

# Evaluation of physical and mental workload and transfusion time in trauma resuscitation

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| <b>Submission date</b><br>25/10/2023   | <b>Recruitment status</b><br>No longer recruiting                     | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>31/10/2023 | <b>Overall study status</b><br>Completed                              | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>31/10/2023       | <b>Condition category</b><br>Injury, Occupational Diseases, Poisoning | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input type="checkbox"/> Results                     |
|  |   | <input type="checkbox"/> Individual participant data |
|  |   | <input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Bleeding is the number one cause of preventable death. 90% of prehospital and 80% of hospital survivable deaths were attributed to trauma-related hemorrhage (TRH). Evidence-based guidelines recommend the use of blood component therapy (BC) (packed red blood cells [PRBCs], plasma, platelets [PLTs]) approximating a 1:1:1 ratio to mimic the composition of whole blood (WB). The early transfusion of blood products in trauma patients has demonstrated decreased death rates, yet there seems to be no difference in outcomes for patients with significant trauma who are resuscitated using WB or CT transfusions. Resuscitation after TRH is resource-intensive and logistically complex for the healthcare team. Nurses must balance attention to the correction of the patient's coagulopathic state, the need for additional interventions, and the ratio of components already transfused. Such constant workflow changes during a TRH resuscitation create the potential for cognitive overload for the trauma team, particularly nurses who are administering the blood, which may ultimately impact patient outcomes. Use of WB (one unit) versus CT (three units) in TRH resuscitation includes a theoretical 33% decrease in workload and cognitive effort for the bedside nurse, both in management of the blood products (verification, tubing setup, use of rapid infuser, etc.) and monitoring of the patient.

The aim of this study is to measure the amount of time and physical and cognitive workload associated with transfusion completion using both a WB and a BC protocol among trauma nurses involved in the treatment of patients with TRH.

### Who can participate?

Trauma nurses who have completed a trauma orientation and who have at least 6 months experience at a Level I trauma center and prior participation in trauma resuscitation

### What does this study involve?

Using in situ simulation, the participants will complete the transfusion of whole blood and blood components to a simulated trauma patient. The time to complete each transfusion will be measured in seconds, and the workload of each transfusion will be measured.

What are the possible benefits and risks of participating?

The participants will receive a monetary incentive for participating. The risks are minimal but include the embarrassment of making a mistake during the simulation.

Where is the study run from?

The University of Alabama at Birmingham (USA)

When is the study starting and how long is it to run for?

15 to 16 June 2023

Who is funding the study?

The TriService Nursing Research Program (USA)

Who is the main contact?

Justin L. Miller, [jlmillier@uab.edu](mailto:jlmillier@uab.edu)

## Contact information

### Type(s)

Public, Scientific, Principal Investigator

### Contact name

Mr Justin Miller

### ORCID ID

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### Contact details

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

IRB-300006008-004

## Study information

## **Scientific Title**

In trauma nurses resuscitating patients who have experienced a trauma-related hemorrhage, how does the transfusion of whole blood compared to blood components affect the amount of time to complete the transfusion and the nurses' physical and mental workload?

## **Study objectives**

The transfusion of whole blood will take less time to complete and lower physical and mental workload than the transfusion of blood components.

## **Ethics approval required**

Ethics approval required

## **Ethics approval(s)**

Approved 28/05/2021, The University of Alabama at Birmingham, Institutional Review Board (470 Administration Building, 701 20th Street South, Birmingham, AL 35294-0104, United States of America; +1 (0)205 934 3789; irb@uab.edu), ref: IRB-300006008-004

## **Study design**

Randomized cross-over pilot study

## **Primary study design**

Interventional

## **Secondary study design**

Non randomised study

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

See trial outputs table

## **Health condition(s) or problem(s) studied**

Transfusion strategy for the resuscitation of trauma-related hemorrhage

## **Interventions**

Using in situ simulation, the participants will complete the transfusion of whole blood and blood components to a simulated trauma patient. Participants will be randomized in a 1:1 ratio using drawing cards with either whole blood or blood components written on them to transfuse whole blood or blood components first. The time to complete each transfusion will be measured in seconds, and immediately after the transfusion simulation, the workload of each transfusion will be measured using the National Aeronautical and Space Agency (NASA) Task Load Index followed by a 15-minute break. Following the break, the participant will complete the other transfusion followed immediately by the NASA TLX.

## **Intervention Type**

Procedure/Surgery

**Primary outcome measure**

Time (s) to complete the transfusion measured using a stopwatch by two independent timekeepers at the end of each transfusion strategy

**Secondary outcome measures**

The workload of each transfusion strategy measured using the National Aeronautics and Space Administration (NASA) Task Load Index (TLX) immediately after each transfusion

**Overall study start date**

02/09/2021

**Completion date**

17/06/2022

**Eligibility****Key inclusion criteria**

1. Completion of a trauma orientation
2. Minimum of 6 months experience at a Level I trauma center
3. Prior participation in trauma resuscitation

**Participant type(s)**

Health professional

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

10

**Total final enrolment**

10

**Key exclusion criteria**

Does not meet the inclusion criteria

**Date of first enrolment**

25/03/2022

**Date of final enrolment**

16/06/2022

**Locations**

**Countries of recruitment**

United States of America

**Study participating centre**

**The University of Alabama at Birmingham Hospital**

1802 6th Ave S,  
Birmingham  
United States of America  
35233

## Sponsor information

**Organisation**

University of Alabama at Birmingham

**Sponsor details**

1720 2nd Ave S  
Birmingham  
United States of America  
35294-1210  
+1 301-319-0596  
subcontracts@genevaua.org

**Sponsor type**

University/education

**Website**

<https://www.uab.edu/nursing/home/>

**ROR**

<https://ror.org/008s83205>

## Funder(s)

**Funder type**

Research organisation

**Funder Name**

TriService Nursing Research Program

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact, peer-reviewed journal around a year after the overall trial date.

## Intention to publish date

31/12/2024

## Individual participant data (IPD) sharing plan

The datasets generated during the current study will be made available upon request from Justin L. Miller (jlmiller@uab.edu). Time to complete the transfusion data and related workload by transfusion strategy and participant data will be shared. All data are anonymous. These data will be available commencing 01/07/2024. Consent from participants was not required or obtained.

## IPD sharing plan summary

Available on request

## Study outputs

| Output type                                   | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---------|--------------|------------|----------------|-----------------|
| <a href="#">Participant information sheet</a> |         |              | 31/10/2023 | No             | Yes             |