AD_____

**AWARD NUMBER:** W81XWH-15-2-0039

**TITLE:** A National Coordinating Center for Prehospital Trauma Research Funding Transfusion Using Stored Fresh Whole Blood

**PRINCIPAL INVESTIGATOR:** Donald Jenkins, M.D., National Trauma Institute

**CONTRACTING ORGANIZATION:** National Trauma Institute

**REPORT DATE:** Nov 2019

**TYPE OF REPORT:** Final

**PREPARED FOR:** U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

# REPORT DOCUMENTATION PAGE

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*OMB No. 0704-0188*



| **1. REPORT DATE** | **2. REPORT TYPE** | **3. DATES COVERED** |
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| Nov 2019 | Final | **08/25/2015 - 08/24/2019** |

**4. TITLE AND SUBTITLE**

A National Coordinating Center for Prehospital Trauma Research Funding Transfusion Using Stored Fresh Whole Blood

**5a. CONTRACT NUMBER**

**5b. GRANT NUMBER**
W81XWH-15-2-0039

**5c. PROGRAM ELEMENT NUMBER**

**6. AUTHOR(S)**
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**5d. PROJECT NUMBER**

**5e. TASK NUMBER**

**5f. WORK UNIT NUMBER**

**7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)**
NATIONAL TRAUMA INSTITUTE
9901 IH 10, SUITE 720
SAN ANTONIO TX 78230-2258

**8. PERFORMING ORGANIZATION REPORT NUMBER**

**9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)**

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

**10. SPONSOR/MONITOR'S ACRONYM(S)**

**11. SPONSOR/MONITOR'S REPORT NUMBER(S)**

**12. DISTRIBUTION / AVAILABILITY STATEMENT**

Approved for public release; distribution unlimited

**13. SUPPLEMENTARY NOTES**

**14. ABSTRACT**
Resuscitation protocols for trauma patients presenting with significant bleeding utilize administration of components of blood including RBCs, plasma, and platelets. Despite improvements in emergency surgery and critical care, trauma patients with severe bleeding still suffer from high incidence of complications and death compared to patients that require fewer or no transfusions. Recent studies from military centers indicate that transfusion of FWB may be more beneficial than individual blood components in patients with severe hemorrhage. This has not been studied in civilian trauma patients mainly due to the technical difficulties and costs. We proposed a feasibility and hospital outcomes study using FWB (storage time of 5 days) for resuscitating trauma patients with significant bleeding. A cohort of adult trauma patients presenting with severe hemorrhage and receiving resuscitation with FWB was prospectively compared to a control group of patients receiving standard component therapy. The shelf-life of whole blood, cost of treatment, levels of clotting and inflammatory markers in patient's blood samples, as well as the incidence of persistent bleeding, development of blood clots, infections, and mortality was compared between the two groups. This study was designed to determine whether FWB transfusions are feasible in a civilian trauma center and to determine whether resuscitation using FWB is superior to component therapy in patients with severe hemorrhage.

**15. SUBJECT TERMS**
Treatment; Hemorrhagic Shock; Transfusion; blood components; products; RBC; Plasma; Platelets; Fresh Whole Blood; Injury; leukoreduction; resuscitation; markers of coagulation; fibrinolysis

| **16. SECURITY CLASSIFICATION OF:** | | | **17. LIMITATION OF ABSTRACT** | **18. NUMBER OF PAGES** | **19a. NAME OF RESPONSIBLE PERSON** |
|---|---|---|---|---|---|
| **a. REPORT** | **b. ABSTRACT** | **c. THIS PAGE** | | | USAMRMC |
| U | U | U | UU | 18 | **19b. TELEPHONE NUMBER** *(include area code)* |

## TABLE OF CONTENTS

**Introduction:**

Most current massive transfusion protocols attempt to treat the early coagulopathic state induced by severe injury and hemorrhagic shock with transfusion of RBC, plasma, and platelets in a 1:1:1 ratio replicating whole blood. At least 2 institutions have now begun to initiate resuscitation of adult male patients with stored whole blood as a standard of care and we intend to do the same while studying the efficacy and feasibility of the change in practice. The main hypothesis behind this study is that transfusion of whole blood (WB) rather than attempted reconstitution from its banked components is safer, more efficient and effective treatment of hemorrhagic shock following injury and will result in less frequent development of clinical coagulopathy and subsequent mortality. The purpose of this study is to investigate the feasibility of developing a system to collect, store, and deliver whole blood for trauma resuscitations in our civilian trauma center. The universal donor blood type for patients with unknown blood type is type O positive blood for males and O negative for females. Because O negative blood is rare we plan to initiate our change in practice in adult male patients and later extend it to female patients if feasible. We will determine the effects of WB transfusion in adult male patients compared to transfusion of RBC, plasma, and platelets in a 1:1:1 ratio in non adult male patients on markers of coagulation, fibrinolysis, and inflammation, as well as the development of complications and hospital mortality following severe injury. One recent pilot study comparing modified whole blood to component therapy in severely injured patients (Cotton et al. Ann Surg.258: 527-533, 2013) did not show a difference in blood product usage or mortality between groups. However, they did not look at the effects of the 2 resuscitation schemes on coagulation function as we propose to do. In addition, in that study both groups received room temperature apheresis platelets because their leukoreduction process removed platelets. Our study proposes to use a leukoreduction process that spares platelets so that patients will receive only whole blood. Another study (Yazer et al JTrauma 81(1):21-6. doi: 10.1097 2016) described a change in practice process improvement initiative demonstrating the safety of transfusing up to 2 units of low titer, platelet sparing leukocyte-reduced whole blood stored for up to 10 days for 145 male patients. Specific aims were to: 1. Determine the appropriate shelf life of FWB that has been leukoreduced with a platelet sparing filter by measuring changes in levels of coagulation factors and global clotting potential of banked units over time; 2. Prospectively determine the effectiveness of trauma resuscitation using FWB compared to component therapy and its effects on transfusion requirements and variables known to reflect potential and actual clotting capacity including markers of coagulation, fibrinolysis, inflammation, platelet function and global hemostatic potential post transfusion, as well as hospital outcomes including development of coagulopathy, infection, venous thromboembolism (VTE), multiple organ failure (MOF), and mortality; and 3. Test the feasibility and implementation of a system to provide FWB for resuscitation of trauma patients in hemorrhagic shock in civilian trauma centers by monitoring cost, storage needs, frequency of blood collection, number of donors, inventory, utilization and wastage of unused units.

**Keywords:**

Treatment; Hemorrhagic Shock; Transfusion; blood components; products; RBC; Plasma; Platelets; Fresh Whole Blood; Injury; leukoreduction; resuscitation; markers of coagulation; fibrinolysis

**Accomplishments:**

The major goals of this project as identified in the Statement of Work are below with percent completion determinations and completion dates as appropriate. What were the major goals of the project?
*Include dates or percent of completion.*

| Aims and Major Goals | Timeline in Months | Completion Date | % Complete |
|---|---|---|---|
| **Specific Aim 1: Determine the shelf life of whole blood months** | | | |
| Collection of whole blood units | 1-9 | 8/24/19 | 100% |
| Testing of whole blood units for coagulation markers | 1-9 | 8/24/19 | 100% |
| Analysis of in vitro study data | 6-12 | Not Needed | 0% |
| **Specific Aim 2: Determine the effectiveness of whole blood compared to component therapy** | | | |
| Enrollment of trauma patients into the control arm, consisting of component therapy resuscitation | 13-30 | 8/24/19 | 100% |
| Collection of whole blood units from volunteer blood donors | 19-30 | 8/24/19 | 100% |
| Enrollment of trauma patients into the intervention group | 19-30 | 8/24/19 | 100% |
| Blood sample collection from trauma patients | 13-30 | 8/24/19 | 100% |
| Testing of blood samples from trauma patients | 13-30 | 8/24/19 | 100% |
| Review of unexpected or adverse events by the medical monitor | 13-30 | Ongoing | 100% |
| Data analysis | 13-33 | Ongoing | 100% |
| **Specific Aim 3: Determine the feasibility of providing whole blood for resuscitation of hemorrhagic shock** | | | |
| Collection of data regarding whole blood utilization and cost | 13-27 | 8/24/19 | 100% |
| Complete blood bank data base | 28-30 | 8/24/19 | 100% |
| Analyze blood bank data base | 28-33 | Ongoing | 100% |
| **Other Major Tasks:** | | | |
| Identification of communities in the UCLA catchment area | 1-3 | N/A | N/A |
| Advertisements for community meetings and focus groups | 1-6 | N/A | N/A |
| Hold community meetings and focus groups | 3-6 | N/A | N/A |
| IRB approval for Exemption from Informed Consent | 4-9 | N/A | N/A |
| Secretary General of the Army approval for Exemption from Informed Consent | 7-18 | N/A | N/A |
| Finalize consent form & human subjects protocol | 10-12 | 12/05/16 | 100% |
| Submit amendments, adverse events, and protocol deviations | As needed | Ongoing | 100% |
| IRB continuing review | Annually | 06/27/2017 | 100% |
| Research group meeting | Quarterly | Ongoing | 100% |

*What was accomplished under these goals?*

During the course of the study we enrolled patients into both the control and whole blood arms of the study. We collected whole blood from the pool of identified low titer donors. The study group helped us determine the feasibility of providing whole blood for resuscitation of hemorrhagic shock. We also collected data (pending final analysis) on the coagulation profiles of patients transfused with whole blood vs component therapy.

Number of subjects recruited/original planned target: **74/60**
Number of subjects screened/original planned target: **74/60**
Number of patients enrolled/original planned target: **74/60**
Number of patients completed/original planned target: **74/60**

*What opportunities for training and professional development has the project provided?*

The project provided training to research resident Anaar Siletz in clinical trial design and management. It also provided training to student research assistants identified through UCLA's Emergency Medicine Research Associate program who assist in identifying patients and collecting data.

*How were the results disseminated to communities of interest?*

Not applicable

**IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

*What was the impact on the development of the principal discipline(s) of the project?*

The project has already led to a change in practice allowing whole blood for transfusion of male trauma patients at UCLA.

*What was the impact on other disciplines?*

The change in practice affects surgical, emergency department, and critical care disciplines.

*What was the impact on technology transfer?*

Nothing to report

*What was the impact on society beyond science and technology?*

Nothing to report

**CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.:

*Changes in approach and reasons for change*

- The study team decided that the in vitro portion of the study was no longer necessary because our questions were addressed in this recent publication by Remy et al, which defined the hemostatic capacity of cold stored whole blood leukoreduced with a platelet sparing filter, including platelet mapping. For this reason, we did not conduct that portion of the analysis.

  Publication: Effects of platelet-sparing leukocyte reduction and agitation methods on in vitro measures of hemostatic function in cold-stored whole blood. J Trauma Acute Care Surg. 2018 Jun;84(6S Suppl 1):S104-S114. doi: 10.1097/TA.0000000000001870. Randomized Controlled Trial; Research Support, U.S. Gov't, Non-P.H.S.

*Actual or anticipated problems or delays and actions or plans to resolve them*

- The study was approved for a No Cost Extension in order to close out study activities. All activities are now complete.

*Changes that had a significant impact on expenditures*

- None

*Significant changes in use or care of human subjects, biohazards, and/or select agents*

- None

*Specify the applicable Institutional Review Board approval dates.*

- Continuing review submitted on July 24, 2019
- IRB close out was submitted on 10-11-2019. IRB closure pending.

*Significant changes in use or care of human subjects*

- None

*Significant changes in use of biohazards and/or select agents*

- None

**PRODUCTS:**

Publications, conference papers, and presentations

1. Abstract accepted for poster presentation at AAST 2019. *Transfusion of whole blood for civilian trauma patients: Preliminary report on coagulation capacity and outcomes.* Anaar Siletz, N. Charity Nguyen, Scott Lewis, Amy Fang, Dawn Ward, Jonathan Grotts, Danielle Doppee, Jonathan Hwang, Richelle Cooper, Alyssa Ziman, Henry Magill Cryer.

2. Abstract accepter for presentation at AABB 2019 meeting*. Logistics of Managing a Trauma Whole Blood Inventory in a Hospital Setting.* Michelle Phan-Tang, Amy Fang, Dennis M. Miranda, Jowin Rioveros, Irene Stalcup, Andrea M. McGonigle, Alyssa Ziman, Henry Cryer, Anaar Eastoak-Siletz and Dawn C. Ward.

Journal publications. *List peer-reviewed article or paper citation; include status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

- Nothing to report-final data analysis for publication pending

Books or other non-periodical, one-time publications.

- Nothing to report

Other publications, conference papers, and presentations. *Use an asterisk (*) if presentation produced a manuscript.*

- Nothing to report

Website(s) or other Internet site(s)

- Not applicable

Technologies or techniques

- Not applicable

Inventions, patent applications, and/or licenses

- Not applicable

Other Products

- Not applicable

**PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

What individuals have worked on the project?

| Name | Project Role | Nearest person month worked | % Effort | Contribution to the project |
|---|---|---|---|---|
| Donald Jenkins | Principal Investigator | 2.4 | Year 1- 5%<br>Year 2- 5%<br>Year 3- 5%<br>Year 4-5% | Oversight of entire project |
| Roy Estrada | Program Manager | 1.92 | Year 1- 8%<br>Year 2- 8% | Regulatory oversight and coordination of regulatory reviews and reporting |
| Monica Philips | Research Operations Director | .48 | Year 1- 2%<br>Year 2- 2% | Negotiated and executed subaward. |
| Michelle Price | Research Director | 1.29 | Year 2- 2.5%<br>Year 3:<br>2.5% (Sept-June)<br>10% (July-August)<br>Year 4<br>5% (Sept)<br>9% (Oct)<br>5% (Jan-Aug) | Regulatory and research oversight and reporting |
| Lizette Villarreal | Program Manager | 1.42 | Year 3<br>2% (Oct-Nov)<br>10% (Dec-August)<br>Year 4- 4% | Regulatory oversight and coordination of reviews and reporting from site to NTI and from NTI to MRMC |
| Amy Flores | Controller | 1.89 | Year 2- 2%<br>Year 3:<br>5% (Sept-Nov)<br>10% (Dec-August)<br>Year 4<br>10% (Sept)<br>5% (Nov-Aug) | Grant expense tracking, invoice processing and payments. |

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
No

What other organizations were involved as partners?

| Organization Type *(Academic institutions, other nonprofits, industrial or commercial firms, state or local governments)* | Organization Name | Location | Partner's contribution<br>• *Financial support*<br>• *In-kind support*<br>• *Facilities* |
|---|---|---|---|
| Academic Institution | UCLA | 757 Westwood Blvd, Los Angeles CA 90024 | Facilities and bioinformatics support |

**SPECIAL REPORTING REQUIREMENTS**

QUAD CHART: Updated and attached

**APPENDICES:**

- Quad Chart

- Abstract accepted for poster presentation at AAST 2019. *Transfusion of whole blood for civilian trauma patients: Preliminary report on coagulation capacity and outcomes.* Anaar Siletz, N. Charity Nguyen, Scott Lewis, Amy Fang, Dawn Ward, Jonathan Grotts, Danielle Doppee, Jonathan Hwang, Richelle Cooper, Alyssa Ziman, Henry Magill Cryer.

- Abstract accepted for poster presentation at AABB 2019 meeting. *Logistics of Managing a Trauma Whole Blood Inventory in a Hospital Setting.* Michelle Phan-Tang, Amy Fang, Dennis M. Miranda, Jowin Rioveros, Irene Stalcup, Andrea M. McGonigle, Alyssa Ziman, Henry Cryer, Anaar Eastoak-Siletz and Dawn C. Ward.

- Study Closure Submission Form

# Transfusion of Stored Fresh Whole Blood in a Civilian Trauma Center: A Prospective Evaluation of Feasibility and Outcomes

ERMS/Log Number: JW140027

Award Number: W81XWH-15-2-0039

**Grant PI: Donald Jenkins** **Study PI:** Henry M Cryer **Org:** UCLA **Award Amount:** $499,995

### Study/Product Aim(s)

- Determine the shelf life of FWB
- Prospectively determine the effectiveness of trauma resuscitation using FWB compared to component therapy
- Test the feasibility and implementation of a system to provide FWB for resuscitation of trauma patients in hemorrhagic shock

### Approach

After determining the shelf life of FWB, by measuring coagulation markers, trauma patients in hemorrhagic shock presenting to the ED will either receive component therapy or whole blood resuscitation. Blood samples, collected from time of presentation until 7 days after admission, will be analyzed and compared for markers of inflammation and coagulation. Clinical data, including blood transfusion requirements, development of coagulopathy, venous thromboembolism, infections, and mortality, will be collected and compared prospectively.


Non-filtered FWB stored at 4C retains functional global clotting capacity for up to 35 days, suggesting that FWB leukoreduced with a platelet-sparing filter, stored for prolonged periods of time, will be an acceptable stand-alone product for resuscitation from hemorrahagic shock.

## Timeline and Cost

| Activities CY | 16 | 17 | 18 | 19 |
|---|---|---|---|---|
| Determine the shelf life of FWB | | | | $250 |
| Determine the effectiveness of trauma resuscitation using FWB compared to component therapy | | | | $150 |
| Test the feasibility and implementation of a system to provide FWB for resuscitation of trauma patients in hemorrhagic shock | | | | $100 |
| **Estimated Budget ($K)** | | **$250** | **$150** | **$100** |

**Updated: (11/28/2019)**

### Goals

**CY15 & 16 Goals** – Determine the shelf life of FWB

☑ Measure coagulation markers in stored FWB

☐Analyze data from in vitro study

☑ Begin community consent process to get IRB and DoD approval for clinical study (No longer necessary)

☑Get IRB approval for the clinical study

**CY17 Goals** – Begin clinical study

☑Establish rolling inventory of banked whole blood

☑Enroll patients in control and experimental arms of the study

☑ Measure coagulation markers in patient samples

**CY18-19 Goals** – Complete clinical study; Test feasibility of a system to provide for resuscitation of trauma patients in hemorrhagic shock

☑ Finalize patient enrollment

☐Analyze clinical sample data

☐Analyze data regarding whole blood utilization and cost

# TRANSFUSION OF WHOLE BLOOD FOR CIVILIAN TRAUMA PATIENTS: PRELIMINARY REPORT ON COAGULATION CAPACITY AND OUTCOMES

Anaar Siletz, N. Charity Nguyen, Scott Lewis, Amy Fang, Dawn Ward, Jonathan Grotts, Danielle Doppee, Jonathan Hwang, Richelle Cooper, Alyssa Ziman, Henry Magill Cryer

**Background:**

Military services have found that WB offers a survival advantage over component therapy (CT). Initial civilian studies and preclinical work suggest hemostatic capacity of WB may be superior to CT, though it remains to be seen whether this will translate into clinical relevance. Here we report preliminary findings from an ongoing single-institution prospective observational study of WB vs CT for initial resuscitation of civilian trauma patients.

**Methods:**

Adult male trauma patients presenting with systolic blood pressure < 100 were eligible to receive up to 4 units of low titer (anti-A/B) group O+ WB leukoreduced with a platelet-sparing filter (WB group). Patients receiving CT as initial resuscitation served as controls. Blood for thromboelastography (TEG) was drawn on admission and after resuscitation was complete with either medical or surgical hemostasis. All hypothesis tests were two-sided with $\alpha$=0.05.

**Results:**

Twenty-three male patients received WB as initial resuscitation followed by additional CT as needed, compared to 27 controls who received CT alone (18 male, 9 female; sensitivity analysis showed no significant differences in coagulation profile when females were excluded). There were no significant differences in age, injury mechanism, ISS, ABC score, or BMI between groups. There were no transfusion reactions or positive direct antibody tests.

**TEG parameters before (0h) and immediately after resuscitation (AR), median (IQR)**

| | CT, 0h | WB, 0h | | CT, AR | WB, AR | |
|---|---|---|---|---|---|---|
| Variable | (n = 23) | (n = 22) | p | (n = 22) | (n = 19) | p |
| R (min, nml 5-10) | *4* (3.3-4.6) | *3.8* (3.1-4.4) | 0.74 | *4.6* (3.8-6) | 5 (4.4-5.8) | 0.30 |
| K (min, nml 1-3) | 1.8 (1.2-2.1) | 2 (1.2-2.2) | 0.44 | 2.3 (1.8-2.7) | 2 (1.4-2.6) | 0.48 |
| Angle (deg, nml 53-72) | 65.9 (64.2-70.9) | 67.7 (62.7-73.4) | 0.60 | 63.5 (57.1-64.2) | 63.4 (55.4-72.3) | 0.56 |
| MA (mm, nml 50-70) | 62.9 (56.4-66.1) | 60.7 (52.7-68.3) | 0.79 | 55.2 (51.9-59.5) | 56 (51.5-61.9) | 0.62 |

**Blood Product Transfusion 4h after Admission and Clinical Outcomes, median (IQR)**

| Variable | Component therapy (n = 27) | Whole blood (n = 23) | p |
|---|---|---|---|
| WB units (n) | 0 (0-0) | 2 (1-3) | <0.001 |
| Platelets/PRBC ratio | 0.6 (0-1.2) | 0.5 (0-1.2) | 0.88 |
| FFP/PRBC ratio | 0.7 (0-0.8) | 0.7 (0-0.8) | 0.776 |
| Total Volume of Products (mL) | 3050 (1187.5-4512.5) | 2287.5 (1612.5-3400) | 0.748 |
| 30 day Mortality (n) | 5 (18.5%) | 1 (4.5%) | 0.204 |
| ICU Stay (days) | 7 (4-11) | 4.5 (2.2-9.8) | 0.146 |

**Conclusion:** Resuscitation with CT and WB leukoreduced with a platelet-sparing filter resulted in normal post-resuscitation TEG coagulation profiles in both groups, with the exception of low R time in the CT group. Patients transfused with CT and WB received similar total volumes of blood product and had similar clinical outcomes.

# Abstract #6560

Logistics of Managing a Trauma Whole Blood Inventory in a Hospital Setting

**Michelle Phan-Tang**[1], Amy Fang[2], Dennis M. Miranda[3], Jowin Rioveros[3], Irene Stalcup[3], Andrea M. McGonigle[4], Alyssa Ziman[4], Henry Cryer[5], Anaar Eastoak-Siletz[5] and Dawn C. Ward[4], (1)UCLA Medical Center David Geffen School of Medicine Department of Pathology and Laboratory Medicine, Los Angeles, CA, (2)UCLA Medical Center, Los Angeles, CA, (3)Wing-Kwai and Alice Lee-Tsing Chung Transfusion Service, Department of Pathology and Laboratory Medicine, David Geffen School of Medicine at UCLA, Los Angeles, CA, (4)Division of Transfusion Medicine, Department of Pathology and Laboratory Medicine, David Geffen School of Medicine at UCLA, Los Angeles, CA, (5)UCLA Medical Center David Geffen School of Medicine, Department of Surgery, Los Angeles, CA

Abstract Text:

Background/Case Studies: Fresh whole blood (WB) transfusion for massive hemorrhage has demonstrated a survival advantage over component therapy in the military setting. These benefits can also be observed in adult male trauma patients with hemorrhagic shock in the hospital setting. We describe the recruitment, collection and maintenance of a trauma WB (tWB) inventory (4 units in stock) at a Level 1 trauma center along with the feasibility and obstacles of managing this WB inventory.

Study Design/Methods: At our medical center, a group O positive, low-antibody (anti-A/anti-B) titer WB inventory was implemented to support adult male trauma patients in hemorrhagic shock (systolic blood pressure of <100 with massive transfusion protocol activation). Male WB donors are screened for anti-A/B titers, and if titers are <100, they are recruited as future tWB donors. tWB units are collected in an IMUFLEX WB-SP Blood Bag System with a platelet-sparing leukocyte filter (Terumo Corporation). Unused tWB units at a 14-day shelf life are fractionated into packed red blood cell (RBC) units; the associated plasma is discarded. The process of obtaining and processing whole blood products is analyzed, and a retrospective analysis of the product inventory and transfused tWB is performed from 11/2017 to 12/2018.

Results/Findings: Seven hundred twenty-four male WB donors were screened for low titer anti-A/anti-B with 368 donors qualifying as future tWB donors (51%) (6/2017-12/2018; screening began prior to implementation of inventory given 8 week deferral following WB donation). One hundred thirty-four donors donated 244 tWB at our hospital-based donor center. Two hundred thirty-seven units were available for transfusion. An inventory of 1 to 4 units was maintained for an average of 26 days for each month of the study period. Correspondingly, there were days without units available for transfusion. Twenty-three adult male patients were transfused 91 (38%) tWB units as initial resuscitation followed by component therapy as needed. Trauma patients received 1-4 tWB units. Of the units that reached their 14-day shelf life, 132 (56%) were reprocessed into packed RBC units, and 14 (6%) were discarded.

Conclusions: Our transfusion service and donor center were able to provide a group O low-titer WB inventory for male trauma patient resuscitation though not without multiple challenges (sufficient donor pool, inability to maintain the requisite 4 stock tWB units, additional processes to titer donors and fractionate unused WB products, significant amount of plasma wastage). Given the low rate of tWB transfusion (44%) at our institution, it will be important to ensure that the clinical benefit of tWB justifies allocating the resources needed to maintain a WB inventory in the civilian setting.

Title:
Logistics of Managing a Trauma Whole Blood Inventory in a Hospital Setting

Submitter's E-mail Address:
mtang@mednet.ucla.edu
Preferred Presentation Format:
Poster only
Keywords:
Collections and Product Manufacturing, Inventory Management and Trauma and Massive Transfusion Practices

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**I agree to the above statements.**
**Any relevant financial relationships?** No
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**USAMRMC Office of Research Protections**
**Human Research Protection Office**
**Closure of Ongoing Study - Submission Form**

| | |
|---|---|
| Protocol Title | "Transfusion of Stored Fresh Whole Blood in a Civilian Trauma Center: A Prospective Evaluation of Feasibility and Outcomes" |
| Submitted By | Dr. Henry M. Cryer, III, University of California, Los Angeles, Los Angeles, CA |
| Supporting Proposal | "A National Coordinating Center for Prehospital Trauma Research Funding Transfusion Using Stored Fresh Whole Blood" |
| Submitted By | Dr. Donald H. Jenkins, National Trauma Institute, San Antonio, TX |
| Proposal/Study Number | JW140027 |
| Award Number | W81XWH-15-2-0039 |
| HSRRB Log Number | A-18689 |

**Please complete the following questions to request closure of your protocol at HRPO.**

1. **Is the study currently ongoing at your institution (including data analysis activities)?** **Y** **N** **N**

2. **Number of subjects who signed the study consent form since the study was first approved:** **N/A**

3. **Since the last Continuing Review Report have any of the following occurred:**

**Y** **N**

____ **N** Major/Substantive modifications to the research protocol and any modifications that could potentially increase risk to volunteers,
Note: The USAMRMC ORP HRPO defines a substantive modification as a change in Principal Investigator, change or addition of an institution, change to the IRB, change of Medical Monitor, elimination or alteration of the consent process, change to the study population that has regulatory implications (e.g. adding children, adding active duty population, etc), significant change in study design (i.e. would prompt additional scientific review) or a change that could potentially increase risks to subjects.

____ **N** Suspensions or terminations of the research by the IRB, institution, Sponsor, or regulatory agencies.

____ **N** Unanticipated problems involving risks to subjects or others (UPIRTSO). Copies of the event(s) description and documentation of IRB review if a UPIRTSO occurred and was not submitted to HRPO previously.

Note: UPIRTSOs are defined as problems/events that are:

- Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

- Related or possibly related to participation in the research (*possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

4. **Signature of Principal Investigator** _____

5. **Date (DDMMYYYY)** 11/21/2019

6. **Name of individual to contact with questions regarding this submission** Anaar Estrada-Sileta

7. Contact phone number (____) _____ E-mail: aeastoak-siletz@mednet.ucla.edu