

HOW DO I DO IT

Transfusion Practice

TRANSFUSION

How do we implement a prehospital whole blood administration program for shock trauma patients on a statewide basis?

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Abstract

Background: Since bleeding is a major cause of early mortality in trauma, there is continued interest in providing transfusion support as early as possible to trauma patients. Various approaches have been taken to accomplish this, including the rapid provision of blood products upon arrival at the hospital, as well as a variety of prehospital approaches. However, implementing prehospital blood availability statewide for use in all populations has been limited.

Study Design and Methods: The program described for prehospital transfusion identifies a direct partnership between state EMS providers and the local blood center. Predictive modeling is compared to early outcome data of the first 100 patients who received whole blood from this program. Additional discussion contains key elements of the program, including planning, validation, and implementation.

Results: Between May 2023 and July 2024, an average of 11 prehospital whole blood units were transfused per month against the projected average of 10–16 units administered per month, with the median time to transfusion of 29.2 min. The leading reason for blood administration was due to blunt

Abbreviations: AABB, Association for the Advancement of Blood & Biotherapies; BBD, Blood Bank of Delmarva; CPD, citrate phosphate dextrose; LTOWB, Low titer group O+ Whole Blood; NCCEMS, New Castle County EMS; NYBCe, New York Blood Center Enterprises; SCEMS, Sussex County EMS; STRAC TSA-P, Southwest Texas Regional Advisory Council Trauma Service Area; THOR, Trauma, Hemostasis, and Oxygenation Research; TIC, thermally insulated chambers.

trauma. Of the patients who were not in prehospital cardiac arrest prior to paramedic arrival or excluded for other reasons, approximately 95% survived to hospital discharge.

Discussion: Implementation of prehospital whole blood across the state has demonstrated effectiveness early within the first year of the program. Continued process improvements will be implemented with statewide ground paramedic agency utilization of whole blood as well as expansion into aviation divisions for more expedient whole blood administration times.

1 | INTRODUCTION

Bleeding is a significant cause of prehospital and early mortality in trauma.¹ The choice of resuscitation fluid has evolved, with the physiologic goals of optimizing both hemostasis and oxygen delivery.² There is renewed interest in whole blood because it includes clotting factors, platelets, and volume, as well as oxygen-carrying capacity. All of these may benefit a patient with hemorrhagic shock, and receiving timely blood replacement can correct the effects of hemorrhage, potentially improving morbidity and mortality.^{3,4}

Several meta-analyses have examined whole blood administration to acutely bleeding patients in the hospital setting. These studies have demonstrated less blood component use,⁵ and an early (up to 24 h) decrease in mortality with whole blood resuscitation strategies.^{6,7} While the analysis by Morgan et al.,⁷ demonstrated improvement in late mortality, this has not been a consistent finding, and additional work needs to be done in this regard.

Administration of whole blood in the prehospital setting begins the resuscitation process earlier, improving the possibility of decreasing morbidity and mortality.⁸ Interest in prehospital blood administration has progressed in the past 5 years; however, given the challenges of prehospital transfusion, programs by EMS and first responders have been limited. To this end, a joint working group from THOR (Trauma, Hemostasis, and Oxygenation Research) and AABB (Association for the Advancement of Blood & Biotherapies) published guidance for prehospital blood product administration.³ Reports on the administration of prehospital blood products have been mixed.⁴ However, a prospective, cluster-randomized study demonstrated hemostatic benefit⁹ for whole blood in a prehospital setting, and a recent retrospective cohort study demonstrated 37% lower mortality at 24 h in severe trauma patients who received resuscitation with whole blood.¹⁰

Delaware is a small state made up of three counties and a population of just over 1 million people.¹¹ New

Castle County is the northernmost county in the state. Delaware's only Level I (highest level) trauma center is located centrally within this county. It is the most populous and includes the state's largest urban population center. New Castle County experiences the most penetrating trauma cases from gunshot or stab wounds. The southernmost county, Sussex County, faces the challenge of significant distance from a Level I trauma center with limitations in providing immediate and comprehensive care for critically injured patients. Sussex County has two Level III trauma centers, but the management of critically ill patients needing longer patient transport times for definitive trauma care is a significant challenge.

With the goal of improving resuscitation care, Sussex County EMS (SCEMS) and New Castle County EMS (NCCEMS) approached Delaware's primary blood supplier, the Blood Bank of Delmarva (BBD), a division of the New York Blood Center Enterprises (NYBCe), as a partner to create a program to provide whole blood in the prehospital setting. This prehospital whole blood transfusion program involves a direct supply of blood from a regional blood supplier in qualified, validated Crêdo coolers for immediate availability on EMS vehicles. We describe key elements of our program, as well as the initial results of this program.

2 | METHODS

2.1 | Pre-initiation data analysis

Prior to deployment, the criteria for blood eligibility were applied to patients treated by the two ALS agencies in the previous year. Detailed analysis was performed on all identified cases to evaluate the arrival of a field supervisory unit that would be transporting blood. This review indicated expected monthly utilization of 8–12 units of blood in New Castle County and 2–4 units of blood in Sussex County.

Additionally, Geographic Information System data was used to predictively model the responsiveness of

district supervisors in high-risk trauma scenarios. The modeling considered the ability to respond, arrive on the scene, and administer blood without causing delays in patient care. Based on this modeling, strategic decisions were made to begin automatically assigning EMS field supervisors to trauma-related priority dispatch codes with the highest probability of receiving whole blood.

2.2 | Transfusion criteria

The Delaware Division of Public Health, Office of EMS, outlined the patient eligibility criteria in the Blood Administration Pilot Protocol (Figure 1) (Statewide Standard Treatment Protocols, 2022). The clinical protocol addresses patients exhibiting signs of severe hemorrhagic shock, sustained tachycardia, or hypotension. In instances of traumatic hemorrhage, the protocol incorporated isotonic crystalloids, tranexamic acid, and potential blood transfusions. Oversight by EMS medical directors helps to establish understanding and responsibilities in adhering to the protocol. The standing order to transfuse is applicable for patients greater than age 15 when the following criteria are met:

- Hemorrhagic shock with suspected or ongoing major hemorrhage and at least one clinical indication of shock, including:
 - Shock Index greater than 1
 - ETCO_2 less than 25
 - Tachycardia
 - Delayed capillary refill
 - Hypotension
 - Mental status changes
- Traumatic brain injury and systolic blood pressure below 110 mm Hg.

2.3 | Program design-blood product and equipment selection

Low titer group O+ Whole Blood (LTOWB) was the blood product of choice for the prehospital blood program. LTOWB provides the benefit of multiple blood components in a single unit. Blood Bank of Delmarva (BBD) collects LTOWB from males, never-been-pregnant females, and females who are HLA antibody negative since their last pregnancy to mitigate the risk of transfusion-related acute lung injury in the receiving patient. Terumo Immuflex WB-SP blood collection containers containing citrate phosphate dextrose (CPD) are used to manufacture platelet-sparing leukocyte-reduced whole blood products with a 21-day expiration date. Anti-A and anti-B isohemagglutinin titers are performed using immediate spin tube methodology and must be <100 to qualify the product as low titer.

After an assessment of equipment, the following was selected:

- Pelican BIO-thermal Crēdo Cooler 4 L Series 4
- Ideal Sciences Temp Stick® Wifi Sensor (−40–60°C)
- Quantum LifeWarmer Blood & Fluid Warming System
- QinFlow Warrior Lite
- Fluke Infrared & Contact Thermometer Model 561
- Freezer to meet thermally insulated chambers (TIC) temperature requirements

2.4 | Validation and training

Validation test cases were drafted by the Blood Bank of Delmarva (BBD) to ensure all equipment and processes performed as intended and according to regulatory standards set by the FDA and AABB for the storage and

HEMODYNAMICALLY COMPROMISING HEMORRHAGE

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 On-Line Medical Control (OLMC)
- Calcium Chloride 1g IV/IO over 3 minutes after each unit of transfused blood

FIGURE 1 Criteria for blood administration as defined by the Delaware Division of Public Health, Office of EMS.

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 if blood is available.

transport of blood products.^{12,13} The FDA sets standards of temperatures for blood product storage at 1–6°C and blood product transport at 1–10°C.^{12,13} The blood products deployed in the field for prehospital use could be considered to be both in storage and transport. A conservative approach was taken to validate the coolers to maintain acceptable temperature ranges for blood product storage and transport activities within the 1–6°C for a 72-h period. Performance qualification was performed following the defined process of replacing the TICs every 24 h. A cooler packed with one unit of LTOWB and a Temp Stick® (Ideal Sciences, Bountiful, UT) was deployed on a district supervisor vehicle for an extended period of time. We exchanged the TICs in the cooler with TICs from the freezer every 24 h. The Temp Stick® was used as a reliable continuous temperature monitoring device within the cooler which reports real-time data using Wi-Fi connectivity to end-user cellphones. The Temp Stick® was calibrated against a reference thermometer before use. Alert set points were established to ensure immediate notification and allowable time to act before any temperature excursion occurred. The Temp Stick® readings compared favorably to calibrated infrared Fluke thermometer readings of the product taken every 24 h during the rotation process. The cooler maintained acceptable temperatures of 1–6°C over the period of validation testing qualifying its use.

Comprehensive training and competency were performed for all paramedics. Specific training materials were utilized including material provided by device manufacturers, protocol discussions, didactic training, and high-fidelity simulation exercises. Continuing education webinars were conducted following several cases of whole blood administration, including direct participation and education from County and State EMS Medical Directors and BBD. These sessions provided operational guidance, clinical insights, and supplemental training.

2.5 | Blood management

Integration of technology allows for continuous, active monitoring and oversight of the blood inventory. Design of an electronic blood product management system ensures tracking and traceability of prehospital products deployed in the field. Daily inventory management steps are performed to log donor identification number, expiration date, cooler number, Temp Stick® number, visual product inspection and review of temperature monitoring. The system is also used as a tool for tracking administrations and waste.

The statewide blood product administration standing order allows for blood administration to patients

experiencing hemorrhagic shock (Figure 1). Transfusions may only be initiated by trained, qualified personnel following approval from medical control, which ensures that the standing order criteria are met. Immediately prior to administration, blood products are removed from the cooler and undergo a time-out process where quality checks are performed to verify the temperature and expiration date of the blood product prior to transfusion. Administration protocols are followed for blood warming, infusion rates, and continuous vital sign monitoring. Documentation occurs in the patient's electronic medical record and is electronically transferred to the receiving hospital facility at handoff. In the event of an adverse reaction, the transfusion would be stopped, and medical control would be notified for the next steps. Handoff documentation forms and empty blood bag sets are left with the receiving facility to pass along to the blood bank.

Each case of blood administration undergoes immediate quality review, with real-time feedback provided to the administering paramedics. The active engagement of BBD in quality reviews, coupled with reviews by County EMS Medical Directors, ensures immediate review and feedback, prompting any needed adjustments in the guidelines and procedures for administration.

3 | RESULTS

The total number of blood products transfused compared to minimum and maximum projected usage from the beginning of the project in May 2023 through July 2024 is summarized in Figure 2. In the first 15 months of EMS whole blood administration, there were 170 units of blood given in Delaware. When examining blood units transfused by each county, the combined average was over 11 units per month, within the projected average of 10–16 units administered per month between both counties (Figure 3).

The mechanisms that lead to whole blood administration were blunt trauma (57%), penetrating trauma (39%), and 4% “other” circumstances. The “other” circumstances included postpartum hemorrhage, dialysis shunt rupture, gastrointestinal variceal bleeding, and one mixed mechanism (Figure 4).

The median time of initiation of blood transfusion from the initial call to 911 was 29.2 min. Some patients required a second unit of blood, and the initiation time for those units was not included in this calculation (Figure 5). Ground patient transport from departure from the scene to transfer of care at a hospital facility in New Castle County was 10.7 min. Similar data for Sussex County, which services a larger geographical region, was 21 min. Additionally, patients in Sussex County who

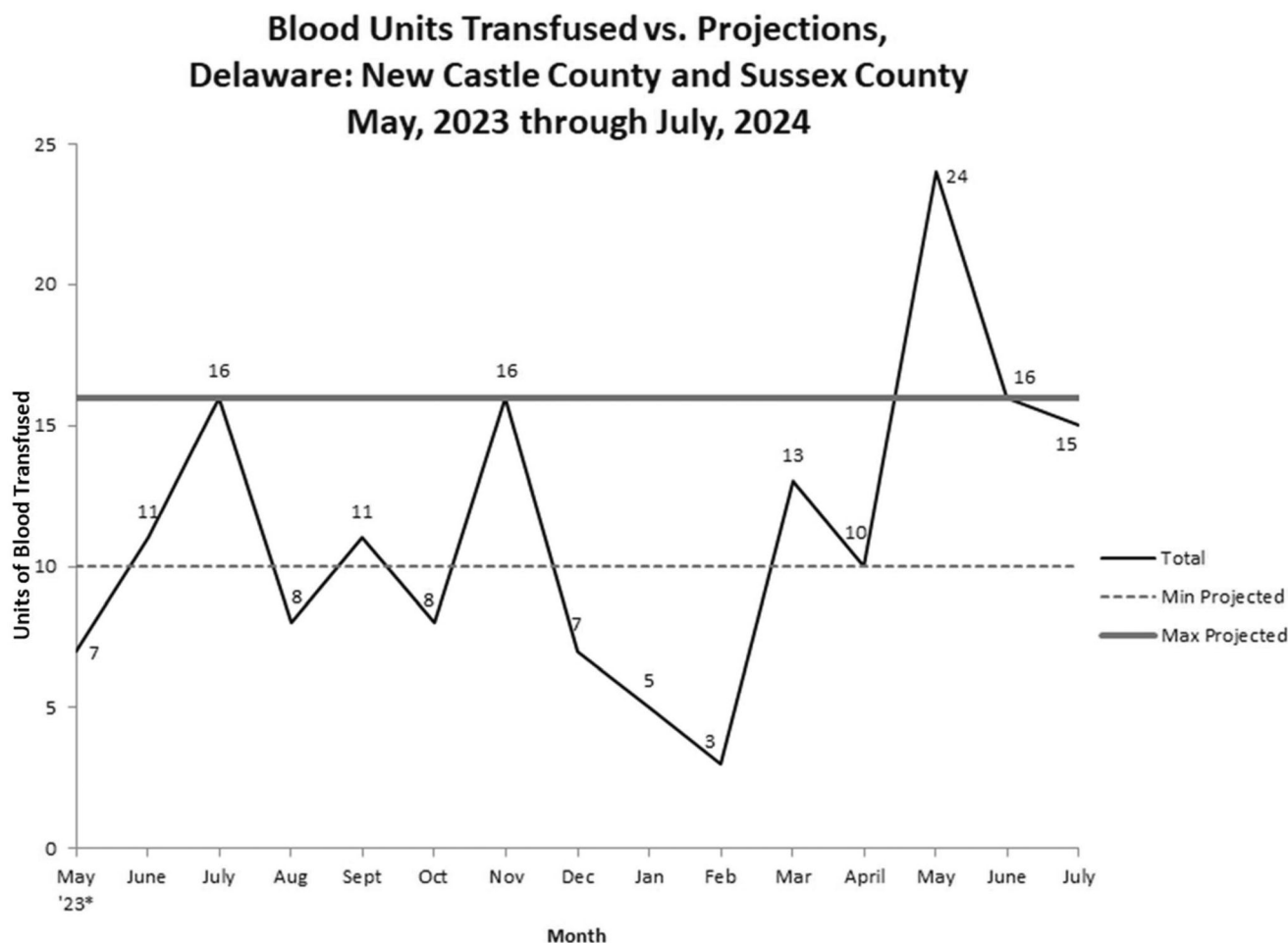


FIGURE 2 Whole blood administration. The number of whole blood units administered each month is shown. Projected numbers from pre-program modeling are shown as dotted (minimum) and gray (maximum) lines.

were transported by aviation averaged 45 min from departure of scene to transfer of care at the hospital.

New Castle County paramedics collected outcome evaluations on the 100 patients who were given blood between May 2023 and July 2024. Of the patients who were not in prehospital cardiac arrest prior to paramedic arrival or excluded for other reasons, 72 of 76 patients (94.7%) survived to hospital discharge (Figure 6). Of the 100 patients, there were 24 exclusions from this calculation, including 13 patient arrests before EMS arrival (none of whom survived to discharge), 10 patient outcomes were unknown or pending at the time of this report, and one patient had an isolated extremity wound with tourniquet application (blood administration felt to be outside of standing orders criteria on quality review). Upon quality review, there were 89 patients with appropriate blood administration decisions by standing order with known outcomes. Of these patients, 72 (81%) survived to hospital discharge.

Blood product wastage was monitored very closely. Statewide, within year 1, there was a 13% wastage of

whole blood products that were not able to be utilized by a patient before the product reached expiration. Due to the quality of the developed system to maintain cold chain storage with no temperature excursion events, a zero waste program was implemented to eliminate blood product wastage utilizing late-stage whole blood for further manufacturing into packed red blood cells for future transfusion at a local high volume hospital partner.

4 | DISCUSSION

Delaware paramedic agencies have demonstrated successful implementation of prehospital whole blood administration by working directly with the BBD. This program has already shown benefits to patients experiencing hemorrhagic shock and hypotension related to trauma. The incorporation of whole blood stands out as a critical element in overcoming geographical limitations, enhancing the overall capabilities of paramedic agencies in trauma care. Patients in underserved areas of

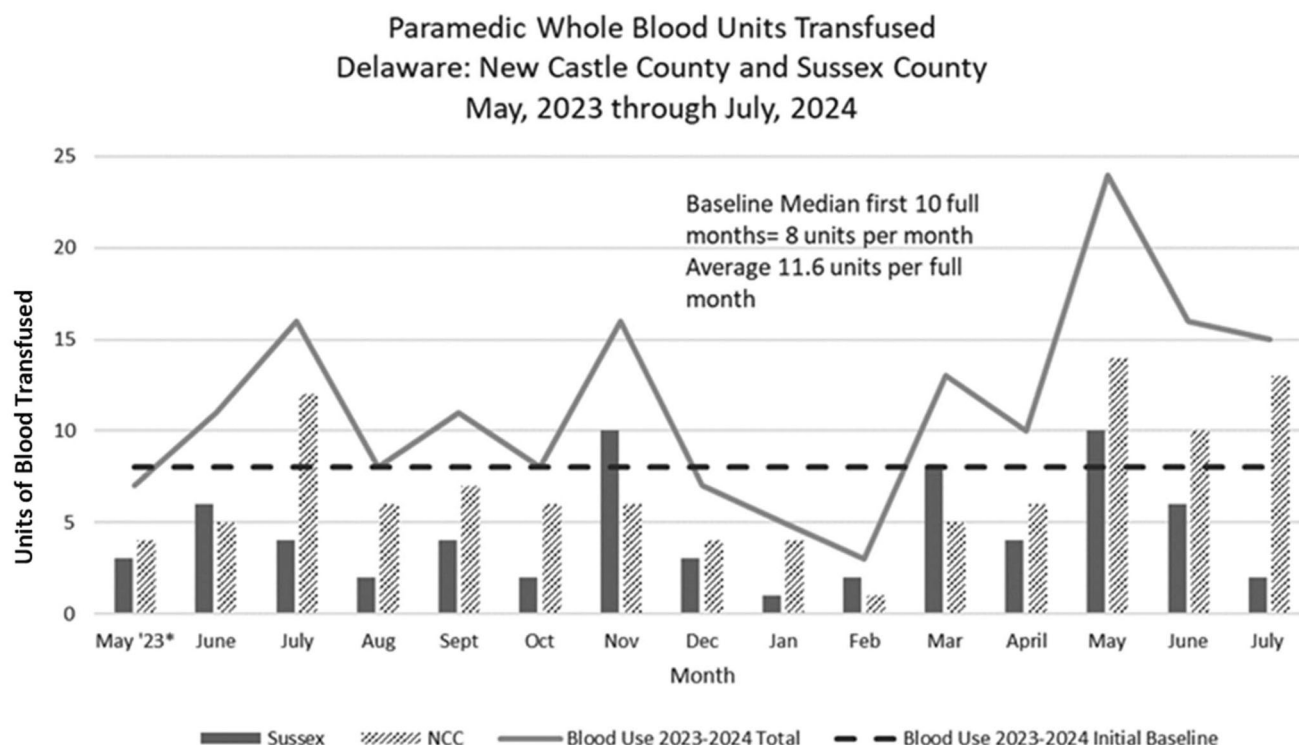


FIGURE 3 Paramedic whole blood units administered by county. Total and median blood use are shown. “*” indicates a partial month.

the state are expected to have better outcomes following traumatic injury. Increased survivability of traumatic injuries beyond typically expected levels has been shown by both counties in Delaware utilizing whole blood. Southwest Texas Regional Advisory Council Trauma Service Area (STRAC TSA-P) reports similar findings where trauma patients who receive prehospital LTOWB transfusion had greater improvement in SI and reduction in early mortality.^{8,14} Our program framework could be used in any geographical region, including international countries with similar characteristics. However, details may need to be modified to accommodate local procedures and ensure compliance with applicable regulatory practices.

The San Antonio Whole Blood Collaborative has reported similar success, acknowledging the unique partnerships needed between blood centers, medical centers, and emergency medical systems to ensure high-quality functioning systems are implemented and maintained.^{8,14} Their program uses CPDA-1 LTOWB with 35-day expiration which increases the shelf life and usability time of the product. In contrast, our system uses CPD LTOWB with a 21-day expiration.

Although the shelf life is shorter for the CPD product, it provides the benefit of manufacturing a leukoreduced product produced through a platelet-sparing filter. Further, several hospital customers in the area are using CDP LTOWB. Anti-A and anti-B isohemagglutinin titer

cutoffs also differ. San Antonio⁸ uses the 1:256 cutoff, which is consistent with the military, while we use a more conservative cutoff of 1:100. Currently, there is no industry standard or best practice for what blood to transfuse.

The Palm Beach County Fire Rescue in West Palm Beach, Florida, recently reported on their prehospital whole blood program.¹⁵ They report a survival rate of 45%. While they receive blood from their local blood center, they store whole blood in validated refrigerators in fire stations, as opposed to our program that provides the blood directly in validated coolers. The Maryland Institute for Emergency Medical Services System has also recently reported a similar program in Howard County, MD, outlining the success of prehospital whole blood and the importance of collaboration with key stakeholders, which includes a regional third-party blood bank.¹⁶

Whole blood is also used outside of the United States. The European Blood Alliance performed a survey of member nations for the use of blood products in massive hemorrhage. Of 17 responding nations, 11 provide blood products in the prehospital setting, with only two (Sweden and Norway¹⁷) incorporating whole blood.¹⁸ Described models of European prehospital blood administration typically include an anesthesiologist or trauma surgeon as part of the response team and serving as the decision maker on blood or blood product administration. EMS response teams in the United States do not

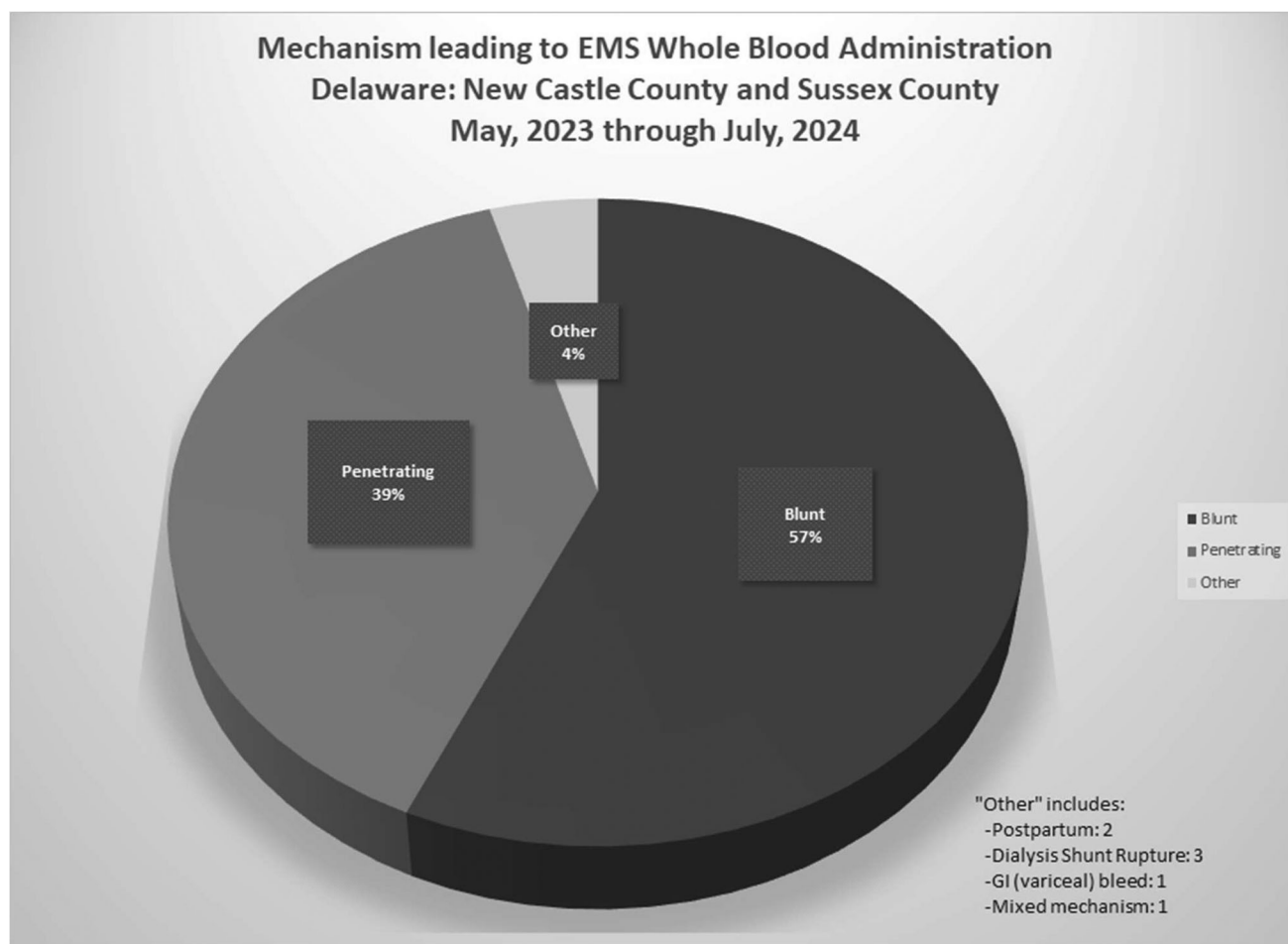


FIGURE 4 Mechanism of trauma. Pie chart denoting the relative contribution of blunt and penetrating trauma in the first 100 patients receiving whole blood. Several additional conditions resulted in whole blood being administered and are denoted as "other."

typically include physicians, and our program is designed for paramedic decision-making regarding transfusion of blood in patients meeting established criteria. The paramedic communicates with an emergency medicine physician who provides online medical control via radio to confirm the decision-making process. This system design matches most US-based prehospital systems, which utilize paramedics as the highest-level prehospital providers operating within standing orders and having online medical control contact for complex cases.

The project's pilot phase identified operational challenges to overcome. The most notable is related to the whole blood unit cold chain storage. An increase in cooler size was implemented to allow for the whole blood to be stored without jeopardizing the ports and associated tubing needed for transfusion. The change in cooler size also gained efficiencies in freezer storage space for the conditioning of the thermal insulation panels. High humidity within the closed coolers caused condensation to build up on the Temp Stick[®] temperature monitoring devices, which began to negatively impact performance.

Interventions were put in place to store the Temp Stick[®] in a plastic bag bundled between the blood product and satellite bags (Figure 7). This measure ensured the integrity of the device to report accurate, reliable readings.

Decreased or slow infusion rates to patients in the field were documented on some initial transfusions thought to possibly involve the use of the LifeWarmer device. Stakeholders held brainstorming sessions to discuss the ongoing issues and identified possible causes such as kinking of tubing and the angi catheter gauge size. Formal directives were put in place by the performance improvement office in coordination with the State and County EMS Medical Directors to utilize 18 gauge or larger angi catheters and prime first with saline. Once saline flows freely, whole blood is then added to the administration set which prevents any additional waste due to obstructions and/or failures. The directive and additional training have since resulted in a 100% success rate in the administration of whole blood. Mid-project, Sussex County opted to change the infusion system (QinFlow Warrior infusion system) to evaluate if

Blood Administration Time from 911 Call to Initiation Delaware EMS: May, 2023 to July, 2024

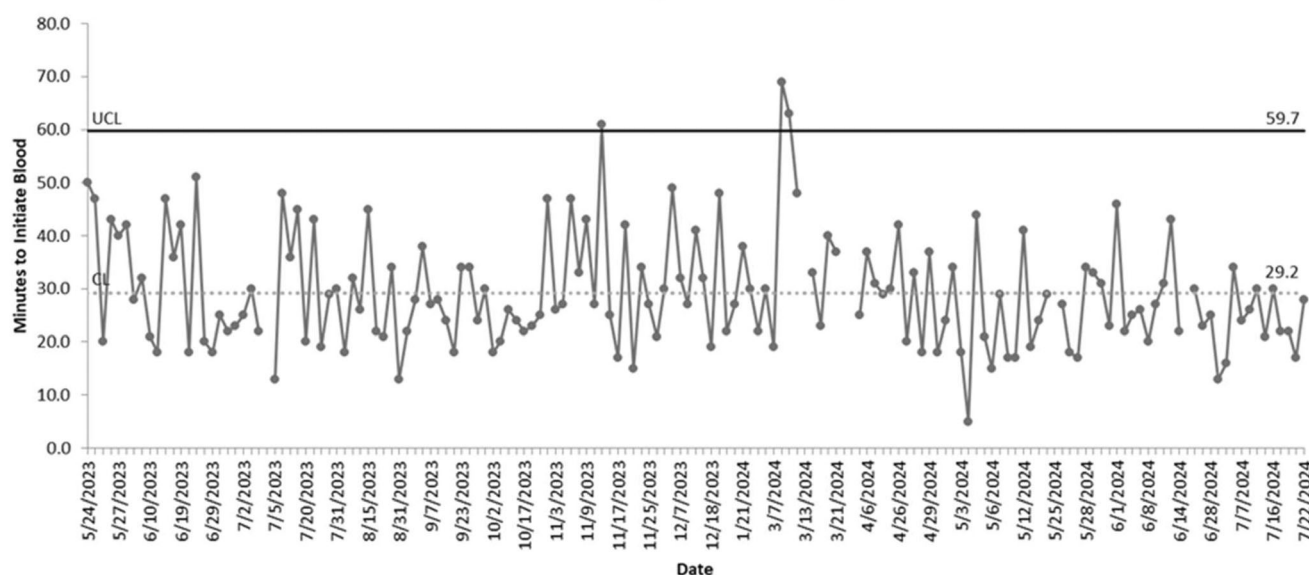


FIGURE 5 Time to blood administration: The time from receipt of a 911 call to initiation of blood administration is shown for each patient. The median time of 29.2 min and upper control limit of 59.2 min are depicted in dotted and black solid lines, respectively.

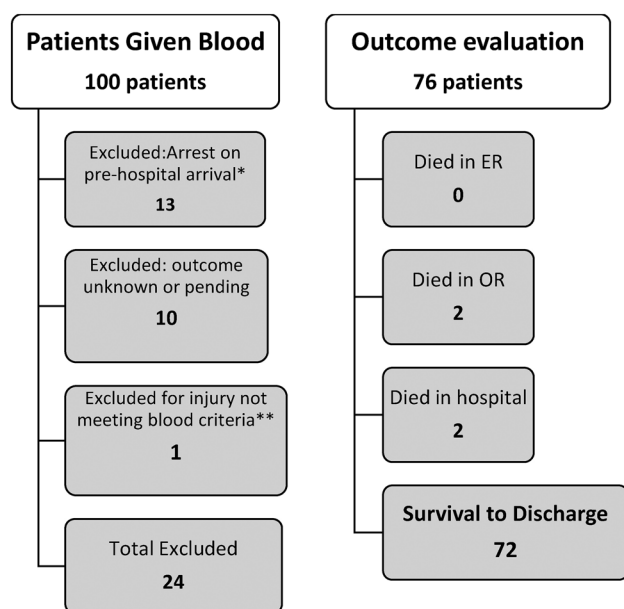


FIGURE 6 CONSORT diagram: up-front exclusions are shown to the left. Outcome exclusions are shown to the right. *Patients were in prehospital cardiac arrest and did not survive to discharge. **Patient had an isolated extremity wound with tourniquet application; excluded from data set due to administration outside of standing order.

comparable or faster infusion rates could be demonstrated. The system change demonstrated effectiveness with no adverse effects and is continuing to be utilized in Sussex County.

Specific successes from this pilot include the development and implementation of a dashboard providing detailed oversight such as expiration date monitoring, identification numbers of blood unit, cooler, Temp Sticks®, and the inspecting party. This allows for continuous monitoring and usage of EMS whole blood and supplies. Access to real-time temperature monitoring for each deployed unit, instant notification of cooler temperature excursions via a smartphone application, and formal equipment validation ensure the safety and quality of the blood supply. Coordinated education and troubleshooting, including the use of the same cooling and storage devices in both counties, allows for continued learning opportunities on best practices.

The direct partnership of EMS agencies and the regional blood center demonstrate the potential for non-hospital-based EMS agencies to implement an EMS whole blood program. The integration of the BBD's courier service ensured the prompt and secure delivery and replacement of whole blood to each county paramedic agency, reducing downtime. Maintaining extra coolers and Temp Sticks® allowed equipment to be consistently available at the BBD and enabled immediate fulfillment of blood products after administration.

Future program initiatives include zero waste opportunities and expansion within the state of Delaware. Given the high level of the quality system created around continuous temperature monitoring and with the demonstration of safe handling, paramedic agencies are working

FIGURE 7 Image of whole blood and Temp Stick® as prepared for loading into the cooler. Note that care is taken to reduce tension on the ports, tubing, and satellite bags as they are used for further manufacturing of the blood product.



with the Blood Bank of Delmarva and hospital partners toward eliminating waste due to expiration. Late-phase whole blood is removed from the field several days before expiration and is further manufactured into packed red blood cells for utilization at a local high-volume hospital center. This initiative allows all partners to be good stewards of the blood supply and avoid unnecessary waste of precious resources.

Delaware will expand prehospital blood utilization to include additional indications and agencies. Pediatric patients as young as age 5 are included in updated standing orders, which begin on November 1, 2024. Non-traumatic indications such as gastrointestinal bleeding, postpartum hemorrhage, or suspected massive internal bleeding can also be considered if previously defined indications of shock are present. The demonstrated feasibility, quality, and success of this pilot project has prompted the remaining prehospital paramedic agencies in Delaware to move forward with plans to carry whole blood in their respective service areas.

Kent County paramedics began carrying whole blood on November 12, 2024. Delaware is now the first state where all primary responding paramedic agencies statewide carry and administer whole blood. Delaware State Police Aviation will add whole blood in December 2024. At that point, every prehospital paramedic agency in Delaware will carry and administer whole blood.

CONFLICT OF INTEREST STATEMENT

The authors declare that there is no conflict of interest.

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How to cite this article: Rosenbaum RA, Dworkin M, Eisenman J, Cowan P, Burch K, Dattoli J, et al. How do we implement a prehospital whole blood administration program for shock trauma patients on a statewide basis? *Transfusion*. 2025. <https://doi.org/10.1111/trf.18160>