

Journal Club

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Your Blood. Your Hospital. Your Neighbors.

ORIGINAL ARTICLE

Prehospital Whole Blood in Traumatic Hemorrhage — a Randomized Controlled Trial

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<https://www.nejm.org/doi/abs/10.1056/NEJMoa2516043>

My experience

- Trauma conference presentation I gave on prehospital transfusions (PHTF)
 - PHTF work but there was not a clear answer on which products were superior → RBCs, plasma, platelets, whole blood, crystalloids, some combination
- Research from battlefield trauma
 - PHTF work
 - Only whole blood used
 - Push for PHTF in civilian world with whole blood



My experience

- Meta-analyses and other studies show mixed results on the superiority of whole blood versus components
- Whole blood is challenging for blood centers
 - Takes away three components (RBCs, plasma, platelets)
 - Disruptive to the blood supply
 - Logistical issues
 - Cost



Introduction

- The evidence that whole blood being superior to blood products (RBCs, plasma) in prehospital transfusions is limited and contradictory

Tucker et al. *Critical Care* (2023) 27:25
<https://doi.org/10.1186/s13054-022-04279-4>

Critical Care

RESEARCH

Open Access



Association of red blood cells and plasma transfusion versus red blood cell transfusion only with survival for treatment of major traumatic hemorrhage in prehospital setting in England: a multicenter study

Harriet Tucker¹, Karim Brohi^{1,2}, Joachim Tan³, Christopher Aylwin⁴, Roger Bloomer⁵, Rebecca Cardigan⁶, Ross Davenport^{1,2}, Edward D. Davies⁷, Phillip Godfrey⁸, Rachel Hawes^{9,10}, Richard Lyon¹¹, Josephine McCullagh², Simon Stanworth^{6,12}, Julian Thompson^{13,14}, James Uprichard¹⁵, Simon Walsh^{4,16}, Anne Weaver² and Laura Green^{1,2,6*}

Association of Prehospital Blood Product Transfusion During Medical Evacuation of Combat Casualties in Afghanistan With Acute and 30-Day Survival

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Introduction

- Data from observational studies have suggested possible benefits of whole blood, including a reduction in the overall use of blood products
- Previous systematic reviews have identified one small, single-center pilot trial that was not powered to assess survival and used whole blood that lacked platelets (due to leukoreduction)



Introduction

- Debate over whole blood's superiority is ongoing



Study of Whole Blood in Frontline Trauma (SWiFT)

- England
- Goal → determine whether prehospital transfusion of up to two units of whole blood was superior to standard blood components in reducing the risk of death or massive transfusion in patients with life-threatening traumatic hemorrhage
 - Traumatic hemorrhage defined as administration of 10 or more units within 24 hours



Methods

- Design

- Pragmatic, phase 3, multicenter, unblinded, randomized, controlled, superiority trial
 - **Pragmatic:** designed to evaluate the effectiveness of an intervention in real-world clinical practice, rather than under idealized conditions
 - **Phase 3:** a late-stage trial, typically enrolling hundreds to thousands of participants, designed to confirm the therapeutic benefit of an intervention and establish its safety profile
 - **Multicenter:** conducted across multiple clinical sites (hospitals, clinics, or health systems), which enhances generalizability by capturing variation in patient populations, practice patterns, and care settings
 - **Unblinded (open-label):** neither participants nor investigators are blinded to treatment assignment
 - **Randomized, controlled:** participants are randomly assigned to an intervention or control group → minimizes confounding and selection bias thus preserving internal validity even in a pragmatic design
 - **Superiority:** the statistical hypothesis is designed to demonstrate that the experimental intervention is better than the control, as opposed to a non-inferiority or equivalence design



Methods

- Design

- Trauma patients with life-threatening bleeding
- 10 air ambulance services
- 19 hospitals



Methods

- Design

- **Whole blood:** leukoreduced, group O, with low levels of anti-A and anti-B antibodies
- **Standard-care:** RBCs and plasma



Methods

- Consent

- Initially, consent was not obtained due to the need for immediate treatment
 - Was obtained as soon as feasible after resuscitation from patients who survived and regained capacity, or from a legal representative if the patient lacked capacity



Methods

- Patient population

- Transfusion was initiated based on...
 - Clinician judgment, and
 - Air ambulance service's criteria
- Any age
- Excluded if...
 - IV or IO access could not be established
 - Had a known objection to blood transfusion
 - Had received blood components or products before the arrival of the air ambulance service



Methods

- Patient population

- Because the trial boxes contained the only blood products carried by most air ambulance services, non-trauma patients were enrolled in the trial but replaced in the sample size
- Patients in traumatic cardiac arrest (absence of a palpable pulse or signs of life) were excluded from the primary analysis
 - Survival is lower in these patients than among other patients with trauma



Methods

- Randomization and treatment

- Blood boxes were randomly assigned in a 1:1 ratio to be packed with either whole blood or standard blood components
- Transfusion laboratory teams prepared the sealed, identical trial boxes according to the assigned treatment and dispatched them to air ambulance services
- Clinical teams were unaware of the assignments



Methods

- Randomization and treatment

- Participants were considered to be enrolled once the trial box was opened with an intent to transfuse
 - Once opened, the assigned treatment could not be concealed
- Participants received up to two units of whole blood or up to two units of red cells and two units of plasma (thawed plasma or lyophilized plasma)



Methods

- Primary outcome

- A composite of death from any cause or massive transfusion within 24 hours after randomization

- Adult

- ≥ 10 units of any blood components

- Pediatric

- < 16 y

- < 50 kg

- Transfused ≥ 40 ml/kg



Methods

- Secondary outcomes

- Death from any cause at 6 hours, 24 hours, 30 days, and 90 days
- Massive transfusion
- Days free from organ failure (up to 30 days)
- Days in critical care and hospital (up to 90 days)
- Number of units of blood component or product
- Cell salvage received within 24 hours
- Use of additional hemostatic agents within 24 hours
- Prothrombin time above normal
- Acid-base disturbance



Methods

- Safety outcomes

- Thrombotic events up to 30 days
- Transfusion reactions or adverse events considered to be related to prehospital blood components or serious adverse events occurring within...
 - 14 days after transfusion
 - Up to the time of hospital discharge, or
 - Up to the time of death, whichever occurred first



Methods

- **Statistical analysis**

- For the purposes of analysis, 2 units of whole blood (approximately 940 ml) were prespecified as equivalent to 4 units of total units of red-cell and plasma components (approximately 1104 ml) to account for volume differences



Methods

- **Statistical analysis**

- The analysis of the primary outcome was replicated across four predefined subgroups

1. **Presence of traumatic brain injury** → defined by a score of ≥ 3 on the Abbreviated Injury Scale for the head; scores range from 0 to 6, with a score of 0 indicating no injury and a score of 6 indicating an unsurvivable injury
2. **Population** → adults or pediatric patients < 16 yo
3. **Injury type** → blunt or penetrating
4. **Injury Severity Score** → ≤ 15 , 16–25, or ≥ 26 ; scores range from 0 to 75, with higher scores indicating greater injury severity; an Injury Severity Score of > 15 indicates major trauma



Methods

- **Statistical analysis**

- Also explored the treatment effect on the primary outcome of several postintervention factors
 - Prehospital anesthesia → yes or no
 - Prehospital transport time → ≤ 20 or > 20 minutes
 - For participants in the whole blood group, the age of the whole blood units → 1–14 or > 14 days



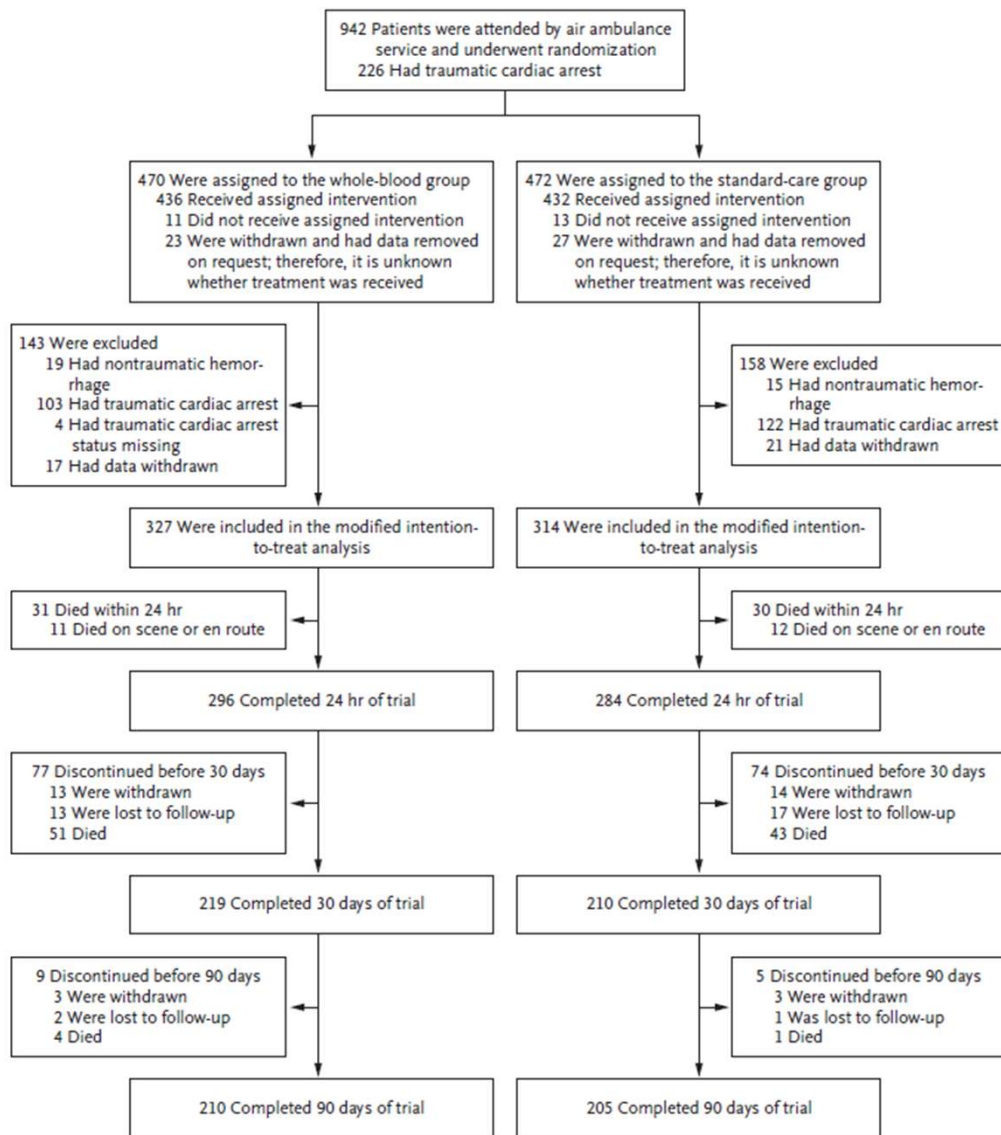


Figure 1. Screening, Randomization, and Follow-up.

Of the 50 participants who were withdrawn from the trial and requested data removal, 21 were involved in a serious breach of protocol and their “treatment received” data were removed (11 participants in the whole-blood group and 10 participants in the standard-care group). Of the 34 participants who were excluded because of nontraumatic hemorrhage, 2 were involved in a serious protocol breach. Of the 38 participants who were excluded because they had data withdrawn, 17 were involved in a serious protocol breach and their data regarding traumatic cardiac arrest status were removed (9 participants in the whole-blood group and 8 participants in the standard-care group); therefore, we could not assess these exclusions. There were 2 participants involved in a serious protocol breach who were withdrawn more than 90 days after randomization. All other withdrawals were related to patient or consultee withdrawal. One patient who was withdrawn from the trial had nontraumatic hemorrhage and traumatic cardiac arrest; this patient was included in the group of 226 participants who were in traumatic cardiac arrest when the air ambulance service arrived but not in the group of 225 participants with traumatic cardiac arrest.

Results

- Total of 641 participants
 - 327 in the whole blood group
 - 314 in the standard-care group



Table 1. Demographic and Clinical Characteristics of the Participants at Baseline and Treatment Characteristics.*

Characteristic	Whole-Blood Group (N = 327)	Standard-Care Group (N = 314)
Patient characteristics		
Median age (IQR) — yr†	38 (25–58)	35 (24–57)
Age <16 yr — no./total no. (%)	12/325 (3.7)	9/314 (2.9)
Male sex — no./total no. (%)‡	228/306 (74.5)	221/289 (76.5)
Median estimated weight on arrival of air ambulance service (IQR) — kg§	80 (70–90)	80 (70–90)
Injury characteristics		
Injury type — no./total no. (%)		
Blunt	238/325 (73.2)	214/309 (69.3)
Penetrating	87/325 (26.8)	95/309 (30.7)
Abbreviated Injury Scale score for the head — no./total no. (%)¶		
<3	127/219 (58.0)	104/196 (53.1)
≥3	92/219 (42.0)	92/196 (46.9)
Median Injury Severity Score (IQR)‖	33 (18–48)	34 (18–45)
Prehospital measurements**		
Median systolic blood pressure (IQR) — mm Hg	95 (75–121)	96 (79–120)
Median heart rate (IQR) — beats/min	110 (85–129)	110 (83–130)
Median respiratory rate (IQR) — breaths/min	22 (16–29)	23 (17–30)
Median oxygen saturation (IQR) — %††	95 (85–99)	94 (85–99)
Glasgow Coma Scale score — no./total no. (%)‡‡		
≤8	126/317 (39.7)	116/310 (37.4)
9–12	38/317 (12.0)	40/310 (12.9)
≥13	153/317 (48.3)	154/310 (49.7)
Median Glasgow Coma Scale score (IQR)	12 (5–15)	12 (6–15)

Table 1. (Continued.)

Characteristic	Whole-Blood Group (N=327)	Standard-Care Group (N=314)
Prehospital treatment characteristics		
Intervention — no./total no. (%)§§		
Airway support	142/289 (49.1)	133/266 (50.0)
Breathing support	139/289 (48.1)	141/266 (53.0)
Thoracostomy	80/289 (27.7)	68/266 (25.6)
Spinal immobilization	118/289 (40.8)	116/266 (43.6)
Chest drain	8/289 (2.8)	10/266 (3.8)
Other	132/289 (45.7)	120/266 (45.1)
Median age of blood transfused (IQR) — days¶¶	13.5 (10–17)	18 (13–22.3)

Table 1. (Continued.)		
Characteristic	Whole-Blood Group (N=327)	Standard-Care Group (N=314)
Prehospital treatment characteristics		
Intervention — no./total no. (%)§§		
Airway support	142/289 (49.1)	133/266 (50.0)
Breathing support	139/289 (48.1)	141/266 (53.0)
Thoracostomy	80/289 (27.7)	68/266 (25.6)
Spinal immobilization	118/289 (40.8)	116/266 (43.6)
Chest drain	8/289 (2.8)	10/266 (3.8)
Other	132/289 (45.7)	120/266 (45.1)
Median age of blood transfused (IQR) — days¶¶	13.5 (10–17)	18 (13–22.3)

- * Some of the prehospital interventions may have occurred after administration of the intervention and therefore are not strictly baseline characteristics. The baseline data do not include data for participants with traumatic cardiac arrest. Data on the Abbreviated Injury Scale score, the Injury Severity Score, and prehospital interventions were obtained from the National Major Trauma Registry form. IQR denotes interquartile range.
- † The median age was estimated for participants who died before arrival at the hospital. Data were missing for 2 participants.
- ‡ The sex of the participants was not known for those who died before arrival at the hospital.
- § Data were missing for 21 participants.
- ¶ The Abbreviated Injury Scale scores range from 0 to 6, with higher scores indicating more severe injury; a score of ≥ 3 indicates a severe traumatic brain injury.
- || The Injury Severity Score was defined as the sum of the squares of the highest Abbreviated Injury Scale grade in each of the three most severely injured areas. Scores range from 0 to 75, with higher scores indicating more severe injury; a score higher than 15 indicates major trauma. If the patient was dead on arrival at the hospital, then the Injury Severity Score was not calculated and hence was assumed to be 75 (maximum score). Data were missing for 201 participants.
- ** Measurements of systolic blood pressure were missing for 15 participants, heart rate for 9 participants, respiratory rate for 27 participants, and oxygen saturation for 111 participants.
- †† Oxygen saturation was measured by pulse oximetry.
- ‡‡ Scores on the Glasgow Coma Scale range from 3 to 15, with higher scores indicating a greater level of consciousness.
- §§ Multiple interventions could have been selected for each patient. If no interventions were selected but other data from the surrounding questions on the same form were complete, it was assumed that no intervention was delivered. If data from surrounding questions were missing and no interventions were reported, these data were considered by the investigator to be missing.
- ¶¶ The age of blood transfused was calculated only when the correctly assigned product or component was administered. The age of blood was calculated as the number of days elapsed between the date the donor blood was collected (bled) and the date of transfusion to the recipient. For the standard-care group, only the age of the red cells was used in this calculation. If 2 units of blood were used, the average of the 2 units was taken. Data were missing for 51 participants.

Table 2. Primary Outcome.

Outcome	Whole-Blood Group (N=327)	Standard-Care Group (N=314)	Relative Risk (95% CI)*	P Value†
Death or massive transfusion within 24 hours after randomization — no./total no. (%)				
Modified intention-to-treat population	153/314 (48.7)	144/302 (47.7)	1.02 (0.80–1.31)	0.84
Per-protocol population	145/291 (49.8)	130/273 (47.6)	1.05 (0.83–1.32)	

Table 3. Secondary Outcomes in the Modified Intention-to-Treat Population.*

Population and Outcome	Whole-Blood Group (N=327)	Standard-Care Group (N=314)	Treatment Difference (95% CI)†
mITT			
Death from any cause — no./total no. (%)‡			
6 hr after randomization	27/318 (8.5)	22/301 (7.3)	RR, 1.16 (0.38–3.55)
24 hr after randomization	32/317 (10.1)	30/301 (10.0)	RR, 1.02 (0.39–2.66)
30 days after randomization	82/298 (27.5)	73/281 (26.0)	RR, 1.06 (0.70–1.61); HR, 1.08 (0.79–1.48)
90 days after randomization	87/286 (30.4)	74/272 (27.2)	RR, 1.12 (0.74–1.70); HR, 1.13 (0.83–1.55)
Massive transfusion — no./total no. (%)‡	136/303 (44.9)	123/290 (42.4)	RR, 1.07 (0.80–1.41)
Units of blood component received in the 24 hr after randomization, including prehospital transfusions — median (IQR); no. of participants with data§¶			
Whole blood	4 (2–4); 314	4 (2–4); 7	RRa, NA
Red cells	4 (2–7); 220	4 (2–7); 294	RRa, 1.02 (0.85–1.22)
Fresh-frozen plasma	4 (2–7); 191	3 (2–6); 289	RRa, 1.14 (0.94–1.38)
Lyophilized plasma	2 (1–4); 11	2 (2–4); 18	RRa, NA
Platelets	1 (1–2); 94	1 (1–2); 89	RRa, 0.95 (0.58–1.54)
Cryoprecipitate	2 (2–3); 85	2 (2–4); 82	RRa, 0.91 (0.67–1.22)
Octaplas	4 (2–4); 4	4 (3–6); 3	RRa, NA
mITT minus those who died before arrival at acute care hospital 			
Prothrombin time above normal range on hospital arrival — no./total no. (%)	94/231 (40.7)	71/233 (30.5)	RR, 1.31 (1.10–1.56)
mITT minus those who died before arrival at acute care hospital or withdrew within 30 days after randomization**††			
Overall days free from organ failure within 30 days after randomization — median (IQR); no. of participants with data	22 (0–29); 285	21 (0–29); 266	
Days free from advanced cardiovascular support — median (IQR); no. of participants with data	27 (12–30); 285	27 (10–30); 266	
Days free from advanced respiratory support — median (IQR); no. of participants with data	23 (1–29); 285	22 (0–29); 266	
Days free from advanced renal support — median (IQR); no. of participants with data	30 (18–30); 285	30 (24–30); 266	
mITT minus those who died before arrival at acute care hospital or withdrew within 90 days after randomization†††‡‡			
Time in critical care up to 90 days — median (IQR); no. of participants with data	8 (4–19.5); 184	8 (3–19); 180	
Time in acute care hospital up to 90 days — median (IQR); no. of participants with data	17.5 (6–41); 300	20 (6–48); 284	

Table 4. Safety Outcomes.

Outcome	Whole-Blood Group (N = 327)	Standard-Care Group (N = 314)	Total (N = 641)
Serious adverse events*			
Total no. of events	31	37	68
Participants with ≥ 1 serious adverse event — no. (%)	24 (7.3)	31 (9.9)	55 (8.6)
Transfusion-associated adverse events reported to National Hemovigilance scheme up to 14 days after randomization			
Participants with ≥ 1 event — no. (%)	0	2 (0.6)	2 (0.3)
Thrombotic events within 30 days after randomization			
Pulmonary embolus — no./total no. (%)	17/268 (6.3)	17/252 (6.7)	34/520 (6.5)
Deep venous thrombosis — no./total no. (%)	13/268 (4.9)	11/252 (4.4)	24/520 (4.6)
Myocardial infarction — no./total no. (%)	0/268 (0.0)	1/252 (0.4)	1/520 (0.2)
Stroke — no./total no. (%)	6/268 (2.2)	7/252 (2.8)	13/520 (2.5)
Peripheral ischemia causing tissue loss — no./total no. (%)	1/268 (0.4)	2/252 (0.8)	3/520 (0.6)
Other — no./total no. (%)	11/268 (4.1)	9/252 (3.6)	20/520 (3.8)
Participants with ≥ 1 event — no./total no. (%) [†]	38/268 (14.2)	40/252 (15.9)	78/520 (15.0)

Results

- The percentages of participants who had died from any cause at 6 hours, 24 hours, 30 days, and 90 days after randomization...
 - Similar between the two groups
- Percentage of participants who received massive transfusion within 24 hours...
 - Similar between the two groups



Results

- Exceeding normal prothrombin time
 - Whole blood → 40.7%
 - Standard care → 30.5%
- Secondary outcomes
 - Similar between the two groups



Results

- **Serious adverse events**
 - Whole blood → 31
 - Standard-care → 37
- **Transfusion-related events**
 - Whole blood → none
 - Standard-care → two
- **Thrombotic events**
 - Similar



Discussion

- Prehospital transfusion of up to two units of whole blood was not superior to standard care in reducing the risk of death or massive transfusion at 24 hours
- Results similar between the two groups...
 - Number of participants who died at the prespecified time points
 - The incidence of massive transfusion at 24 hours
 - Other secondary clinical outcomes
- No safety concerns were identified with whole blood transfusion



Discussion

- A prothrombin time that exceeded the normal range in the whole blood did not translate into any difference in clinical outcomes
 - Due to the age of plasma?
 - In vitro studies have shown that coagulation factors decline with storage
 - Whole blood units → up to 21 days
 - Standard care group → typically less than five days



Discussion

- Subgroup analyses were consistent with those of the primary analysis
 - Reinforces the conclusion that no substantial differences were observed between the two groups
 - Dose of whole blood (up to two units) may have been insufficient to show an effect
 - Future research may clarify which populations may benefit from the use of whole blood



Discussion

• Limitations

- Variability inherent to the prehospital environment and time-critical decision making
- Pragmatic design
 - Relied on clinical judgment to initiate transfusion, which may have introduced population heterogeneity and led to the inclusion of some patients without life-threatening hemorrhage
 - Dependent on the routine use of the Trauma Audit and Research Network database for injury characteristics
 - A cyberattack on this database in 2023 resulted in some missing data



Conclusion

- Adopting the use of whole blood must balance logistic advantages against...
 - Supply constraints
 - Cost
 - Overall availability of blood



Trauma–Sang TOrtal dans les Hémorragies Massives (T-STORHM)

- “Whole Blood Transfusion in Massive Hemorrhage”
- A prospective, randomized, multicenter clinical trial designed to compare low-titer group O fresh whole blood versus standard blood component therapy in the in-hospital management of trauma patients with massive hemorrhage
- France
- Data currently being aggregated
- <https://pubmed.ncbi.nlm.nih.gov/31645305/>



Questions?

Outreach



- Physician available 24/7
 - Practitioners with transfusion-related questions/issues
 - Blood bank-related questions/issues
 - (515) 309-4840
- Educate on transfusion-related topics
 - Presentations to medical personnel, lab personnel, etc.
 - Contact me: alex.smith@lifeservebloodcenter.org
- Quarterly webinars
 - <https://www.lifeservebloodcenter.org/for-hospitals/resource-guide/education>
 - To request to be on the notification list please contact Shelly Schnell-Petersen: shelly.schnell-petersen@lifeservebloodcenter.org



Thank you!

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