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

Submission date
25/10/2023

Recruitment status
No longer recruiting

Registration date
31/10/2023

Overall study status
Completed

Last Edited
31/10/2023

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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, jlmiller@uab.edu

Contact information

Type(s)
Public, Scientific, Principal investigator

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Mr Justin Miller

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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 Adminstration 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

Study type(s)
Treatment

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

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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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

ROR
https://ror.org/008s83205

Funder(s)

Funder type
Research organisation

Funder Name
TriService Nursing Research Program

Results and Publications

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?
Participant information sheet			31/10/2023	No	Yes