JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE (JTS CPG)

Whole Blood Transfusion (CPG ID: 21)

This CPG provides the rationale and guidelines for WB transfusion, including but not limited to product definitions, indications, collection, storage, testing, transfusion, and documentation.

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First Publication Date: 01 Oct 2006 | Publication Date: 15 May 2018 | Supersedes CPG dated 24 Oct 2012

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DEFINITIONS

Whole blood (WB) collected in the anticoagulants CPD or CPDA-1 is an FDA-approved product when it is appropriately collected, stored and tested for transfusion transmitted disease (TTD) by a licensed blood donor center. It can be stored for 21 days at 1-6°C in CPD or 35 days at 1-6°C in CPDA-1 and is designated stored whole blood (SWB) in this CPG. SWB retains in vitro hemostatic parameters to an acceptable level during approved storage duration;[1] however, after the first 2 weeks of storage, the hemostatic function of WB may vary and supplementation with fresher whole blood units or blood components, especially platelets, may be necessary.

Fresh whole blood (FWB) refers to WB collected on an emergency basis from a "walking blood bank" (WBB). FWB can either be stored at room temperature and used within 24 hours of collection (and then destroyed if not used) or it can be refrigerated within 8 hours of collection, after which point it becomes WBB-SWB. FWB is considered to have full hemostatic function. FWB is collected from pre-screened donors when possible, but does not undergo TTD testing prior to transfusion; this fact makes it not approvable by the FDA. Because FWB presents a higher risk of disease transmission, it is reserved for situations in which tested blood products are unavailable or ineffective (further discussion below).

The most important safety consideration in transfusing WB is that donor red blood cells (RBCs) be compatible with the recipient to avoid acute hemolytic transfusion reactions (a.k.a., major mismatch). WB from group O donors contains RBCs that are compatible with all recipients, but the plasma in group O WB may contain anti-A and anti-B antibodies that could cause hemolysis in a non-group O recipient (a.k.a., minor mismatch). There are two approaches to mitigating this risk: 1) transfuse only group-specific WB (i.e., A to A, B to B, AB to AB and O to O), or 2) anti-A and anti-B antibody titers can be measured in group O WB and only units containing a low titer of antibody (e.g., <1:256 saline dilution, immediate spin method) are designated "low titer O WB" (LTOWB) and these are used as "universal WB." LTOWB has been used extensively to resuscitate combat casualties and was a standard of care in WWII, and the conflicts in Korea and Vietnam.[2] Note that LTOWB may be either SWB or may be collected from pre-screened O donors in a WBB protocol and thus be considered FWB (e.g., the Ranger O Low titer or ROLO protocol).[3] In practice, the only SWB supplied by the Armed Services Blood Program (ASBP) to OCONUS locations will be LTOWB due to the relatively higher risk of donor-recipient blood group mismatch and resulting hemolysis during group-specific WB transfusion, compared to the much lower risk of hemolysis with LTOWB.[2] Collecting LTOWB from WBB pre-screened donors is also preferred to group-specific transfusion. In short, most WB transfused during future contingency operations will be LTOWB, and most of this is likely to be SWB. Use of LTOWB is recognized under AABB Standard 5.15.1 (31st Edition, AABB Standards, in effect beginning 01 April 2018).[4]

It should be noted that anti-A and anti-B titers may vary in group O donors. Ideally, WBB donors should be re-titered every 90 days in conjunction with TTD testing. However; since availability of titer testing in the deployed setting is very limited, every effort should be made to ensure that donors are titered at least annually if not prior to each deployment. ASBP collects WB from male and never-pregnant female donors, or from female donors testing negative for anti-HLA antibodies (this mitigates risk of transfusion-associated acute lung injury, TRALI). WB is primarily collected from Rh positive donors and there is a limited supply of Rh negative blood products in the deployed environment. Every effort should be made to provide Rh negative whole blood or red cells to females of child-bearing potential (age<50 years) who are Rh negative or of unknown blood type. However; should transfusions of Rh positive blood products occur in these patients, these must be thoroughly documented in the patient's medical record due to the risk of allo-immunization to Rh and potential for hemolytic disease of the fetus/newborn (HDFN) in future pregnancies.

All WB products (SWB, FWB, and LTOWB) are indicated for the resuscitation of massive blood loss. WB, and in particular LTOWB, is the preferred resuscitation product for the pre-hospital treatment of patients in hemorrhagic shock.[5,6] This CPG will distinguish between stored whole blood (SWB) and fresh whole blood (FWB), and discuss uses and limitations of both products.

BACKGROUND

The first documented animal-to-animal (dog) blood transfusion was performed at Oxford in 1665 by Richard Lower, followed by the first animal-to-human blood transfusion in 1667 by Jean Denis. The first human-to-human blood transfusion was performed by James Blundell in 1818. In the year 1900, the ABO blood grouping system was classified by Landsteiner and, based on this, the first pre-transfusion cross-match was done by Ottenberg in 1907. The system of Rh typing was invented by Landsteiner and Wiener in the year 1940.[7] In military settings, whole blood has been used extensively to resuscitate casualties in military conflicts since 1917, during World War I.[8] Whole blood is the starting point for blood donation and continues to be used extensively worldwide where component production is not available.

Blood safety and sustainability are global issues. Component development supports the sustainability of blood services where demand can outstrip supply. Component use also permits optimal storage conditions for each element of the blood, minimizes hemolytic reactions and supports precision treatment. Examples include the use of red blood cells (RBCs) for anemia, fresh frozen plasma (FFP) to replace lost or consumed clotting factors, platelets (PLTs) for platelet abnormalities and thrombocytopenia, and cryoprecipitate (Cryo) for hyperfibrinogenemia. Whole blood contains all of these elements in a smaller volume of anticoagulant and thus provides a more concentrated product for treating bleeding patients who need all elements of blood replaced. The widespread use of component therapy is driven by blood product availability. For the reasons outlined above, blood banks have preferred to stock components over WB.

The clinical data comparing WB to components have recently been reviewed.[6] Currently available clinical data indicate that use of WB to treat hemorrhage results in outcomes that are at least as favorable as those that can be expected with component therapy that includes RBCs, plasma and platelets.

Severely injured combat casualties requiring transfusion have a significant mortality rate (16%) and have the greatest potential to benefit from early and appropriate transfusion strategies. A large retrospective cohort study of casualties requiring transfusions during Operations Iraqi Freedom (OIF) and Enduring Freedom (OEF) suggests a significant survival benefit for transfused casualties when RBCs, fresh frozen plasma, and platelets are transfused at a 1:1:1 ratio.[9] A recent randomized trial in civilian trauma patients demonstrated that a 1:1:1 transfusion ratio resulted in improved early hemostasis, though no statistically significant improvement in survival.[10] Two retrospective analyses in combat casualties comparing FWB to component therapy (which included platelets) have also been published. One study showed a potential survival benefit to the use of FWB during resuscitation of severe combat injuries, and the other showed FWB to be equivalent to component therapy.[11,12] These studies underscore the importance of providing all elements of whole blood (RBCs, plasma and platelets) to severely bleeding patients and suggest that use of either WB or components in a 1:1:1 ratio for resuscitation of bleeding patients is acceptable; product choices can be guided by practical considerations.

ADVANTAGES OF WHOLE BLOOD OVER COMPONENTS

SWB and FWB provide FFP:RBC:PLTs in a physiologic ratio and return to the bleeding patient what has been lost. It should be noted that the 1:1:1 ratio of blood components (platelets: plasma:RBC) recommended for damage control resuscitation does not faithfully reconstitute WB. The 1:1:1 ratio yields a dilute blood mixture with a hematocrit of 29%,[13] 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. In addition, WB delivers all needed elements of blood in only one product, which only requires refrigeration for storage. In contrast, component therapy requires multiple products and storage modalities (refrigeration, freezing and generally room temperature storage with agitation for platelets – though platelets can also be refrigerated), greatly increasing workload and complexity for clinical teams.

SWB collected in licensed blood centers offers the same level of TTD safety as component therapy collected in licensed centers. It should be noted that due to the extremely short shelf life of standard room temperature stored platelets (5 days), all platelet products transfused in the deployed setting are collected in theater and do not undergo TTD testing prior to transfusion. Therefore, SWB collected in licensed centers and fully tested presents a lower TTD risk than component therapy using in-theater collected platelets or FWB.

For U.S. casualties presenting in hemorrhagic shock, a transfusion strategy that included FWB with RBCs and plasma was associated with an improved survival compared to the use of stored components only (FFP, RBCs, and PLTs).[11] Compared to SWB or component therapy, FWB is more readily available in austere conditions and requires only the presence of donors and simple collection equipment, though safe collection and transfusion of FWB requires appropriate pre-deployment training [14,15] and careful donor evaluation. FWB has no loss of the labile clotting factors or platelet activity that is often associated with storage, has close to physiological hematocrit and has no red blood cell "storage lesion". Storage lesion describes the degradation of the RBC involving loss of membrane plasticity,[11,12] diphosphoglycerate, adenosine triphosphate, nitric oxide, and other factors leading to potentially reduced delivery of oxygen to tissues and contribution to a variety of pathophysiologic processes.[16] It should be noted that recent randomized trials assessing the effects of red blood cell storage age have not confirmed a clinically detectable deleterious effect of the red cell storage lesion in the populations evaluated. The effect of red cell storage age, whether in component therapy or SWB has not been rigorously evaluated in certain vulnerable populations, such as trauma patients.[17]

Overall, both SWB and FWB offer at least comparable performance and safety compared with components, as well as compelling logistical advantages that are particularly important in pre-hospital resuscitation and indeed, in most deployment settings.

CONSIDERATIONS IN CHOOSING SWB OR FWB

There are risks associated with the use of FWB, including but not limited to increased risk of transfusion-transmitted infections (e.g., HIV, hepatitis B/C, syphilis), and an increased risk of clerical errors leading to major mismatch when ABO-identical WB is provided, due to the potentially chaotic conditions during which FWB is requested. Additionally, field conditions are inherently unsanitary and are presumed to increase the risk of bacterial contamination of the blood. Recent history with approximately 10,000 FWB transfusions to U.S. personnel during OIF/OEF have resulted in one Hepatitis C (HCV), one Human T-Lymphocyte Virus (HTLV) seroconversion, and one fatal case of transfusion-associated graft-versus host disease that was potentially due to a FWB transfusion.[4] FWB is not FDA-approved and is not intended or indicated for routine use. It is NOT appropriate, as a matter of convenience, to use FWB as an alternative to more stringently controlled blood products for patients who do not have severe, immediately life-threatening injuries. FWB is to be used only when other blood products cannot be delivered at an acceptable rate to sustain the resuscitation of an actively bleeding patient, when specific stored products are not available (e.g., SWB, RBCs, FFP, PLTs, Cryo), or when stored components are not adequately resuscitating a patient with an immediately life-threatening injury. FWB should not routinely be collected from pre-screened donors as a way to maintain a routine inventory of WBB-SWB products. In other words, the use of WBB for collection of FWB is for emergency use only. It should be noted that studies of FWB donors have not documented significant decrements in military-relevant task performance following donation. Thus, concerns that FWB collections will adversely affect mission outcomes have not been substantiated and should not preclude WBB activation when conditions for FWB use are met.[18]

In patients receiving LTOWB (SWB or FWB), every effort should be made to obtain a pre-transfusion blood sample in order to establish the original blood group. If blood samples are obtained after transfusion with LTOWB, it may be impossible to definitively establish a patient's blood group with the equipment available in the deployed setting. As a result, patients of unknown blood group receiving LTOWB will continue to receive LTOWB or group O RBC units for their acute transfusion requirements for up to a month following admission. This can deplete inventories of LTOWB and group O RBCs.

WHOLE BLOOD RECOMMENDATIONS

- SWB, which will in practice be LTOWB, is the preferred product for pre-hospital resuscitation.
- In a facility capable of providing surgical care (Role 2 or higher), SWB (in practice, LTOWB) or component therapy (including RBCs, plasma and platelets) can used for damage control resuscitation. SWB simplifies transfusion and may facilitate more rapid resuscitation of casualties, and may enhance a facility's capacity to manage MASCAL challenges.
- The use of FWB should be reserved for casualties with clinically significant shock or coagulopathy (e.g. bleeding with associated metabolic acidosis, thrombocytopenia or INR>1.5) and when SWB or optimal component therapy (e.g. apheresis platelets and FFP) are unavailable, or when stored component therapy is not adequately resuscitating a patient with immediately life-threatening injuries.

GUIDELINES FOR WALKING BLOOD BANK PROGRAM FOR FWB

The decision to use FWB is a medical decision that must be made by a physician who has full knowledge of both the clinical situation and the availability of compatible blood products. A Walking Blood Bank (WBB) Program should be established based on a risk assessment and the potential for casualties. The calculation of risk should include a medical intelligence assessment which includes infection prevalence and the need for preventative force protection measures. In practice, all forward-deployed MTFs should establish a WBB. Coordination with the Area Joint Blood Program Officer (AJBPO) is required to establish a WBB Program. (Appendix B: Blood Donor Pre-screening Standard Operating Procedure [SOP]). FWB should be collected for transfusion as outlined in Appendix C: Emergency Whole Blood Drive SOP. In general, the use of FWB should be limited to casualties who are anticipated to require a transfusion when the physician determines that SWB or optimal component therapy is unavailable or in limited supply, or in patients that are not responding to SWB or component therapy. The decision to initiate a FWB drive should be made in consultation with the appropriate MTF medical authority (e.g., Deputy Commander for Clinical Services (DCCS), Trauma Director, Trauma Surgeon) and Laboratory/Blood Bank OIC. At Role 2 facilities, the lead surgeons and/or facility OIC should be consulted on the decision to initiate the drive.

Pre-screened donors registered into the WBB Program are preferably composed of active duty, active reserve, active National Guard, and other DoD beneficiaries. The preferred donors for FWB are fully pre-screened, low titer O donors. Next, consider fully pre-screened donors of other blood groups for group-specific transfusions (e.g., A to A). Donors who have not been pre-screened for TTDs should be considered only when no other donors are available. Note that in chaotic circumstances such as tactical care under fire or mass casualty (MASCAL) scenarios, or if blood grouping equipment is not available in adequate quantities, use of group O FWB of unknown anti-A and anti-B titer may be safer than attempting to match blood groups between donors and recipients, since the risk of hemolysis from major mismatch is greater than the risk of transfusing a very high titer group O unit (very high titers units being relatively uncommon) to a non-group O recipient. Indeed, this strategy was successfully employed by a Forward Surgical Team in Afghanistan.[19]

Donors should be screened to international mandated and national standards. Coalition Forces will not be utilized routinely as donors, due to national variances in screening for blood borne diseases and differences in disease prevalence. Blood may be collected from pre-screened coalition partner forces if the screening program has been reviewed by the JBPO and deemed acceptable by the COCOM Surgeon and the ASBP Director. Planned coalition activity should address the interoperability of donor panels. Non-Coalition Force foreign nationals should be used as a last resort.

The decision to use FWB that has not been completely screened for infectious agents is a medical decision that must be made after thorough consideration of risks and benefits. Decision-making should be adequately documented in the casualty record.

The blood type on identification tags is occasionally incorrect (last correlated data equated to about 4% inaccurate) [20-22] and must not be relied upon routinely to determine blood type for either donors or recipients. Identification tags for ABO/Rh verification should be utilized as a last resort only.

Use of non-standard blood donation material and equipment may lead to coagulation during the collection process potentially causing an adverse transfusion reaction; therefore, only authorized equipment will be utilized (Appendix C enclosure: WBB Supply List [with NSNs]).

Prior to issuing FWB for transfusion, the ABO and Rh type should be verified and approved rapid infection disease tests (e.g., HIV, HCV, and HBV) should be performed as outlined in Appendix C: Emergency Whole Blood Drive SOP to the greatest extent possible.

Theater Medical Data Stores (TMDS), Blood Portal, shall be utilized to record FWB donations and infectious disease testing results.

Frequency of FWB donation must be tracked. In general, WB units should not be collected from donors more frequently than every 8 weeks (56 days). This interval between donations is important to allow the donor to recover RBC mass and iron stores and should not be shortened except under the most extreme circumstances. Donors who give blood frequently may develop iron deficiency even in the absence of anemia. Iron deficiency can cause fatigue, difficulty concentrating, pica, restless leg syndrome (RLS), and eventually anemia if untreated. Iron deficiency can be diagnosed by measuring serum ferritin levels (deficiency defined as ferritin <30 mcg/L in males and <20 mcg/L in females). In deployed settings, it may be impossible to measure ferritin levels but donors at particular risk of iron deficiency include: young donors (to early 20's), premenopausal females, frequent donors (males ≥ 3x/year, females ≥ 2x/year), and donors near hemoglobin cutoff for donation (males 13.0 g/dL, females 12.5 g/dL). Consideration should be given to screening ferritin prior to deployment in high risk donors, particularly low titer O donors who may be called upon to donate more frequently. Consideration should be given to empiric iron supplementation in high risk donors or donors with symptoms of iron deficiency (available as ferrous sulfate 325mg (65mg elemental iron), ferrous gluconate 325 mg (38mg elemental iron), or multivitamins with iron (18-19 mg elemental iron); one tablet per day for 60-120 days may be adequate to replete iron stores).[23,24] Patients with documented iron deficiency (low ferritin levels as above) should be offered iron supplementation and monitored for response.

WBB PLANNING

Since the need for FWB cannot be predicted, a robust contingency operational plan should be developed by the MTF staff to include the Laboratory/Blood Bank and surgical and anesthesia providers in coordination with the Area Joint Blood Program Officer. The plan should be reviewed and rehearsed regularly. Equipment and consumables should be inspected with due attention paid to storage conditions and expiry dates.

The key elements for planning and readiness to administer FWB are knowledge and rehearsal of two SOPs: Blood Donor Pre-Screening (Appendix B) and Emergency Whole Blood Drive (Appendix C).

- A contingency plan should be developed for collecting, storing, and transfusing FWB in MASCAL situations or when it may be deemed that the current blood inventory will be exhausted prior to re-supply (e.g., when multiple type-O trauma casualties are exhausting the type-O RBC inventory).
- The physical donation site should be organized in such a way as to maintain the integrity of the screening and donation process, and to minimize the possibility of clerical errors. This is especially important in emergency situations involving more than one casualty.
- Every effort should be made to adhere to the same screening, drawing, labeling, and issuing standards required for U.S. FDA-approved blood products.

- Pre-screened donors in the WBB Program determined to be suitable should be utilized, to the greatest extent possible, before using personnel who: (1) have been pre-screened or donated in the past but do not have current (within 90 days) screening and infectious disease testing; (2) have no pre-screen or donation history. All donors must be rescreened at the time of donation.
- Use LTOWB donors if available. Otherwise, upon determining the ABO/Rh status of the casualty, activate the WBB Program, re-calling pre-screened donors with the same ABO/Rh using the TMDS>Manage Donor>View Donor List, if available, or other record keeping systems. All donors should have their ABO/Rh verified (i.e. Eldon card or laboratory testing) at the time of donation. Titers for LTOWB donors should be obtained pre-deployment, which should be no more than 12 months prior to donation. The ABO and RhD group should be the same as that on the dog tag and records. Before any FWB is transfused, rapid infectious disease testing (i.e. HIV, HBV, HCV) of donor specimens shall be performed, to the greatest extent possible.
- Retrospective samples must be sent to a licensed laboratory for FDA-approved testing, regardless of whether the rapid infectious disease testing is performed pre- or post-transfusion, as these tests are not licensed for donor testing.
- Upon the notification of confirmed positive infectious disease results, a medical provider or preventive medicine personnel will be notified to ensure that the donor is notified and counseled. Donors and unit commanders must understand the importance of donor tracing.
- If a patient receives a confirmed positive infectious disease unit, the AJBPO will notify the Armed Services Blood Program immediately to initiate patient notification and an evaluation of both the donor and patient.
- In accordance with HA Policy 10-002, Policy on the Use of Non-U.S. Food and Drug Administration, recipients of FWB shall receive follow-up advice and infectious disease testing as soon as possible, and at 3-, 6-, and 12-months post-transfusion.
- Procedure. See Appendix B enclosure: ASBP 572–EWB (Emergency Whole Blood).
- Only one unit of FWB should be collected per donor. In situations where there are a limited number of donors and a dire need for blood, no more than two units may be taken from a donor. Performance decrements may occur after two-unit collections and volume resuscitation of the donor may be necessary. Collection of more than one unit per donor should only be considered under extreme circumstances and these should be thoroughly documented.

WB PEDIATRIC CONSIDERATIONS

WB has been administered to pediatric patients in recent conflicts.[25] WB has not been rigorously studied in pediatric trauma resuscitation, but has been shown to reduce blood loss and transfusion requirements in pediatric cardiac surgery.[11]

There are no established clinical criteria for administration of WB in bleeding pediatric patients. Physiologic variables should be interpreted by age (e.g. hypotension = systolic blood pressure < 70 + 2*age in years).

For patients <40kg, WB should be delivered in “unit doses” of 10-15 ml/kg. WB is more readily volume-titrated than component therapy. There are no known contraindications to using WB in pediatric casualties.

A massive transfusion in children is defined as 40 ml/kg (total blood volume is approx. 70-80ml/kg).[25]

PERFORMANCE IMPROVEMENT (PI) MONITORING

INTENT (EXPECTED OUTCOMES)

- SWB, particularly LTOWB, is used when available for pre-hospital resuscitation.
- SWB or component therapy is routinely used for damage control resuscitation and FWB is reserved for casualties who meet one of these two criteria:
- Patients with clinically significant shock or coagulopathy (e.g., bleeding with associated metabolic acidosis, thrombocytopenia or INR >1.5) when SWB or optimal component therapy (e.g., PLTs and FFP) are unavailable
- SWB or component therapy is not adequately resuscitating a patient with immediately life-threatening injuries.

PERFORMANCE / ADHERENCE MEASURES

- SWB was used in prehospital resuscitation.
- SWB or component therapy was routinely used for damage control resuscitation.
- FWB was used for casualties who fall into one of these two criteria:
  1. Patients with clinically significant shock or coagulopathy (e.g., bleeding with associated metabolic acidosis, thrombocytopenia or INR >1.5) when SWB or optimal component therapy (e.g., PLTs and FFP) was unavailable
  2. SWB or component therapy was not adequately resuscitating the patient with immediately life-threatening injuries.

DATA SOURCE

- Patient Record
- DoD Trauma Registry
- Blood transfusion databases

SYSTEM REPORTING & FREQUENCY

The above constitutes the minimum criteria for PI monitoring of this CPG. System reporting will be performed annually; additional PI monitoring and system reporting may be performed as needed.

The system review and data analysis will be performed by the Joint Trauma System.

REFERENCES

1. Pidcoke HF, McFaul SJ, Ramasubramanian AK, et al. Primary hemostatic capacity of whole blood: a comprehensive analysis of pathogen reduction and refrigeration effects over time. Transfusion. 2013 Jan;53 Suppl 1:137S-149S.

2. Strandenes G, Berséus O, Cap AP, et al. Low titer group O whole blood in emergency situations. Shock. 2014 May;41 Suppl 1:70-5.

3. Fisher AD, Miles EA, Cap AP, Strandenes G, Kane SF. Tactical Damage Control Resuscitation. Mil Med. 2015 Aug;180(8):869-75. doi: 10.7205/MILMED-D-14-00721.

4. Yazer MH, Cap AP, Spinella PC. Raising the Standards on Whole Blood. J Trauma Acute Care Surg. 2017 Dec 28

5. Butler FK, Holcomb JB, Schreiber MA, et al. Fluid Resuscitation for Hemorrhagic Shock in Tactical Combat Casualty Care: TCCC Guidelines Change 14-01--2 June 2014. J Spec Oper Med. 2014 Fall;14(3):13-38.

6. Spinella PC, Cap AP. Whole blood: back to the future. Curr Opin Hematol. 2016 Nov;23(6):536-542.

7. Arya RC, Wander GS, and Gupta, P. Blood component therapy: Which, when and how much. J Anaesthesiol Clin Pharmacol. 2011 Apr-Jun; 27(2): 278–284.

8. Stansbury LG, Hess JR. The 100th anniversary of the first blood bank. Transfusion. 2017 Nov;57(11):2562-2563.

9. Pidcoke HF, Aden JK, Mora AG, et al. Ten-year analysis of transfusion in Operation Iraqi Freedom and Operation Enduring Freedom: increased plasma and platelet use correlates with improved survival. J Trauma Acute Care Surg. 2012 Dec;73(6 Suppl 5):S445-52.

10. Holcomb JB, Tilley BC, Baraniuk S, et al. 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. PROPPR Study Group. JAMA. 2015 Feb 3;313(5):471-82.

11. Spinella PC, Perkins JG, Grathwohl JG, et al. Warm fresh whole blood is independently associated with improved survival for patients with combat-related traumatic injuries. J Trauma. 2009;66:S69-S76.

12. Perkins JG, Cap AP, Spinella PC, et al. Comparison of platelet transfusion as fresh whole blood versus apheresis platelets for massively transfused combat trauma patients (CME). Transfusion. 2011 Feb;51(2):242-52.

13. Hess JR. Resuscitation of trauma-induced coagulopathy. Hematology Am Soc Hematol Educ Program. 2013;2013:664-7.

14. Strandenes G, De Pasquale M, Cap AP, et al. Emergency whole-blood use in the field: a simplified protocol for collection and transfusion. Shock. 2014 May;41 Suppl 1:76-83.

15. Doughty H, Thompson P, Cap AP, et al. A proposed field emergency donor panel questionnaire and triage tool. Transfusion. 2016 Apr;56 Suppl 2:S119-27.

16. Hess JR. Measures of stored red blood cell quality. Vox Sang. 2014 Jul;107(1):1-9.

17. Belpulsi D, Spitalnik SL, Hod EA. The controversy over the age of blood: what do the clinical trials really teach us? Blood Transfus. 2017 Mar;15(2):112-115.

18. Strandenes G, Skogrand H, Spinella PC, et al. Donor performance of combat readiness skills of special forces soldiers are maintained immediately after whole blood donation: a study to support the development of a prehospital fresh whole blood transfusion program. Transfusion. 2013 Mar;53(3):526-30.

19. Nessen SC, Eastridge BJ, Cronk D, et al. Fresh whole blood use by forward surgical teams in Afghanistan is associated with improved survival compared to component therapy without platelets. Transfusion. 2013 Jan;53 Suppl 1:107S-113S.

20. Rentas FJ1, Clark PA. Blood type discrepancies on military identification cards and tags: a readiness concern in the U.S. Army.Mil Med. 1999 Nov;164(11):785-7.

21. Frohman EM. Blood typing errors on U.S. army identification cards and tags. Mil Med. 1989 May;154(5):273-4.

22. Gaydos JC, Polk AJ, Cowan DN, et al. Blood typing errors on U.S. Army identification (ID) cards and tags. Mil Med. 1990 Apr;155(4):A19.

23. Mast AE, Bialkowski W, Bryant BJ, Wright DJ, Birch R, Kiss JE, D'Andrea P, Cable RG, Spencer BR. A randomized, blinded, placebo-controlled trial of education and iron supplementation for mitigation of iron deficiency in regular blood donors. *Transfusion* 2016;56:1588-1597. PMID: 26813849

24. Bialkowski W, Kiss JE, Wright DJ, Cable RG, Birch R, D'Andrea P, Bryant BJ, Spencer BR, Mast AE. Estimates of total body iron indicate 19 mg and 38 mg oral iron are equivalent for the mitigation of iron deficiency in a longitudinal study. *American Journal of Hematology* 2017; 92:851-857. PMID: 28494509).

25. Repine TB, Perkins JG, Kauvar DS, Blackborne L. The use of fresh whole blood in massive transfusion. J Trauma. 2006;60:S59-S69.

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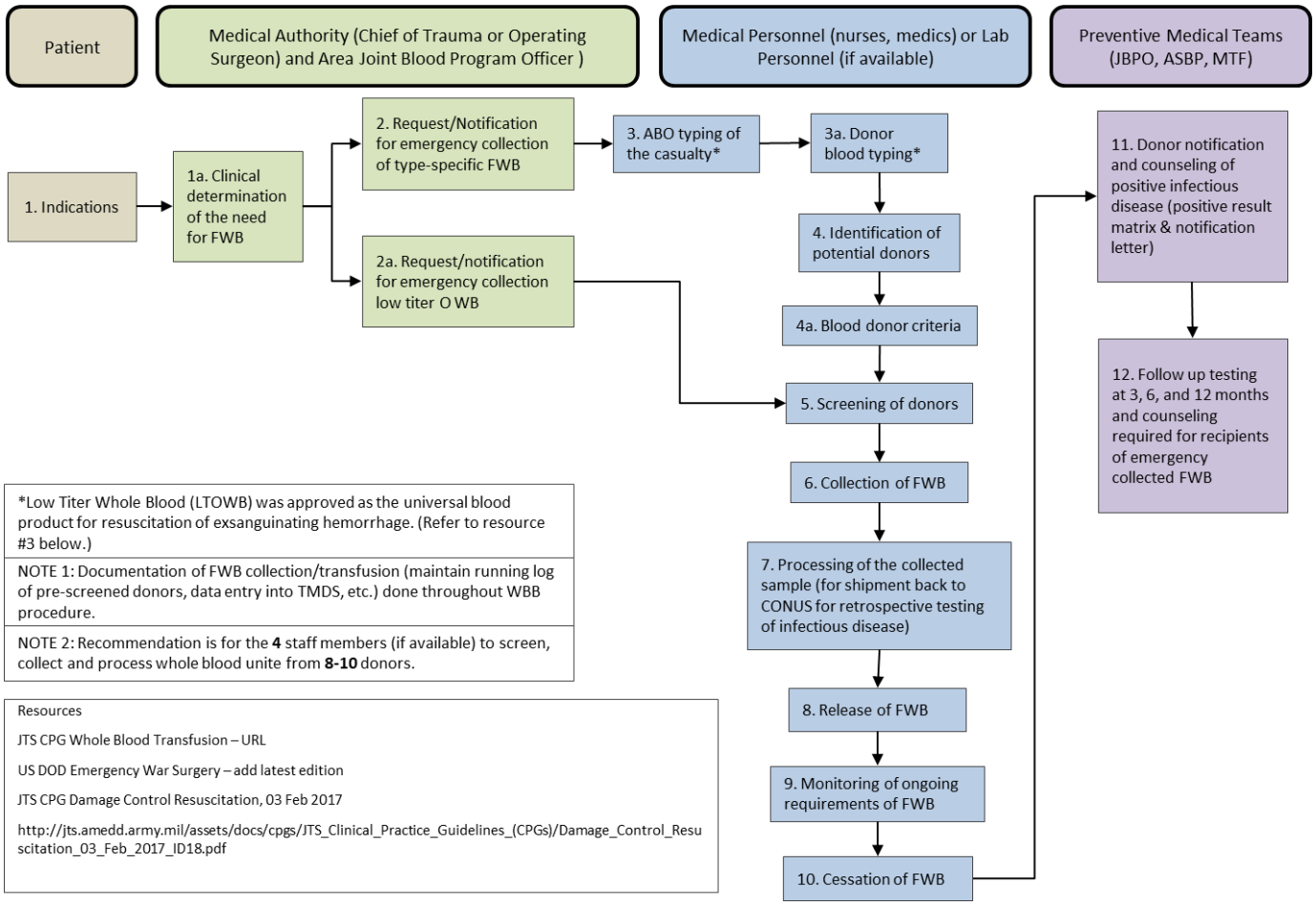
APPENDIX A: WALKING BLOOD BANK PROCESS MAP



*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 B: BLOOD DONOR PRE-SCREENING SOP

Blood Donor Pre-Screening Standard Operating Procedures

This Standard Operating Procedure (SOP) accompanies the Whole Blood Transfusion Clinical Practice Guideline published by the Joint Trauma System, the DoD Center of Excellence for Trauma.

1.0 Material and Equipment

Use the following:

- ASBP 572- Emergency Whole Blood (EWB)
- Clip Boards
- Gloves
- Testing Collection Set: premade bags with 2x2 gauze, 2 red top tubes, 4 purple top tubes,
  Note: More tubes may be required if using short draw or small volume tubes
  Note: Gold/yellow top (serum separator) tubes may be substituted for red top tubes.
  Note: Pearl top (plasma preparation) tubes may be substituted for 3 of the purple top tubes.
- Blood Collection Needles
- BD Vacutainer Hubs
- Coban
- Assigned Pre Screen ISBT Labels (500 number series)
- Sharps Containers
- ABO/Rh Testing Card (e.g., Eldon Military Kit or other FDA-approved device)
- Centrifuge
- Disposable Pipettes
- Plastic Aliquot tubes/lids 13X100mm (or 12X75mm)
- Para-Film
- Biohazard Bags
- Trash Bags
- Leak Resistant Chucks
- Disposable Lab Coats
- Cold Packs
- Test Tube Racks

2.0 Records/Forms

- ASBP 572-EWB, Form 147, Form 148
- Theater Medial Data Store (TMDS), Blood Portal

3.0 Quality Control

- If possible, perform quality check on ABO/Rh Testing Card (See package inserts for procedures).
- Medical personnel should be trained by blood donor center/Blood Support Detachment or other qualified personnel.

4.0 Procedure

Pre-screening of a prospective emergency whole blood donor pool is mandatory. Development of a pre-screened donor pool should be considered a commander's priority when preparing for deployment and/or after arrival into theater. It is imperative that a donor pool once established is maintained because of the frequent redeployment of units out of theater and change of assigned personnel. Due diligence in establishing a pre-screened whole blood donor pool will decrease the risk of transmitting infectious disease while simultaneously increasing the efficiency of the whole blood collection process.

1

Perform the following steps when pre-screening donors:

1. Prepare for donor pre-screening event

Coordinate with appropriate units/contacts for times and location of event. May need to conduct a site survey to ensure appropriate site (i.e. space, lighting, privacy for interview). Samples need to be sent to the testing lab/donor center/blood support detachment as soon as possible after collection, so prior coordination with transport assets is a must.

2. Conduct the pre-screening event

- **Medical history**: Provide prospective donor an ASBP 572-EWB– ensure demographic info is legible and as complete as possible.
- **Interview**: Trained medical personnel will need to determine if the donor is eligible to donate based on the information collected.

  ***NOTE**: ONLY GROUP A questions (1-8) on the ASBP 572-EWB must be completed by the donor for pre-screening.*

- If/Then Scenarios
  a. **If:** Response to question 1 is "Yes" AND Responses for questions 2-8 are "No"
     Then: Document acceptability of Group A question responses on ASBP 572-EWB and proceed to step 3

  b. **If:** There are any "Yes" responses for questions 2-8 AND/OR Response to question 1 is "No"
     Then: Document the reason for the "Yes" response (questions 2-8) or "No" response to question 1. Defer the donor and document unacceptability of Group A question responses on ASBP 572-EWB.

3. Phlebotomy

a. Collect 4 Purple Top and 2 Red Top tubes and label with small Pre-Screen (500 number series will be used in theater) ISBT labels (without barcodes).

b. Apply the same ISBT label number to the ASBP 572-EWB. If no ISBT labels available, label tubes with donor's full name and DoD ID.

4. Register donor in TMDS per Manage Donations/Donors
See steps below in section 5.0 Maintain Database (TDMS)

***Note**: **Rapid Infectious Disease Testing is not required for the pre-screen of donors.** If performed, see Emergency Whole Blood Collection SOP for instructions.*

5. Perform ABO/Rh Testing

a. Utilizing blood from purple top tube, perform ABO/Rh confirmation using Eldon Card or other FDA-approved method to verify ABO listed on ASBP 572-EWB. (Refer to package inserts and approved facility/unit SOPs for further instructions).

b. Record Lot # of reagents, EXP Date and Results on Form 147.

c. Record blood type in TMDS.

6. Process Samples for Shipment & Testing

a. Centrifuge 2 Red Top and 3 Purple Top Tubes for 5 minutes at 4000 RPM.

b. Label three aliquot (pour off) tubes with corresponding ISBT Labels with small barcodes. Position the ISBT label vertically toward top of tube as shown at left. 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.

c. Place plasma from 3 Purple Top tubes into the 2 aliquot tubes labeled "Plasma". *3ml sample requirement per aliquot.

d. Place serum from 2 Red Top tubes into the 1 aliquot tube marked as "Serum". Do not fill over ¾ full to allow for expansion from freezing

e. The seal of capped aliquot tubes should be reinforced with para-film wrap and placed into a biohazard shipping bag or rack. If a rack is not used, rubber-band tubes from the same donor together. Repeat for each series.

f. Record sample and donor demographic data on Form 148 (Shipping Manifest). Include a printed copy of manifest with shipment and e-mail to donor center, BSD or designated facility, if possible.

g. Maintain the (pre-screening) ASBP 572-EWB at your site until the potential donor redeploys. As soon as possible ship samples and Form 148 in a blood box (Collins Blood Box) with ice bag(s) to your respective blood detachment or designated receiving facility. E-mail a copy of manifest to BSD or designated facility, if possible, and call to alert about incoming shipment.

***NOTE*: *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.*

***NOTE:** Depending on pre-screening unit 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.* All donor tubes MUST be centrifuged and serum/plasma removed from RBCs within 72 hours of collection.

h. 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**: The prospective donor is NOT considered pre-screened and fully qualified for FWB donation until negative or non-reactive testing results are received from a testing facility. Once confirmatory testing is received back from the testing facility and results entered into TMDS, the donors are prescreened and eligible for donation and can be verified utilizing TMDS.*

NOTE: *Testing for type 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. Donor should not be used as a universal type O whole blood donor until titer results verify low titer status.*

i. Any positive testing that is received by BSD or unit will be forwarded to Preventive Medicine Consultant or available Provider (MD, DO, PA, NP) to ensure proper donor care and follow-up is initiated. At no time will laboratory staff notify donors directly regarding positive testing results.

5.0 Maintain Database (TMDS)

1. Transfer demographic information from the modified ASBP 572-EWB and Form 147 to Donor Management Database in TMDS. This will act as a deferral list or an eligible donor list when a whole blood drive is necessary. It is recommended that a hard copy of Donor Database and deferral list be printed monthly (or at some regular interval) for use during Emergency Whole Blood Collection when computer assets are unavailable. Information in database must be kept confidential.

   NOTE: Ensure TMDS user is logged into TMDS under the correct blood facility account. For TMDS account guidance, contact the COCOM JBPO.

2. To enter demographic data into TMDS, go to the Manage Donation tab and select Donate Product. Enter the Donor SSN, first name, last name in appropriate fields and click NEXT.

3. 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.*

4. In product description field, enter E9999V00 – PRE-SCREEN. In the expiration date field, enter date 90 days from today and click Add Product.

5. Verify donation ID, product description, product type, ABO/Rh and expiration date are correct, then click NEXT.

6. Carefully Re-verify all demographic data that populates on the screen, then click Confirm Donation. Prospective donor is now entered in TMDS.

7. From Manage Donation tab, select Update Donation. Enter donation ID number and click NEXT.

8. Enter ABO/Rh test result and date tested from Form 147 under Rapid Testing Results. In "Samples sent to" field, select BSD or unit from pull down menu and enter date samples were sent out from your facility. Now click Update Tests.

Blood Donor Pre-Screening Standard Operating Procedures *15 May 2018*

9. To register another donor, select Donate Product under Manage Donation tab and repeat process above.

10. Once pre-screen donations have been created utilizing the process above, a re-deployment date must be entered to ensure the active donor list will auto-update upon donor's exodus from theater. To accomplish this, select Manage Donor from beneath Manage Donor tab. Enter donor SSN and click Next. Select re-deployment date from the calendar tool in the "Update Re-deployment Date" field and click Update Donor. Once the displayed entry is confirmed to be correct, click Confirm Update. TMDS will now remove donor from active donor list on the re-deployment date that was entered.

11. BSD or designated unit will populate donor testing results and forward to submitting facility. Donor alerts will also be activated by BSD or unit, as necessary. This data, once populated, will be the basis by which potential donors will be deemed fully qualified for Fresh Whole Blood (FWB) donations, should the need for a Walking Blood Bank (WBB) arise at your facility.

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

    NOTE*: Investing time and care into building a donor pool will make performing whole blood drives easier and safer when the time comes. Your donor pool does not need to be enormous. 50 people covering most of the blood types (O, A, B) is ideal for most locations.*

Remember whole blood must be transfused group specific or from a group O/low titer donor.

6.0 Sources

- AABB Technical Manual, current edition.
- AABB Standards for Blood Banks and Transfusion Services, current edition.
- JTS Clinical Practice Guideline: Fresh Whole Blood (FWB) Transfusion
- Theater Medical Data Store (TMDS) System User's Manual, current edition.

7.0 Forms

- ASBP 572-EWB (Emergency Whole Blood)
- Form 147–Eldon Card ABO/Rh Typing Record
- Form 148–Pre-Screen/Whole Blood Sample Shipping Manifest

~ END ~

BLOOD DONOR PRE-SCREENING SOP ENCLOSURES (1)

ASBP 572: Emergency Whole Blood (front)

PRE-SCREEN / EMERGENCY WHOLE BLOOD DONATION RECORD

Form is only to be used for pre-screening or collecting donors in support of contingency / deployed operations.

DONATION IDENTIFICATION NUMBER (DIN)

(Use Donor SSN if ISBT # Not Available)

TODAY'S DATE	NAME (Last, First, Middle Initial)	RANK/RATE	USA USAF USN USMC CIV	SSN: DoD ID:
UNIT	UNIT LOCATION (Base and State)	AOR BASE & TENT# (if deployed)	DOB (DDMMMYYYY)	SEX: M F / ABO/Rh (Blood Type)
CURRENT MAILING ADDRESS		EMAIL ADDRESS		BEST CONTACT PHONE NUMBER

Group A Questions (ALL DONORS Must Complete)

1	Have you read and do you understand the educational materials provided to you?	Y	N	5	Have you ever received money, drugs, or other payment for sex?	Y	N
2	Have you ever used needles to take drugs, steroids, or anything not prescribed by your doctor?	Y	N	6	Have you ever had cancer, heart problems, bleeding conditions, or lung disease?	Y	N
3	Have you taken any of the medications listed on the back of this form within the timeframes shown? If Yes, write medications here: _____	Y	N	7	Have you ever had hepatitis, or have you ever taken medication for treatment or exposure to hepatitis?	Y	N
4	Have you ever had a positive test for the HIV/AIDS virus?	Y	N	8	Have you ever had Malaria, Chagas or Babesiosis?	Y	N

Interviewer: Document review and eligibility below for walking blood bank (WBB) and/or low titer group O whole blood (LTOWB) donor program.

DONORS: If you are being **prescreened** for a WBB or LTOWB program, **STOP!!** Answer no more questions and sign at the bottom.
If you are here to donate a unit of blood, proceed to **Group B Supplemental Questions** and then sign at the bottom.

Group A responses acceptable (all no except Q1)? Y N ***Interviewer (initials):	All disease tests negative? Y N	Eligible for WBB? Y N	Titer Result (If group O): _____ (accept if < 256)	Eligible for LTOWB? Y N	Approving Official	Low Titer ID Issued? Y N NA

Comments:

Group B Supplemental Questions (Complete if Donating a Unit of Blood Today)

9	Are you feeling healthy and well today?	Y	N	18	In the past 12 months, have you lived with or had sex with a person who has hepatitis?	Y	N
10	Female donors: Have you ever been pregnant or are you pregnant now?	Y	N	19	In the past 12 months, have you had a transplant (such as organ, tissue, or bone marrow) or graft (such as bone or skin)?	Y	N
11	Female donors: Have you had sexual contact with a male who had sexual contact with another male in the past 12 months?	Y	N	20	In the past 12 months, have you had sexual contact with anyone who has HIV/AIDS or has had a positive test for the HIV/AIDS virus?	Y	N
12	Male donors: In the past 12 months, have you had sexual contact with another male?	Y	N	21	In the past 12 months, have you come into contact with someone else's blood?	Y	N
13	Are you currently taking malaria prophylaxis?	Y	N	22	In the past 12 months, have you had an accidental needle-stick?	Y	N
14	Are you currently taking any medications for an infection?	Y	N	23	In the past 12 months, have you had a blood transfusion?	Y	N
15	Have you had physical contact with someone who was vaccinated for smallpox in the past 8 weeks?	Y	N	24	In the past 12 months, have you had sexual contact with anyone who takes money or drugs or other payment for sex?	Y	N
16	In the past 48 hours, have you taken aspirin or anything that has aspirin in it?	Y	N	25	In the past 12 months, have you had or been treated for syphilis or gonorrhea?	Y	N
17	In the past 8 weeks, have you donated blood, platelets, or plasma?	Y	N	26	In the past 12 months, have you had sexual contact with anyone who has ever used needles to take drugs or steroids, or anything not prescribed by their doctor?	Y	N

Comments:

Today's Date:	Temperature: °F/°C (≤ 99.5°F/37.5°C)	Blood Pressure: _____/_____ Systolic: 90-180 Diastolic: 50-100	Pulse: _____ (50-100 bpm)	Hemoglobin: _____ Male: ≥ 13.0 g/dL Female: >12.5 g/dL	Weight: _____ (≥ 110 pounds/50kg)	Vital Signs Tech:

Does Donor Qualify? Y N ***Reviewer (initials):	Phlebotomist	Start Time	Stop Time (<15 mins)	Bag Manufacturer	Lot #	Expiration Date:	Segment #

I verify that I have answered the questions honestly, I had an opportunity to ask questions, I consent to donating blood today, and I feel my blood is safe to be transfused. If I am donating a unit of whole blood today, my blood will **NOT** be tested for viral diseases prior to transfusion due to the emergency situation. If for any reason I feel that my blood may not be safe, I will not donate today.

_____ *Donor's Signature* *Date*

ASBP 572-EWB (Emergency Whole Blood), 5 Apr 2018

ASBP 572: Emergency Whole Blood (back)

DONOR EDUCATIONAL MATERIAL

Blood donation is a voluntary process requiring the collection of approximately 450-500 mL of blood. The usual collection time ranges from 5 to 10 minutes. Complications at the venipuncture site may include, but are not limited to: discomfort, bruising, swelling, or infection. Other complications could occur during or after your donation such as: fatigue, light-headedness, dizziness, nausea, vomiting, and/or fainting. On very rare occasions, a more severe reaction may occur.

MEDICATION LIST: Donors **SHOULD NOT** discontinue medications prescribed by their physician in order to donate blood. Certain medications in your system can cause harm to some patients if your blood is transfused. If your last dose of the following medications was taken within the timeframe listed, you should not donate today nor should you participate in a walking blood bank program because the medication has not cleared from your system.

Prescreen or Donating Blood Today:

Erivedge, Odomzo	Soriatane	Bovine Insulin, Human Growth Hormone, Tegison
2 years	3 years	**EVER** in your life

Donating Blood Today (must screen donor for drugs below AND list above if donating whole blood):

Eliquis, Feldene, Fragmin, Lovenox, Pradaxa, Savaysa, Xarelto	Arixtra, Brilinta, Coumadin, Effient, LMW Heparin, Jantoven, Warfilone
2 days	7 days

Plavix, Ticlid, Zontivity	Absorica, Accutane, Amnesteem, Claravis, Myorisan, Propecia, Proscar, Sotret, Zenatane	Avodart, Jalyn	Experimental Meds/Vaccines
14 days	1 month	6 months	1 year

Your signature on the other side of this form acknowledges that you understand the questions and this educational material and that you agree to not donate any blood products if you are at risk of transmitting Human Immunodeficiency Virus (HIV) or any other virus. We know that you would not donate unless you think your blood is safe. However, in order for us to assess all risks that may affect you or a patient receiving a transfusion, it is essential that you answer each question completely and accurately on the other side of this form. If you do not understand a question, ask a staff member. All information you provide is confidential. It is critical that you alert your unit provider or medic if any of your responses change or if you have any concerns about the safety of your blood. This will facilitate notification and follow up testing for the recipient if needed.

Your blood will be tested for several types of viral markers including Hepatitis B, Hepatitis C, HIV, syphilis and other infections. You will be notified about any positive test result which may disqualify you from donating in the future, and your name will be entered onto a list of permanently deferred donors. If testing does not occur (due to specimen acceptability) or if testing results are not clearly negative or positive, your name may be placed on a deferral list without you being informed until the results are further clarified. For active duty personnel and reservists, positive screening and confirmatory results will be forwarded to appropriate medical personnel for further evaluation and "fitness for duty" determination (if required).

HIGH RISK BEHAVIORS:

Certain diseases such as HIV/AIDS and hepatitis can be spread through sexual contact OR by sharing drug needles/syringes. These viruses can enter your blood stream and can be transmitted to another person who is transfused with your blood, plasma, or platelets. Sexual contact includes: Vaginal contact (contact between penis and vagina), oral sex (mouth or tongue on someone's vagina, penis, or anus), and/or anal sex (contact between penis and anus). **YOUR BLOOD CAN TRANSMIT DISEASES,** including HIV/AIDS, even if you feel well and all your tests are normal. This is because even the best tests cannot detect the virus for a period of time after you are infected.

DO NOT DONATE IF YOU:

- Have AIDS or have ever had a positive HIV test
- Have ever used needles to take any drugs not prescribed by your doctor
- Are a male who has had sexual contact with another male in the past 12 months
- Have ever taken money, drugs or other payment for sex
- Have had sexual contact in the past 12 months with anyone described above
- Have had syphilis or gonorrhea in the past 12 months
- Have been in juvenile detention, lockup, jail or prison for more than 72 consecutive hours in the past 12 months

DO NOT DONATE TO GET A TEST! If you think you may be at risk for HIV/AIDS or any other infection, do not donate simply to get a test. See your medical provider to obtain an HIV/AIDS test. The following symptoms can be present before an HIV test turns positive: fever, enlarged lymph glands, sore throat, and/or rash.

NOTIFY YOUR UNIT MEDIC OR UNIT PROVIDER IF:

- Anything changes that would cause a different response to a question
- If you think your blood may not be safe for another person to receive
- If you become sick within 14 days after donating a unit of blood

THANK YOU FOR DONATING BLOOD!

ASBP 572-EWB (Emergency Whole Blood), 5 Apr 2018

BLOOD DONOR PRE-SCREENING SOP ENCLOSURES (2)

Form 147 Eldon Card ABO/Rh Typing Record

Rapid ABO/RhTesting

	Eldon Card ABO/Rh Typing						
	Lot #						
Assigned Unit # / Pptient ID	Exp:					Tech Initials	
	Anti-A	Anti-B	Anti-D	Control	Interpretation		
	+ =	+ =	+ =	+ =			
	+ =	+ =	+ =	+ =			
	+ =	+ =	+ =	+ =			
	+ =	+ =	+ =	+ =			
	+ =	+ =	+ =	+ =			
	+ =	+ =	+ =	+ =			
	+ =	+ =	+ =	+ =			
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	+ =	+ =	+ =	+ =			
	+ =	+ =	+ =	+ =			
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	+ =	+ =	+ =	+ =			
	+ =	+ =	+ =	+ =			
	+ =	+ =	+ =	+ =			

Supervisor Review: _____ Date: _____

Form 147
V: 20 Dec 2015

QA/QC Review: _____ Date: _____

BLOOD DONOR PRE-SCREENING SOP ENCLOSURES (3)

Form 148–Pre-Screen/Whole Blood Sample Shipping Manifest

Prescreen/Whole Blood Sample Shipping Manifest

Blood Unit Number				Donation Date	Donor Name		Branch of Service	Nationality	SSN or ID #	DOB	FOB/Base	Unit	Donation Type (PS or FWB)
Facility ID (W0138)	YR	Unit Id #	ABO RH		Last	First							

Form 148
V. May 2012

APPENDIX C: EMERGENCY WHOLE BLOOD COLLECTION SOP

Emergency Whole Blood Collection Standard Operating Procedures

Purpose: This Standard Operating Procedure (SOP) accompanies the Whole Blood Transfusion Clinical Practice Guideline published by the Joint Trauma System, the DoD Center of Excellence for Trauma.

1.0 Materials and Equipment

Use the following materials and equipment as applicable

- Vitals Machine
- Blood Collection Beds
- Stethoscope
- Blood Pressure cuff
- Digital Thermometer and/or Tempadots
- Lancets
- POCT Hemoglobinometer
- Electronic table top scale (optional)
- Alcohol Pads
- Coban
- Blood Bags (CPDA-1 or CPD)

  ***NOTE**: If an additive solution (AS) bag is present with a multiple bag set-up, the AS SHALL NOT be added to the whole blood.*
- Blood Trip Scale with 585±2g trip counter-weight and QC weights or HemoFlow.
- Testing Collection Set: premade bags with sterile 4x4 gauze, Chloraprep, 2 red top tubes, 4 purple top tubes

  ***NOTE**: Gold/yellow top (serum separator) tubes may be substituted for red top tubes.*

  Note: Pearl top (plasma preparation) tubes may be substituted for 3 of the purple top tubes.
- ChloraPrep
- Adapter Luer
- ABO/Rh Testing Card (e.g., Eldon Military Kit or other FDA-approved device)
- 4x4 Gauze
- Adhesive Tape
- Hemostats
- Gloves
- Tourniquet
- Rapid HIV, Malaria, HBsAg, and HCV test kits
- Serological RPR kit
- Plastic Aliquot tubes/lids
- Parafilm
- Clinical Rotator
- Centrifuge
- Disposable Pipettes
- Scissors
- Strippers
- Metal Clips
- Biohazard Container/ Sharps Container
- Whole Blood ISBT Labels (100 number series)

  OR
  - **Fresh Whole Blood Collection Set**

(Donor & Recipient Modules) contains all items above (or alternatives), other than those shaded gray

1

2.0 Records/Forms

- Forms required:
- Modified ASBP 572-EWB
- Form 145
- Form 147
- Form 148
- Form 150A
- Form 150B
- Form 151 and SF 518 (as applicable)
- Theater Medical Data Store (TMDS)
- Blood Portal

3.0 Quality Control (QC)

- Perform QC on POCT Hemoglobinometer
- Perform QC on ABO/Rh Testing Card, RPR, HCV, HBsAg, HIV, and Malaria Kits (See package inserts and local SOPs for procedures.)
- Medical personnel should be trained by blood donor center/Blood Support Detachment or other qualified personnel.

4.0 Procedures

Perform the following steps when a physician requests whole blood units:

1. Permission to Conduct the Blood Drives

- Notify Role 2/3 Commander, DCCS and Laboratory OIC/NCOIC that a physician is requesting whole blood for transfusion.
- Once the Commander/DCCS/Medical OIC grants permission, initiate the emergency whole blood collection. Notify the Area Joint Blood Program Officer that facility is performing whole blood collection. Trained medical personnel should oversee the process.

2. Donor Recruitment

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

  a. Donors who have been prescreened within the last 90 days with the full panel of FDA-licensed donor infectious disease tests and found to be negative for all tests.
  NOTE: *Any donor with a positive test result will not be listed as an approved, prescreened donor and must not be collected.*

  b. 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.

  c. Donors who report being repeat blood doors in the past and have not been deferred for transfusion-transmitted disease.

  d. Donors who have not been prescreened with FDA-licensed tests, nor have been blood donors in the past.

- To the maximum extent possible:
  a. Blood will only be collected from United States personnel to include military members, DoD civilians or contractors, or beneficiaries.
  b. 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.
  c. On the day of donation, prospective donors will be screened for eligibility using approved donor history screening protocols and be tested for infectious diseases using ASBP-approved rapid screening tests. As much as possible, rapid screening tests should be performed before issuing the product.
- 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 TMDS). LTOWB collected from these donors may be given to a recipient of any ABO type during damage control resuscitation.
- Non-LTOWB FWB donors must be an ABO type-specific match to the casualty. If not matched, 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.

3. **Pull a pre-screened donor list from TMDS: Manage Donor>View Donor List.**
4. **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.*
5. **Verify donor**

The donor ABO/Rh must be verified (by rapid ABO/Rh card or laboratory testing) prior to transfusion even if donor is in TMDS with pre-screening results.

5.0 Donor and Testing Area Preparation

1. Set up blood donor beds.
2. Perform QC on weighing device if available, (i.e., HemoFlow or Trip Scale).

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

3. Ensure the necessary equipment to perform donor screening, testing and collection are available. (See WBB Supply List with NSNs)

6.0 Perform Donor Screening

1. To the greatest extent possible, potential whole blood donors should be selected from among the pre-tested 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.
2. 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).
3. 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 pre-tested population be exhausted prior to resorting to collections from the untested population.
4. A qualified interviewer will review the ASBP 572-EWB for completeness and donor suitability criteria following steps below.

   If/Then Scenarios

   IF: Responses for questions 1 and 9 are "Yes" AND Responses for questions 2-8 and 10-26 are "No"*
   THEN: Proceed to step 5 for donor temperature.

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

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

   If/Then Scenarios

   IF: ≤99.5 ºF or 37.5 ºC
   Then: Proceed to the next step.
   IF: >99.5 ºF or 37.5 ºC
   Then Stop the donation process. The donor is "Ineligible" at this time.

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

   IF: Systolic BP is 90-180
   Diastolic BP is 50-100
   Pulse is 50-100 bpm

   THEN: Proceed to step 7 for donor hematocrit.

IF: Systolic BP is <90 or >180
Diastolic BP is<50 or >100
Pulse is <50 or >100
THEN: Stop the donation process. The donor is "Ineligible" at this time.

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

If/Then Scenarios

IF: Male: ≥13.0 g/dL
Female: ≥12.5 g/dL
THEN: Proceed to next step.

IF: Male: <13.0 g/dL
Female: <12.5 g/dL
THEN: Defer donor and stop the donation process. The donor is "Ineligible" at this time.

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

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

IF/Then Scenarios
IF: Acceptable.
THEN: Donor is "Eligible," proceed to Step 10.

IF: Unacceptable.
THEN: Donor is "Ineligible," stop donation process and document deferral as appropriate in TMDS.

10. Issue blood bag and test collection set to donor. Label bag and ASBP 572-EWB with Whole Blood ISBT labels. Blood collection tubes (2 red top 4 purple top) should be labeled with the corresponding small ISBT labels (without barcode). See Illustration to the left. 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.

7.0 Whole Blood Collections

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.
   - Have donor grip their hands or a squeezable object
   - Palpate the antecubital area of the arm in order to locate a suitable vein
   - 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.

   - 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.
   - Ensure date is recorded in the "Today's Date" field under the Group B questions.

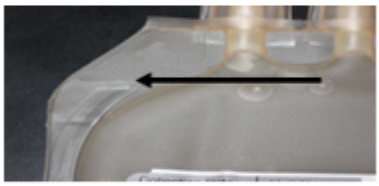
   Inspect the bag and tubing for cuts, kinks, discoloration or any kind of damage and discard bag if present.

7. Set-up trip scale (Manual or Electronic). Perform quality control, if possible, to obtain a counter-weight 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)*

   The target weight for 450 mL is 585 grams.

   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 10º 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.

    IF/THEN Scenarios

    IF Blood flow is impeded
    THEN: Try adjusting the needle with least discomfort without hurting the donor.

    IF: Blood flow is still impeded
    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 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 20-40 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:

    - Time phlebotomy was started
    - 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.

8.0 Process 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. 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*

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.*

9.0 Create Whole Blood Units in TMDS

1. From Manage Donation tab, select Donate Product.
2. Enter the Donor SSN, first name, last name in appropriate fields and click NEXT.
3. 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.*
4. Enter product code E0053V00 for whole blood collected in CPDA-1 anticoagulant or E0009V00 for whole blood collected in CPD anticoagulant.
5. 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*
6. Click Add Product.
7. Verify donation ID, product description, product type, ABO/Rh and expiration date are correct, then click NEXT.
8. Re-verify all demographic and unit data then click Confirm Donation.
9. Repeat steps 1-8 for each product collected.

10.0 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 HBsAg, HCV, HIV, 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 #, Exp 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.

11.0 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 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.

12.0 Process Samples for Shipment and Testing

1. Label three aliquot (pour off) tubes with corresponding ISBT Labels with small barcodes. Position the ISBT label vertically toward the top of 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.
2. Place plasma from 3 Purple Top tubes into the 2 aliquot tubes labeled "Plasma". *3ml sample requirement per aliquot.
3. Place serum from 2 Red Top tubes into the 1 aliquot tube marked as "Serum".

   Do not fill over ¾ full to allow for expansion from freezing
4. 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
5. Record sample and donor demographic data on Form 148 (Shipping Manifest). Include a printed copy of manifest with shipment and e-mail to BSD or designated facility, if possible.
6. Form 151- Whole Blood Transfusion Checklist must be submitted with shipment for every unit of whole blood transfused.
7. 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. E-mail 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.
8. **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.
9. 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 pre-screen for donor's next donation.*

10. Any positive testing that is received by BSD or unit will be forwarded to Preventive Medicine Consultant or available Provider (MD, DO, PA, NP) 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.

13.0 References

- AABB Technical Manual, current edition
- AABB Standards for Blood Banks and Transfusion Services, current edition.
- JTS Clinical Practice Guideline: Fresh Whole Blood (FWB) Transfusion
- Theater Medical Data Store (TMDS) System User's Manual, current edition.

14.0 Enclosures

- Form 145-A Rapid Testing Worksheet
- Form 150A–Emergency Release Letter of Understanding (tested)
- Form 150B–Emergency Release Letter of Understanding (un-tested)
- Form 151–Whole Blood Transfusion Checklist
- Standard Form 518-Blood or Blood Component Release
- WBB Supply List (with NSNs)

~END~

EMERGENCY WHOLE BLOOD COLLECTION SOP ENCLOSURES (1)

Form 145: Rapid Testing Worksheet

Date:_____
Tech:_____

Disease Rapid Testing

	Rapid Tests												RPR	
	Malaria			HIV 1/2			HCV			HBsAg			Rotator (100 +/- 5 rpm):100	
	Lot #:			Lot #:			Lot #:			Lot #:			Lot #:	
Assigned Unit #	Exp:			Exp:			Exp:			Exp:			Exp:	
	Sample results		IQC OK?	Sample results		IQC OK?	Sample results		IQC OK?	Sample results		IQC OK?	"R" Reactive	"NR" Non-Reactive
	R	NR		R	NR		R	NR		R	NR		R	NR
	R	NR		R	NR		R	NR		R	NR		R	NR
	R	NR		R	NR		R	NR		R	NR		R	NR
	R	NR		R	NR		R	NR		R	NR		R	NR
	R	NR		R	NR		R	NR		R	NR		R	NR
	R	NR		R	NR		R	NR		R	NR		R	NR
	R	NR		R	NR		R	NR		R	NR		R	NR
	R	NR		R	NR		R	NR		R	NR		R	NR
	R	NR		R	NR		R	NR		R	NR		R	NR
	R	NR		R	NR		R	NR		R	NR		R	NR
	R	NR		R	NR		R	NR		R	NR		R	NR

Supervisor Review: _____ Date: _____

QA/QC Review: _____ Date: _____

Form 145
V: 07 Sep 2015

EMERGENCY WHOLE BLOOD COLLECTION SOP ENCLOSURES (2)

Form 150A: Emergency Release Letter of Understanding (tested)

Provider Letter of Understanding for Emergency (Non-FDA) Whole Blood Units

I understand that Emergency Whole Blood Units are NOT FDA approved and transfusion of these units may result in unintended disease and/or transfusion reactions. I accept full responsibility for the units and the consequences that may follow transfusion.

Print	Sign	Date
_____	_____	_____
Provider		

Form 150a

EMERGENCY WHOLE BLOOD COLLECTION SOP ENCLOSURES (3)

Form 150B: Emergency Release Letter of Understanding (Untested)

Provider Letter of Understanding for Untested Emergency Whole Blood Units

I understand that these Emergency Whole Blood Units have not had complete Rapid Testing prior to transfusion and transfusion of these units may result in an increased risk of unintended disease and/or transfusion reactions. I accept full responsibility for the units and the consequences that may follow transfusion.

Print	Sign	Date
_____	_____	_____
Provider		

Form 150b

EMERGENCY WHOLE BLOOD COLLECTION SOP ENCLOSURES (4)

Form 151: Whole Blood Transfusion Checklist

WHOLE BLOOD TRANSFUSION CHECKLIST

COMPLETE THIS CHECKLIST FOR EACH UNIT TRANSFUSED POST EVENT

LOCATION OF TRANSFUSION:	DATE:
WHOLE BLOOD UNIT #	

1. DONOR PRESCREENED FOR TRANSFUSION TRANSMITTED DISEASE (TTD) MARKERS WITH FDA APPROVED TESTS WITHIN LAST 90 DAYS?

YES_____ NO_____

2. DONORS SCREENED AT TIME OF COLLECTION USING RAPID TESTS FOR:

MALARIA YES_____ NO_____
HIV YES_____ NO_____
HBV YES_____ NO_____
HCV YES_____ NO_____
RPR YES_____ NO_____

3. RAPID TEST RESULTS AVAILABLE PRIOR TO PRODUCT RELEASE?

YES_____ NO_____

4. DONORS SCREENED USING **DD572** & CURRENT SOP ? YES_____ NO_____

5. BLOOD TUBES COLLECTED AT THE TIME OF COLLECTION FOR FOLLOW UP WITH FDA TTD TESTING YES_____ NO_____

6. INTERNATIONAL SOCIETY FOR BLOOD TRANSFUSION (ISBT) LABELS USED YES_____ NO_____

7. TUBES AND A COPY OF **DD572** FORWARDED TO BSD? YES_____ NO_____

8. UNIT ACCOUNTED FOR IN TMDS? YES_____ NO_____

9. WAS COMPONENT THERAPY AVAILABLE WHEN FWB WAS GIVEN YES_____NO_____

10. PLEASE PROVIDE ANY INFLUENCING FACTORS THAT PREVENTED YOU FROM FOLLOWING THE SOP FOR THIS TRANSFUSION EVENT (IF APPLICABLE):

_____

_____

_____

_____

INDIVIDUAL COMPLETING CHECKLIST

Print Name	Signature

This checklist is to be kept on file for a minimum of one (1) year. Forward a copy to BSD with corresponding samples for Every unit of Whole Blood transfused.

Form 151

EMERGENCY WHOLE BLOOD COLLECTION SOP ENCLOSURES (5)

Standard Form 518-123: Blood or Blood Component Release

518-123 NSN 7540-00-634-4158

MEDICAL RECORD | **BLOOD OR BLOOD COMPONENT TRANSFUSION**

SECTION I - REQUISITION

COMPONENT REQUESTED *(Check one)*
- ☐ RED BLOOD CELLS
- ☐ FRESH FROZEN PLASMA
- ☐ PLATELETS *(Pool of _____ units)*
- ☐ CRYOPRECIPITATE *(Pool of _____ units)*
- ☐ Rh IMMUNE GLOBULIN
- ☐ OTHER *(Specify)* _____

TYPE OF REQUEST *(Check ONLY if Red Blood Cell Products are requested.)*
- ☐ TYPE AND SCREEN
- ☐ CROSSMATCH

DATE REQUESTED

DATE AND HOUR REQUIRED

REQUESTING PHYSICIAN *(Print)*

DIAGNOSIS OR OPERATIVE PROCEDURE

I have collected a blood specimen on the below named patient, verified the name and ID No. of the patient and verified the specimen tube label to be correct.

VOLUME REQUESTED *(If applicable)* _____ ML

KNOWN ANTIBODY FORMATION/TRANSFUSION REACTION *(Specify)*

SIGNATURE OF VERIFIER

REMARKS:

IF PATIENT IS FEMALE, IS THERE HISTORY OF:

RhIG TREATMENT? DATE GIVEN: _____

HEMOLYTIC DISEASE OF NEWBORN? _____

DATE VERIFIED

TIME VERIFIED

SECTION II - PRE-TRANSFUSION TESTING

UNIT NO. | TRANSFUSION NO. | PATIENT NO.

DONOR: ABO, Rh | RECIPIENT: ABO, Rh

TEST INTERPRETATION: ANTIBODY SCREEN | CROSSMATCH

PREVIOUS RECORD CHECK: ☐ RECORD ☐ NO RECORD

SIGNATURE OR PERSON PERFORMING TEST

☐ CROSSMATCH NOT REQUIRED FOR THE COMPONENT REQUESTED | DATE

REMARKS:

SECTION III - RECORD OF TRANSFUSION

PRE-TRANSFUSION DATA

INSPECTED AND ISSUED BY *(Signature)*

AT *(Hour)* | ON *(Date)*

IDENTIFICATION

I have examined the Blood Component container label and this form and I find all information identifying the container with the intended recipient matches item by item. The recipient is the same person named on this Blood Component Transfusion Form and on the patient identification tag.

1st VERIFIER *(Signature)*

2nd VERIFIER *(Signature)*

PRE-TRANSFUSION

TEMP. | PULSE | BP

DATE OF TRANSFUSION | TIME STARTED

POST-TRANSFUSION DATA

AMOUNT GIVEN | TIME/DATE COMPLETED/INTERRUPTED

REACTION ☐ NONE ☐ SUSPECTED | TEMPERATURE | PULSE | BLOOD PRESSURE

If reaction is suspected – IMMEDIATELY:
1. Discontinue transfusion, treat shock if present, keep intravenous line open.
2. Notify Physician and Transfusion Service.
3. Follow Transfusion Reaction Procedures.
4. Do NOT discard unit. Return Blood Bag, Filter Set, and I.V. Solutions to the Blood Bank.

DESCRIPTION OF REACTION
- ☐ URTICARIA ☐ CHILL ☐ FEVER ☐ PAIN
- ☐ OTHER *(Specify)*

OTHER DIFFICULTIES *(Equipment, clots, etc.)*
☐ NO ☐ YES *(Specify)*

SIGNATURE OF PERSON NOTING ABOVE

PATIENT IDENTIFICATION – USE EMBOSSER (For typed or written entries give: Name–Last, first, middle; grade; rank; rate; hospital or medical facility) | SEX | WARD

BLOOD OR BLOOD COMPONENT TRANSFUSION
Medical Record

STANDARD FORM 518 (REV. 9-92)
Prescribed by GSA/ICMR, FIRMR (41 CFR) 201-9.202-1

Standard Form 518-123: Blood or Blood Component Release (instructions)

INSTRUCTIONS FOR NON SELF-EXPLANATORY ITEMS

SECTION I – REQUISITION

Component Requested

"Other (Specify)" – List any whole blood or blood product not on menu, i.e., washed RBC's deglycerolized RBC's, etc.

"Volume Requested (If applicable)" – Use only when different from standard amount, i.e., exchange transfusion 50 ml.

"Known Antibody Formation/Transfusion Reaction" – Check Medical Records. Annotate N/A if appropriate.

"If Patient is Female, Is There History Of" – Check medical records. Annotate N/A if appropriate.

SECTION II – PRE-TRANSFUSION TESTING

"Transfusion Number/Patient Number" – List either based on local procedures.

"Previous Record Check" – Current tests should be compared with prior records for ABO and Rh type, difficulty in blood typing, clinically significant unexpected antibodies, and severe adverse reactions.

"Test Interpretation" – Use the following standard notations. "NEG or "POS" for antibody screen block. "COMPAT" or "INCOMPAT" for crossmatch block.

SECTION III – RECORD OF TRANSFUSION

"Pre-Transfusion Data"

"Inspected and Issued by _____ at _____ on _____."
(Signature) (Hour) (Date)

This statement is to be completed by the issuing laboratory person once he/she has inspected the blood immediately before issue from the laboratory. The blood must not be abnormal in color or appearance or expired, and if any of these conditions exist the blood will not be used for transfusion.

"Signature" blank must contain the signature, as opposed to name, of issuing laboratory person.

"Hour" and "Date" are as of actual issue.

The issuing laboratory person will secure this form to the blood bag by string, rubberband, or tie knotted to the tag and the blood container before issuing the blood.

"Post-Transfusion Data" – Completed by transfusionist.

"Amount Given _____ ml" – Visual approximation.

"Description of Reaction" – Check appropriate reaction or describe "other" on separate sheet, if necessary, and attach to SF 518.

"Other Difficulties"– Check item or describe on separate sheet and attach to SF 518.

STANDARD FORM 518 BACK (REV. 9-92)

EMERGENCY WHOLE BLOOD COLLECTION SOP ENCLOSURES (6)

WBB and Pre-screen Supply List

WBB and Pre-Screen Supply List

Item	NSN
Fresh Whole Blood Collection Kit	6515-01-657-4750
Fresh Whole Blood Donor Set	6515-01-664-0306
Fresh Whole Blood Recipient Set	6515-01-663-9469
Purple top tubes	6640-01-378-0086
Gold top tubes	6640-01-585-5768
Pearl top tubes	6640-01-573-5282
Transfer Pipettes	6640-01-088-4246
Eldon Cards	6550-01-587-1889
Transfer pipettes	6640-01-088-4246
Malaria	6550-01-554-8731
HCV	6550-01-589-9845
HIV	6550-01-526-7424
HBsAg	6550-01-658-8877
RPR	6550-00-159-5011
Plastic tubes	6640-08-133-0372
Para film	6515-01-509-2783
Tape	6510-00-926-8882
Terumo Single Blood Bags	6515-01-480-2307
Chloraprep	6510-01-551-3496
Coban	6510-01-156-2366
Hand Stripper/Sealer/Cutter	6515-01-140-5267
Hand Sealer Clips	6515-01-070-1532
Scissors	6515-00-365-0640
Lancets	6515-01-367-8980
Sphygmomanometer	6515-01-039-4884
Stethescope	6515-00-935-4008
Blood Scale Hemoflow (optional)	6515-12-513-7010
Scale Stand (Optional)	6515-00-411-4375

APPENDIX D: ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGS

PURPOSE

The purpose of this Appendix is to ensure an understanding of DoD policy and practice regarding inclusion in CPGs of "off-label" uses of U.S. Food and Drug Administration (FDA)–approved products. This applies to off-label uses with patients who are armed forces members.

BACKGROUND

Unapproved (i.e. "off-label") uses of FDA-approved products are extremely common in American medicine and are usually not subject to any special regulations. However, under Federal law, in some circumstances, unapproved uses of approved drugs are subject to FDA regulations governing "investigational new drugs." These circumstances include such uses as part of clinical trials, and in the military context, command required, unapproved uses. Some command requested unapproved uses may also be subject to special regulations.

ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGS

The inclusion in CPGs of off-label uses is not a clinical trial, nor is it a command request or requirement. Further, it does not imply that the Military Health System requires that use by DoD health care practitioners or considers it to be the "standard of care." Rather, the inclusion in CPGs of off-label uses is to inform the clinical judgment of the responsible health care practitioner by providing information regarding potential risks and benefits of treatment alternatives. The decision is for the clinical judgment of the responsible health care practitioner within the practitioner-patient relationship.

ADDITIONAL PROCEDURES

Balanced Discussion

Consistent with this purpose, CPG discussions of off-label uses specifically state that they are uses not approved by the FDA. Further, such discussions are balanced in the presentation of appropriate clinical study data, including any such data that suggest caution in the use of the product and specifically including any FDA-issued warnings.

Quality Assurance Monitoring

With respect to such off-label uses, DoD procedure is to maintain a regular system of quality assurance monitoring of outcomes and known potential adverse events. For this reason, the importance of accurate clinical records is underscored.

Information to Patients

Good clinical practice includes the provision of appropriate information to patients. Each CPG discussing an unusual off-label use will address the issue of information to patients. When practicable, consideration will be given to including in an appendix an appropriate information sheet for distribution to patients, whether before or after use of the product. Information to patients should address in plain language: a) that the use is not approved by the FDA; b) the reasons why a DoD health care practitioner would decide to use the product for this purpose; and c) the potential risks associated with such use.