Standardized Walking Blood Bank Policies and Procedures on Amphibious Readiness Groups to Expedite the Transfusion of Fresh Whole Blood

Vincent E. DiVenti, Cynthia P. Matters, and Adam R. Robles

Daniel K. Inouye Graduate School of Nursing

Uniformed Services University of the Health Sciences

May 1, 2023

Distribution Statement

Distribution A: Public Release.

The views presented here are those of the author and are not to be construed as official or reflecting the views of the Uniformed Services University of the Health Sciences, the Department of Defense or the U.S. Government.

Copyright Acknowledgement Statement

The authors hereby certify that the use of any original work by another author or copyrighted material used in the DNP project entitled: "Standardized Walking Blood Bank Policies and Procedures on Amphibious Readiness Groups to Expedite the Transfusion of Fresh Whole Blood," is either appropriately cited within the manuscript or used with formal written permission of copyright release by the owner of the original work.

DIVENTI.VINCENT.ERNEST.1505398757
Digitally signed by DIVENTI.VINCENT.ERNEST.1505398757
Date: 2023.04.30 20:42:39 -04'00'

LCDR Vincent E. DiVenti
Daniel K. Inouye Graduate School of Nursing
Uniformed Services University

Cynthia Matters
Digitally signed by Cynthia Matters
Date: 2023.05.01 06:50:24 -04'00'

LCDR Cynthia P. Matters
Daniel K. Inouye Graduate School of Nursing
Uniformed Services University

ROBLES.ADAM.R.1364371167
Digitally signed by ROBLES.ADAM.R.1364371167
Date: 2023.04.30 21:03:04 -04'00'

LT Adam R. Robles
Daniel K. Inouye Graduate School of Nursing
Uniformed Services University

Table of Contents

Disclaimer

The views expressed in this report are those of the authors and do not necessarily reflect the official policy or position of the Uniformed Services University, Naval Medical Center Portsmouth, the Department of Defense, or the United States Government. There are no financial relationships that exist between the speakers and a commercial entity.

ABSTRACT

Phase II Site(s): Naval Medical Center Portsmouth

Project Title: Standardized Walking Blood Bank Policies and Procedures on Amphibious Readiness Groups to Expedite the Transfusion of Fresh Whole Blood

Authors: DiVenti, V.E., Matters, C.P., & Robles, A.R.

Background or Problem/Issue: Health care providers can prevent trauma-related deaths if blood products are available and administered promptly. ARGs are not equipped to store an adequate amount of Fresh Frozen Plasma (FFP) and are devoid of platelet storage. As a result, standard of treatment (1:1:1 for plasma units to platelets to red blood cells) for trauma resuscitation is not available for patients experiencing massive hemorrhage. Inconsistent and non-standardized practices for establishing, initiating, and maintaining a WBB among the ARGs delay damage control resuscitation by necessitating the use of frozen packed red blood cells (PRBCs) and FFP. Furthermore, frozen blood products undergo degradation—FFP plasma proteins are destroyed, PRBCs develop storage lesions, and clotting factors are diluted from anticoagulant and preservative additives.

Clinical Question or Purpose: Implementing standardized screening, training, and administration processes for FWB via a WBB will enhance treatment and decrease the mortality of service members and civilians during humanitarian missions. Furthermore, military service members deploy to austere environments, and ARGs possess platforms that serve as casualty receiving ships that are expected to manage many trauma patients and resuscitation efforts in such environments using blood component therapy are impractical and suboptimal.

Project Design: We are conducting a gap analysis of the amphibious readiness group walking blood bank policy and evaluating their practice according to that policy.

Analysis of Results: Overall, there was not a statistical difference when comparing pre- and post-test scores; however, when subcategories were applied, there was a statistical difference with an improvement with Enlisted and Officer scores. The overall scores of the post-test yielded an increase of 4.8% when compared to the pre-test overall scores. Although there was an 8% decrease in questions directly pertaining to WBB policy, the clinical application questions increased 8%–an improvement in such is encouraging given the complex nature and depth of knowledge needed for safety execution. An overall increase in score was seen in approximately 45.5% of participants and a decrease in score was experienced by 27.3% of participants.

Organizational Impact/ Implications for Practice: We anticipate that implementing a standardized CPG will reduce service member deaths in forward deployed platforms. Additionally, equipping trainers among the Fleet Surgical Team will allow them to go forward on the ARGs, like the USS Bataan, to implement a standardized CPG. Finally, these standardized practices will result in cohesive practices among the personnel on any operational platforms that ultimately will save lives by recovering blood products via the WBB.

Abbreviated Abstract

Project: Standardized Walking Blood Bank Policies and Procedures on Amphibious Readiness Groups to Expedite the Transfusion of Fresh Whole Blood.

Impact: With a negative outcome of 68% from the paired sample t-test showing areas are deficient in WBB policy, thus addressing this deficiency and creating a standardized process allows for purposeful redundancies, designed to limit confusion, expedite transfusion, and provide the best chance of survival in the maritime austere environment.

Standardized Walking Blood Bank Policies and Procedures on Amphibious Readiness Groups to Expedite the Transfusion of Fresh Whole Blood

The United States military views uniformity and standardization as expectations and not as suggestions. There continue to be significant gaps when intertwining the waterfront platforms with medical practices, leading to life-sustaining care that fails to meet evidence-based best practices. Whole blood administration is the best product to administer for trauma resuscitation but is only obtainable via Walking Blood Bank (WBB) on an amphibious warship. There is a pre-identified primary Casualty Receiving and Treatment Ship (CRTS) within the Amphibious Readiness Group (ARG) that is capable of activating and executing a WBB for the delivery of fresh whole blood (FWB) as the primary replacement for blood loss; however, the WBB is treated as a secondary means to frozen blood products. Current practices designate WBB policies to the Senior Medical Officer (SMO) assigned to the ARG, resulting in variability between platforms. By removing individualized WBB policies and replacing them with standardized practices, the reduction in variance will increase efficiency and the most optimal course of FWB administration.

Problem Synthesis

ARGs are equipped to store a limited amount of Fresh Frozen Plasma (FFP) and are devoid of platelet storage. As a result, ARG healthcare providers cannot meet the standard of treatment to resuscitate a patient experiencing massive hemorrhage due to the inability to provide a balanced ratio (1:1:1 for plasma units to platelets to red blood cells) of blood products (Holcomb et al., 2015). Inconsistent and non-standardized practices for establishing, initiating, and maintaining a WBB among the ARGs delay damage control resuscitation by necessitating the use of frozen packed red blood cells (PRBCs) and FFP. Furthermore, frozen blood products undergo

degradation—FFP plasma proteins are destroyed, PRBCs develop storage lesions, and clotting factors are diluted from anticoagulant and preservative additives (Gaskin et al., 2015).

Military Relevance

Military servicemembers deploy to austere environments—an ARG platform being one of the most common—and resuscitation efforts in such environments using blood component therapy are impractical and suboptimal (Cap et al., 2015). An ARG—a collection of naval warships, military aircraft, amphibious assault crafts, and marine expeditionary units—conducts various missions, with healthcare providers serving on the casualty-receiving ship. During combat and humanitarian response missions, ARG healthcare providers are expected to manage many trauma patients; thus, implementing standardized screening, training, and administration processes for FWB via a WBB will enhance treatment and decrease the mortality of servicemembers.

Defense Health Agency Quadruple Aim

As introduced by the Defense Health Agency (DHA), the Quadruple Aim strategy is the process of implementing and improving integrated systems of mission readiness and health throughout military medicine (DHA, 2019). The four primary goals—increased readiness, better health, better care, and lower cost—align synergistically with establishing a standardized WBB program across ARG platforms. For example, research supports improved treatment and reduced morbidity and mortality when standardized practices for screening, training, and administering FWB are in place. The implementation of this standard will ensure an enhanced medically-ready force and allow for increased deployability by optimizing the health outcomes of the warfighter. Furthermore, associated reductions in morbidity and mortality will decrease the long-term costs associated with delayed administration of the inferior treatment of frozen blood products.

Nursing Relevance

Health care providers can prevent up to 91% of trauma-related deaths if blood products are available and administered promptly (Eastridge et al., 2019). A standardized process for WBBs would streamline trauma resuscitation efforts and decrease the timeframe of blood product receipt for patients. With thawing, water bathing, and deglycerolization averaging 140 minutes, prescreened FWB is readily available (Cap et al., 2018). Furthermore, another concern with utilizing frozen products is the concern for hemolysis during the thawing and preparatory process. Research shows that of 18 PRBC units stored more than 28 days and thawed, nearly 24% of the units showed visual signs of hemolysis (Choudhury, 2011). The loss of blood products due to hemolysis from frozen products results in a further delay in transfusion for patients. Thus a decreased timeframe and quick availability make FWB transfusion the best option to hemodynamically stabilize patients and reduce complications associated with hemorrhagic shock.

Potential Benefits

The development of standardized procedures for establishing, initiating, and maintaining a WBB for FWB transfusion by medical providers attached to ARGs will increase patient survival when blood administration is required. For example, standardizing the activation and execution of a WBB to treat hemorrhagic shock will result in the transfusion of warm FWB and the complete complement of all clotting factors in a more rapid fashion when compared to frozen blood products. The class of ship identified as the CRTS is ARG dependent, but all have a limited amount of frozen blood products—easily exhaustible in a mass casualty event. Additionally, the phenomenon of trauma's lethal triad (hypothermia, acidosis, and coagulopathy) reduces the prompt administration of FWB compared to FFP and PRBCs alone (Credland, 2016).

Description of Search

PICOT Question

Among East Coast ARG shipboard platforms, how does the implementation of the Joint Trauma System Clinical Practice Guidelines (JTS CPG) as a standardized policy for a WBB for fresh whole blood transfusions compare to individualized SMO's ship policies improve the time from activation to the administration of a transfusion?

Databases and Criteria

The authors initially searched PubMed for articles using a combination of the keywords "whole blood"[tiab] OR "modified whole blood"[tiab] OR "Blood components"[tiab] OR "fresh frozen plasma"[tiab] OR "massive blood transfusion"[tiab] OR "massive blood transfusions"[tiab] OR "large volume transfusion"[tiab] OR "large volume transfusions"[tiab] OR "massive transfusion"[tiab] OR "massive transfusions"[tiab] OR "increased platelet:RBC ratios"[tiab]) **AND** ((implement*[tiab]) AND (protocol[tiab] OR policy[tiab] OR policies[tiab] OR guidelines[tiab] OR "best practices"[tiab] OR requirement*[tiab] OR instruction*[tiab] OR standard*[tiab] OR "standard operating procedure"[tiab] dating back to 2011, for production of this narrative review, including case reports and series, retrospective and prospective studies, systematic reviews, and meta-analyses, and other narrative reviews. The purpose of using the [tiab] field code after each free text term was done to restrict the query to search the title or abstract of the articles to increase the likelihood of obtaining all relevant articles—the search revealed 582 articles. The authors, through Covidence, determined which studies to include for the review by majority consensus. A total of 37 resources were selected from PubMed for inclusion and review.

Inclusion and Exclusion

Resources initially screened for inclusion must have been published in 2011 or later and published in English. This method was utilized to obtain the most up-to-date literature and to abstain from potential language translation errors. The author's initial search generated 582 articles, of which 347 were irrelevant, 48 were removed due to being duplicates, and 16 were excluded due to not inapplicability to this topic (Appendix A). Some of the excluded articles included human immunodeficiency virus, malaria, and transfusion of patient populations not representative of forward-deployed service members. Articles relevant to improving patient outcomes associated with early transfusion of FWB compared to individually frozen blood products were selected for a full review. Additionally, resources related to the standardization and implementation of protocols and policies were reviewed to assess efficiency.

Solution Synthesis

A thorough investigation to identify the gap in practice, determine the underlying deficiency in FWB transfusion and WBB utilization was due to the lack of standardization among ARG SMOs, artificially promoting situations that favor the pre-stocked frozen blood products (PRBCs and FFP) over FWB. Nessen et al. (2013) reported that FWB in austere environments for combat injuries resulted in no increase in adverse reactions and independently improved survival compared to resuscitation with PRBCs and FFP alone. Although each ARG conducts missions independent of each other, the application of trauma resuscitation and blood management are practices that should not vary from platform to platform.

The lack of standardization is a cause for concern when caring for the warfighter, and streamlining will avoid the delay of blood transfusion receipt. Furthermore, studies conducted at a

Role 2 showed an average timeframe from initiation of WBB to time of transfusion averaged 33 minutes (Bassett et al., 2016). Whereas the activation of a massive transfusion (MT) protocol for frozen products averaged 140 minutes. The timeframe between the two processes should be considered as complications increase with the delay in transfusion, thus further enforcing the need to ensure a streamlined process for a WBB, just like the ARGs have for an MT with frozen blood products.

Thus, the recommendation is to first assess the ARGs for discrepancies in uniformity by comparing past and present policies for each ARG within an East Coast homeport. Data gathering to compare commonalities between the platforms to understand efficiencies and deficiencies considered when implementing a standardized process. Training assessments conducted on each platform are necessary because implementation mandates incorporating this tool as a resource. The quantifiable measurement of the problem is an initiation of WBB to the administration time so that a comparison between pre-implementation and post-implementation can be analyzed.

Considering literature, the United States Army Special Forces have tested and standardized a process that has proven efficient for the transfusion of FWB—the Ranger O Low Titer (ROLO) program. The initiation of the program was due to the lack of availability of cold-stored blood products. This program provides a streamlined, standardized process which has yielded higher survival rates among FWB recipients 30-days post-transfusion when compared to non-FWB recipients at the point of injury (Jones et al., 2019). The ROLO program provides valuable insight into the benefits of process standardization—this program model, although not identical, can be adapted to the ARG platforms to standardize WBB procedures.

Currently, in practice, the JTS has already researched and published specific evidence-based practices for the CPGs pertinent to WBBs. The JTS CPGs decrease variability and increase

efficiency in the care provided to patients across austere environments and platforms. Thus, the adaptation of the outlined guidelines provides a streamlined process that would be adaptable and explicitly tailored for ARG CRTS.

The JTS CPGs are beneficial because they outline a detailed process for implementation, with predefined measures for screening, initiating, planning, and training as referenced in Appendix B (Cap et al., 2018). Modifications required to CPGs, due to limitations in equipment availability and allowances, but the fundamental guidelines remain stable as a structural foundation. Furthermore, the CPG fails to recommend the number of individuals needed for prescreening, and this variable will remain ship-specific and determined as a baseline percentage of the ship's company. Research supports streamlined processes with a systematic checklist to create efficiency by decreasing processing times (Inal et al., 2018).

Treating trauma patients in austere environments offers several unique challenges—the compilations of challenges when processes and standards differ among platforms with parallel personnel and capabilities. The ARGs would benefit from standardized practices and procedures related to WBBs and FWB administration. Although equipped with the ability to provide component therapy with frozen blood products, the inability to store platelets renders patients susceptible to exsanguination. Literature is robust and plentiful with the physiologic benefits of using FWB for damage control resuscitation; however, the delay in delivery is equally significant. Utilizing the JTS CPG as a model for standardizing practices for WBBs among ARG platforms will bridge the gap between current procedures and evidence-based best practices.

Focus Areas

This project had three focus areas. First, an extensive literature search was conducted to describe the superiority of FWB over BCT when resuscitating a trauma casualty. When active duty medical personnel are deployed in austere environments, such as an ARG, unique challenges are encountered, challenges not confronted by civilian counterparts–limited resources. The limitation of resources contributes to rapid exhaustion and inadequate treatment modalities. The second area of focus centered around the utilization of a WBB and FWB transfusion during operational missions–which was plentiful in substance, but limited in quantity. While examining the literature on operational usage of WBB, the standardization of procedures emerged as a commonality for efficiency. The last area of focus examined specific programs within the military that are currently executing WBB as the primary source of blood replacement for trauma resuscitations and an After Action Report (AAR) from an ARG which activated and utilized the WBB during a mass casualty event.

Organizing Framework

The Iowa Model of Research-Based Practice to Promote Quality Care

There are several factors that contribute to an inability to best manage a casualty within an ARG–resources, preparedness, training, and personnel are significant contributors. The Iowa Model offers the most appropriate and accurate means for implementation of a standardized policy for a WBB (Appendix C). Focusing on the interdisciplinary team, rather than an individual provider, the Iowa Model encourages clinicians to identify questions of current practice as opportunities to improve practice and delivery of healthcare, and identify knowledge-focused triggers that isolate an opportunity for improvement via scientific evidence that is not currently practiced (Melnyk & Fineout-Overholt, 2019). Additionally, the environment in which implementation will occur is dynamic and not subject to traditional regulatory standards set forth

by the Food and Drug Administration (FDA)–the creative nature of this research project allows for fluidity and maneuverability with policy implementation. The Iowa Model, composed by a stepwise progression from pre-implementation to post-implementation, has negative feedback loops intertwined throughout, allowing for "on-the-spot" modifications and alterations (Melnyk & Fineout-Overholt, 2019).

Project Design

General Approach

This evidence based project drew on improving the delivery and quality of care of our forward deployed service members. The current standard of care for a patient suffering from a massive hemorrhage is blood component therapy in a 1:1:1 ratio. ARG healthcare providers are unable to meet this standard when using component replacement therapy due to the inability to store platelets while also being limited in the availability of stored plasma. Establishing a WBB program while also standardizing the process in which the WBB is activated, leads to improved patient outcomes.

Setting and Population

The primary location of implementation will take place on a pre-identified CRTS that is part of an ARG–LHD or LPD. Ship selection is contingent on several factors, outside the control of the researchers; however, the ship must be located on the East Coast for the duration of the project. The only population authorized to take part in pre and post-implementation measurements are medical and dental personnel that are assigned to the platform selected–this stipulation could prove problematic with change of duty stations and personnel transfers. Those eligible to participate in the gap analysis identification were limited to medical and dental personnel assigned to an East Coast Fleet Surgical Team (FST).

Procedural Steps

Phase One

The initiation step included an assessment of the cost of a WBB versus the utilization of frozen products. The resources available to analyze this cost would be to refer to the authorized medical allowance list (AMAL) within a military command. This list can provide a cost of the consumables that would be utilized when frozen products are delivered and compared to consumables that would be utilized when implementing a WBB. The list was then compared and a cost-benefit analysis was developed.

Phase Two

As anticipated, identifying a CRTS for implementation proved to be a daunting task. Several external factors directly affect selection, implementation, progression, and sustainability of the project. Serving as an operational platform, the ship's movement can vary at a moment's notice–unless the selected platform is drydocked and unable to get underway. Once an operational platform was identified and selected, the WBB SOP was reviewed and compared against the JTS CPGs to determine level of variability and discrepancies in practices. In addition to a pre-implementation questionnaire assessing the level-of-knowledge (LOK) on the differing type of blood products, medical personnel assigned to the selected platform will undergo basic understanding of the tactile skills and steps required to proficiently perform phlebotomy for FWB transfusion.

Phase Three

This phase required the authors to develop an actual standardized process for implementation. The previous two phases were about data gathering and then taking this information into consideration when reviewing the JTS CPGs for a standard WBB. A focus group would be developed to review the current JTS CPGs with consideration of the data previously gathered. The focus group would allow for a broad range of insight into the development of a standardized process that will be implemented on the ARGs' operational platform.

Phase Four

This phase requires the implementation of the standardized process that was developed from the focus group in phase three. A SMO was identified and agreed to assess the LOK of those personnel expected to carry-out and execute the WBB when activated in an emergency situation. Afterwards, an assessment of the results after implementation to ensure modifications that are required are addressed appropriately.

Phase Five

The last step in this procedural process is the selection and implementation of the standardized process on a secondary platform. The implementation on a secondary platform will allow assessment of the versatility of the standardized process and ensure it can be implemented on varying platforms. Thus the process would require the identification of a SMO on a secondary platform willing to coordinate, modify, and implement a newly developed standardized process to obtain blood products via a WBB. The last step would be analyzing the overall outcome and ensuring a successful implementation on the secondary platform.

Data Analysis Plan

After synthesizing and critically appraising thirty seven articles, a data analysis plan was developed to compare individualized SMO policies regarding activation of WBB and the proposed standardized plan for activation of the WBB.

Potential Barriers

Potential barriers included: frequent leadership challenges and personnel turnover; ship's schedule and movement; availability of personnel and space; and training delivery. Support from the Ship's Commanding Officer and SMO was required for supporting process improvement initiatives, improving WBB execution, and modifying current SOPs to mirror a more simplified version constructed after the JTS CPGs. A simplified plan for WBB procedures was adapted from the USS Mesa Verde (LPD 19) and utilized for pre- and post-training assessments–this platform's SOP was modeled after the JTS CPG**.**

The availability of personnel and space barriers can be mitigated by the utilization of an already assigned SWB space on the ship. The activation of the WBB for the transfusion of FWB is reserved for massive hemorrhage in emergency situations and DCR–not for situations when minimal blood products are needed–allowing for utilization of frozen blood products in clinically appropriate situations**.** Rigorous pre-screening measures along with coordination with Naval Medical Center Portsmouth allows for appropriate screening that tremendously decreases the risk of disease transmission.

Dissemination Plan

The dissemination plan would identify a SMO on a primary platform that is willing to coordinate, modify, and implement a newly developed standardized process to obtain blood products via a WBB. Once implemented, the process would have to be assessed to ensure it is properly introduced on the ship via training sessions. After the process has been successful, a

secondary platform can be selected where the standardized process can be implemented. The end goal would be standardization across the complete ARG.

HIPAA Concerns

Health Insurance Portability and Accountability Act was not a concern when completing the project because no Personally Identifiable Information was collected. Additionally, the pre- and post-assessments administered for LOK gap analysis did not require access to any health records or patient participation.

Business Case Analysis

Financial Impact

Standardizing WBB policies among East Coast ARGs with JTS CPG provides continuity, repetition, and uniformity that are necessary when life-saving measures rely on the transfusion of fresh whole blood. Current practices are platform-independent and facilitate inadequate and suboptimal resuscitation measures–via transfusion of frozen packed red blood cells (PRBCs) and fresh frozen plasma (FFP) that inadvertently lead to an increase in morbidity and mortality.

A cost-benefit analysis between frozen to fresh blood products indicated a value-based benefit of $469,800. Although difficult to quantify, the patient safety-related benefit would include current practice failing to meet DCR standards. Failure to meet this standard leads to an increased incidence of transfusion related acute lung injury (TRALI) and transfusion associated circulatory overload (TACO). Other considerations to consider would be the length of ICU stay increased by 6-days which would increase associated cost with the utilization of frozen products. The mortality rate of 44.1%. TRALI occurs up to 15.1% per patient and 1.12% per product, with a survival of 53% for critically ill patients (ASA.org).

The financial benefit of WBB versus frozen products would be that whole blood matches 1:1:1 to the donor. In contrast, FWB equates to 3 units of PRBC, 1.5 units of FFP, 1 unit of cryoprecipitate, and two units of platelets. This would equate to the utilization of fewer frozen blood products to equal one unit of exclusive products. These are considerable financial benefits that should be considered when assessing the use of whole blood over frozen products because fewer products would be consumed and improved outcomes.

Project Results

A 15 question, multiple choice assessment (Appendix K) was administered to medical and dental personnel assigned to the Fleet Surgical Team (FST) attached to the USS Bataan. Participants were given a numbered assessment and asked to provide the following information on the sign-in roster with the corresponding exam number: rank, specialty, and projected rotation date for data stratification. The 15 question assessment was divided into three categories, with each category containing five questions: administrative, clinical, and policy. The participants then received a pre-test to complete in order to provide a baseline for their knowledge. Afterwards, the participants received training for the WBB, which was based on the JTS CPG (Appendix G) and the USS MESA VERDE (LPD 19) Walking Blood Bank Standard Operating Procedure (Appendix I). The post-test was administered thirty-six days later for comparison purposes with the pre-test.

The raw data gathered from the pre and post test data were analyzed using the Kolmogorov-Smirnov test, Mann-Whitney test, and paired sample t-test. Initially, the pre- and post-test results were compared for correlation for each participant. Other data was gathered by comparing each of the individual questions on the questionnaire to determine the strength and weakness of each question. Furthermore, the data was gathered by comparing the Officers versus the Enlisted personnel–this data proved vital when assessing if stand-alone classroom-based

training and education would suffice with the implementation of standardized WBB policies across amphibious platforms. Individually each administrative, clinical, and policy question was assessed to determine the categorical weaknesses and strengths of each participant.

Analysis of Results

The results demonstrated strong foundational clinical and administrative knowledge as evidenced by the Kolmogorov-Smirnov test–found to be non-parametric. The most significant weakness was demonstrated by poor scores in WBB policy understanding. The lack of knowledge in policy centric questions identified a critical deficit to implementing a standardized policy for the WBB. The data was then compared between the Officers and Enlisted personnel using the Mann-Whitney test. The pre-training assessment was statistically significant in clinical and overall responses, $p = 0.026$. Identification of this information can be used for further studies to facilitate the implementation of a standardized process. Enlisted participants had a significant change in overall scores. Lastly, the greatest weakness was policy understanding–supporting additional time and focus are needed to enhance safety when implementing a standardized WBB policy.

The overall scores of the post-test yielded an increase of 4.8% when compared to the pre-test overall scores. Although there was an 8% decrease in questions directly pertaining to WBB policy, the clinical application questions increased 8%–an improvement in such is encouraging given the complex nature and depth of knowledge needed for safety execution. An overall increase in score was seen in approximately 45.5% of participants and a decrease in score was experienced by 27.3% of participants.

Organizational Impact and Implications to Practice and Policy

When caring for a trauma patient, especially in an austere environment, every second is crucial to increasing chances of survival and decreasing morbidity and mortality. Standardizing

WBB policies and procedures allow for a streamlined process for FWB collection and delivery– accompanied with systematic checklists enhancing efficiency and decreasing processing times. Although FWB is not approved by the FDA and does not undergo transfusion transmitted disease testing, the rate of disease transmission (compared to products of BCT) is comparable, and when administered in austere environments, FWB did not have documentation or reported adverse reactions. The areas from the data collected noted that the weakest area for Enlisted and Officers is the Policy pertaining to the WBB. With a negative outcome of 68% from the paired sample t-test, the areas deficient are clearly the knowledge pertaining to the WBB Policy. The difference in the results from the pre and post test could be associated with the variety of Standard Operating Procedures (SOP) from the variety of platforms for the FST. The lack of standardization clearly creates a deficiency that is manifested as confusion and chaos with the implementation of platform specific WBB policy. As a militant, warfighting-ready organization, the benefits of a standardized process allows for purposeful redundancies, designed to limit confusion, expedite transfusion, and provide the best chance of survival in the maritime austere environment.

Future Directions for Research and Practice

The future direction for research and practice is the initiation of a standardized WBB, however multiple aspects must be considered prior to implementation of a standardized SOP across all operational platforms. An aspect to consider is obtaining quantifiable data measuring the initiation of WBB to the administration so that a comparison can be made between pre-implementation and post-implementation. As previously mentioned, there is a large concern pertaining to the timeframe of blood administration. The process of properly preparing blood products along with the lack of certain blood products has been linked to increased morbidity and mortality. Thus an analysis of a WBB timeframe can provide insight into the timeframe for blood

administration as well as obtain valuable information to incorporate into a standardized WBB SOP.

Other considerations are to assess the ARGs for discrepancies in uniformity by comparing past and present policies for each ARG within an East Coast homeport. Data gathering to compare commonalities between the platforms to understand efficiencies and deficiencies considered when implementing a standardized process. The standardization can include commonalities between the platforms as well as assess the differences between the platforms to research the best practices. Finally training assessments and WBB drills should be conducted on each platform with the intention of mandating the standardized WBB.

Conclusion

Decreasing morbidity and mortality on the operational forefront– through efficiently streamlining the administration of FWB– is a significant gap that requires correction. Current clinical practices on the CRTS are vitally deficient in providing life-sustaining resuscitation within operational environments and fail to meet evidence-based best practice standards. Although amphibious ships are capable of storing and preparing frozen blood products, these platforms are unable to adequately store platelets. The inability to store and administer platelets leaves the trauma patient without one-third of life-saving BCT.

The timeframe for preparing frozen blood products to administer for a massive hemorrhage is an extremely time-consuming (triple the time needed for FWB) and labor intensive process. The lack of complete blood product administration and the substantial time required to prepare blood products adequately, could be the difference between survival and mortality. Furthermore, Special Forces personnel utilize their whole blood products for quick administration on the combat field. Administering intravenous fluids is not an option in the trauma algorithm for Special Forces

personnel. Thus, when hemorrhagic shock is the determination for decompensation, the administration of whole blood removed from personnel within their team is the immediate step to stabilization. The efficiency and standardization of their WBB training yield a higher survival rate but, in some instances, allows for stabilization of the combat personnel so they may stay engaged if in combat.

The evidence has proven that a WBB is highly beneficial to trauma situations, especially on forward-deployed platforms. A considerable barrier identified was the significant weakness within the policy section pertaining to a WBB among military personnel. Identifying the deficient areas paves the pathway for further research to identify the specific aspects of policy knowledge. Another consideration in paving the way forward with a WBB is analyzing SOP on all amphibious CRTS and determining the most efficient process for a standardized WBB. Finally, developing a standardized strategy and training personnel to ensure the process is unified across all amphibious CRTS platforms allows for the most successful, predictable, and productive outcome–an outcome that ultimately results in saving the lives of military personnel.

References

Bassett, A.K., Auten, J.D., Zieber, T.J., & Lunceford, N.L., (2016). Early, prehospital activation of the walking blood bank based on mechanism of injury improves time to fresh whole blood transfusion. *Joint Special Operations Medicine*, *16*(2), 5-8. https://pubmed.ncbi.nlm.nih.gov/27450595/

Cap, A., Badloe, J., Woolley, T., Prat, N., Gonzales, R., Milloy, W., Taylor, A., Corley, J., Pidcoke, H., Reade, M., & Schreiber, M. (2018). The use of frozen and deglycerolized red blood cells. *Military Medicine*, *183*,52-54. doi:10.1093/milmed/usy061

Cap, A.P., Beckett, A., Benov, A, Borgman, M., Bryant, B., Chen, J., Corley, J., Doughty, H., Fisher, A., Glassberg, E., Gurney, J., Gonzales, R., Kane., Malloy, W., Nessen, S., Perkins, J., Prat, N., … Yazer, M. (2018). Whole blood transfusion. *Joint Trauma System Clinical Practice Guidelines.* https://jts.amedd.army.mil/assets/docs/cpgs/JTS_Clinical_Practice_Guidelines_(CPGs)/Whole_Blood_Transfusion_15_May_2018_ID21.pdf

Cap, A. P., Pidcoke, H. F., DePasquale, M., Rappold, J. F., Glassberg, E., Eliassen, H. S., Bjerkvig, C. K., Fosse, T. K., Kane, S., Thompson, P., Sikorski, R., Miles, E., Fisher, A., Ward, K. R., Spinella, P. C., & Strandenes, G. (2015). Blood far forward: Time to get moving! *Journal of Trauma & Acute Care Surgery*, *78*(6), S2-6. https://doi-org.usu01.idm.oclc.org/10.1097/TA.0000000000000626

Credland, N. (2016). Managing the trauma patient presenting with the lethal triad. *International Journal of Orthopaedic & Trauma Nursing*, *20*, 45–53. https://doi-org.usu01.idm.oclc.org/10.1016/j.ijotn.2015.09.003

Choudhury, N., & Mathur, A. (2011). Visual detection of hemolysis in a blood bag before issue. *Asian Journal of Transfusion Science*, *5*(1), 61–62. https://doi.org/10.4103/0973-6247.76013

Defense Health Agency. (2019). *Quadruple aim performance process: Transforming performance improvement.* https://health.mil/Reference-Center/Presentations/2019/02/11/Quadruple-Aim-Performance-Process-Transforming-Performance-Improvement

Eastridge, B., Holcomb, J., & Shackelford, S. (2019). Outcomes of traumatic hemorrhagic shock and the epidemiology of preventable death from injury. *Transfusion*, *59*(S2), 1423–1428. https://doi.org/10.1111/trf.15161

Gaskin, D., Kroll, N.A., Ochs, A.A., Schreiber, M.A., & Pandalai, P.K. (2015). Far forward anesthesia and massive blood transfusion: Two cases revealing the challenge of damage control resuscitation in an austere environment. *American Association of Nurse Anesthetists Journal, 83*(5), 337-343. https://www.aana.com/aanajournalonline

Holcomb, J. B., Tilley, B. C., Baraniuk, S., Fox, E. E., Wade, C. E., Podbielski, J. M., del Junco, D. J., Brasel, K. J., Bulger, E. M., Callcut, R. A., Cohen, M. J., Cotton, B. A., Fabian, T. C., Inaba, K., Kerby, J. D., Muskat, P., O'Keeffe, T., Rizoli, S., Robinson, B. R. H., & Scalea, T. M. (2015). Transfusion of plasma, platelets, and red blood cells in a 1:1:1 vs a 1:1:2 ratio and mortality in patients with severe trauma: The PROPPR randomized clinical trial. *Journal of the American Medical Association, 313*(5), 471–482. https://doi-org.usu01.idm.oclc.org/10.1001/jama.2015.12

Inal, T. C., Goruroglu Ozturk, O., Kibar, F., Cetiner, S., Matyar, S., Daglioglu, G., & Yaman, A. (2018). Lean six sigma methodologies improve clinical laboratory efficiency and reduce

turnaround times. *Journal of Clinical Laboratory Analysis*, *32*(1). https://doi.org/10.1002/jcla.22180

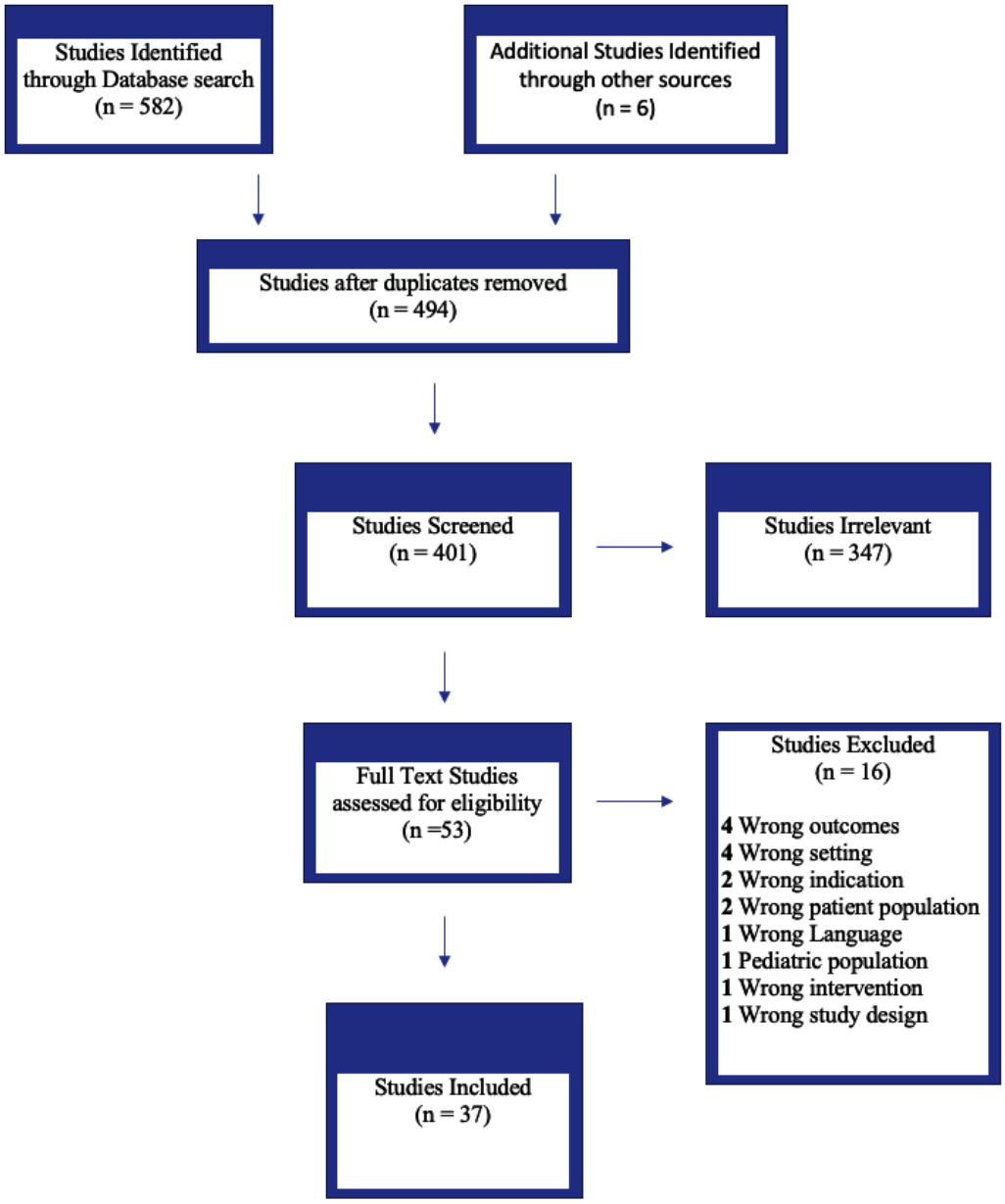
Jones, T. B., Moore, V. L., & Shishido, A. A. (2019). Prehospital Whole Blood in SOF: Current Use and Future Directions. *Journal of Special Operations Medicine : A Peer Reviewed Journal for SOF Medical Professionals*, *19*(4), 88–90. https://pubmed.ncbi.nlm.nih.gov/31910478/

Melnyk, B.M & Fineout-Overholt, E. (2019).*Evidence-based practice in nursing and healthcare(4th ed).* Wolters-Kluwer.

Nessen, S.C., Eastridge, B.J., Cronk, D., Craig, R.M., Berseus, O., Ellison, R., Remick, K., Seery, J., Shah, A., & Spinella, P.C. (2013). Fresh whole bool use by forward surgical teams in Afghanistan is associated with improved survival compared to component therapy without platelets. *Transfusion, 53*(S1), 107S-113S. https://onlinelibrary.wiley.com/doi/epdf/10.1111/trf.12044

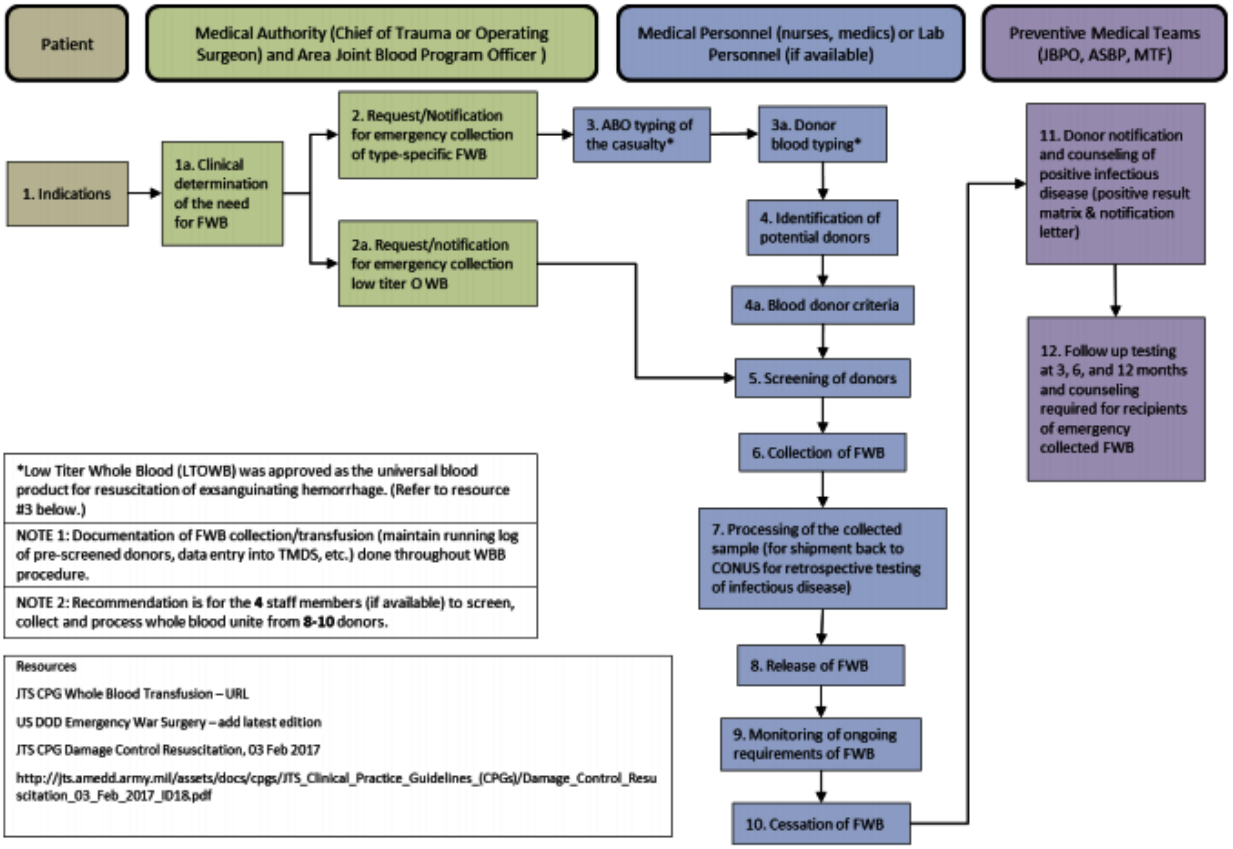
Appendix A

Systematic Reviews and Meta-Analyses (PRISMA) Chart of systematic search

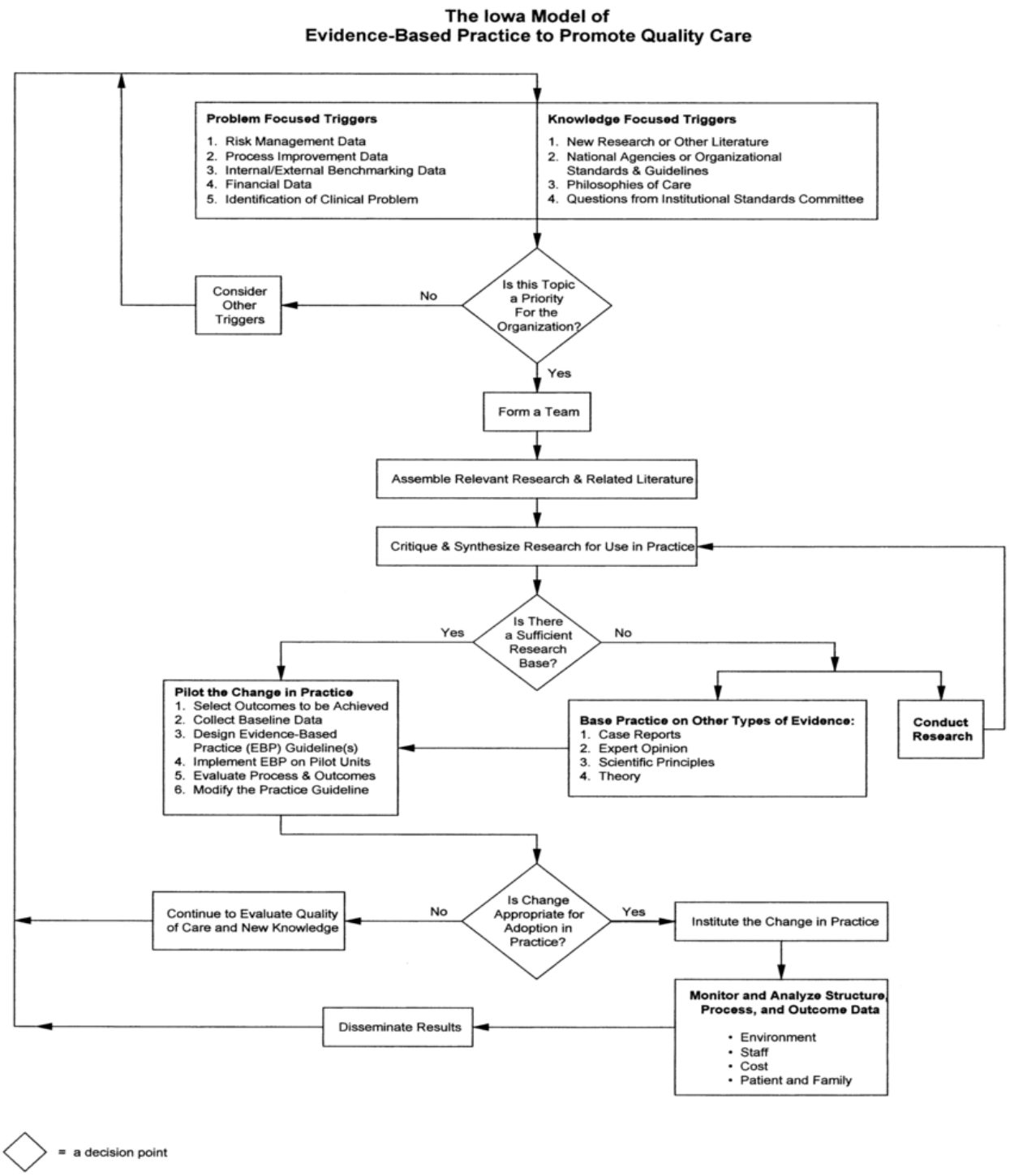


Appendix B

Walking Blood Bank Process Map


Patient
Medical Authority (Chief of Trauma or Operating Surgeon) and Area Joint Blood Program Officer)
Medical Personnel (nurses, medics) or Lab Personnel (if available)
Preventive Medical Teams (JBPO, ASBP, MTF)
1. Indications
1a. Clinical determination of the need for FWB
2. Request/Notification for emergency collection of type-specific FWB
2a. Request/notification for emergency collection low titer O WB
3. ABO typing of the casualty*
3a. Donor blood typing*
4. Identification of potential donors
4a. Blood donor criteria
5. Screening of donors
6. Collection of FWB
7. Processing of the collected sample (for shipment back to CONUS for retrospective testing of infectious disease)
8. Release of FWB
9. Monitoring of ongoing requirements of FWB
10. Cessation of FWB
11. Donor notification and counseling of positive infectious disease (positive result matrix & notification letter)
12. Follow up testing at 3, 6, and 12 months and counseling required for recipients of emergency collected FWB
*Low Titer Whole Blood (LTOWB) was approved as the universal blood product for resuscitation of exsanguinating hemorrhage. (Refer to resource #3 below.)
NOTE 1: Documentation of FWB collection/transfusion (maintain running log of pre-screened donors, data entry into TMDS, etc.) done throughout WBB procedure.
NOTE 2: Recommendation is for the 4 staff members (if available) to screen, collect and process whole blood unite from 8-10 donors.
Resources
JTS CPG Whole Blood Transfusion – URL
US DOD Emergency War Surgery – add latest edition
JTS CPG Damage Control Resuscitation, 03 Feb 2017
http://jts.amedd.army.mil/assets/docs/cpgs/JTS_Clinical_Practice_Guidelines_(CPGs)/Damage_Control_Resuscitation_03_Feb_2017_ID18.pdf

Appendix C



Appendix D: Business Case Analysis

BUSINESS CASE with VALUE BASED CARE ASSESSMENT

Proposed Title for Project/Initiative/Opportunity to Improve

Standardizing Walking Blood Bank (WBB) Policy for East Coast Amphibious Readiness Groups (ARG)

Opportunity Statement *(Description of proposed project/initiative/opportunity to improve)* *Opportunity statement*

Standardizing WBB policies among East Coast ARGs with Joint Trauma System Clinical Practice Guidelines (JTS CPG)provides continuity, repetition, and uniformity that are necessary when life-saving measures rely on the transfusion of fresh whole blood. Current practices are platform independent, and facilitate inadequate and suboptimal resuscitation measures- via transfusion of frozen packed red blood cells (PRBCs) and fresh frozen plasma (FFP) only- that cause an increase in mortality and morbidity.

Business Opportunity/Objectives *(Prioritize listing – macro and micro objectives)*

The goal is to maximize usage of fresh whole blood (FWB) and minimize time from WBB activation to transfusion
1. Macro objectives: The overall big picture goal of this business case would be a standardized WBB policy for all East Coast ARGs. Identify system-wide and ARG specific gaps in casualty resuscitation.
2. Micro objectives: The micro objectives we need in order to reach the macro objective would be implementation of the JTS CPG for WBB procedures within one ARG and track performance metrics such as: time of WBB activation to FWB transfusion, cost saving associated with decreasing storage needs for frozen products, and training efficacy. Additionally, expanding current WBB capabilities

Potential Impact of the Initiative/Project *(Identify outcome metrics & benchmarks/and how objectives align with Quadruple Aim, Value Based Care, and HRO goals)* *Potential Impact*

The development of standardized procedures for establishing, initiating, and maintaining a WBB for FWB transfusion by medical providers attached to ARGs will increase patient survival when blood administration is required. Standardizing the activation and execution of a WBB to treat hemorrhagic shock will result in the transfusion of warm FWB and the complete complement of all clotting factors in a more rapid fashion when compared to frozen blood products. The implementation of this standard will ensure an enhanced medically-ready force and allow for increased deployability by optimizing the health outcomes of the warfighter. Furthermore, associated reductions in morbidity and mortality will decrease the long-term costs associated with delayed administration of the inferior treatment of frozen blood products and its associated complications. Nessen et al. (2013) reported that FWB in austere environments for combat injuries resulted in no increase in adverse reactions and independently improved survival compared to resuscitation with PRBCs and FFP alone.

Alternatives (courses of action) chosen for Analysis

1. WBB training requirements for medical personnel assigned to ARG platforms.

2. Extending current whole blood holding time from 24-hours to 21-days when collected blood is stored in CPD containers.

3. *"Status Quo"*: Continue to allow the Senior Medical Officer attached to each ARG to implement his or her own policies and procedures while they are serving in that role.

Analysis of Alternatives

Alternative 1:	WBB training requirements for medical personnel assigned to ARG platforms with prioritized funding

Pros	**Cons**

• Formal training delivered via the Navy Blood Program or Valkyrie training program delivered by the USMC. Currently neither program is required, and there are no mechanisms in place to ensure proper and adequate training is delivered- formal training requirements will rectify this concern • Each service member will receive the same training on proper screening, testing, phlebotomy, and transfusion practices- from pre-screening LTOWB donors to the point of delivery- administering the blood to a casualty in a pre-hospital environment • Formalized training and uniformed repetition will expedite the time to transfusion • Reduce donor related injury to phlebotomy	• Even with formal training, testing capabilities can be rudimentary, unreliable, and time-consuming; identification tags are incorrect 2% to 4% of the time; mass casualty situations are inherently chaotic and the administrative burden of matching patients to blood type can incur high levels of risk (Micah, 2021). • Hands-on training is most beneficial when completed on live human subjects
Alternative 2:	Extending current whole blood holding time from 24-hours to 21-days when collected blood is stored in CPD containers.
Pros	**Cons**
• Increased availability of WB for administration • Decreased disposal of WB drawn during medical emergencies • WB is the best product available for trauma resuscitation. It is preferred over reconstituted whole blood from components (aka "component therapy"). In an austere maritime environment, the most feasible method of obtaining WB is via a WBB. • Decrease logistical complications associated with the acquisition of frozen products and delayed supply and cold-chains • Administration of FWB and SWB are not FDA approved	• Cost and storage space needed to hold blood for greater than 24-hours • After 7-days, platelets begin to degrade and provide limited benefit when transfused. • Administration of FWB and SWB are not FDA approved
Alternative 3:	*"Status Quo"*: Continue to allow the Senior Medical Officer attached to each ARG to implement his or her own policies and procedures while they are serving in that role.
Pros	**Cons**
• Each SMO has a level of comfort and experience with their current policies • Does not interrupt or complicate current policies that are set in place	• Inconsistent and non-standardized practices for establishing, initiating, and maintaining a WBB among the ARGs delay damage control resuscitation by necessitating the use of frozen packed red blood cells (PRBCs) and FFP. • Frequent turnover of SMOs, every 2-years, allows for inconsistent training and contradicting procedures. HMs have a minimum of 3-year orders, exposing them to at least 2 different SMOs (and 2 different policies) and variances • FWB is used as second-line treatment to a modified component therapy with frozen blood products consisting of only PRBCs and FFP
Assumptions *Assumptions*	
1. SMOs assigned to ARG would be willing to relinquish current policies and procedures. 2. The extension of holding time, for whole blood, will improve blood product availability. 3. Funding for implementation of the WBB would be made a priority 4. Thawing, water bathing, and deglycerolization averages approximately 140 minutes (Cap et al., 2018)	

5. PRBC units stored more than 28 days and thawed, nearly 24% of the units showed visual signs of hemolysis (Choudhury, 2011)
6. Component therapy (1:1:1 ratio) yields a dilute blood mixture with a Hct of 29%, a platelet count of approximately 90,000/μL, and coagulation factors diluted to approximately 62% of WB concentrations due to the presence of anticoagulants and red cell additive solution (Cap et al., 2018)
Information points needed to compare alternatives:

- Time it takes an identified ARG to thaw one unit of PRBCs and one unit of FFP

Recommendation and Rationale

Recommendation

Select an operational platform and analyze their current standardized process. Then coordinate with the SMO for input to create a standardized process. Ensure to develop a plan that considers all the cons to the process standardization. Then take the standardized process to another operational platform to determine if the process is versatile enough to be standardized.

Rationale

Coordinating with a SMO on an operational platform can provide valuable insight into the process and see how the process can be adjusted for standardization. Taking the plan to another operational platform will determine the feasibility of the standardized plan. ARG healthcare providers cannot meet the standard of treatment to resuscitate a patient experiencing massive hemorrhage due to the inability to provide a balanced ratio (1:1:1 for plasma units to platelets to red blood cells) of blood products (Holcomb et al., 2015)

Value Based Care - Investment Required by the Organization and the Associated "VALUE"

Value = *Quality + Service*: Projections and analysis based on treatment for 1 patient and 1-year supply/maintenance

	Cost
Patient Safety Related Benefit: - Failure to meet standards for damage control resuscitation - Increased incidence of TRALI (acute lung injury from FFP) and TACO (cardiovascular overload) TACO	- Length of ICU stay is increased by 6-days for TRALI treatment (ASA.org) - TRALI occurs in 11% of critically ill patients (ASA.org) - Mortality rate of 44.1%. TRALI occurs up to 15.1% per patient and 1.12% per product with a survival of 53% for critically ill patients. (ASA.org)
Financial Benefit: 1. Blood Component (1:1:1) with cryoprecipitate versus 1 unit of FWB 1 unit of FWB is equivalence 3 units of PRBC, 1.5 units of FFP, 1 unit of cryoprecipitate, and 2 units of platelets 2. Treatment cost for TRALI 3. SGLI payout for an active duty service member 4. Average cost of replacing new servicemember	1. **$1,500**- average cost of 1 unit PRBC ($251), 1 unit FFP ($120.00), 1 unit Cryo ($104.95), 1 unit PLTS ($313.50), 1 unit FWB ($189.91) (Cap et al., 2018) 2. TRALI treatment: **$18,300** (ASA.org) 3. SGLI: **$400,000** 4. **$50,000**

Operational Readiness Benefit	- Decreased medical air evacuation - Decreased servicemember turnover/ replacement - Increase space for armory and artillery by reducing the need for refrigerated blood products
Total	***469,800***

II. Service projected based on:

Environmental Benefit: Oil expenditure/cost to cool four blood bank refrigerators (*Blood bank refrigerators, 2018)*	**$3,604.92 per year** (*Blood bank refrigerators, 2018)*
Blood bank supplies: cost savings from blood products not being wasted when not utilized	**$96,000** (Lab supplies & products, 2021)
Social Impact/Benefit	- Fulfillment of providing for a fellow servicemember, life-saving FWB
Provider Satisfaction/Benefit	- Readily available blood products and improved patient outcomes - Standardize WBB policy allows for increased hours for medical appointments that would otherwise be allotted for training to institute new policies
Total	***$99,604.92***

III. Cost projected based on:

WBB supplies: on the current Authorized Medical Allowance List (AMAL)	**$ 0**
Management and staffing	***$ 0***
Storage and handling of blood products Training staff members aboard the ARG	***$ 0*** ***Free service***
Total	***$0***

Risks and Mitigation Plan	
Risks	**Plan**
1. Leadership Challenges	1. Identify an operational platform with leadership- both Commanding Officer and Senior Medical Officer- that supports process improvement initiatives, open to improving and simplifying their SOPs. Formulate a simplified plan for initiation and execution of WBB procedures utilizing the JTS CPGs.
2. Cost and time	2. Assess the costs involved in the training, handling, maintenance, storage involved with both SWB products, and the establishment of a WBB. Compare and contrast the pros and cons of each. Outline the costs associated with maintaining frozen blood products.
3. Availability of personnel and space	3. SWB products typically have an assigned space on shipboard vessels. Patients are treated in a previously assigned medical space. When a WBB is activated, this may impede on other departments' designated spaces.
4. Training	4. Develop a training plan to ensure training is standardized and consistent across all operational platforms. Utilize the JTS CPG model for training medical personnel. Adopt training plans from USMC and the Navy Blood Program for training.
5. FWB does not undergo transfusion transmitted disease (TTD) testing and is not approved by the Food and Drug Administration	5. Transfusion of FWB is reserved for massive hemorrhage, emergency situations, and damage control resuscitation. Rigorous pre-screening measures and coordination with NMCP will tremendously decrease the risk of disease transmission.

Implementation Plan *Implementation plan*	
Phase 1:	Obtain a list of costs associated with all materials, equipment, and man-hours needed to maintain frozen blood products.
Milestone Description:	Include the storage, handling, training, management, and maintenance pertaining to stored shipboard blood products. Also obtain the historic results from previous test runs pertaining to the implementation of a walking blood bank

Deliverables	Due Date	Accountable Person
List of consumables utilized for the process and utilization of frozen blood products. Secondary list of supplies required to complete a walking blood bank. Lastly, obtain information regarding the last WBB training. Access to the Medical Department's Division Officer for maintenance records associated with hours required to perform maintenance on equipment.	Oct 30, 2021	DNP Team

Resources Needed
Coordinated with a supply officer in the laboratory at Naval Medical Center Portsmouth to obtain a data sheet with cost of consumables. Analyze the process to defrost blood products and administer blood products and then analyze the process for

implementing a WBB including administering blood products as well. Combine cost associated with transfusing 1 unit of PRBCs and 1 unit of FFP compared to FWB.		
Expected Level of Benefit		
The cost of defrosting blood products along with the administration cost can be used to compare the cost-benefit in comparison to the consumables required for implementing a WBB. Furthermore, associated reductions in morbidity and mortality will decrease the long-term costs associated with delayed administration of the inferior treatment of frozen blood products. FWB transfusion will require less supplies, costs, and man hours than FWB.		
Phase 2:	Identify an operational platform to review their current SOP and processes for obtaining whole blood. Further understanding their processes in the event of a mass casualty.	
Milestone Description:	SMO/platform Identification	
Deliverables	Due Dates	Accountable Person
Identify an operational platform, their current policies/procedures pertaining to WBB and FWB transfusion. Evaluate required training of personnel in tactile skills needed to obtain and transfuse FWB.	Oct 30, 2021	Focus Group, Navy Blood Program
Resources Needed		
Identify a SMO that is willing to coordinate, modify, and implement a new process to obtain blood products via a WBB. Ideally, this would be completed during the ship's phase that is currently undergoing significant training and limits the amount of interruptions in day-to-day operations.		
Expected Level of Benefit		
Examination of current policies and procedures, when compared to the CPG, for gaps in WBB plan, operations, and personnel level of experience and expertise.		
Phase 3:	Develop a standardized WBB with the utilization of the operational platform's SOP and the Joint Trauma Clinical Practice Guidelines.	
Milestone Description:	Creating the standardized process for the WBB	
Deliverables	Due Dates	Accountable Person
A complete standardized WBB SOP	July 11, 2022	ASBP, Navy Blood Program, JTS, and Focus Group,
Resources Needed		
Coordination between the ASBP, Navy Blood program, JTS, and Focus Group to develop a written process with everyone's insight.		
Expected Level of Benefit		
The JTS CPGs are incredibly beneficial because they outline a detailed process for implementation, with predefined measures for screening, initiating, planning, and training (Cap et al., 2018). Modifications required to CPGs, due to limitations in equipment availability and allowances, but the fundamental guidelines remain stable as a structural foundation. Furthermore, the CPG fails to recommend the number of individuals needed for pre-screening, and this variable will remain ship-specific and determined as a baseline percentage of the ship's company. Research supports streamlined processes with a systematic checklist to create efficiency by decreasing processing times (Inal et al., 2018). Thus the overall expected level of benefit is increased efficacy to administer blood products on multiple operational platforms.		
Phase 4:	Complete test runs of standardized JTS CPG directed WBB SOP on the identified subject platform	

Milestone Description:	JTS CPG standardized WBB SOP implementation, when compared to previously instituted SOP, yields a decrease in time in the delivery of FWB.	
Deliverables	Due Dates	Accountable Person
JTS CPG standardized WBB SOP	July 2023	DNP Team, NMCP Site Director for Research, and SMO of identified platform
Resources Needed		
Staff, resources		
Expected Level of Benefit		
Implementing a standardized process via the JTS CPG will provide a streamlined modality to appropriately resuscitating a trauma patient undergoing care on an amphibious warship. Through standardization, the elimination of variencies will expedite the delivery of FWB as the primary utilized blood product.		
Phase 5:	Select a secondary platform to implement and test to ensure feasibility of the standardized process and that the new standardized process can work across multiple varying platforms.	
Milestone Description:		
Deliverables	Due Dates	Accountable Person
Results of test runs from the WBB on the secondary platform	July 2023	DNP Team, NMCP Site Director for Research, and SMO of identified platform
Resources Needed		
Identify a SMO on a secondary platform that is willing to coordinate, modify, and implement a newly developed standardized process to obtain blood products via a WBB. Ideally, this would be completed during the ship's phase that is currently undergoing significant training.		
Expected Level of Benefit		
Treating trauma patients in austere environments offers several unique challenges—the compilations of challenges when processes and standards differ among platforms with parallel personnel and capabilities. The ARGs will not have the ability to provide optimal care because of a lack of standardized practices and procedures related to WBBs and FWB administration. Although equipped with the ability to provide component therapy with frozen blood products, the inability to store platelets renders patients susceptible to exsanguination. Literature is robust and plentiful with the physiologic benefits of using FWB for damage control resuscitation; however, the delay in delivery is equally significant. Utilizing the JTS CPG as a model for standardizing practices for WBBs among ARG platforms will bridge the gap between current procedures and evidence-based best practices. Thus the overall expected level of benefit is that this standardized process can be adapted to multiple operational platforms and thus saving lives		

Appendix E: CITI Certificates

CITI PROGRAM

Completion Date 09-Apr-2021
Expiration Date 08-Apr-2024
Record ID 41959289

This is to certify that:

Vincent DiVenti

Has completed the following CITI Program course:

Not valid for renewal of certification through CME.

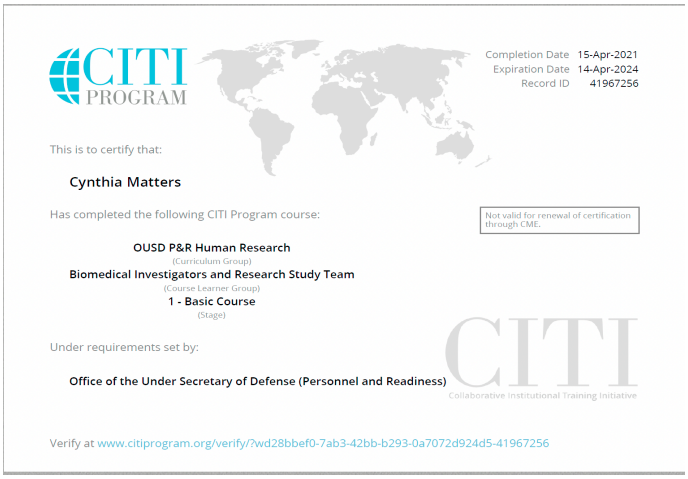
OUSD P&R Human Research
(Curriculum Group)
Biomedical Investigators and Research Study Team
(Course Learner Group)
1 - Basic Course
(Stage)

Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w49f60ba4-b3bd-4eea-8d0b-5667f5cf594d-41959289



CITI PROGRAM

Completion Date 15-Apr-2021
Expiration Date 14-Apr-2024
Record ID 41967256

This is to certify that:

Cynthia Matters

Has completed the following CITI Program course:

Not valid for renewal of certification through CME.

OUSD P&R Human Research
(Curriculum Group)
Biomedical Investigators and Research Study Team
(Course Learner Group)
1 - Basic Course
(Stage)

Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?wd28bbef0-7ab3-42bb-b293-0a7072d924d5-41967256

CITI PROGRAM

Completion Date 08-Apr-2021
Expiration Date 07-Apr-2024
Record ID 42012831

This is to certify that:

Adam robles

Has completed the following CITI Program course:

Not valid for renewal of certification through CME.

OUSD P&R Human Research
(Curriculum Group)
Biomedical Research Support Staff
(Course Learner Group)
1 - Basic Course
(Stage)

Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w2183a0c1-ebff-4299-ba65-705bb5867680-42012831

Appendix F: Evidence-Based Practice Table & Approval

NMCP Evidence Table

Author and Year	Study Purpose/Aims	Research Questions/Hypotheses	Study Design	Total Sample Size	Sampling Plan
Cotton B.A. et al. (2013)	To assess the use of whole blood for early resuscitation of civilian patients with trauma	Hypothesis was that resuscitation of severely injured patients with modified whole blood would result in fewer overall transfusions compared with component therapy	Randomized control trial	107 patients	Setting: single-center level 1 trauma center presenting to the emergency department Inclusion: 18 years of age or older, met the facilities highest-level for trauma activation, evidence of active bleeding requiring emergent uncrossed-matched blood while in the ED Exclusion: Received more than 4 units of RBC prerandomization, were moribund CPR or ED thoracotomy prerandomization), noted religious objection to transfusion, had DNR order documented, were "obviously pregnant," incarcerated/prisoners, or had an "opt-out" bracelet, B and AB blood type, severe TBI, and physician deemed unable to delay for additional time needed for blood typing

Independent Variables	Dependent Variable	Statistical Analyses	Results	Strengths	Weaknesses	Level of Evidence
Treatment: Group 1- received mWB Group 2- received COMP	overall transfusion received	Continuous data are presented as medians with 25th and 75th interquartile range (IQR), with comparisons between groups performed using the Wilcoxon rank sum test (Mann-Whitney U test). Categorical data are reported as proportions and, where appropriate, tested for significance using $\chi 2$ or Fisher exact tests.	Intend-to-Treat:A total of 55 patients were assigned to the mWB arm and 52 to the COMP arm, thereby composing the intent-to-treat group Per-Protocol: 39 WB and 42 COMP= no differences in 24-hour RBC, plasma, or platelet use between the 2 per-protocol groups (Table 2). However, there was a trend toward less platelet transfusions in the first 3 hours after arrival among mWB subjects (P = 0.06) Both 24-hour and 30-day mortality were similar between the 2 groups. The disparity in non-survivable TBI between groups was again observed and likely accounts for the difference observed in 30-day mortality (although not significant). Nonsurvivable TBI was the	Patients were randomized by the blood bank, and randomization of blood products they received. Compared with a per-protocol group. Comparison using the Wilcoxon rank sum test. P<0.05	Single-center, pilot study, failure to excluded patients with severe TBI from initial protocol- this led to several severe TBI patients to be randomized into the study early on; length of study was 4 years from the initial enrollee- there were many changes in standard of care over that time	1B- JHNEBP tool utilized for grading level of evidence
		All statistical tests were 2-tailed, with P < 0.05 set as significant. STATA Statistical software (version 12.1; College Station, TX) was used for analysis.	cause of death in 60% of mWB subjects vs 33% of COMP patients. Exsanguination accounted for 30% of mWB deaths compared with 67% COMP			

NMCP Evidence Table

Author and Year	Study Purpose/Aims	Research Questions/Hypotheses	Study Design	Total Sample Size	Sampling Plan
Weymouth et al., 2019	This narrative review describes modern-day whole blood transfusion, its benefits, potential drawback, and implementation.	The current form of stored low-titer O whole blood seems to be the safest and most effective solution.	Systematic review of peer reviewed journals	None Identified	Electronic search from the databases Pubmed and Google Scholar.

Independent Variables	Dependent Variable	Statistical Analyses	Results	Strengths	Weaknesses	Level of Evidence
NA	NA	NA	Although stored whole blood holds promise, it is not without its distinct challenges, including logistical issues, which this article addresses.	Thoroughly discusses the advantages and disadvantages of both fresh whole blood and stored whole blood. Also compares each against component therapy.	Further studies are needed, especially from the sickest patients. One RCT exists in regards to this topic.	III-B

NMCP Evidence Table

Author and Year	Study Purpose/Aims	Research Questions/Hypotheses	Study Design	Total Sample Size	Sampling Plan
Jones et al., 2019	To review CPG and TCC guidelines, also review current practices in special operating forces and future directions.	The JTS CPG for whole blood transfusion reflects the most recent clinical evidence, but poses unique challenges for execution by special operating forces.	CPG and TCCC guidelines	None Identified	Review of CPG and TCCC guidelines, and application into special operating forces

Independent Variables	Dependent Variable	Statistical Analyses	Results	Strengths	Weaknesses	Level of Evidence
NA	NA	NA	Utilization of LTOWB as a universal blood product shattered preexisting medical practice. Adoption of whole blood at the point of injury as a standard expectation.	Discusses current practices , and what has worked well. Also, openly discusses advantages and limitations.	Limited scope. Only discussing military perspectives. Scope narrowed to special forces.	III-B

NMCP Evidence Table

Author and Year	Study Purpose/Aims	Research Questions/Hypotheses	Study Design	Total Sample Size	Sampling Plan
Tamer C Inal, Ozlem Goruroglu Ozturk,, Filiz Kibar, Salih Cetiner, Selcuk Matyar,, Gulcin Daglioglu, Akgun Yaman 2017 Feb 15	Lean Six Sigma to simplify the laboratory work process and decrease the turnaround time by eliminating non-value-adding steps	Does Lean six sigma methodologies improve clinical laboratory efficiency and reduce turnaround times	longitudinal, before–after analysis of process improvements	250 to 300 tubes a day or 25-30% of all samples were erroneously labeled.	For Inpatient, samples are collected in the wards, mostly by nurses and interns, and then barcoded and sent to the central laboratory reception unit via a pneumatic tube system.For outpatients, samples are collected by an experienced seven-nurse phlebotomy team in the sample-collection area, and sent to the sample-reception area via the pneumatic tube system.

Independent Variables	Dependent Variable	Statistical Analyses	Results	Strengths	Weaknesses	Level of Evidence
focused Lean-based reorganization of the flow of the laboratory process. Collection Process	turnaround times	the percentage of samples associated with medical errors and potential biological risk dropped from 30% to 3% (P=.0000).	After the successful implementation of quality-improvement strategies, all selected performance metrics showed significant improvements and sustainability in the subsequent 3 years	Data analysis was performed with the statistical software Minitab Version 17 (Minitab, Ltd., Coventry, UK). Differences between two proportions were estimated by Fisher's Exact test and P<.05 was considered to be statistically significant.	study was performed at a single institution, and the findings might not be generalizable to other clinical laboratories with markedly different laboratory process flows.	IIB

NMCP Evidence Table

Author and Year	Study Purpose/Aims	Research Questions/Hypotheses	Study Design	Total Sample Size	Sampling Plan
Bahr et al., 2020	Practical Considerations for a Military Whole Blood Program	-demonstrate the advantages of intervention with early transfusion of blood products at the point of injury -FWB transfusion is more effective in the resuscitation of a massively hemorrhaging patient and can be done with minimal complications from adverse reactions	Systematic review of peer-reviewed journal articles	N/A	Electronic search from the databases of PubMed Central (MEDLINE) and the Cochrane Library

Independent Variables	Dependent Variable	Statistical Analyses	Results	Strengths	Weaknesses	Level of Evidence
Administration of WB specifically LTOWB, Fresh WB collected before a mission, Buddy transfusions	24 hr to 30 day mortality	By hour 24, three prehospital transfusion recipients died (5%) compared with 69 nonrecipients (20%). By day 30, six prehospital transfusion recipients died (11%) compared with 78 nonrecipients (23%).	WB provides all of the components of blood in a convenient package that is easy to store and transport, and with the recent JTS and CoTCCC adoption of WB as part of its clinical prac- tice guidelines, the utilization of WB, despite the shortage of prospective high-value data, has the potential to improve our current approach to treating military patients in hemorrhagic shock Resuscitation strategies that included FWB were associated with improved 30-day survival compared to the use of individual componentsAdditionally, soldier function is preserved after donating fresh WB in the field. Currently, the collection and implementation of WB is accomplished through several different protocol-driven techniques	Identifying and comparing the multiple avenues available for administering WB.	limitation in available journal articles	IIB

NMCP Evidence Table

Author and Year	Study Purpose/Aims	Research Questions/Hypotheses	Study Design	Total Sample Size	Sampling Plan
Naumann et al., 2020	- to perform the first systematic review and meta-analysis of the published literature regarding the delivery of FWB for patients with traumatic hemorrhagic shock, and compare outcomes between FWB and non-FWB (component therapy) treatment strategies	- patient outcomes would be equivalent or superior for FWB when compared with component therapy alone, but that adverse effects might be greater	Meta-analysis and systematic review -3,181 records found in the search, of which 2,720 unique records were screened for eligibility. There were 135 full texts assessed, from which there were 27 studies eligible for inclusion	-included for qualitative synthesis= 27	Full search and data extraction from OVID SP, PubMed, Web of Science, Clinicaltrials. gov, and Google Scholar were searched. Search terms included those relating to patients (injury, trauma, hemorrhage, bleeding) and the intervention (whole blood, fresh whole blood, emergency donor panel, walking blood bank, transfusion, buddy), with relevant variations in English spelling, and using the "AND" and "OR" functions.

Independent Variables	Dependent Variable	Statistical Analyses	Results	Strengths	Weaknesses	Level of Evidence
Delivery of FWB vs non-FWB (component therapy)	Patient outcomes- superior with FWB when compared to non-FWB alone	Meta-analysis was undertaken using odds ratios (ORs) and 95% confidence intervals (CIs) for categorical (dichotomous) outcomes. The ORs were calculated.from extracted original data and analyzed using the Mantel-Haenszel technique and a random-effects model. The OR represents the OR of the event (i.e., mortality) of the intervention (i.e., FWB) versus control (i.e., non-FWB). Statistical significance was judged using $\chi 2$ analysis, and I 2 analysis was used to quantify heterogeneity between studies. A p value of <0.05 was considered statistically significant. Statistical analysis was undertaken using Review Manager version 5.3	-no difference in adverse events in patients that received combined FWB and non-FWB alone	this was the first study that compared all the adverse events for transfusion or FWB and non-FWB -military heavy and showed a low risk for infection associated with FWB- biggest concern being ABO compatibility	-studies were graded as "low" quality according to the Grading of Recommendations, Assessment, Development, and Evaluation system, except for one study which was "moderate," and six studies were graded "very low -low gradings for quality were mainly due to the observational design of all studies, putting them at risk of bias, imprecision, inconsistency, and indirectness	IIIb

NMCP Evidence Table

Author and Year	Study Purpose/Aims	Research Questions/Hypotheses	Study Design	Total Sample Size	Sampling Plan
Bassett et al., 2016	case series reviews the four cases in which the WBB was activated prior to patient arrival	N/A	Case review	4	WBB activated prior to patient arrival

Independent Variables	Dependent Variable	Statistical Analyses	Results	Strengths	Weaknesses	Level of Evidence
N/A	N/A	N/A JTS CPG- JTTS CPG was established during the conflicts in Iraq and Afghanistan. The CPG thoroughly discusses the indications for use of FWB transfusion. One of the specific indications is the austere medical setting where blood-banking capabilities may be limited or exhausted	Overall- average time to transfusion was 18.7 minutes; three cases in which the WBB was activated through the initial nine-line communication, FWB was available within 14 minutes of patient arrival Case 1- ISS 17- arrived 28 minutes after sustaining bilateral, lower extremity traumatic amputations and left upper extremity soft tissue injury from a dismounted complex blast injury-first unit of FWB was transfused approximately 13 minutes after arrival Case 2- ISS 18- patient arrived 32 minutes after sustaining bilateral, lower extremity traumatic amputations from a DCBI--e first unit of FWB was transfused approximately 21 minutes after arrival Case 3- ISS 33- arrived 26 minutes after sustaining bilateral, lower extremity traumatic amputation from a DCBI--first unit of FWB was transfused approximately 10 minutes after arrival Case 4- ISS 18- arrived 31 minutes after sustaining a left lower extremity amputation and shrapnel injury to the right lower extremity--first unit of FWB was transfused approximately 31 minutes after arrival A shorter time to transfusion has the potential to allow medical personnel at forward deployed units the ability to provide FWB when access to apheresis platelets is limited or nonexistent. The benefit of FWB transfusion has been shown in the austere, forward deployed environment.	US Army PI project recently reported an average time to transfusion of 26.7 minutes by implementing a prescreening program and extensive training in the collection and administration of FWB -CPG integration and recommendations for prescreening, methods for obtaining warm FWB	4 cases only variable on time when 9-line was actually received	IIIa

NMCP Evidence Table

Author and Year	Study Purpose/Aims	Research Questions/Hypotheses	Study Design	Total Sample Size	Sampling Plan
Nessen et al., 2013	-to examine the association of FWB use versus use of component therapy (RBCs and FFP) only, with in-hospital mortality in combat casualties admitted to FSTs -examine the association between receipts of ABO type-specific FWB versus uncrossmatched Type O FWB on in-hospital mortality	those that received FWB would have better outcomes and decreased mortality	Retrospective analysis	6 FSTs with a total of 488 patient that met inclusion criteria	Convenience sample of 6 FSTs from December 2005-December 2010 -These units were chosen because they developed a comprehensive PI plan that included collection of data regarding blood transfusion

Independent Variables	Dependent Variable	Statistical Analyses	Results	Strengths	Weaknesses	Level of Evidence
FWB vs combined therapy	mortality rates	Univariate analysis was performed with the use of SAS 9.1. Two separate propensity score analyses were performed utilizing STATA 11.2	-no statistical difference in in-hospital mortality between study groups - unadjusted mortality rate was 5.3% (5/94) for those ransfused FWB and 8.8% (35/394) -WB use was also associated with improved survival OR (95% CI), 0.11 (0.02-0.78) -mortality rate in those patients who received MBT with RBCs, FFP, and FWB was 8.16% and those who received MBT with RBCs and FFP alone had a mortality of 26.67% (p=0.025)	-transfusion of RBCs, FFP, and FWB is independently associated with improved in-hospital survival compared with RBCs and FFP alone *****theater practice guideline was published, which recommended the use of FWB for circumstances when PLTs were not available**	-inherent retrospective analyses. A convenience sample may introduce sampling bias. More importantly, our results may be affected by survival bias as it takes a mean of 30-45 minutes to receive the first unit of FWB. - eliminated patients who died within the first hour of treatment at the FST, which minimizes survival bias	IIIb

NMCP Evidence Table

Author and Year	Study Purpose/Aims	Research Questions/Hypotheses	Study Design	Total Sample Size	Sampling Plan
Fisher et al., 2019	Provide a structured foundation for training programs to increase adherence to TCCC guidance by administration of FWB	Increasing provider knowledge and proficiency regarding FWB transfusions	N/A	N/A	N/A

Independent Variables	Dependent Variable	Statistical Analyses	Results	Strengths	Weaknesses	Level of Evidence
N/A	N/A	N/A	- Recent literature has discovered an uneven focus on medical training by conventional military units, which may contribute to potentially survivable death when compared to units that consistently incorporate medical training into standard military training. Recent research also points to poor Tactical Combat Casualty Care (TCCC) guideline adherence in other areas of prehospital care - To optimize provider knowledge and proficiency and patient outcomes, it is critical for units to prepare for combat environments by conducting FWB transfusion training. Lack of proper training not only makes it less likely that providers will use FWB, but also will likely increase procedural delays and error rates given a lack of proficiency	This is the first article of it's kind that outlines the training that should be conducted when facilitating the implementation of FWB transfusion in austere environments	- training strategy is limited to the authors' best practice experiences with implementing FWB transfusion training among conventional and nonconventional forces - current lack of knowledge and proficiency among leaders is likely preventing this skill from being implemented in the far forward areas	III-b

Appendix F (continued): Evidence-Based Practice Improvement Approval

USUHS FORM 3202N
DANIEL K. INOUYE GRADUATE SCHOOL OF NURSING
EVIDENCE-BASED PRACTICE/PERFORMANCE IMPROVEMENT PROPOSAL

VPR Date Stamp

Project Number: GSN-61-13075 (VPR will assign)

Project Title: Implementation of the Joint Trauma System Clinical Practice Guidelines onboard an Amphibious Readiness Group and its effect on activation to administration time for fresh whole blood

SECTION A: STUDENT POC INFORMATION

1. Name (Last, First, MI): DiVenti, Vincent, E — Student E-mail: vincent.diventi@usuhs.edu
2. Home Address: [redacted] — Cell Number: [redacted]

SECTION B: COMMITTEE CHAIR / SENIOR MENTOR INFORMATION

3. Name (Last, First, MI): Batteau, Todd, A
4. Telephone: [redacted] Fax: — E-mail: todd.batteau@usuhs.edu
5. USUHS Building/ Room No.: NMCP Building 3

SECTION C: PROJECT INFORMATION

6. Attach the Abstract for the proposal, including the following sections: Site Location of the Project, Title, Authors, Background or Problem/Issue, Clinical Question/Purpose, Project Design, Anticipated Organizational Impact/Implications for Practice and also include the Proposed Timeline. Single space the abstract and use Times New Roman font, size 12.
7. Is this proposal related to an active research project of the Chair/Senior Mentor identified in Section B? ☐ Yes ☒ No
   If yes, complete below; if no, proceed to Part 8.
   Project Number:
   Project Title:
   Project Start Date: Project End Date:
8. Anticipated period of performance: Project Start Date: 10/15/2022 Project End Date: 4/1/2023
9. Performance Site(s): USS Baatan (LHD-5); USS Mesa Verde (LPD-19)
10. Does this project involve any classified information? (Contact the USUHS Security Office for guidance) ☐ Yes ☒ No
11. Do you have a funding source for this project? ☐ Yes ☐ No ☒ NA
    If yes, specify the funding agency and the amount provided:

SECTION D: SIGNATURES

The following signatures attest to the validity of the above information:

DIVENTI.VINCENT.ERNEST.1505398757 Digitally signed by DIVENTI.VINCENT.ERNEST.1505398757 Date: 2022.09.30 10:25:16 -04'00'
Student (Project Point of Contact for the Group) (Signature and Date)

BATTEAU.TODD.ANTHONY.1235562878 Digitally signed by BATTEAU.TODD.ANTHONY.1235562878 Date: 2022.10.05 11:25:49 -04'00'
Chair/Senior Mentor (Signature and Date)

Chair/Program Director (Signature and Date)

BARBER.KENNETH.DOUGLAS.1177263644 Digitally signed by BARBER.KENNETH.DOUGLAS.1177263644 Date: 2022.10.28 11:43:33 -04'00'
Chair/Program Director (Signature and Date)

DNP Project Director or PhD Director (Signature and Date)

SEIBERT.DIANE.C.1084932279 Digitally signed by SEIBERT.DIANE.C.1084932279 Date: 2022.10.28 12:07:35 -04'00'
Associate Dean for Academic Affairs, GSN (Signature and Date)

SIMMONS.ANGELA.MARIE.1143313375 Digitally signed by SIMMONS.ANGELA.MARIE.1143313375 Date: 2022.11.03 11:17:23 -04'00'
Associate Dean for Research, GSN (Signature and Date)

ROMANO.CAROL.A.1032050294 Digitally signed by ROMANO.CAROL.A.1032050294 Date: 2022.11.03 12:40:35 -04'00'
Dean, DKI Graduate School of Nursing (Signature and Date)

In light of the above signatures, the project is approved.

WOODBERRY.MITCHELL.WAYNE.1060957114 Digitally signed by WOODBERRY.MITCHELL.WAYNE.1060957114 Date: 2022.12.09 08:49:26 -05'00'
USUHS Vice President for Research

Date

USUHS Form 3202N (VPR) - Revised Sep 2015 v1.2
Previous versions are obsolete

Appendix G: IRB Approval

NAVAL MEDICAL CENTER PORTSMOUTH
RESEARCH SUBJECTS PROTECTION DIVISION
usn.hampton-roads.navhospporsva.list.nmcp-irboffice@mail.mil

March 28, 2022

MEMORANDUM

From: Naval Medical Center Portsmouth IRB Office
To: LT Adam Robles

Subj: DETERMINATION OF NOT RESEARCH
EIRB Reference: 948518

Ref: (a) DODI 3216.02
(b) 2019 DASD (HRP&O) Operating Instruction
(c) NAVMEDCENPTSVAINST 6500.9B
(d) NAVMEDCENPTSVAINST 6500.2G

1. Your project titled NMCP.2022.0041 "On a pre-identified ARG, how does the implementation of the Joint Trauma System Clinical Practice Guidelines (JTS CPG) as a standardized policy for a WBB for fresh whole blood transfusions compare to individualized ship policies improve the time from activation to the administration of a transfusion?" has been evaluated by an Exemption Determination Official (EDO). This project DOES NOT meet the definition of RESEARCH in accordance with 32 CFR 219.102 and DoDI 3216.02.

2. An EDO must review any study design changes that may change the scope of the project to ensure that they do not affect this determination. All modifications must be submitted in EIRB.

3. Projects that do not require IRB approval are not eligible for Clinical Investigation Department travel funds.

4. Any publication resulting from this project must be cleared through the publication clearance process, which is required for all works presented or published outside of your command. Investigators at NMCP may obtain information from the CID SharePoint page. Investigators from other commands should contact their local Public Affairs Office.

5. The NMCP IRB Office may be contacted via phone at (757) 953-5939 or via email at usn.hampton-roads.navhospporsva.list.nmcp-irboffice@mail.mil.

With best regards,

[redacted]

Kersten N. Wheeler, MS
Human Research Director

#DHA000002 | FWA #00006001

Appendix H: JTS CPG Development Process

JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE (JTS CPG)

JTS CPG Development Process (CPG ID: 54)

This document provides an overview of the processes for developing, reviewing, updating, approving, adopting, and monitoring JTS CPGs.

Contributors

Dallas R Burelison, MBA
CAPT Zsolt T Stockinger, MC, USN
Col Stacy Shackelford, USAF, MC
Mary Ann Spott, PhD, MPA, MSIS, MBA, RHIA
Cynthia R Kurkowski, B.J.
COL Kirby Gross, MC, USA
LTC Jennifer Gurney, MC, USA

First Publication Date: 30 Apr 2009 | Publication Date: 01 Dec 2017 | Supersedes CPG dated 02 Apr 2012

TABLE OF CONTENTS

CPG Documentation Process *CPG ID: 54*

INTRODUCTION

The Joint Trauma System (JTS) Clinical Practice Guidelines (CPGs) were developed out of necessity to reduce variability in care, improve quality, measure outcomes, and weigh the benefits against the risks and costs of specific interventions. These CPGs provide recommendations to deployed clinicians about the care of trauma patients with specific conditions and are in no way a substitute for clinical judgment. The CPGs were developed through evidence-based research, systematic review of the literature, Performance Improvement (PI) indicators and input from Subject Matter Experts (SMEs). To date, 44 CPGs have been instituted as proposed standards of care for the US military in the deployed setting and are reflective of the current "state of the art" at the time of release. CPGs undergo revisions when the clinical or operational need arises, historically every one to two years. The JTS recommends that every deploying clinician in their respective Combatant Command (COCOM) who will be providing care for casualties becomes familiar with the CPGs posted on the JTS website. Department of Defense trauma cases worldwide will be reviewed for compliance at JTS with PI indicators specified in each CPG.

This CPG describes the current process, used for CPG development and implementation.

BACKGROUND

CPGs are "statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options." [1] CPGs are developed on the best available data and SME consensus, providing clinicians with recommendations to improve the quality of care, appropriateness of care and serve as an educational resource while deployed. A systematic and operationally responsive approach to development and implementation is taken to ensure rapid field dissemination and provide quality indicators to measure effectiveness.

The JTS CPGs currently do not meet all of the National Academies of Sciences Engineering and Medicine (NASEM's) standards for CPGs.[1] The reason for this are multifactorial, but relate mostly to the expediency required for their development and promulgation. The NASEM estimates that development of a single guideline costs $200,000 in 2003, with up to $200,000 for dissemination.[1] The U.S. Department of Health and Human Services (USDHHS) Agency for Healthcare Research and Quality (AHRQ) requires that guidelines be updated at least every five years (*https://www.hhs.gov/*). JTS guidelines on the other hand, are updated much more frequently (Appendix A) and have all been developed at no cost.

In addition, there is often little published literature (military or civilian) to guide battlefield or operational medicine, requiring heavy reliance on SME opinion or unpublished analysis of military data. JTS CPGs are therefore more timely and better reflect evolving threats, technologies and current realities on the battlefield.

Strong evidence demonstrates CPG compliance is associated with a reduction in mortality.[2-4] The Donabedian Model for quality improvement in health care states that, besides patient characteristics, institutional structures and clinical practices determine patient outcome.[5] Evidence-based CPGs were developed to avoid unnecessary variation and promote consistency in healthcare practice throughout the continuum to achieve optimal outcomes. JTS CPGs complement the deployed Performance Improvement (PI) process. Since the early days of the United States Central Command (CENTCOM) trauma system, the guidelines have been developed and implemented by clinical SMEs in response to needs identified in the Combatant Command (COCOM) Area of Operations (AOR). More recently, as the trauma system has matured, the process for identifying, developing, vetting, approving, and implementing CPGs has also matured.

To the greatest extent possible, JTS CPGs are evidenced-based. The evidence is derived from the published literature or internal JTS analysis of combat casualty data. When evidence is lacking or unclear, but a CPG is needed, guidelines are developed based on the best available evidence and SME consensus. To ensure CPGs

include the latest techniques and innovations, monitoring of all CPGs is essential. To ensure monitoring, each individual CPG will include a system-level PI monitoring plan that will be a written part of the CPG. This system-wide monitoring will be conducted by the JTS PI division. The PI plan will state the intent and minimum performance measures that will be utilized for monitoring. Trauma directors or their equivalents at the deployed Military Treatment Facility (MTF) level are expected to implement local PI processes to ensure compliance with the CPG; the PI monitoring plan will help guide these efforts. Routine updates to CPGs occur every five years or as the operational need arises or as new evidence surfaces. SMEs include, but are not limited to, military and Department of Defense (DoD) civilian experts, deployed clinicians, service trauma/surgical consultants, JTS/Joint Theater Trauma System (JTTS) Director, JTS Branch Chiefs, and JTS PI Nurse Coordinator(s).

Although the JTS CPGs were originally developed for the CENTCOM AOR, they are no longer specific to any particular COCOM or contingency. Individual COCOMs are welcome to utilize or to modify the JTS CPGs into COCOM-specific CPGs, which can be posted on the JTS CPG website if requested

NEW CPG DEVELOPMENT

TOPIC IDENTIFICATION

Any **DoD Service Member** can propose a topic for CPG development or revision to the JTS Director. At a minimum, a new CPG topic must include:

1. A description of the proposed guideline and perceived gap in care.
2. Identification of end-users of the guideline.
3. Identification of changes in performance to be driven by the guideline.

TOPIC SELECTION

The **JTS clinical leadership** will evaluate the proposed CPG for:

1. Incidence or prevalence of the disease or condition addressed by the guideline.
2. Potential for reduction of clinically significant variations in the prevention, diagnosis, treatment, or clinical management of the disease or condition.
3. Relevance to the deployed environment.

The **JTS clinical leadership** will approve the CPG topic and identify a lead author if not already determined.

EDITORIAL WORKING GROUP

The **lead author** will:

1. Develop a working group comprised of SMEs. A working group ideally will include 10 experts and other key clinical leaders, representing all three U.S. military service medical departments. Input from civilian and foreign military SMEs is permissible, but should not substitute for U.S. tri-service input.
2. Identify and disclose any areas of potential conflict of interest.
3. Define responsibilities of participants and project timelines for each phase of guideline development.
4. Distribute the CPG proposal to the working group to create the draft CPG.
5. Review available evidence and producing a working draft of the new CPG.

6. Collate and reconcile SME input.
7. Will serve as the point person to the JTS PI Division Chief upon completion of a first draft.

REVIEW & APPROVAL

The **JTS PI Division Chief** will review the first draft and may distribute the document for an additional review by a second level of experts which may include:

- Former JTS directors who are on active duty or are still associated with the DoD in an official capacity.
- Trauma chiefs/directors at deployed, continental U.S. or overseas facilities.
- Service trauma consultants or specialty leaders.
- The Chairman, Committee on Tactical Combat Casualty Care.

The **JTS Director** has final clinical approval. The decision is based upon the best existing clinical evidence and/or experience.

Upon JTS Director approval, the CPG must undergo Operations Security/Public Affairs Office (OPSEC/PAO) review. The approved CPG will then be published on JTS CPG webpage: https://jts.amedd.army.mil/index.cfm/PI_CPGs/cpgs

Approval authority for implementation of the CPG in any COCOM rests with each COCOM. See *COCOM Adoption of JTS CPGs* below

REVIEW & UPDATE OF EXISTING JTS CPGS

1. At minimum, existing CPGs will be revised every five years, or sooner in response to clinical or operational needs.
2. The JTS PI Division Chief will review each CPG to determine the need for significant revision.
   - If an update is needed, the PI Division Chief will initiate the update by inviting the current CPG's lead author(s) to head the revision process.
   - If declined, a new lead author will be identified and the revision process will follow that of a new CPG.
   - IF no update is required, the CPG is submitted to the JTS Director for re-approval.
3. Once approval has been granted, the CPGs will undergo OPSEC/PAO review prior to posting on the JTS CPG webpage.

COCOM ADOPTION OF JTS CPGS

Because COCOMs are greatly different in climate, terrain, and resources, the JTS CPGs are not representative of a specific COCOM or contingency. The JTS recommends that each COCOM Surgeon evaluate and determine the appropriateness of the JTS CPGs to their AOR. Each COCOM Surgeon may choose to:

1. Reject the CPG in its entirety.
2. Endorse the CPG in its entirety.
3. Modify the CPG.

- If the COCOM Surgeon requests, the JTS PI Division Chief will work in concert with the COCOM Surgeon to create a COCOM-specific CPG.
- If requested by the COCOM Surgeon, the COCOM-specific CPG may be placed on the public JTS CPG webpage.

MONITORING JTS CPGS

JTS CPG adherence is monitored by the JTS PI Director. System level monitoring of the CPGs is conducted by the JTS PI division. Monitoring specifics (e.g., timing, frequency, performance measures) are written in the PI Monitoring Plan contained in and individualized to each CPG.

PERFORMANCE IMPROVEMENT (PI) MONITORING

INTENT (EXPECTED OUTCOMES)

- Existing JTS CPGs will be updated at least every five years.
- Existing CPGs will be reviewed for need for revision annually.

PERFORMANCE ADHERENCE MEASURES

All JTS CPGs are to be reviewed no later than 60 days after the anniversary of the last annual review date.

RESPONSIBILITIES

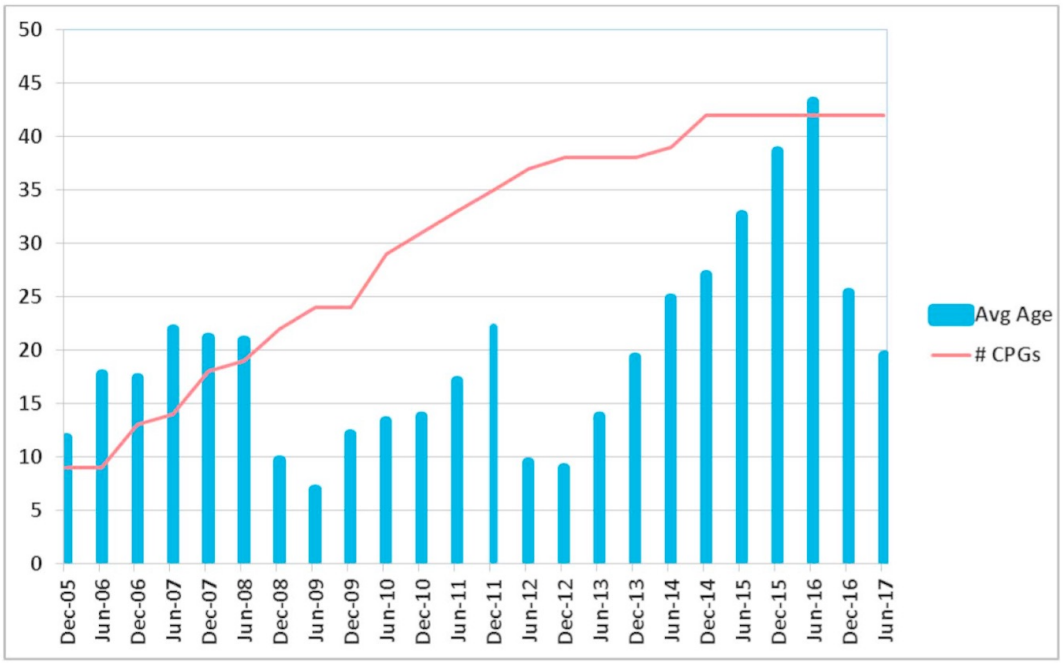
It is the responsibility of the Chief of the JTS PI Division to ensure system-level compliance with this CPG. It is the trauma team leader's responsibility to ensure familiarity, appropriate compliance and PI monitoring at the local level with this CPG.

REFERENCES

1. IOM (Institute of Medicine). 2011. Clinical Practice Guidelines We Can Trust. Washington, DC: The National Academies Press.
2. Shafi S, Barnes SA, Rayan N, et al. Compliance with recommended care at trauma centers: association with patient outcomes. J Am Coll Surg. 2014;219(2):189-98.
3. Eastridge BJ, Costanzo G, Jenkins D, et al. Impact of joint theater trauma system initiatives on battlefield injury outcomes. Am J Surg 2009;198(6): 852-7.
4. Bailey JA, Morrison JJ, Rasmussen TE. Military trauma system in Afghanistan: lessons for civil systems? Curr Opin Crit Care 2014;19(6):569-577.
5. Donabedian, A. The quality of care. How can it be assessed? JAMA. 1988;260:1743–1748.

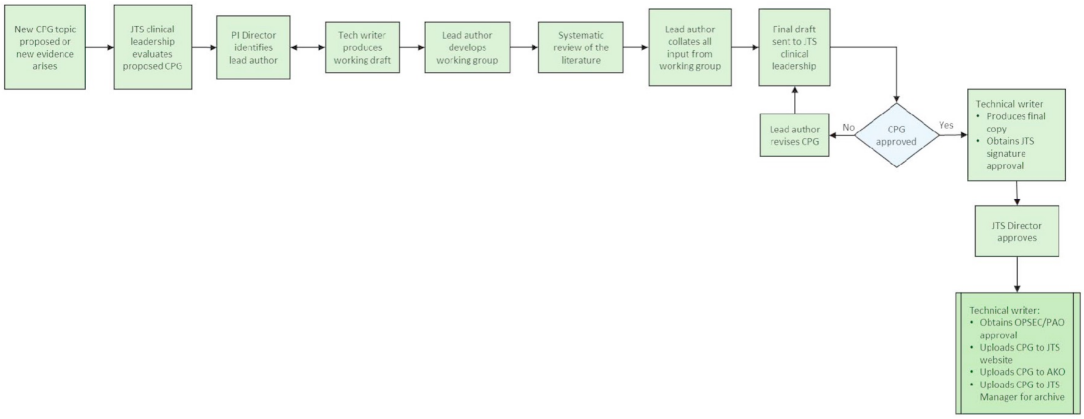
APPENDIX A: CLINICAL PRACTICE GUIDELINE SHELFLIFE

Number of CPGs has surpassed this number since the publication of this chart.



CPG Development Process *CPG ID: 54*

APPENDIX B: CLINICAL PRACTICE GUIDELINE PROCESS



Appendix I: USS Mesa Verde (LPD 19) WBB SOP

From: Commanding Officer, USS MESA VERDE (LPD 19)

Subj: USS MESA VERDE (LPD 19) WALKING BLOOD BANK

Ref: (a) OPNAV INSTRUCTION 6530.2E, 01 APR 2019
(b) OPNAV INSTRUCTION 6530.4B, 13 AUG 2007
(c) BUMED INSTRUCTION 6530.17, 25 JUN 2019
(d) CPG ID: 21 Joint Trauma System Clinical guideline
(e) AABB Tech Manual, Current Edition – Standards for Blood Banks and Transfusion Services.
(f) JTS Clinical Practice Guideline: Fresh Whole Blood (FWB) Transfusion
(g) Combat Medical Whole Blood Collection and Transfusion Kit
(h) USS MESA VERDE (LPD 19) Walking Blood Bank Standard Operating Procedure(s) (SOP)

Encl: (1) USS MESA VERDE (LPD 19) Walking Blood Bank Standard Operating Procedures.

1. Purpose. This instruction establishes Command policies concerning the Walking Blood Bank in accordance with references (a) through (h). Walking Blood Bank is a contingency program set-up to provide ABO type specific/compatible units to individuals for transfusion purpose in times of medical emergencies (i.e. massive casualty). The Walking Blood Bank was established to meet operational requirements to obtain and transfuse fresh whole blood in emergency cases. Due to operational constraints, fresh packed red blood cells (RBC) and Fresh Frozen Plasma (FFP) cannot be stored onboard.

To conduct the collection, transport, and administration of donated whole blood in the most expedited and safe manner during emergency situations. Additionally, to minimize, and when possible, eliminate the possibility of transfusion reactions, and to ensure any medical personnel can carry out the duties of collection, cross matching, and issuance of blood products in the absence of a Medical Laboratory Technician.

2. Applicability. This instruction applies to all personnel authorized and qualified in the role for the Walking Blood Bank in this Command.

3. Responsibilities.

a. The Senior Medical Officer (SMO) identifies an emergent situation and activates the "Walking Blood Bank." Only the SMO may activate the WBB. Responsibility and authority for the operation of the Blood Bank is delegated to the Senior Medical Officer. This individual will ensure all the regulations and standards are in compliance as described in this instruction.

b. The Medical Dental Doctor will be assigned as the Medical Triage Officer to quickly

asses, evaluate, and tag the casualties to have the first responders to treat the victims according to the tag. The Medical Triage Officer is responsible for expediting treatment to those most seriously injured, and avoids wasting resources on less seriously injured, through a system of rapid "triage" or sorting: Minor (Green), Delayed (Yellow), Immediate (red), and Expectant (Black).

c. Each Medical Personnel whose main responsibility is to collect, test, transfuse, or take part in any aspect of whole blood transfusion shall review and be familiar with the Command's Walking Blood Bank SOP. Once read, applicable personnel will sign page three acknowledging their role and responsibilities.

USS MESA VERDE
(LPD 19)

WORLD BLOOD
DONOR
LPD 19

HEALTH SERVICES
DEPARTMENT

WALKING BLOOD BANK

STANDARD OPERATING PROCEDURES

SIGNATURE LIST **2021**

WALKING BLOOD BANK SOP

Your signature below indicates that you have reviewed the following SOP, and understand the guidelines, rules, and regulations contained herein. Requests for changes or additions to the SOP should be submitted via the chain of command to the Senior Medical Officer.

NAME	DATE	SIGNATURE

REF: (a) OPNAV INSTRUCTION 6530.2E, 01 APR 2019

20SEP21

MEMORANDUM

From: Senior Medical Officer, USS MESA VERDE (LPD 19)
To: Health Services Department, USS MESA VERDE (LPD 19)

Subj: WALKING BLOOD BANK STANDARD OPERATING PROCEDURES (SOP) MANUAL

1. I have reviewed and approved the Walking Blood Bank SOP Manual dated 20 SEPTEMBER 2021.

2. This SOP shall be reviewed by all applicable Health Services Department staff. A roster containing the reviewer's printed and signed name and the date of review shall accompany this SOP.

3. This SOP will be reviewed by the Health Services Department chain of command annually, or as needed.

S. C. IZAH

(b) OPNAV INSTRUCTION 6530.4B 13 AUG 2007
(c) BUMED INSTRUCTION 6530.17, 25 JUN 2019
(d) CPG ID: 21 Joint Trauma System Clinical guideline
(e) AABB Technical Manual, Current Edition - Standards for Blood Banks and Transfusion Services
(f) JTS Clinical Practice Guideline: Fresh Whole Blood (FWB) Transfusion
(g) Combat Medical ® Whole Blood Collection and Transfusion Kit

Enclosure(s): (a) Form 145-A Rapid Testing Worksheet
(b) Form 150A- Emergency Release Letter of Understanding (tested)
(c) Form 150B – Emergency Release Letter of Understanding (untested)
(d) Form 151 – Whole Blood Transfusion Checklist
(e) Standard Form 518-Blood or Blood Component Release
(f) Optional Form 522 – Request for Administration of Anesthesia
(g) Transfusion Reaction Investigation Worksheet.
(h) Emergency Release Form
(i) Blood Bank Patient History Card

I. Purpose

A. The Walking Blood Bank is a contingency program set up to provide ABO type specific/compatible units to individuals for transfusion purpose in times of medical emergencies. The Walking Blood Bank was established to meet operational requirements to obtain and transfuse fresh whole blood in emergency situations. Due to operational constraints, fresh packed red blood cells (RBC) and Fresh Frozen Plasma (FFP) cannot be stored aboard.

B. To conduct the collection, transportation, and administration of donated whole blood in the most expedited and safe manner during emergency situations. Additionally, to minimize, and when possible, eliminate the possibility of transfusion reactions, and to ensure any medical personnel can carry out the duties of collection, cross matching, and issuance of blood products in the absence of a Laboratory Technician.

C. Each medical personnel whose main responsibility is to collect, test, transfuse, or take part in any aspect of whole blood transfusion shall review and be familiar with this SOP. Once read, applicable personnel will sign page three acknowledging their role and responsibilities.

II. Walking Blood Bank Activation

A. **The Senior Medical Officer (SMO) identifies an emergent situation and activates the Walking Blood Bank (WBB). Only the SMO may activate the Walking Blood Bank.**
B. The Walking Donor contingency is performed only in emergent scenarios. All walking units collected and transfused must be considered non-FDA licensed blood products.
C. Once the Walking Blood Bank is activated, all donors will muster at the pre-designated area (Dental Clinic) and complete the approved donor history screening protocols and be tested for infectious disease using ASBP-approved

rapid screening tests. All previously screened and tested donors will be identified and brought to the front of the process to be collected first. Specifically, pre-tested low-titer O blood in emergency/mass causality scenarios. **All attempts will be made to transfuse type-specific pre-tested donor whole blood. However, if this is not possible given the urgent nature of the trauma, low-titer O whole blood will be transfused until the recipient blood type can be confirmed and type-specific donor whole blood is available.**

D. In addition to announcing the activation of the WBB via 1MC, type-specific and/or low-titer O donors already listed in the active WBB roster may/will be contacted and told to muster at the WBB collection site (Dental Clinic).
E. Once the WBB has been activated, pre-assigned dental/medical corpsmen will set up the predesignated area for donor screening and collection of WBB donors.
F. Ensure all forms and required paperwork are up to date/current and readily accessible (TMDS, WBB Roster, etc.)
G. Identify approximately 10% of the crew who are willing to participate in the walking blood donor program. Representation from all blood types is required.
H. Documentations will include:
   1. Donor screening will use ASBP 572-EWB.
      a. Complete sections I and II of the ASBP 572-EWBs for each volunteer.
      b. ASBP 572-EWBs are organized by Blood Group and filed in the Laboratory.
   2. SF 518 will be completed and used for all transfused blood
   3. If time is allowed, all recipients will complete blood transfusion consent form - Request for Administration of Anesthesia and for Performance of Operations and Other Procedures (DD522).
I. The Dental department has been designated as the primary location for donor unit collection and the Mess Deck shall be designated as the secondary location.
J. Pre-staged supplies will be kept on hand in the dental spaces and/or any other predesignated WBB collection area.
   1. Ensure all items will not expire prior to being out to sea.
   2. Ensure all items are inventoried as needed by the Laboratory Technician.

III. Donor Recruitment

A. When emergency whole blood collections are required, donors will be selected in the following order, in descending priority.

   1. Donors who have been prescreened within the last 90 days and 365 days with the full panel of FDA-licensed donor infectious disease tests and found to be negative for all infections.

      NOTE: *Any donor with a positive test result will not be listed as an approved, prescreened donor and must not be collected.*

   2. Donors who have been prescreened between 90 days and 365 days with the full panel of FDA-licensed donor infectious disease tests and found to be negative for all tests.

3. Donors who report being repeat blood donors in the past and have not been deferred for transfusion-transmitted disease.
4. Donors who have not been prescreened with FDA-licensed tests, nor have been blood donors in the past.

B. To the maximum extent possible:

1. Blood will only be collected from United States personnel to include military members, DoD civilians, or contractors, or beneficiaries.
2. Blood may be collected from pre-screened coalition partner forces if screening program has been reviewed by the JBPO and deemed acceptable by the COCOM Surgeon and the ASBP. Note, screening results must be available to the JBPO.
3. On the day of donation, prospective donors will be screened for eligibility using approved donor history screening protocols and be tested for infectious disease using ASBP-approved rapid screening tests. As much as possible, rapid screening tests should be performed before issuing the product.

C. Low Titer Group O Whole Blood (LTOWB) donors have been tested and found to have anti-A/anti-B antibody titers of <1:256 (recorded in electronic database). LTOWB collected from these donors may be given to a recipient of any ABO type during damage control resuscitation.
D. Non-LTOWB Fresh Whole Blood (FWB) donors must be an ABO type-specific match to the casualty. If not a match, a fatal hemolytic reaction may occur. Casualty ABO/Rh type must be determined by using rapid ABO/Rh card or laboratory testing before conducting type-specific FWB collection.
E. Pull a prescreened donor list from TMDS: Manage Donor> View Donor List or from an already pulled list in hand.
   1. If pulling prescreened donor list from TMDS: SELECT FILTERS
      a. Select filters for ABO/Rh of the potential whole blood recipient if using type-specific FWB, Screened (select ALL), Alert (select ALL), COCOM select applicable).
      b. Highlight your facility in the Available Facilities tab and click Add.
      c. Once your facility appears in the Search Facility box, click Display Donor List.
      d. The potential donor list for the blood type required will now appear on the screen.

      NOTE: *If searching for LTOWB pre-screened donors, use same process above except select O pos and O neg in the ABO/RH selection area.*

F. **Verify Donor**
   1. Make sure to verify all donors. Donors ABO/RH must be verified by rapid ABO/Rh or laboratory testing prior to transfusion even if donor is in TMDS with pre-screening results.

IV. Donor and Testing Area Preparation

A. Set up blood donor beds.
B. Perform QC on weighing device if available.

NOTE: *If no trip scale is available, see section below Whole Blood Collection: Set up the whole blood Collection: Set up the whole blood collection bag.*

C. Ensure the necessary equipment to perform donor screening, testing and collection are available.
   (1) Blood Donor Card (ASBP 572-EWBs 5 APR 18) overprinted with donor questions. Direct questions for high risk and other oral questions.
   (2) ASBPO Links to Travel, Drugs, Immunizations and Medical Conditions lists for donor limitation and/or deferrals.
   (3) Blood Component Transfusion form (DD-518).
   (4) Blood pressure cuff and stethoscope (or IVAC Model 4200 vital sign monitor).
   (5) Thermometer.
   (6) Whole Blood Collection and Transfusion Kits (Combat Medical®)
      - Fresh Whole Blood Collection Kit
      - Fresh Whole Blood Donor Set
      - Fresh Whole Blood Recipient Set
   (7) Balance level and arm (support stands also needed when donor beds are not used) (Alternative: battery operated rocker and scale).
   (8) "Sharps" Autoclave container
   (9) Test Tube Rack

D. If space available, the following extra supplies will also be added.
   (10) Validated tourniquet (for donation process).
   (11) Hand squeezer.
   (12) Donor arm sanitizing preps (ChloraPrep with Chlorhexidine).
   (13) Sterile gauze
   (14) Tape.
   (15) Hemostat.
   (16) Scissors.
   (17) Purple (EDTA) top tubes (4 ml).
   (18) Gold Top Tubes
   (19) Pearl Top Tubes
   (20) Coban
   (21) Blood unit tubing heat sealer
   (22) Terumo Single Blood Bags
   (23) Plastic/Glass tubes
   (24) Transfer pipettes
   (25) Lancet
   (26) Para film
   (27) Rapid Testing: HIV/Malaria/HCV
   (28) Eldon Cards
   (29) Hand Stripper/Sealer/Cutter

Walking Blood Bank Donor Screening

A. Donors will be screened utilizing the ASBP 572-EWB.

B. New donors will be encouraged to be screened each quarter of the fiscal year during scheduled shipwide Armed Services Blood Program (ASBP) blood donations as well as prior to any major deployments. All efforts will be made to encourage at least yearly screening for all transmittable disease and blood typing including low-titer O whole blood donors.

C. Volunteer donor blood types will be confirmed via ASBP donations results.

D. The **WBB roster** will be kept up to date once a quarter and a digital copy will be saved in the WBB sharedrive as well as a paper copy printed and held on hand in the laboratory. In case of WBB Activation, this list will be referenced for all available donors.

   (a) As such, **no less than ten percent** of ship's force will be screened and maintained.

E. To the greatest extent possible, potential whole blood donors should be selected from among the pretested and qualified population documented in TMDS. This is the best practice to mitigate the risk to the recipient of Transfusion Transmitted Diseases (TTD) and hemolytic reactions.

F. Give donor ASBP 572-EWB and instruct donor to complete demographic information and to answer questionnaire by circling "Yes" or "No". While donor is completing questionnaire, screen for donor alerts and completed FDA test results in TMDS (deferrals).

G. Locate donor's name on the Donor List displayed in TMDS. To the left of their name, click VIEW. If all TTD results are negative (within last 90 days) and there are no Donor Alerts, then the Donor is deemed fully Pre-Screened/Tested. To minimize risk to the recipient, it is recommended that pretested population be exhausted prior to resorting to collections from the untested population.

H. A qualified interviewer will review the ASBP 572-EWB for completeness and donor suitability criteria following steps below:

   (a) **If/Then Scenarios**-

      i. **IF**: Responses for questions 1 and 9 are "Yes" AND responses for questions 2-8 and 10-26 are "No"*

      ii. **THEN**: Process to step 5 for donor temperature.

      iii. **IF**: Responses to question 1 or 9 is "No" AND/OR there are any "Yes" responses for questions 2-8 or 10-26*

      iv. **THEN**: Document the reason for the "Yes" response (questions 2-8 or 10-26) or "No" response (questions 1 or 9). Defer the donor.

   NOTE: *For questions 13, if the donor is required by the chain of command to take malaria prophylaxis due to deployed location, then response should be "Yes". If donor answers "No" despite being required to take prophylaxis, then donor should be deferred unless all other suitable donors are unavailable.*

I. Perform and record temperature on the ASBP 572-EWB.

(a) **If /Then Scenarios-**

i. **IF**: < or = 99.5 degrees F or 37.5 degrees C
ii. **THEN**: Proceed to the next step.
iii. **IF**: >99.5 degrees F or 37.5 degrees C

Then stop the donation process. The donor is "Ineligible" at this time.

J. Perform and record measurements of donor pulse and blood pressure on the ASBP 572-EWB.

i. **IF**: Systolic BP is 90-180
Diastolic BP is 50-100
Pulse is 50-100 bpm
ii. **THEN**: Proceed to step 7 for donor hematocrit.
iii. **IF**: Systolic BP is <90 or >180
Diastolic BP is <50 or >100
Pulse is <50 or >100
iv. **THEN**: Stop the donation process. The donor is "ineligible" at this time.

K. Perform and record hematocrit/hemoglobin results on ASBP 572-EWB, if possible.

(a) If/Then Scenarios:

i. **IF**: Male: > or = 13.0 g/dL
Female: > or = 12.5 g/dL
ii. **THEN**: Defer donor and stop the donation process. The donor is "ineligible" at this time.

L. Donor is physiologically acceptable to donate, have the donor sign the ASBP 572-EWB and proceed to the next step.

M. A competent medical authority should review the ASBP 572-EWB to determine the eligibility of the donor.

(a) If/Then Scenarios-

i. **IF**: Acceptable
ii. **THEN**: Donor is "Eligible", proceed to Step 10.
iii. **IF**: Unacceptable
iv. **THEN**: Donor is "Ineligible." Stop donation process and document deferral as appropriate in TMDS.

N. Issue blood bag and test collection set to donor. Label bag and ASBP 572-EWB with Whole Blood International Society of Blood Transfusion (ISBT) labels. Blood collection tubes (2 red tops and 4 purple tops) should be labeled with the corresponding small ISBT labels (without barcode). If no labels are available, bags and all samples should be labeled with donor's full name and DoD ID or Blood Bag Segment Number.

Whole Blood Collection and Transfusion Kit (Combat Medical ® Whole Blood Kit)

A. **Combat Medical Whole blood kits**

1. The Combat Medical Whole blood kits for whole blood collection and transfusion are complete in sets and can be utilized from donor to patient. The kits include all paperwork and supplies needed to produce viable whole blood

for transfusion. Whole blood transfusion carries infectious disease risk and this must be weighed in relation to the urgency of the situation. Per current guidelines only one unit of blood from a single donor can be taken every 56 days.

2. An Advanced Laboratory Technician shall perform the blood bank procedures utilizing safe and accurate laboratory practices, under normal guidelines. However, in the case a laboratory technician is no longer available; any medical personnel can carry out these duties. This is only done in extreme circumstances and the SMO can authorize a maximum of two units at one time.

3. Equipment supplied in the kit:

   (a) Fresh Whole blood **RECIPIENT SET:**
   (b) Fresh Whole Blood **DONOR SET:**
   (c) Forms – ASBP 572-EWB
   (d) Instructions

4. How the Combat Medical Whole blood kit is used.

5. Identify appropriate patient.

6. Confirm donor and recipient ABO/Rh compatibility by using tube method. Blood collection will be performed to obtain two lavender top tubes, two gold tubes, and one HIV tube to be submitted to the laboratory.

7. Consider casualty for possible transfusions for presence of signs of worsening shock such as decreased mental status in absence of TBI, weak or absent radial pulse,, HR>100, RR>30 and systolic BP<100. If possible, use US Military donor who has had regular immunizations and medical care. All attempts must be made to stop any bleeding.

8. Draw Blood from donor:

   a. Open and inspect collection bag for cuts, kinks, discoloration, or other damage.
   b. Place collection bag on a flat surface lower than the donor's heart. Make every effort to keep the collection bag insulated to keep the blood from cooling or reaching temperatures exceeding 102 degrees Fahrenheit.
   c. Prepare arm with ChloraPrep and apply tourniquet (Do not leave tourniquet on longer than 3 minutes).
   d. Create a loose knot in the tubing near collection bag loose enough to prevent or impeded blood flow into bag.
   e. Place a hemostat or pinch the line with tube clamp approximately six inches from the needle prior to removing the needle cap. Remove 16G needle cap and insert needle bevel up. **Failure to clamp or pinch line**

could allow air enter line and cause incomplete filling of the bag and contamination.

f. Release hemostat or tube clamp and monitor for blood flow, moving needle as appropriate to maximize flow. Secure needle in place and loosen the tourniquet for better blood flow.
g. Gently agitate collection bag every few minutes to mix anticoagulant agent present in bag.
h. Bag should take about 10 minutes to fill. Lay the blood collection bag on a flat surface, place 10-inch piece of 550 cord under the bag and wrap it around the width of the bag. When the ends of the cord barely touch without compressing or lifting the bag, the bag is adequately filled. Only fill the collection bag with 450mL of blood. Under filling the bag could result in citrate toxicity. Overfilling the bag can cause a clot to occur. Never collect more than one unit from a single donor.
i. Before withdrawing the needle seal the tubing by tightening the knot created earlier and then clamp the tube with hemostat or tube clamp between the knot and needle. If able, double the knot on the collection tube approximately four inches from collection bag and cut line between the two knots. Do not allow air to enter bag.
j. Fill in Blood Bag Label and attach to Blood Bag: Name, SSN, DOB, ABO/Rh, HM name, date and time.
k. Collect 1 tiger top, two gold tops, and two lavender tops (in that order) for ABO/Rh and infectious disease testing using phlebotomy supplies provided. Label tubes with Name, SSN, DOB, ABO/Rh, HM name, date and time. Things to be tested immediately in the lab will be Rapid HIV and Rapid HCV. Tests to be sent off will be HIV/HTLV; Hepatitis Panel, RPR, and ABO/RH confirmation to be performed by an AABB certified facility.
l. Blood should be transfused immediately! After 24hrs, destroy all room temperature stored fresh whole blood units. If whole blood is stored within eight hours of collection, it may be stored for up to 21 days, with diminished clotting factor and platelet functions. Approval by the theater blood program or command surgeon is needed to keep collected whole blood unit beyond 24 hours.

B. **WHOLE BLOOD COLLECTION METHOD**

1. Seat donor in blood donor table or reclining chair. Ask the donor their name and verify donor demographic information is correct on the ASBP 572-EWB. Verify also that the labels on the blood bag, sample tubes, and ASBP 572-EWB correctly correspond to each other and the donor.

   NOTE: *If a discrepancy is noted, STOP and correct before proceeding further.*

2. Apply the tourniquet to the arm that will be used for phlebotomy.
   a. Have donor grip their hands or a squeezable object.
   b. Palpate the antecubital area of the arm in order to locate a suitable vein.

c. Remove the tourniquet.

NOTE: *The vein of choice must be large enough for venipuncture using a 16-gauge needle and straight enough to accommodate at least one-fourth of the needle length.*

3. Utilizing ChloraPrep, remove applicator from package; do not touch applicator tip.

4. Holding sponge tip down, pinch barrel of applicator to release antiseptic and wet sponge tip by pressing and releasing the sponge against the treatment area until liquid is visible on the skin.

5. Use gentle back-and-forth strokes over the 3 inch treatment area for 30 seconds and then allow area to dry for 30 seconds. Do not blot or wipe away antiseptic.
NOTE: *It is not necessary to use the entire amount of the solution in the applicator.*

6. Set up the whole blood collection bag.
   a. Ensure that the donor's ISBT Label or ID has been recorded in the Unit Number field on the CPD whole blood collection bag if not previously performed.
   b. Ensure date is recorded in the "Today's Date" field under the Group B questions.
   c. Inspect the bag and tubing for cuts, kinks, discoloration or any kind of damage and discard bag if present.

7. Set up trip scale (Manual or Electronic). Perform quality control, if possible, to obtain a counterweight of 585 grams.

   NOTE: *If no trip scale is available, the Terumo Single Blood Bag (CPDA-1) can be filled with whole blood to the mark pictured below. It is however recommended that weight then be checked with table top scale (if available)*

   a. The Target weight for 450 ml is 585 grams.

   NOTE: *Do not use if overfilled as blood clots may develop from an incorrect ratio of whole blood to anti-coagulant causing potential harm to the patient.*

8. Using a hemostat, clamp tubing between the needle and the main bag. This will prevent air contamination of blood after the needle cover is removed. Place tape within reach for anchoring the needle during phlebotomy.
NOTE: *Place a loose knot in the tubing approximately 6 inches from the needle prior to uncapping needle, if metal seal clips and hand crimpers are not available.*

9. Apply tourniquet with enough pressure. If using a blood pressure cuff adjust to approximately 40-60 mm Hg.

10. Twist off the needle cover and inspect the needle for barbs or other defects.

11. Pull the skin taut below the venipuncture site.

12. With the bevel up, hold the needle at the hub, at approximately a 30-45 degree angle and pierce the skin with a smooth, quick thrust at the selected point of entry.

13. When the bevel is completely under the skin, lower the angle of the needle to approximately 10 degrees or less and, with a steady push, advance needle to penetrate the vein wall. Thread needle approximately ½ inch inside the vein to maintain a secure position and to lessen the chance of a clot forming.

14. Release the hemostat clamp on the collection bag tubing and observe the blood flow through the tubing and into the collection bag.
    a. If/Then Scenarios:
        i. IF: Blood flow is impeded
        ii. THEN: Try adjusting the needle with least discomfort without hurting the donor.
        iii. IF: Blood flow is still impeded
        iv. THEN: Seek assistance from another phlebotomist before discontinuing the phlebotomy.

15. Fill sample tubes using tube adapter if available. After filling sample tubes, gently rock tubes to mix contents and verify once again that donation identification number on tubes corresponds to donation identification number on the collection bag and the ASBP 572-EWB.
    NOTE: *If no tube adapter available on the whole blood bag tubing, fill sample tubes by performing a venipuncture phlebotomy on the arm not used for whole Blood bag donation.*

16. Instruct donor to relax their grip and to rhythmically squeeze every 5 to 10 seconds, relaxing between squeezes.

17. Secure the needle to the donor's arm with tape, across the hub or on the tubing near the hub of the needle. This will optimize the positioning of the needle to prevent rotation of the needle or drag on the tubing, which may impede blood flow. An additional piece of tape may be placed across the tubing lower on the arm.

18. Partially reduce the pressure by loosening the tourniquet or blood pressure cuff to approximately 20-44 mm Hg. Mix blood bag several times during the collection to prevent clotting.

19. Cover the phlebotomy site with sterile gauze dressing, to keep the site clean and needle out of view. Lift the gauze occasionally to monitor for a hematoma.

20. If a hematoma is evident, remove tourniquet and needle from donor's arm and place sterile gauze square over the hematoma and apply firm digital pressure while donor's arm is held above the heart level.

21. Record the following in the appropriate blocks on the ASBP 572-EWB:
    a. Time phlebotomy was started
    b. Initials of the phlebotomist

22. Watch for the signal of a filled unit by monitoring for the completion indicator of the weighing device or visual reference point (see step 6), if not using a weighing device. Record stop time on the ASBP 572-EWB.

    NOTE: *A 10-inch piece of 5-50 cord/nylon cord may be used to check for unit fill. As bag fills, place cord around middle/center of bag and continue to monitor until both ends of the cord wrap around the bag and touch.*

23. Seal the tubing 1 to 2 inches below the "Y" segment of the tubing using a metal seal slip and a hand crimper (or pulling tight the loose knot in the tubing).

24. Grasp the tubing on the donor side of the seal and press to remove a portion of blood in the tubing. Crimp the tubing at this spot. Cut the tubing between the two seals.

25. Remove tourniquet or blood pressure cuff and tape strips from donor's arm.
26. Place the fingers of one hand gently over the sterile gauze. DO NOT APPLY PRESSURE OVER THE NEEDLE. With the other hand, smoothly and quickly withdraw the needle. Apply firm pressure to the phlebotomy site.

27. Instruct donor to apply firm pressure over the gauze. Encourage donor to maintain a relaxed elevated position, rather than tensing the muscle. This precaution will minimize the bleeding into the venipuncture area.

28. Secure the dressing with Coban or similar bandage wrap. Observe the donor for an appropriate length of time after the donation for any signs of an adverse event.

29. Discard the needle assembly into a sharps container.

30. Using a hand stripper/crimper, strip all blood from the tubing into the primary collection bag. This should be done ASAP after collection. (Stripping is pushing the blood in the tubing into the blood filled bag with the rollers on the stripper/crimper device).

31. Mix contents in the primary collection bag. DO NOT strip the tubing and allow tubing to refill without mixing. Release the stripper and allow the

anti-coagulated blood to reenter the tubing. Perform this procedure three times.

C. **PROCESSING DONOR UNITS**

1. Take donor unit and donor sample tubes (2 red top tubes, 4 purple top tubes) to processing area.

2. Strip donor units segment tubing three times and mix, so as to avoid the development of clots.

3. Perform ABO, Rh type utilizing ABO/Rh Testing Card and purple top tube. Record results on Form 147.

4. Write the donor blood type on the bag (ABO/Rh Testing Card) along with date, time and phlebotomist initials of collection.

5. If whole blood unit is drawn from a low titer donor, "Low Titer for Anti-A/Anti-B" should be written on the label or use a sticker with the same verbiage.

6. Write the expiration date of the unit on the label, which is 24 hours from collection if stored at room temperature. If placed into refrigerated storage within 8 hours of collection, the unit may be stored for 21 or 35 days depending on anticoagulant. Joint Blood Program Office (JBPO) approval is required for storage of whole blood unit for longer than 24 hours.

   NOTE: *CPDA-1 units have a 35-day expiration/CPD units have a 2- day expiration.*

7. Create product in TMDS while Rapid Testing is being performed.

   NOTE: *Rapid tests should be performed and found to be negative prior to transfusion, to the greatest extent possible. In situations requiring whole blood, available blood component inventory should continue to be transfused in lieu of whole blood until rapid testing has been performed and found to be negative.*

D. **Create Whole Blood Units in TMDS**

a. From Manage Donation tab, select Donate Product.
b. Enter the Donor SSN, first name, last name in appropriate fields and click NEXT.
c. In Demographic information area, enter donor's ABO/Rh, nationality and branch. Military unit and contact instructions may also be entered in the demographic information fields. Enter donor's redeployment date if known along with further contact information. In the Donation information area, enter the pre-screen date, document status of ASBP 572-EWB completion, donor's ABO/Rh and Donor Identification Number (DIN). Click ADD PRODUCT(s).

NOTE: *If any of the TMDS auto-populated information fields in demographic information area is incorrect, contact the JBPO or TMDS Help Desk for guidance. TMDS contact information can be found on the TMDS log-in screen.*

NOTE: *The Donation Location field information will be auto-populated within TMDS.*

d. Enter product code E0054V00 for whole blood collected in CPDA-1 anticoagulant or E0009V00 for whole blood collected in CPD anticoagulant.
e. Enter the expiration date of the unit, which is 24 hours from collection if stored at room temperature. If placed into refrigerated storage within 8 hours of collection, the unit may be stored for 21 or 35 days depending on anticoagulant. JBPO approval is required for storage of whole blood unit for longer than 24 hours.

NOTE: *CPDA-1 units have a 35-day expiration/CPD units have a 21 day expiration.*

f. Click Add Product.
g. Verify donation ID, product description, product type, ABO/Rh and expiration date are correct, then click NEXT.
h. Re-verify all demographic and unit data then click Confirm Donation.
i. Repeat steps 1-8 for each product collected.

E. **Pre-Transfusion Rapid Testing**

1. Rapid tests should be performed and found to be negative prior to transfusion, to the greatest extent possible. In situations requiring whole blood, available blood component inventory should continue to be transfused in lieu of whole blood until rapid testing has been performed and found to be negative.
2. Centrifuge 2 red top and 3 purple top tubes for 5 minutes at 4000 RPM.
3. Perform Rapid ABO/Rh using whole blood from 4th purple top tube and record results on Form 147.
4. Perform HCV, and Malaria using whole blood from 4th purple top tube. Perform RPR using serum from centrifuged red top tube. Testing should be performed IAW test kit package inserts and local SOP. Record reagent Name, Lot #, Expiration Date, and Results on Form 145.
5. Upon completion of rapid tests with negative results, whole blood unit may be issued for transfusion.
6. When time allows, rapid test results need to be entered into TMDS. To do this click on update Donation under the Manage Donation tab.

F. **Issue and Manage Whole Blood Inventory**

1. It is recommended that some sort of blood product issue document (ex., SF 518) be utilized to account for the issue of whole blood from the laboratory.

WBB operations are at times chaotic and do not often allow for real-time updates of TMDS.

2. Provider requesting Fresh Whole Blood should sign Emergency Release letter of understanding Form 150a or 150b as appropriate. Forms should be maintained in a patient transfusion records.
3. Accurate dispositions of all Whole Blood units collected MUST be properly dispositioned in TMDS. Every unit must be created, transfused, expired or destroyed as appropriate.

V. Administration of blood products

A. **Only the Ship's Nurse or Anesthesia provider may initially administer blood.** In addition, all blood products must be verified by **2 medical providers (physician, anesthetist, or nurse)** prior to any administration in order to confirm blood type.
B. Recipient should have NS TKO and large bore IV/IO in place. 16G short IV catheter preferred, a 18G can be used with greater hemolysis and longer infusion times.
C. Open and inspect Y tubing, ensure all clamps are closed and spike NS bag.
D. Invert and hang NS about 3 feet above recipient to prevent backflow of blood into saline.
E. Open clamp and saline side of Y tubing and fill drip chamber to cover filter with saline.
F. Open clamp on blood side of Y tubing and allow line to fill with saline and drain off air and then close clamp on blood line.
G. With the NS line clamp still open, open the main line clamp and prime the lower infusion tubing and then close main line clamp.
H. Hang blood bag next to NS and aseptically spike blood bag with blood side Y tubing.
I. **Check vital signs just prior to the administration of whole blood, paying closer attention to RR and HR.**
J. Start blood at TKO rate of one drop every 5 seconds. Record time as blood enters recipient.
K. **Take vital signs again and monitor for transfusion reaction**
L. **Continue TKO rate for 10 minutes, recheck vital signs. If no significantly increased heart rate, respiration rate or other signs of severe hemolytic transfusion reaction, then you may increase rate. Take vital signs every 5 minutes for the first 15 minutes, then every 15 minutes.**
M. Draw **five** additional units of whole blood as first unit is being given.
N. Treat hypothermia aggressively.
O. Ensure all blood samples and collection bags are labeled appropriately and transported with casualty to next level of care for following testing.
P. **Complete SF518 with transfusion information and make sure document follows casualty for record entry.**

VI. **IF ANY TRANSFUSION REACTION OCCURS, STOP THE TRANSFUSION IMMEDIATELY AND TRANSFER THE BLOOD BAG AND ITS TUBING TO THE LABORATORY WHERE IT WILL BE SENT FOR DIAGNOSTIC TESTING. ALL BLOOD BAGS ASSOCIATED WITH A TRANSFUSION REACTION WILL THEN BE FORWARDED TO AN ASBP FACILITY FOR TESTING. ALL TRANSFUSION REACTIONS ARE CONSIDERED MEDICAL EMERGENCIES AND DOCUMENTATION WILL BE MADE UPON TREATMENT**.

VII. **Post Transfusion Follow-Up Actions (*Process Samples for Shipment and Testing*)**

A. Label three aliquot (pour off) tubes with corresponding ISBT Labels with small barcodes if available. Position the label vertically toward the top of the tube. Write "Serum" on one tube and "Plasma" on the other two tubes. If ISBT labels are not available utilize the Donor's DoD ID # or other unique identifier as appropriate to label the pour off tubes.
B. Place plasma from 3 purple top tubes into the 2 aliquot tubes labeled "Plasma". 3ml sample requirement per aliquot.
C. Place serum from 2 red top tubes into the 1 aliquot tube marked as "Serum".

NOTE: *Do not fill over ¾ full to allow for expansion from freezing.*

D. The seal of capped aliquot tubes should be reinforced with para-film wrap and placed into a biohazard shipping bag or rack. Repeat for each series.
E. Record sample and donor demographic data on Form 148 (Shipping Manifest). Include a printer copy of manifest with shipment and e-mail to BSD or designated facility, if possible.
F. Form 151- Whole Blood Transfusion Checklist must be submitted with shipment for every unit of whole blood transfused.
G. Send copies of ASBP 572 – EWB for each unit collection along with Form 145, Form 147, and Form 148 in a blood box (Collins Blood Box) with ice bag(s) to your respective blood detachment or designated receiving facility. Email a copy of manifest to BSD or designated facility, if possible, and call to alert about incoming shipment. Ensure originals of all forms remain at collecting location.
H. **Samples may be** frozen until they can be shipped to a designated laboratory to perform FDA-approved testing. Contact COCOM Joint Blood Program Office (JBPO) for guidance on specimen acceptability requirements. Depending on collecting unit/facility location and prior coordination, it may be possible to ship specimens directly to a testing or processing facility without performing the tube centrifugation and sample pour offs. Prior coordination MUST be made with COCOM JBPO or testing facility to ensure samples will remain viable if centrifugation step above will be skipped.
I. All donor tubes MUST be centrifuged and serum/plasma removed from RBCs within 72 hours of collection. The BSD or designated unit/facility will send all samples to designated laboratory for FDA-approved testing. BSD or designated facility will enter results in TMDS and forward to submitting Role 2 or Role 3

upon completion. In some cases, the submitting Role 2 or Role 3 may have to enter results into TMDS if not supported by a BSD.

NOTE: *Testing for group O donors may include anti-A and anti-B titer testing. The titer testing must be coordinated with the testing facility prior to sample shipment.*

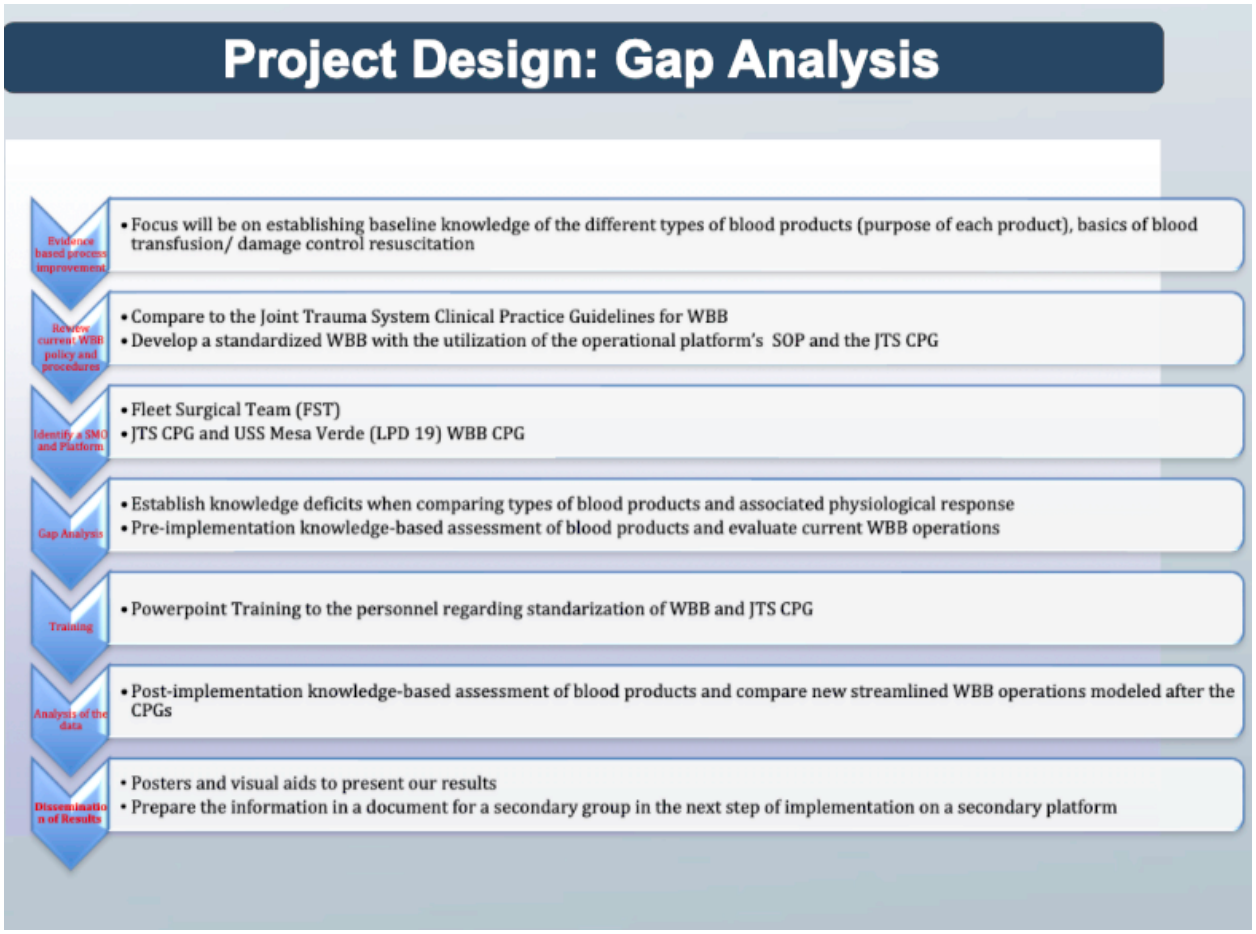
NOTE: *The results of this testing will be viewed as a prescreen for donor's next donation.*

J. Any positive testing that is received by BSD or unit will be forwarded to Preventive Medicine Consultant or available Provider to ensure proper donor care and follow-up is initiated. At no time will laboratory staff notify donors directly regarding positive testing results. JBPO will be notified of positive results to ensure recipient notification is completed for transfused units.

VIII. **Record Keeping**

a. A report of any adverse reaction will be kept on record as a part of the donor/recipient record.
b. All transfusion records and their 518's will be stored for no less than 10 years.
c. All donor reactions must be documented.
d. Attach the Donor reaction report to the ASBP 572 –EWB and forward to Medical Officer for review.

Appendix J: Project Design



Appendix K: Pre/Post Exam

Daniel K. Inouye Graduate School of Nursing

Questions Pre-test

1. **Who is authorized to activate the Walking Blood Bank (WBB)?**
   a) Commanding Officer
   b) Senior Medical Officer (SMO)
   c) Medical or Dental Personnel
   d) Bystander

2. **What classifies an emergent situation to activate the WBB?**
   a) Casualty situation where five or more individuals require blood products
   b) SMO classifies the situation as an emergent situation requiring activation
   c) One casualty requiring blood products
   d) Whenever casualties are expected

3. **What percentage of the ship will be designated as donors for the WBB?**
   a) 45%
   b) 30%
   c) 25%
   d) 10%

4. **When the WBB is activated, where are the donors required to muster for screening?**
   a) Dental
   b) SMO's office
   c) Mess deck
   d) Hangar Bay

5. **Pre-tested donor and type-specific WB is most optimal for transfusion; however, when not available, what alternative WB type can be transfused?**
   a) AB
   b) A-
   c) B-
   d) O-

6. **Who is responsible for staging pre-designated areas for screening and collecting blood products?**
   a) Pre-assigned Medical or Dental Personnel
   b) SMO
   c) ICU Nurse
   d) CO

Daniel K. Inouye Graduate School of Nursing

7. **What form is used to screen donors?**
   a) ASBP 572-EWB
   b) SF 518
   c) DD522
   d) AC 417

8. **What is the secondary pre-designated area if the primary designated area is unavailable?**
   a) Dental
   b) SMO's office
   c) Mess deck
   d) Hangar Bay

9. **Pre-screened donors are to be screened within what time frame if selected for donation when the WBB is activated?**
   a) 90 days and 365 days with the full panel of FDA-licensed donor infectious disease tests and found to be negative for all infections.
   b) 30 days and 365 days with the full panel of FDA-licensed donor infectious disease tests and found to be negative for all infections.
   c) 60 days and 365 days with the full panel of FDA-licensed donor infectious disease tests and found to be negative for all infections.
   d) 90 days and 190 days with the full panel of FDA-licensed donor infectious disease tests and found to be negative for all infections.

10. **Who may initiate a blood transfusion?(Select all that apply)**
    a) Anesthetist
    b) SMO
    c) Medical or Dental Personnel
    d) Nurse

11. **Who is allowed to verify blood products?**
    a) Physician
    b) Anesthetist
    c) Nurse
    d) All the above

12. **What is the minimum number of providers required to verify blood?**
    a) One provider is only required
    b) Two licensed providers are quired to verify blood
    c) Three providers
    d) Zero providers are required to verify the blood as the blood bank verifies before release

Daniel K. Inouye Graduate School of Nursing

13. What are the signs of a transfusion reaction?

a) Decreased blood pressure
b) Rash
c) Increased heart rate, respiratory rate, and temperature
d) All of the above

14. What actions should you take if you suspect a transfusion reaction?

a) Stop the transfusion immediately and send the blood bag and its components to the lab
b) Administer diphenhydramine (50mg IV) and allow the blood products to continue infusing
c) Finish transfusion and continue vigilant monitoring of the patient's vitals
d) Stop the transfusion and discard all blood products and materials used

15. How long are transfusion records required to be stored for?

a) All transfusion records and their 518's will be stored for no less than 1 year
b) All transfusion records and their 518's will be stored for no less than 5 years
c) All transfusion records and their 518's will be stored for no less than 10 year
d) All transfusion records and their 518's will be stored for no less than 20 year

Daniel K. Inouye Graduate School of Nursing

Rate/Rank	NEC/Specialty	PRD	Exam Number

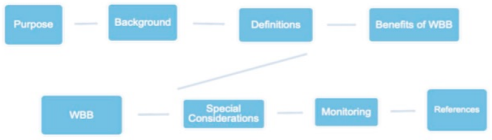
Appendix L: Educational Presentation

Utilizing the JTS CPG as the Standard for WBB Operations on Amphibious Platforms

Adopted from the Joint Trauma System (JTS) Clinical Practice Guideline (CPG) Training Series

Vincent E. DiVenti, LCDR, NC, USN
Cynthia T. Matters, LCDR, NC, USN
Adam R. Robles, LT, NC, USN

Roadmap



2

Purpose

- Provide education in regards to Whole Blood, Stored Whole Blood, and frozen blood products
- Administration of blood products in austere environments
- Discuss the current JTS CPGs for WB transfusion
- Explore the importance of standardizing WB transfusion via Walking Blood Bank on amphibious platforms

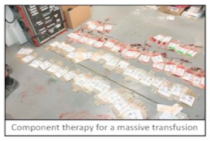
Presentation is based on the JTS Whole Blood Transfusion CPG, 15 May 2018 (ID: 21).

3

Background- Component Therapy

WB transfusion to treat hemorrhage results in outcomes that are at least as favorable as expected outcomes with component therapy

- **Component therapy** (RBC:FFP:platelets) is inferior to WB when administered in a 1:1:1 ratio
  - Disadvantages
    - Requires multiple products
    - Storage demands
    - Dilute blood mixture



Component therapy for a massive transfusion

4

Frozen and Deglycerolized RBCs

- Thawing and deglycerolization are time-consuming processes
  - Takes at least 35 minutes to thaw
  - Takes 60 minutes to deglycerolize one unit in ACP 215
- Equivalent to a fresh unit of RBCs
  - Provides the same physiologic benefit as liquid RBCs
- Significantly lower concentrations of proteins & associated with non-hemolytic transfusion reactions

Background- Whole Blood

WB provides the most physiologic blood mixture

- Single product requiring only one storage modality
- Survival is greatest with FWB
- 91% of trauma related deaths are preventable if blood products are administered promptly

Photo by Lance Cpl. Ashley Lawson, Courtesy of Defense Visual Information Distribution Service.

6

Definition: Fresh Whole Blood

FWB

- Blood collected on an emergency basis from a "walking blood bank"
- Stored at room temperature and useable within 24 hours
- Stored within 8 hours in appropriate refrigeration ➡ SWB

Walking Whole Blood Bank
Photo courtesy of Defense Visual Information Distribution Service

7

Definition: Whole Blood

WB can be transfused as Fresh Whole Blood (FWB) or Stored Whole Blood (SWB)

- Collected in anticoagulants CPD (21 day use) or CPDA-1 (35 day use) and stored at 1-6°C
- FDA approved when appropriately collected, stored, and tested for transfusion-transmitted disease
- Contains all components of blood products, with smaller volume of anticoagulant, and maintains in-vitro hemostatic capability for 2 weeks in storage

8

Definition: Low Titer O Blood

Low Titer O Blood (LTOWB)

- Patients with low Anti-A and Anti-B antibodies (< 1:256 saline dilution)
- Preferred resuscitation product for the pre-hospital treatment of patients
- Donors should be re-titered every 90 days

9

Using Whole Blood

- SWB is the preferred product for resuscitation
  - LTOWB is most commonly collected and used
- SWB or component therapy in appropriate ratio can be used for damage control resuscitation
- FWB should be reserved for casualties with clinically significant shock/coagulopathy when SWB or optimal 1:1:1 therapy is unavailable
  - Component therapy available within an ARG is limited

10

Using Whole Blood

- If given WB, patients with an unknown blood group will require LTOWB or group O RBCs for any acute transfusion requirements for 1 month
  - Impossible to definitively identify blood group with field equipment if blood tested after patient receives LTOWB
- Rh negative blood should ideally be given to females of child- bearing age who are Rh negative

11

Using LTOWB

- LTOWB or group O red blood cells will be given to patients with an unknown blood group receiving WB
  - Obtaining pre-transfusion blood sample can establish patient's original blood group
  - Once patient receives LTOWB, impossible to definitively identify blood group with field equipment
  - These patients will therefore require LTOWB or group O RBCs for any acute transfusion requirements for up to 1 month after admission

12

Fresh Whole Blood Benefits

Fresh Whole Blood: Benefits

- Used when other blood products cannot be delivered at an acceptable rate to sustain resuscitative efforts
- Absence of degradation in donor performance
- More readily available than SWB

13

Whole Blood Risks

Fresh Whole Blood: Specific Risks

- Increased risk of transfusion-transmitted infections
  - Possible case of transmission of Hepatitis C
- Increased risk of clerical errors
  - 1 fatal case of graft vs host disease
- Unsanitary conditions in field
- Not FDA approved

14

Walking Blood Bank

WBB Program should be established at all forward-deployed medical treatment facilities (MTF)

- WBB used to collect FWB
- Requires identification and pre-screening of donors
- Coordination required with the Blood Bank Program Officer
- Follows specific guidelines for pre-screening of donors and collecting whole blood in only authorized equipment

Preferred donors for FWB are pre-screened.
Photo by Petty Officer 2nd Class Charles Oki, Courtesy of Defense Visual Information Distribution Service.

15

Walking Blood Bank

WBB Ideal Donors

- Preferably composed of active duty/guard/reserves and other DoD beneficiaries.
- Fully pre-screened, LTOWB
  - Group-specific donors may be appropriate for group-specific transfusion (e.g., A to A)
  - Group O FWB of unknown titer safer than attempting to match donor-recipient blood group in emergency situations

16

Walking Blood Bank

Decision to use FWB

- Not completely screened to international and national standards
- Consideration of risks and benefits
- Must be thoroughly documented in casualty record
- Inaccuracy of blood type on ID tags are approximately 4%
- Coalition forces are not routinely utilized as donors
- Foreign nationals are used as a last resort

17

Walking Blood Bank

Theater Medical Data Stores (TMDS) will be used to record donations and disease testing results

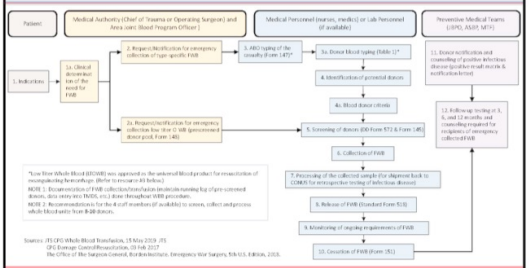
- Prior to issuing FWB, blood type and approved rapid infection disease tests should be performed
- Retrospective samples must be sent to a licensed laboratory for FDA-approved testing regardless of in-theater results
  - ❑ Positive infectious disease results require informing the donor and recipient

Frequency of FWB donation must be tracked

- WB units should not be collected from donors more frequently than every eight weeks to prevent injury to donor
- 1 unit collected per donor– maximum of 2 in dire situations

18

Walking Blood Bank

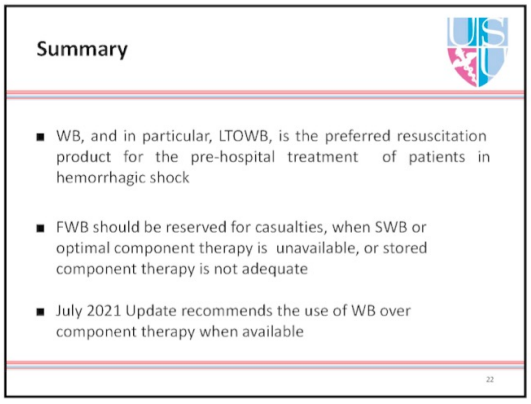


19

2017- USS BATAAN AAR

USS BATAAN received 6 casualties

- Total of 62 units transfused
  - ❑ 12 PRBCs
  - ❑ 10 FFP
  - ❑ 40 units of FWB
- 2 casualties initially received PRBCs and FFP, but developed coagulopathies
  - ❑ FWB products were then administered


Summary
WB, and in particular, LTOWB, is the preferred resuscitation product for the pre-hospital treatment of patients in hemorrhagic shock
FWB should be reserved for casualties, when SWB or optimal component therapy is unavailable, or stored component therapy is not adequate
July 2021 Update recommends the use of WB over component therapy when available
22

Appendix M: Project Timeline

Project Timeline
● Develop practice question: NOV2021
● Literature review of standardized communication during transitions of care: NOV2021-MAR2022
● Communicate with clinical leadership to determine best dates/times for pre-
implementation data collection: MAR2022
● IRB submission and approval: 28 MAR2022
● Create training presentation: complete by Friday 21 OCT2022
● Secure training location with the Fleet Surgical Team: 07 OCT2022
● Schedule training sessions: 14 OCT 2022
● Pre-implementation data collection: 7NOV2022
● Data evaluation, tool modification, intervention implementation: 8 NOV 2022-12 DEC2023
● Post-implementation data collection: 13 DEC2023
● Analyze data - complete by: 01 DEC2022 - MAY2023

● Disseminate data - complete by: 21 MAY2023

Appendix N: Measured Results

N=11 matched subjects with Pre and Post intervention evaluations.

Each category based on 5 yes/no questions for a possible total of 15 points.

	Pre				Post				Overall
Subject	Policy	Clinical	Admin	Total	Policy	Clinical	Admin	Total	Change
8	4	5	2	11	3	5	3	11	0
9	5	5	1	11	3	5	3	11	0
10	3	4	2	9	2	5	2	9	0
11	4	5	1	10	3	5	3	11	1
12	4	3	1	8	5	5	1	11	3
13	5	5	2	12	3	5	3	11	-1
14	5	5	3	13	5	5	1	11	-2
15	1	3	2	6	5	4	2	11	5
16	5	3	2	10	4	3	1	8	-2
17	5	4	1	10	4	5	2	11	1
18	5	5	1	11	5	5	4	14	3
Ave	4.2	4.3	1.6	10.1	3.8	4.7	2.3	10.8	0.7
St Dev	1.25	0.90	0.67	1.92	1.08	0.65	1.01	1.47	2.20

Paired sample t-test showed no significant change, p=.298

Knowledge Status	Overall	Policy	Clinical	Admin
Negative	27.3%	63.6%	0.0%	9.1%
Maintained	27.3%	18.2%	63.6%	45.5%
Improved	45.5%	18.2%	36.4%	45.5%

Question	Pre		Post		Change
Q1-P	11	100.0%	10	90.9%	-1
Q2-C	9	81.8%	10	90.9%	1
Q3-P	7	63.6%	9	81.8%	-1
Q4-P	9	81.8%	8	72.7%	-1
Q5-C	10	90.9%	11	100.0%	1
Q6-P	10	90.9%	10	90.9%	0
Q7-A	5	45.5%	7	63.6%	2
Q8-P	9	81.8%	5	45.5%	-4
Q9-A	0	0.0%	4	36.4%	4
Q10-A	0	0.0%	0	0.0%	0
Q11-C	9	81.8%	10	90.9%	1
Q12-A	10	90.9%	10	90.9%	0
Q13-C	10	90.9%	11	100.0%	1
Q14-C	9	81.8%	10	90.9%	1
Q15-A	3	27.3%	4	36.4%	1

The data was tested for normality using the Kolmogorov-Smirnov test and found to be non-parametric. The data was compared between Enlisted and Officer subjects using the Mann-Whitney test. Only the Pre Intervention Clinical and Overall responses were found to be significant, p=.026.

	Enlisted (n=5)			Officer (n=6)			
Field	Mean	Median	Std. Dev.	Mean	Median	Std. Dev.	Mann Whitney *p*-value
Num correct_Pre	8.8	10	1.789	11.2	11	1.329	0.026
Num Correct P_Pre	3.8	4	1.643	4.5	5	0.837	0.421
Num Correct C_Pre	3.6	3	0.894	4.8	5	0.408	0.026
Num Correct A_Pre	0.6	1	0.548	0.8	1	0.753	0.609
Num correct_Post	10.4	11	1.342	11.2	11	1.602	0.486
Num Correct P_Post	4.2	4	0.837	3.5	3	1.225	0.291
Num Correct C_Post	4.4	5	0.894	5.0	5	0.000	0.104
Num Correct A_Post	1.0	1	0.707	1.7	2	1.033	0.212

Appendix O: DNP Project Completion Verification Form

Appendix G: Daniel K. Inouye Graduate School of Nursing
DNP Project Completion Verification Form

DOCTOR OF NURSING PRACTICE PROJECT
Completion Verification Form

The DNP Project titled:

Standardized Walking Blood Bank Policies and Procedures on Amphibious Readiness Groups to Expedite the Transfusion of Fresh Whole Blood

was completed at: Naval Medical Center Portsmouth; Portsmouth, VA

by the following student(s):

(type student name)	*(signature)*	*(date)*
Vincent E. DiVenti	DIVENTI.VINCENT.ERNEST.1505398757 Digitally signed by DIVENTI.VINCENT.ERNEST.1505398757 Date: 2023.05.01 07:50:21 -04'00'	05/01/2023
Cynthia P. Matters	Cynthia Matters Digitally signed by Cynthia Matters Date: 2023.05.01 06:41:24 -04'00'	05/01/2023
Adam R. Robles	ROBLES.ADAM.R.1364371167 Digitally signed by ROBLES.ADAM.R.1364371167 Date: 2023.05.01 06:56:42 -04'00'	05/01/2023

The DNP Practice Project Team verifies that the following components of the DNP project, accomplished by the above students, is of sufficient rigor and demonstrates doctoral level scholarship to meet the requirements for USUHS GSN graduation:

- Presentation of DNP project to the leadership/stakeholders at the Phase II Site,
- Abstract/Impact Statement (*Appendix F*), and
- DNP Project written report.

Verified by:

	(type name)	*(signature)*	*(date)*
Senior Mentor:	Todd A. Batteau	BATTEAU.TODD.ANTHONY.1235562878 Digitally signed by BATTEAU.TODD.ANTHONY.1235562878 Date: 2023.05.01 11:13:51 -04'00'	5/1/23
Team Mentor:			
Team Mentor:			
Phase II Site Director:	Katherine Kiddé		

For RNA Students only *- add the following additional signature for final verification of project completion:*

Kenneth Barber	BARBER.KENNETH.DOUGLAS.1177263644 Digitally signed by BARBER.KENNETH.DOUGLAS.1177263644	03MAY2023
RNA Project Director *(type name)*	*(Signature)*	*(Date)*

Form Version: 26 Aug 2017/30 Mar2020