



**ARMY MEDICINE**  
*One Team...One Purpose!*  
*Conserving the Fighting Strength Since 1775*

# Low Titer Group O Whole Blood Program

2018 RDCR Symposium

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**COL Audra L. Taylor**

Director, Army Blood Program

18 June 2018

# Mission

Provide quality blood products and support to military healthcare operations worldwide



# Blood on the Battlefield

- Whole Blood Transfusion 2001-2016 focused at R2/R3
- 90% of combat deaths occur before reaching R2
- 25% of combat deaths preventable
- 90% of preventable deaths – due to Hemorrhage

Eastridge et al. *J Trauma* 2013. Kotwal et al. *Arch Surg* 2011.

## **TCCC Guidelines for Medical Personnel** **31 Jan 2017**

Resuscitation fluids of choice:

- Whole blood
- Plasma, red cells and Platelets in 1:1:1 ratio



# Whole Blood on the Battlefield

## Fresh whole blood use by forward surgical teams in Afghanistan is associated with improved survival compared to component therapy without platelets

TRANSFUSION 2013;53:107S-113

Shawn C. Nessen, Brian J. Eastridge, Daniel Cronk, Robert M. Crain, Kyle Remick, Jason Seery, Avani Shah, and Phil...

*The Journal of TRAUMA® Injury, Infection, and Critical Care*

*J Trauma.* 2009;66:S69–S76.

## Warm Fresh Whole Blood Is Independently Associated With Improved Survival for Patients With Combat-Related Traumatic Injuries

Philip C. Spinella, MD, Jeremy G. Perkins, MD, Kurt W. Grathwohl, MD, Alec C. Beekley, MD, and John B. Holcomb, MD

## Comparison of platelet transfusion as fresh whole blood versus apheresis platelets for massively transfused combat trauma patients

TRAUMA AND SHOCK, Vol. 41, No. Supplement 1, pp. 62–69, 2014

Jeremy G. Perkins, Andrew P. Cap...  
Kurt W. Grathwohl, Francisco J. Re...  
Combat Su...

## WHOLE BLOOD: THE FUTURE OF TRAUMATIC HEMORRHAGIC SHOCK RESUSCITATION

Alan D. Murdock,<sup>\*†</sup> Olle Berséus,<sup>‡</sup> Tor Hervig,<sup>§||</sup> Geir Strandenes,<sup>§¶</sup> and Turid Helen Lunde<sup>§</sup>

# Titer Testing

- Almost all blood used in WWII was low titer O WB
- <1:256 cutoff titer used after severe reaction in 1944, units labeled low or high titer
- Korean War - Almost 400,000 units of group O WB used, no reactions attributed to low titer O WB
- Vietnam War – 230,323 WB units (all ABO groups) transfused Sep 1967 to Feb 1969
- No acceptable titer standard from regulatory agencies (FDA, CAP, AABB, etc)
- ROLO program starting to initiate 1 year retesting
- Current process reduces risk of morbidity and mortality
- Benefit of transfusing WB closer to POI where blood component therapy is unavailable outweighs risk of minor ABO incompatibility



# LTOWB

**SHOCK**, Vol. 41, Supplement 1, pp. 70–75, 2014

## LOW TITER GROUP O WHOLE BLOOD IN EMERGENCY SITUATIONS

Geir Strandenes,<sup>\*†</sup> Olle Berséus,<sup>‡</sup> Andrew P. Cap,<sup>§</sup> Tor Hervig,<sup>\*||</sup> Michael Reade,<sup>||</sup>  
Nicolas Prat,<sup>§\*\*</sup> Anne Sailliol,<sup>††</sup> Richard Gonzales,<sup>‡‡</sup> Clayton D. Simon,<sup>§§</sup>  
Paul Ness,<sup>|||</sup> Heidi A. Doughty,<sup>|||</sup> Philip C. Spinella,<sup>§\*\*\*</sup> and Einar K. Kristoffersen<sup>\*||</sup>

- Proposed low-titer Group O WB for emergency situations when type-specific WB unavailable
- Donor pool screened prior to deployment
- WB maintains normal TEG/hemostatic parameters out to almost 21 days but platelet function begins to drop after 14 days

Pidcoke et al. *Transfusion* 53:137S-149S, 2013



# Updated CPG

## Whole Blood Transfusion

- Recently updated and published by JTS
- Not COCOM specific
- Discusses the following whole blood products:
  - Fresh Whole Blood (FWB)
  - Stored Whole Blood (SWB)
  - Low Titer Group O Whole Blood (LTOWB)
- Discusses the following processes:
  - Blood Donor Pre-Screening
  - Emergency Whole Blood Collection



# Available Blood Products

- Red Blood Cells - Liquid
- Red Blood Cells - Frozen
- Plasma (Fresh Frozen / Frozen Within 24 hrs)
- Cryoprecipitate
- Apheresis Platelets (Collected in Theater)
  - Room Temperature
  - Cold Storage
- Whole Blood
  - Fresh Whole Blood (FWB)
  - Stored Whole Blood (SWB)
  - Low Titer Group O Whole Blood (LTOWB)
- Liquid Plasma





Three Distinct Efforts:

- ✓ SOCOM Donor Screening
- ✓ LTOWB Pre-Mission Collections
- ✓ LTOWB Production

ASBP Commitment to Support

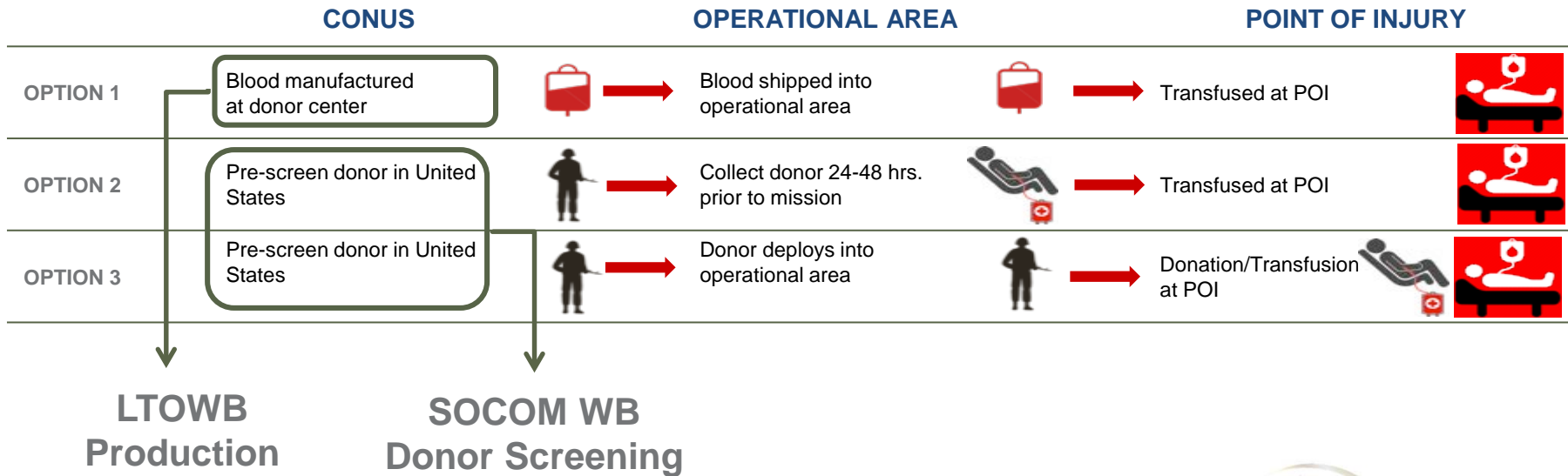


## LOW TITER GROUP O WHOLE BLOOD (LTOWB)



# Whole Blood Support Efforts

## Low Titer O Whole Blood Support



# Pre-Screens for WB Collection

## IN THEATER

- **Goal:** Pre-screen personnel frequently to maintain a current roster (screened within past 90 days) for WB donation
- Performed AFTER personnel arrive into theater
- Pre-screens occurring in US Central Command theater for many years
- Theater pre-screening provides type-specific whole blood
- **Needs:** Lab support to ship donor samples to CONUS for infectious disease testing
- Rapid testing (HIV/HBV/HCV) at time of donation

## PRE-DEPLOYMENT

- **Goal:** Pre-screen personnel frequently to maintain a current roster (screened within past 90 days) for WB donation
- Pre-screen BEFORE arrival into theater
- May provide WB low titer O donors or ABO type specific donors
- Program initiated May 2015 with 75th Ranger Regiment
- SOCOM pre-screenings expanded to multiple units



# Pre-Screens for WB Collection

- Goal: Complete WB Donor Screening Prior to Deployment, to include titer testing for Group O
- Screened/cleared donors may donate at POI or “pre-mission”
- Program initiated May 2015 with 75<sup>th</sup> Ranger Regiment
  - 2015-2016 expanded to HAAF and JBLM to cover all Ranger BNs
- May 2016 – screened 10<sup>th</sup> SFG prior to AFG deployment
- SOCOM pre-screenings expanded to multiple units
  - (3<sup>rd</sup>, 5<sup>th</sup>, 19<sup>th</sup> SFG’s / SOAR)



# SOCOM WB Pre-Screening

- Primary locations: Forts Benning, Bragg, Bliss, and Joint Base Lewis McCord
- We do perform mobile pre-screen events: Eglin AFB, Ft. Carson, Hunter AAF
- Typically an 8-12 person donor center team
- Samples are processed and shipped to contracted testing laboratory
- Positive testing and deferrals are placed into Blood Donor Center computer system and communicated to the Surgeon
- TTD and titer results are placed into the Theater system



# SOCOM WB Pre-Screening

- Screening Process:
  - Basic demographic information\*
  - Assign Donor ID #\*
  - Medical History Screening Questions\*
  - Collection of blood samples
    - ABO/Rh/Disease Testing\*
    - Titer Testing
  - No mini-physical and no collection of WB unit
- Results:
  - Deferrals entered into DoD Blood Donor Management Computer System
  - ALL Pre-Screen donors and results entered into TMDS

## ABSOP for Special Operations Donor Screening

### Overview

Facility Identification and Address <<Insert Facility Name & Address>>

Purpose To standardize the collection, testing, and screening of Special Operations Command (SOCOM) whole blood donors prior to deployment.



# TTD and Titer Results

- Tube for titer testing collected/labelled:
  - Must be coordinated with Department of Pathology
  - Titers  $\geq 1:256$  are considered “High Titer”
  - Titers  $< 1:256$  are considered “Low Titer”
- Titer testing is ordered and resulted in CHCS
- Titer results + TTD Results + DD572's = Donors and results placed into TMDS for visibility by Regimental Surgeon and/or designee
- All positive testing results are reported to Regimental Surgeon and Preventive Medicine for proper counseling and follow-up testing if required
- Planning and coordination required



# Testing Performed

- Collection of Group O Donors must be coordinated with the ABP, designated BDC and Department of Pathology
- Volunteer (potential) donors complete a DD572 and interview process with BDC staff
- Tubes for Transfusion Transmitted Disease (TTD) testing collected/labelled:
  - HBsAg
  - Anti-HBc
  - HBV Nucleic Acid Test (NAT)
  - Anti-HCV + HCV NAT
  - Anti-HIV-1/2 + HIV-1 NAT
  - Anti-HTLV I/II
  - Syphilis (RPR)
  - ABO/Rh, Antibody Screen
  - West Nile Virus NAT
  - T. cruzi
  - Zika
- Tube for Titer Testing is collected





# Pre-Screen Information Management

## TMDS Portal

TMDS Blood

Blood

UNCLASSIFIED//FOR OFFICIAL USE ONLY

viewing 10th SF Group (BNS003)

FACILITY

Manage Donation Manage Donor Manage Inventory Transfusion Reports Blood Admin Change Blood Facility

Your Location: Blood > Manage Donation > Update Donation

### Update donation - update tests

The following donor:

Branch: U.S. Army  
 Gender: M  
 ABO/Rh: O POS  
 Military Unit: 3-75 RR RASP1

...donated the following blood products

DIN: W013516750023 Donation Date: 25 Jan 2016 Donation Location: 75th Ranger Regiment (BNS001)

### Donated Product(s)

PRODUCT DESCRIPTION	ABO/RH	EXP. DATE	DISPOSITION	LOCATION
PRESCREE - PRESCREE	O POS	25 Jan 2017	AVAILABLE	75th Ranger Regiment (BNS001)

#### Enter rapid testing results here:

ABO/Rh: -- Select ABO/Rh -- HIV: ?? HCV: ?? HBsAg: ??

RPR: ?? Other: ?? Other Test Types:

Date Tested: Samples sent to: on:

#### Enter TTD testing results here:

ABO/Rh: O Positive ABS: Negative STS: Negative HBsAg: Negative HbCAb: Negative

HCV: Negative HIV 1/2: Negative HTLV 1/2: Negative WNV: Negative NAT: Negative Chagas: Negative

Comments: HIGH TITER, PERFORMED BY LABCORP

Date Shipped CONUS: Date Tested: Donor Notified?: No

DD-572 Complete?: Yes

Browse...

# SOCOM WB Pre-Screening

- Type O donor low titer rates of 65-70%
  - Some individual unit screenings have seen rates as low as 50%
- 2 HBV cases and 1 HCV case detected
  - Personnel treated, fully recovered, returned to military duty
- Beyond positive testing, can also be deferred for certain medical history
- ABP does not defer from WB program based on malaria or vCJD travel
  - Deferral will be recorded in donor center database to prevent later donations
- Screened units/Medical personnel can access TMDS or request excel roster of screening results



# CONUS Whole Blood Shipments



DEPARTMENT OF DEFENSE  
ARMED SERVICES BLOOD PROGRAM OFFICE  
DEFENSE HEALTH HEADQUARTERS  
7700 ARLINGTON BLVD.  
FALLS CHURCH, VA 22042



REPLY TO  
ATTENTION OF

ASBPO

11 APR 2016

MEMORANDUM FOR: Army Blood Program  
Navy Blood Program  
Air Force Blood Program

SUBJECT: Low Titer Group O Whole Blood for Contingency Support

1. Low titer Group O Whole Blood (WB) is a blood product which has been tested and found to have anti-A/anti-B antibody titers of <1:256. This product may be given to a recipient of any ABO type during damage control resuscitation based on the Tactical Combat Casualty Care (TCCC) guidelines dated 2 June 2014. Low titer Group O WB may be supplied to far forward special operations medical teams or to Role of Care 2/3 facilities which lack apheresis platelets.

2. ASBPO requests each Service Blood Program to be capable of producing FDA licensed low titer Group O Whole Blood NLT 1 Oct 2016 at one or more of their blood donor centers to support our blood program. Each donated unit of whole blood must be tested and found to have anti-A and anti-B titers of <1:256 as per current guidelines. While ASBPO is not requesting the Service Blood Programs maintain a whole blood inventory for routine mission support, the Services have the discretion to utilize this product to augment local facility massive transfusion protocols when deemed appropriate by the medical director and service transfusion medical consultant.

3. ASBPO point of contact [REDACTED]

- Armed Services Blood Program Office memo 11 Apr 2016
- Requesting each Service Blood Program to be capable of producing low titer Group O WB NLT 1 Oct 2016
- Most donor centers are licensed for Whole Blood production, but no longer produce it
- Requires SOP and labeling updates
- Requires identification of a titer testing service

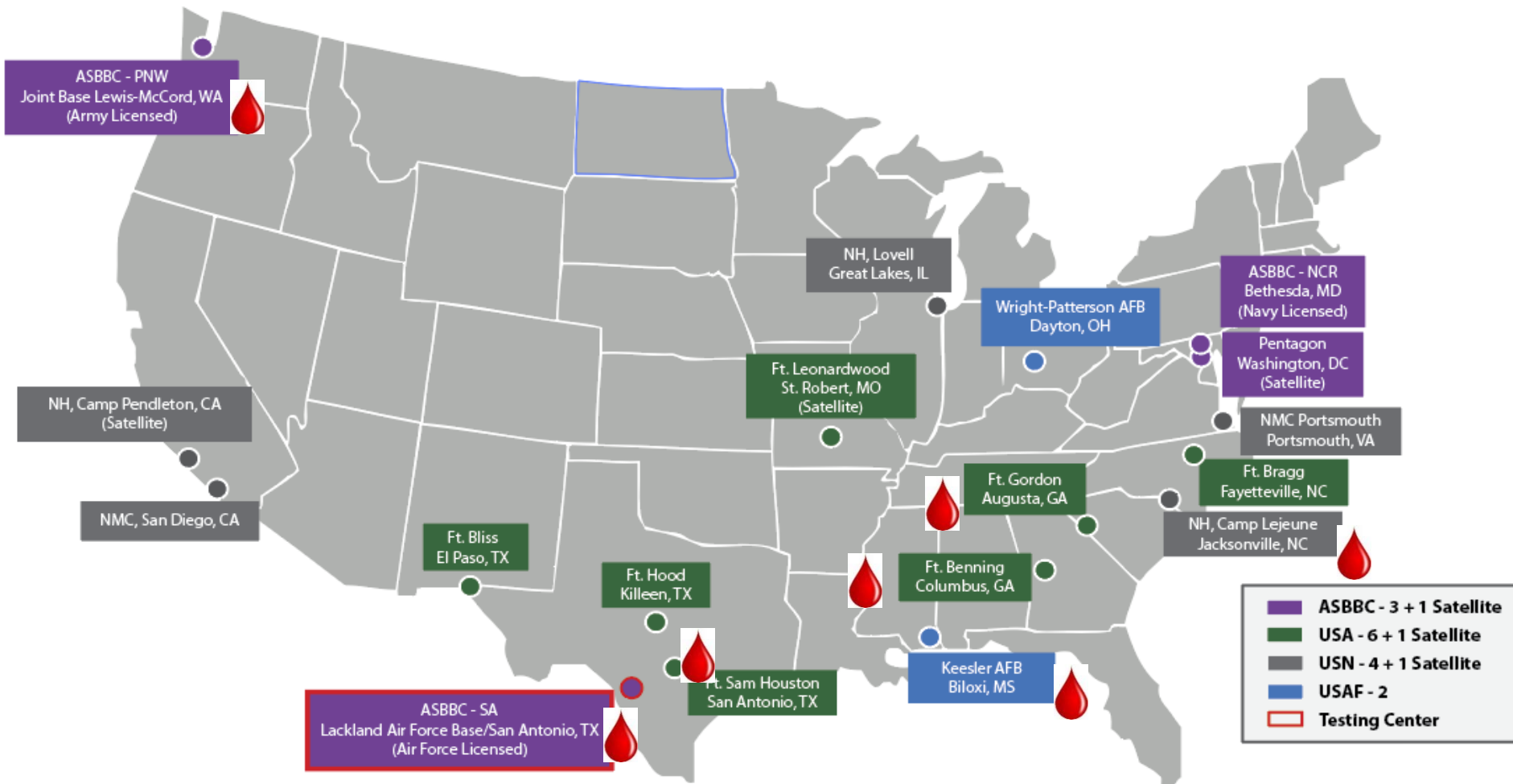


# LTOWB Production

- What is often the delay on producing product at donor centers?
  - Titer testing services (key is TAT on results to maximize shelf life)
    - What doesn't pass titer level must be processed into components in 72 hours
  - Growing requirement for RBCs (CENTCOM and AFRICOM customers)
  - Updating processes and procedures (takes time but not a major factor)
- Focus has been on 21 day CPD products
  - Allows for production of RBCs and frozen plasma/liquid plasma if high titer
  - Could produce 35 day CPDA-1 Whole Blood (requires new FDA licensure packet submission for RBC production)
  - CPD vs. CPDA-1 WB?
- ASBP produced vast quantities of WB for Vietnam/Korea/
  - Many more ASBP donor centers in the past (1970-1990)
  - Today, blood banking is a much more regulated industry
- ASBP committed to producing LTOWB – gradual process
  - 10 units per week April 2016, 50 units per week March 2017

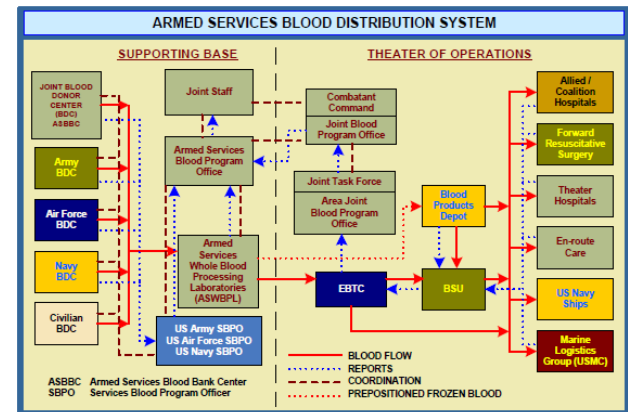


# Current ASBP LTOWB Production



# LTOWB Transportation

- 21 days is what we have to work with – “Each Day Counts”
  - Must arrive to ASWBPL-East within 4 days of collection (ASBP Guidance)
  - Averaging arrival to Al Udiad, Qatar within 6-7 days of collection
  - Movement within theater can take another 1-7 days depending on flights
- We move blood in a leap frog type fashion
  - BDC to ASWBPL (East/West Coast), BTC, BSD, Unit
  - C-17, Contracted Carrier / C-130, C-17, Rotary
- Whole Blood management needs frequent flights to time lost at stop points
- Army Blood Program has recently obtained FDA Licensure/Approval to collect Whole Blood in CPDA-1. Fort Benning is licensed and remaining BDCs will phase in as validations are completed.



# LTOWB Production

- Current LTOWB Distribution – “Where it’s going”
  - 130 units per week to CENTCOM
  - CENTCOM use is primarily reserved for Special Operations
  - A small number of units are at R3/Baghdad
  - Units also on contingency shelf to support rapid deployments
- Future LTOWB Distribution
  - Increased support to CENTCOM
  - Support to other COCOMs (?)
  - Added to MEDEVACs
- MTF LTOWB utilization
  - SAMMC is utilizing LTOWB to support Trauma – November 2017
  - Maybe others – Camp Lejeune, Womack



# Current Situation

- Lack of overall policy, processes and procedures for WB Pre-Screening in support of our Conventional Forces
- Current donor screening efforts with Army Blood Program are built around 75<sup>th</sup> Ranger Regiment/Special Forces
  - Screening Process = Blood Donor Center
  - Training Process = 75<sup>th</sup> Ranger Regiment
- Availability of licensed LTOWB to Conventional Forces (?)
- Balancing traditional Blood Donor Center collection mission with required WB Pre-Screen support (?)
- *Suggested* Work Group - Policy





### MEDCOM WB at POI Work Group Formed

- Initial TCON – 8 February 2018
- Face-to-Face Meeting – held at JBSA 7-8 March 2018
- TCON Conducted – 24 May 2018
- Next Face-to-Face Meeting – held at FBNC on 29 June 2018 in conjunction with a screening event

WORK GROUP TO ADDRESS REQUIRED POLICY

WORK GROUP TO ADDRESS REQUIRED TRAINING

WORK GROUP TO ADDRESS REQUIRED RESOURCES



# Pre-Screen Information Management

- Theater Medical Data Storage (TMDS)
- Used by 75<sup>th</sup> Ranger Regiment and USASOC for visibility of screening while deployed
- Will provide a platform for XVIII ABN Corps Screening Results to be seen by MTF, BSD and JBPO *in theater*
- Will require that unit identify select personnel to receive accounts, complete training and manually input pre-screening results into the system
- Oversight provided by the Army Blood Program Blood Donor Centers
- Blood Donor Centers will assist with TMDS issues/resolution of trouble tickets generated



# In The Meantime.....

- Theater Requests to support screening events has continued
- In addition to XVIII ABN, the ABP has received requests to support Conventional Forces.
- MEDCOM Work Group will continue to push forward - Policy/Training/Resources



# QUESTIONS

