
- Monitoring for any units not administered to patients
 - Identifying agency distribution of units not administered

6. Service Deliverables

OEMS will develop paramedic education from subject matter experts (SMEs) who have EMS experience with Blood product administration. Initial funding for blood product administration to support the pilot project will be the responsibility of each county. A dedicated funding stream will be explored for ongoing blood product expense. County paramedic agencies will ensure secure handling and accountability with use of appropriate storage and administrative processes.

7. Anticipated Costs

The Blood Bank of Delmarva will charge EMS agencies for blood at a cost of approximately \$550 per unit. The projected cost per year for both New Castle and Sussex County is approximately \$120,000 for the blood supply. County agencies have purchased the required temperature-controlled coolers, monitoring equipment, and blood administration warming equipment.

8. Timeline

Whole blood administration has been approved as pilot project in the November 2022 ALS standing order update. County paramedic agencies in New Castle County and Sussex County have worked with Blood Bank of Delaware throughout 2023 to obtain equipment, verify reliability and establish contractual arrangements for purchase of whole blood. The State Operational plan will be reviewed and approved by EMS medical directors on May 17, 2023, and authorized use of whole blood is expected to be approved as of May 24, 2023.

9. Necessary Technology Initiatives

When not being administered, blood shall be stored in a biothermal grade cooler. Blood must be stored between 1-6 Degrees Celsius. The temperature of the stored blood must be monitored constantly. Any deviations in the storage temperature beyond the therapeutic range could result in wasted product.

Rapid Infusion and warming devices should be used to facilitate the rapid infusion of the blood product.

10. Paramedic Education Elements

Who: Training has been conducted by participating county agencies with OEMS approved education program.

What: Didactic training will be provided to all providers affiliated with participating county agencies.

When: Completed prior to implementation of pilot with any updates or refreshers as needed.

11. Required Data Sharing Agreements

Proposed data will be obtained from DEMRS, county agency reports of any complications and of unused units of whole blood. Outcome data will be discussed with Trauma System Committee.

12. Development of New Advanced Life Support (ALS) Protocols/Guidelines

See Attached.

13. Blood Acquisition

Sussex County EMS (SCEMS) and New Castle EMS (NCEMS) have entered an agreement with The Blood Bank of Delmarva. The Blood Bank of Delmarva will provide the agencies with Low Titer O Positive Whole Blood (LTOWB) during this pilot program. SCEMS and NCEMS shall deploy 2 units of LTOWB to the field.

14. Expected Outcomes of Project

Whole Blood is the standard of care for the treatment of hemorrhagic shock. High performance EMS agencies have added whole blood to their treatments to bring this life-saving treatment to patients in the greatest need at the earliest opportunity. The potential to save lives, particularly of younger patients who are the most common victims of trauma, has led Delaware's Paramedic Agencies to actively develop plans, education, and to purchase equipment they will use to deliver whole blood to patients.

Support of whole blood for paramedics will maintain the standard that Delaware EMS has established as a leader in paramedic care in the country and continue to provide the highest level of service to the citizens and visitors to the State of Delaware. While difficult to measure, the goal of initiating whole blood as part of paramedic treatment is improving the opportunity for survival of critically injured patients. Whole blood administration allows for greater stabilizing care and the opportunity for definitive care to be provided at trauma centers and improve the chance for survival.

15. Quality Improvement/Oversight

Blood Transfusion Report – Any time blood products are administered a Blood Transfusion Report shall be completed utilizing the form supplied by the blood bank. The following process shall be completed:

- The Blood Transfusion Report shall be completed.
- Remove barcode sticker from blood product bag and apply to both white and yellow copies of the Blood Transfusion Report.
- Attach the receiving hospital's patient identification label to the original and carbon copies of the Blood Transfusion Report.
- The incident number shall be written on the top of the Blood Transfusion Report. A copy of the Blood Transfusion Report shall remain with the patient.
- The blood transfusion report shall be electronically attached to the ePCR.
- The blood transfusion report shall be electronically attached and emailed to the appropriate agency.

- Transfusion information shall be reported to Blood Bank of Delmarva within 24 hours.
- Each blood transfusion shall be reviewed by each county agency Quality Management Team in coordination with the county and state Medical Directors and The Leadership Team from the Blood Bank of Delmarva.

16. Legislative Concerns

None identified at this time.

HEMODYNAMICALLY COMPROMISING HEMORRHAGE (Updated Pilot)

INDICATIONS: This protocol is for use in the hemodynamically unstable patient, presenting with signs or symptoms of hemorrhagic shock with suspected need for massive blood transfusion due to suspected marked internal and, or external blood loss presenting with sustained tachycardia greater than 110 BPM or sustained hypotension less than 90 mmHg, or a shock index greater than 1.0 (Calculated by HR/SBP).

****Do not delay transport to initiate blood products. ****

Traumatic Hemorrhage:

- Isotonic Crystalloids (0.9 Sodium Chloride)
- Tranexamic Acid 2 grams IV/IO
- Consider Blood Transfusion with OLMC
- Calcium Chloride 1g IV/IO over 3 minutes after each unit of transfused blood product

Injured patients with traumatic brain injury (TBI) who have systolic blood pressure under 110 mm Hg should receive IV fluid volume to prevent hypotension. Whole blood is the recommended fluid in systems that carry blood.

****Administration of blood products is optional, as approved by the jurisdictional medical director****

TRANSFUSION OF BLOOD PRODUCTS

The paramedic must contact online medical control (OLMC) and obtain orders to administer blood products. The paramedic must **speak directly** to the medical control physician. With OLMC approval, Low Titer O Positive Whole Blood (LTOWB) may be administered in accordance with the following indications and the following guidelines:

A. Indications for transfusion

1. Hemorrhagic Shock: Patients with ongoing, or suspected ongoing, major hemorrhage, based on their presenting injury or diagnosis, and with the clinical signs of shock should be given blood (LTOWB) when the normal IV fluid volume replacement has not corrected the problem. Clinical indications of shock include:
 - Shock Index greater than 1
 - ETCO₂ less than 25
 - Tachycardia
 - Delayed capillary refill
 - Hypotension
 - Mental status changes

2. Injured patients with traumatic brain injury (TBI) who have systolic blood pressure under 110 mm Hg should receive IV fluid volume to prevent hypotension. **Whole blood is the recommended fluid in systems that carry blood.**

B. General Guidelines

1. When not being administered, blood shall be stored in a biothermal grade cooler. Blood must be stored between 1-6 Degrees Celsius. The temperature of the stored blood must be monitored constantly. Any deviations in the storage temperature beyond the therapeutic range could result in wasted product.
2. Prior to administration, two paramedics must check and verify blood type, Rh factor, unit numbers, and expiration date.
3. Baseline vital signs, including temperature, should be obtained prior to blood administration with continuous monitoring throughout the transfusion.
4. In adults, blood should be administered through a large bore (at least 18 gauge) peripheral IV, or intraosseous needle. ~~Smaller bore, or intraosseous needle is acceptable in children.~~
5. Blood should be administered with 0.9% Normal Saline through blood tubing with a filter.
6. Rapid Infusion and warming devices should be used to facilitate the rapid infusion of the blood product.
7. Vitals signs, including temperature should be documented every 5 minutes.
8. After the transfusion is complete, amount transfused, and patient's response should be documented.
9. All unused blood products and empty blood product bags should be left with the receiving facility.

C. Transfusion Reaction

1. If signs of a transfusion reaction develop (fever, chills, hypotension, dyspnea, tachycardia, pain at the transfusion site, hives, etc.), stop the transfusion immediately.
2. Consider the Allergic/Adverse Reactions/Dystonic Reaction Protocol
3. The unit of blood, the IV bags, and all tubing must be discontinued and sent to the blood bank upon arrival at the receiving hospital
4. Notify Medical Control immediately for all possible transfusion reactions

Reaction Type and Cause	Signs and Symptoms
<p>Acute Hemolytic: Infusion of incompatible blood product</p>	<ul style="list-style-type: none"> • Flushing, chills, shaking • Pain in chest, head, flank • Change in VS: Fever (>2↑), ↑HR, ↓BP • Blood in urine
<p>Febrile Non-Hemolytic: Leukocyte or platelet antibodies, plasma protein antibodies, cytokines from donor leukocytes</p>	<ul style="list-style-type: none"> • Fever (>2°F↑) – occurs in the absence of any other stimulus for fever • Chills, flushing
<p>Allergic Reaction:</p>	<ul style="list-style-type: none"> • Rash, flushing, chills • SOB, coughing, wheezing • Laryngeal swelling • Hives
<p>Transfusion-Related Acute Lung Injury (TRALI): Donor antibodies interacting with recipient leukocytes; leading to fluid in the lungs</p>	<ul style="list-style-type: none"> • Sudden severe SOB • Bilateral pulmonary edema • Hypoxia • Tachycardia • Hypotension
<p>Transfusion-Related Associated Circulatory Overload (TACO): When too much fluid or transfusion is administered too fast</p>	<ul style="list-style-type: none"> • Dyspnea, orthopnea • Tachycardia • Hypertension • Pink-frothy sputum
<p>Septicemia Transfusion Reaction Occurs when bacteria is contained in the blood product</p>	<ul style="list-style-type: none"> • SOB • Sudden high fever >102°F • Hypoxia • Tachycardia • Hypotension