EXHIBIT 49

Plaintiffs' Supplemental Expert Report of Craig W. Hendrix, M.D.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

RICHARD ROE, ET AL., Plaintiffs, v. MARK T. ESPER, ET AL., Defendants.	CIVIL ACTION NO. 1:18-cv-01565
NICHOLAS HARRISON, ET AL., PLAINTIFFS, V. MARK T. ESPER, ET AL., DEFENDANTS.	CIVIL ACTION NO. 1:18-CV-00641

PLAINTIFFS' SUPPLEMENTAL EXPERT REPORT OF CRAIG W. HENDRIX, M.D.

1. I am the same Craig W. Hendrix, M.D. who submitted an expert report on March 22, 2019. My credentials are set forth in that expert report, along with the other disclosures required by the Federal Rules of Civil Procedure. I also submitted a rebuttal expert report on May 6, 2019.

2. I was asked to review certain documents that I understand the Defendants recently produced or identified on their trial exhibit list. A list of the documents that I reviewed in preparing this report is attached as Appendix A to this report. I was asked to review these documents to determine whether they were relevant to the opinions contained in my expert and rebuttal reports; in particular, whether any of these documents altered the opinions expressed in my expert and rebuttal reports.

3. After reviewing the documents listed in Appendix A, I reached the conclusion that none of those documents change the opinions I have previously provided in my expert and rebuttal reports. However, there were several documents on the list that provided further support for those opinions.

4. In particular, the documents pertaining to the risk of HIV transmission as a result of a suicide bombing were helpful in underscoring just how low (maybe non-existent) that risk actually is. For example, I reviewed DX014 (Kao, R.L. & McAlister, V.C. (2018). Care of victims of suicide bombing. *Can. J. Surg.*, 61(6): S184-87 ("Kao Article")), including references cited in the article, and where necessary, sources cited by those supporting references. This review reinforced my opinion that the risk of a battlefield transmission of HIV from a service member who knows that they are living with HIV is exceedingly low for the following reasons.

5. **First**, the risk of HIV transmission through a suicide bombing is exceedingly low in part because the risk of the bone of an individual with HIV penetrating the skin of another is low. Based on papers that report bone shard injuries resulting from suicide bombing (see footnote 2), I have estimated there is evidence of a bomber's bone shard penetrating the skin—the potential route of exposure to a blood-borne pathogen—in only 2.9%[1] of suicide bombing victims seeking medical care or 1 in 34.[2] Because I did not include any suicide

[1] As with other risk estimates in my expert opinions in this case, I am using the "worst case scenario" (*i.e.*, highest level of risk supported by the data) in calculating the level of overall risk for transmission. In this instance, the studies on victims of suicide bombings do not appear to take into account that some victims may not seek care in an emergency department, meaning that the denominator in this risk estimate is likely larger than the papers suggest and this risk is therefore lower.

[2] I considered 10 people with reported bone shard injuries from five suicide bombings divided by the 343 people recorded as victims of those blasts. In making this assessment, I considered the following papers: Kao Article; Braverman, I., *et al.* (2002). A novel mode of infection with

bombing reports that did not specifically report bone shard injuries and I excluded the largest report (Patel 2012), which has half the rate of studies in the pooled estimate, I am confident the actual number is lower. I am not suggesting, however, that the suicide bomber scenario provides a situation directly analogous to combat; the suicide bomber scenario risk likely represents a much higher estimate. For example, several large mass casualty reports indicate no bone shard injuries after urban terrorist bombings, except when there is a suicide bomber, meaning the 2.9% estimate is a very conservative, worst-case estimate. *See* Turégano-Fuentes, F., *et al*. (2008). Injury patterns from major urban terrorist bombings in trains: The Madrid experience. *World J Surg*., 32(6):1168-75; *see also* Hadden, W.A., *et al*. (1978) The injuries of terrorist bombing: A study of 1532 consecutive patients. *Br. J. Surg*., 65(8):525–31.

6. **Second**, as I have previously discussed, the amount of blood to which a person is exposed through percutaneous injury is key to how likely it would be for HIV transmission to result based on. CDC estimates the HIV transmission risk to be 3 per 1,000[3] exposures for a

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Hepatitis B: penetrating bone fragments due to the explosion of a suicide bomber. *Isr. Med. Assoc. J.*, 4(7):528-29; Eshkol, Z. & Katz, K. (2005). Injuries from biologic material of suicide bombers. *Injury*, 36(2):271-74; Patel, H.D., *et al*. (2012). Human body projectiles implantation in victims of suicide bombings and implications for health and emergency care providers: the 7/7 experience. *Ann. R. Coll. Surg. Engl*., 94(5):313-17 ("Patel 2012"); Wong, J.M., *et al*. (2006). Biological foreign body implantation in victims of the London July 7th suicide bombings. *J. Trauma*, 60(2):402-4; Wolf, D.G., *et al*. (2000). High rate of candidemia in patients sustaining injuries in a bomb blast at a marketplace: a possible environmental source. *Clin. Infect. Dis*., 31(3):712-16; de l'Escalopier N., *et al*. (2016). Infectious risk for suicide bomber attack victims: management of penetrative wounds in French Army personnel. *Int. Orthop*., 40(5):861-64.

[3] Again, this is the more conservative risk estimate, and the actual risk may be lower. The current CDC estimate places this risk at .23%. See Centers for Disease Control. (2015). Estimated Per-Act Probability of Acquiring HIV from an Infected Source, by Exposure Act. *HIV Risk Behaviors*, available at https://www.cdc.gov/hiv/risk/estimates/riskbehaviors.html (citing Patel, P., et al. (2014)); Cardo, D.M., *et al*. (1997). A case-control study of HIV seroconversion

deep injury with a hollow bore needle with known HIV-infected blood to be in the same category as a deep penetrating injury with an object soaked in HIV-infected blood. Patel, P., *et al*. (2014). Estimating per-act HIV Transmission risk: a systematic review. *AIDS*, 28(10):1509-19. Considering that risk (0.3%) along with the risk of a penetrating bone fragment as a result of proximity to a suicide bomber (2.9%), the HIV transmission risk ***without*** viral suppression could be estimated at less than 1 per 10,000.[4]

7. **Third**, I am not aware that there has ever been a documented transmission of HIV as a result of a suicide bombing. The lack of a documented transmission in this manner is at least in part due to the previous two points.

8. **Fourth**, however low the theoretical risk of transmission through this type of exposure may be, it is reduced at least another 100-fold (to roughly 1 in a million) if the person with HIV has a suppressed viral load.

9. **Fifth**, the risk of transmission can be further mitigated by providing post-exposure prophylaxis (PEP). Specifically, the risk of transmission is further reduced another 5-fold if the victim of a suicide bombing victim is provided with post-exposure prophylaxis (PEP) for HIV (taking the risk to roughly 1 in 5 million). Cardo, D.M., *et al*. (1997). A case-control study of HIV seroconversion in health care workers after percutaneous exposure. Centers for Disease Control and Preventions Needlestick Surveillance Group. *N. Engl. J. of*

in health care workers after percutaneous exposure. Centers for Disease Control and Preventions Needlestick Surveillance Group. *N. Engl. J. of Med*., 337(21):1485-90.

[4] And one must keep in mind my first point, which is that the risk of a penetrating bone fragment through a catastrophic injury created by an IED or enemy fire is very likely much lower, if not non-existent when compared to the risk created by a suicide bomber.

Med., 337(21):1485-90. The CDC and several other international bodies recommend PEP in the event of a known exposure to HIV-positive blood or a high-risk exposure during mass-casualty event. British Health Protection Agency. (2005). Post exposure prophylaxis against Hepatitis B for bomb victims and immediate care providers. Consideration of other blood borne viruses (Hepatitis C and HIV) Archived July 14, 2014, available at https://webarchive.nationalarchives.gov.uk/20140714093222/http://www.hpa.org.uk/Topics/EmergencyResponse/ExplosionsAndFires/HealthEffectsOfExplosions/PostExposureProphylaxisAgainstBloodBorneViruses/; Centers for Disease Control (2008). Recommendations for postexposure interventions to prevent HIV infections with Hepatitis B virus, Hepatitis C virus, or Human Immunodeficiency Virus, and Tetanus in Persons Wounded During Bombings and Other Mass-Casualty Events. *Morbidity and Mortality Weekly Report.* 57(RR-6):1-19, available at https://www.cdc.gov/MMWR/preview/mmwrhtml/rr5706a1.htm; Siegal-Itzkovich, J. (2001). Israeli minister orders Hepatitis B vaccine for survivors of suicide bomb attacks. *Br. Med. J*., 323(7310):417.

10. **Sixth**, as I have also previously noted, there is a significantly higher risk of transmission of HIV from a person with HIV who is undiagnosed and not in treatment than from a person who is diagnosed and has a suppressed viral load. About one-third of new diagnoses in the military occur while the service member is deployed—meaning there are service members with HIV who are deployed and who present a greater risk than service members like Plaintiffs, who know they are living with HIV and who are receiving treatment.

11. **Seventh**, the risk of battlefield transmission due to battlefield injury of other conditions, like undiagnosed hepatitis C, for which the military does not even test on a regular basis, is higher than the risk of transmission of HIV from a service member who

knows they are living with HIV. Centers for Disease Control. (2001). Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. *Morbidity and Mortality Weekly Report*. 50(RR-11):1-42, available at https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm. In other words, the risk of transmission of HIV from a service member who knows that they are living with HIV and is receiving treatment is lower than the risk of transmission from someone who is not aware that they are living with HIV or someone living with another condition like hepatitis C.

12. **Finally,** a suicide bombing—where an individual has packed their own body with explosives with the intent to turn their body into an instrument of destruction—is not perfectly analogous to the types of injury experienced by a soldier, even one who triggers an IED or is targeted by an enemy firepower; however, it does provide some relevant data on potential for battlefield infectious disease transmission, described above.

13. I also reviewed the document titled "Active Duty ART Outcomes V2.0" compiled by Seung Hyun Won, using a data cut from February 22, 2019 (DX309). In addition to the "Viral Suppression—Ever" rate of 99.8% for active duty members diagnosed between 2012 and 2016, which is incredibly high and demonstrates just how excellent adherence to HIV medications is in the active duty military, I noted other statistics that support the opinions I have previously presented. *Id.* at 23. In particular, the fact that in the most recent period (2012-16), 75% of active duty service members achieve viral suppression within the first 6 months of starting treatment, 99.8% achieve viral suppression within a year. Fully 92% achieve viral suppression on their first regimen, which increases to 97% with the newest integrase inhibitor class drugs. *Id.*

14. [redacted]

15. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

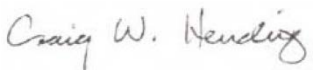
23. If the various policies are to be brought into alignment with modern medicine, the various branches of the military should base their decisions on current state of medical science by updating their accessions, retentions, and deployment policies, not by searching for new justifications to support the current policy.

24. Finally, I also reviewed a study published in Military Medicine only a few days ago that examined "how an operational or OCONUS assignment impacts the ability of an HIV AD service member[] to receive the standard of care HIV medical treatment and maintain viral suppression." Woodson, S. *et al*. (2019). Virologic Suppression in U.S. Navy Personnel Living with Infection and Serving in Operational Assignments. *Mil. Med*. doi:10.1093/milmed/usz169. In 2012, the Navy began allowing service members living with

HIV to serve OCONUS or on large ship platform tours. *Id.* at 1. The study, which notes that ART "has revolutionized the care of [HIV]," concluded that all of the service members reviewed "were able to maintain viral suppression despite the location of their assignments . . . [suggesting] that care is accessible and the standard HIV care continuum is maintained while deployed or stationed overseas." *Id.* While this study was limited, particularly by its small sample size, the conclusions support my opinion that service members with asymptomatic HIV can safely serve in deployed settings.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 18th day of July, 2019



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Craig W. Hendrix, M.D.

APPENDIX A

MATERIALS CONSIDERED

MATERIALS CONSIDERED

[redacted]

Braverman, I., *et al*. (2002). A novel mode of infection with Hepatitis B: penetrating bone fragments due to the explosion of a suicide bomber. *Isr. Med. Assoc. J.*, 4(7):528-29.

British Health Protection Agency. (2005). Post exposure prophylaxis against Hepatitis B for bomb victims and immediate care providers. Consideration of other blood borne viruses (Hepatitis C and HIV). Archived July 14, 2014, available at https://webarchive.nationalarchives.gov.uk/20140714093222/http://www.hpa.org.uk/Topics/EmergencyResponse/ExplosionsAndFires/HealthEffectsOfExplosions/PostExposureProphylaxisAgainstBloodBorneViruses/.

Cardo, D.M., *et al*. (1997). A case-control study of HIV seroconversion in health care workers after percutaneous exposure. Centers for Disease Control and Preventions Needlestick Surveillance Group. *N. Engl. J. of Med*., 337(21):1485-90.

Centers for Disease Control (2015). Estimated Per-Act Probability of Acquiring HIV from an Infected Source, by Exposure Act. *HIV Risk Behaviors*, available at https://www.cdc.gov/hiv/risk/estimates/riskbehaviors.html.

Centers for Disease Control (2008). Recommendations for postexposure interventions to prevent HIV infections with Hepatitis B virus, Hepatitis C virus, or Human Immunodeficiency Virus, and Tetanus in Persons Wounded During Bombings and Other Mass-Casualty Events. *Morbidity and Mortality Weekly Report.* 57(RR-6):1-19, available at https://www.cdc.gov/MMWR/preview/mmwrhtml/rr5706a1.htm.

Centers for Disease Control. (2001). Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. *Morbidity and Mortality Weekly Report*. 50(RR-11):1-42, available at https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm.

de l'Escalopier N., *et al*. (2016). Infectious risk for suicide bomber attack victims: management of penetrative wounds in French Army personnel. *Int. Orthop*., 40(5):861-64.

Department of Defense Personnel Policies Regarding Members of the Armed Forces Infected with Human Immunodeficiency Virus (PX 040).

[redacted]

Eshkol, Z. & Katz, K. (2005). Injuries from biologic material of suicide bombers. *Injury*, 36(2):271-74.

Hadden, W.A., *et al*. (1978) The injuries of terrorist bombing: A study of 1532 consecutive patients. *Br. J. Surg*., 65(8):525–31.

Kao, R.L. & McAlister, V.C. (2018). Care of victims of suicide bombing. *Can. J. Surg*., 61(6): S184-87. (DX014).

[redacted]

Patel, H.D., *et al*. (2012). Human body projectiles implantation in victims of suicide bombings and implications for health and emergency care providers: the 7/7 experience. *Ann. R. Coll. Surg. Engl*., 94(5):313-17.

Patel, P., *et al*. (2014). Estimating per-act HIV Transmission risk: a systematic review. *AIDS*, 28(10):1509-19.

Siegal-Itzkovich, J. (2001). Israeli minister orders Hepatitis B vaccine for survivors of suicide bomb attacks. *Br. Med. J*., 323(7310):417.

Talking Paper on Retention of Airmen with Human Immunodeficiency Virus (HIV) (US 00021290_0001–04) (PX 382).

Turégano-Fuentes, F., *et al*. (2008). Injury patterns from major urban terrorist bombings in trains: The Madrid experience. *World J Surg*., 32(6):1168-75.

Wolf, D.G., *et al*. (2000). High rate of candidemia in patients sustaining injuries in a bomb blast at a marketplace: a possible environmental source. *Clin. Infect. Dis*., 31(3):712-16.

Won, S. (2019). Active Duty ART Outcomes V2.0. (DX309).

Wong, J.M., *et al*. (2006). Biological foreign body implantation in victims of the London July 7th suicide bombings. *J. Trauma*, 60(2):402-4.

Woodson, S. *et al*. (2019). Virologic Suppression in U.S. Navy Personnel Living with Infection and Serving in Operational Assignments. *Mil. Med*. doi: 10.1093/milmed/usz169.

EXHIBIT 50

CDC, HIV Risk Behaviors

HIV Risk Behaviors

December 2015

The risk of getting HIV varies widely depending on the type of exposure or behavior (such as sharing needles or having sex without a condom). Some exposures to HIV carry a much higher risk of transmission than other exposures. For some exposures, while transmission is biologically possible, the risk is so low that it is not possible to put a precise number on it. But risks do add up over time. Even relatively small risks can add up over time and lead to a high lifetime risk of getting HIV. In other words, there may be a relatively small chance of acquiring HIV when engaging in a risk behavior with an infected partner only once; but, if repeated many times, the overall likelihood of becoming infected after repeated exposures is actually much higher.

The table below lists the risk of transmission per 10,000 exposures for various types of exposures.

Estimated Per-Act Probability of Acquiring HIV from an Infected Source, by Exposure Act*

Type of Exposure	Risk per 10,000 Exposures
Parenteral	
Blood Transfusion	9,250
Needle-Sharing During Injection Drug Use	63
Percutaneous (Needle-Stick)	23
Sexual	
Receptive Anal Intercourse	138
Insertive Anal Intercourse	11
Receptive Penile-Vaginal Intercourse	8
Insertive Penile-Vaginal Intercourse	4
Receptive Oral Intercourse	Low
Insertive Oral Intercourse	Low
Other^	
Biting	Negligible
Spitting	Negligible
Throwing Body Fluids (Including Semen or Saliva)	Negligible
Sharing Sex Toys	Negligible

* Factors that may increase the risk of HIV transmission include sexually transmitted diseases, acute and late-stage HIV infection, and high viral load. Factors that may decrease the risk include condom use, male circumcision, antiretroviral treatment, and pre-exposure prophylaxis. None of these factors are accounted for in the estimates presented in the table.

^ HIV transmission through these exposure routes is technically possible but unlikely and not well documented.

Source:

- Patel P, Borkowf CB, Brooks JT. Et al. Estimating per-act HIV transmission risk: a systematic review. AIDS. 2014. doi: 10.1097/QAD.0000000000000298.
- Pretty LA, Anderson GS, Sweet DJ. Human bites and the risk of human immunodeficiency virus transmission. Am J Forensic Med Pathol 1999;20(3):232-239.

EXHIBIT 51

CDC, HIV Treatment as Prevention

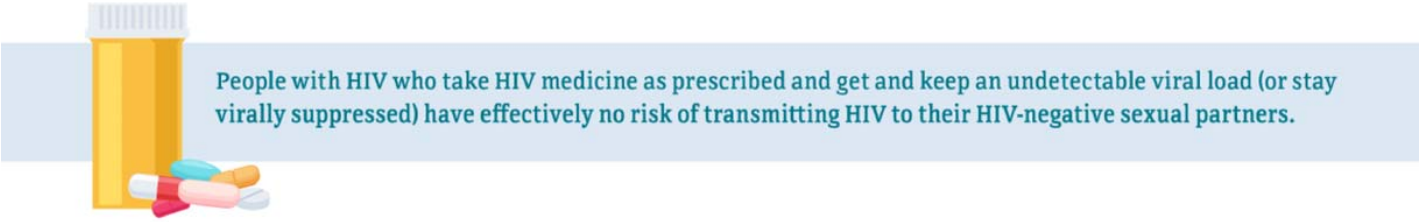
CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

HIV Treatment as Prevention

Overview

People with HIV should take medicine to treat HIV as soon as possible. HIV medicine is called **antiretroviral therapy**, or **ART**. If taken as prescribed, HIV medicine reduces the amount of HIV in the body (**viral load**) to a very low level, which keeps the immune system working and prevents illness. This is called **viral suppression**—defined as having less than 200 copies of HIV per milliliter of blood. HIV medicine can even make the viral load so low that a test can't detect it. This is called an **undetectable viral load**.

Getting and keeping an undetectable viral load* is the best thing people with HIV can do to stay healthy. Another benefit of reducing the amount of virus in the body is that it helps prevent transmission to others through sex or syringe sharing, and from mother to child during pregnancy, birth, and breastfeeding. This is sometimes referred to as **treatment as prevention**. There is strong evidence about treatment as prevention for some of the ways HIV can be transmitted, but more research is needed for other ways.



Risk of HIV Transmission With Undetectable Viral Load by Transmission Category

Transmission Category	Risk for People Who Keep an Undetectable Viral Load
Sex (oral, anal, or vaginal)	Effectively no risk
Pregnancy, labor, and delivery	1% or less†
Sharing syringes or other drug injection equipment	Unknown, but likely reduced risk
Breastfeeding	**Substantially reduces, but does not eliminate risk.** Current recommendation in the United States is that mothers with HIV should *not* breastfeed their infants.

† The risk of transmitting HIV to the baby can be 1% or less if the mother takes HIV medicine daily as prescribed throughout pregnancy, labor, and delivery and gives HIV medicine to her baby for 4-6 weeks after giving birth.

Resources for Providers

CDC's technical fact sheet Evidence of HIV Treatment and Viral Suppression in Preventing the Sexual Transmission of HIV

HIV Transmission Prevention: Information for Health Care Providers

Resources for Consumers

CDC's consumer info sheet HIV Treatment Can Prevent Sexual Transmission

HIV Basics: Living With HIV

HIV/AIDS Management Consultation Service for Clinicians

1-800-933-3413

9 a.m. – 8 p.m. ET, Monday – Friday

For more information, visit the National Clinicians Consultation Center (http://nccc.ucsf.edu/) .

National Clinicians' Post-Exposure Prophylaxis Hotline (PEPline) **1-888-HIV-4911 (1-888-448-4911)** 9 a.m. – 8 p.m. ET, Monday – Friday; 11 a.m. – 8 p.m. ET, weekends and holidays

National Perinatal HIV Consultation and Referral Services (Perinatal Hotline) **1-888-HIV-8765 (1-888-448-8765)** 24 hours a day, seven days a week

National Pre-Exposure Prophylaxis Consultation (PrEPline) **1-855-HIV-PREP (1-855-448-7737)** 9 a.m. – 8 p.m. ET, Monday – Friday

*The benefits of having an undetectable viral load also apply to people who stay virally suppressed.

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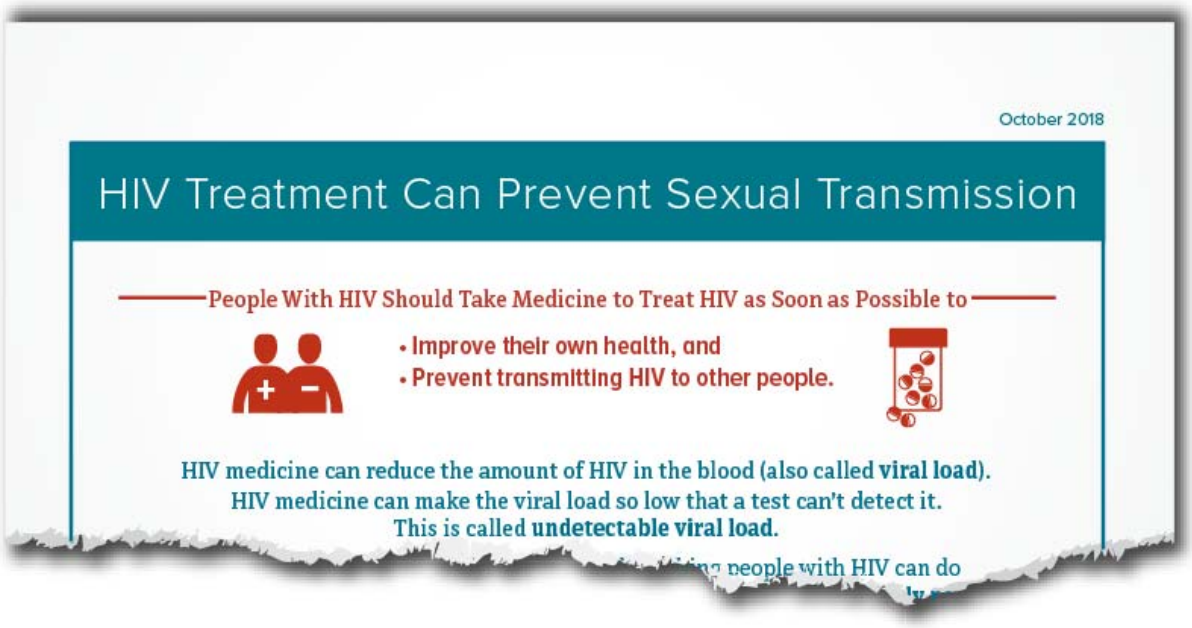

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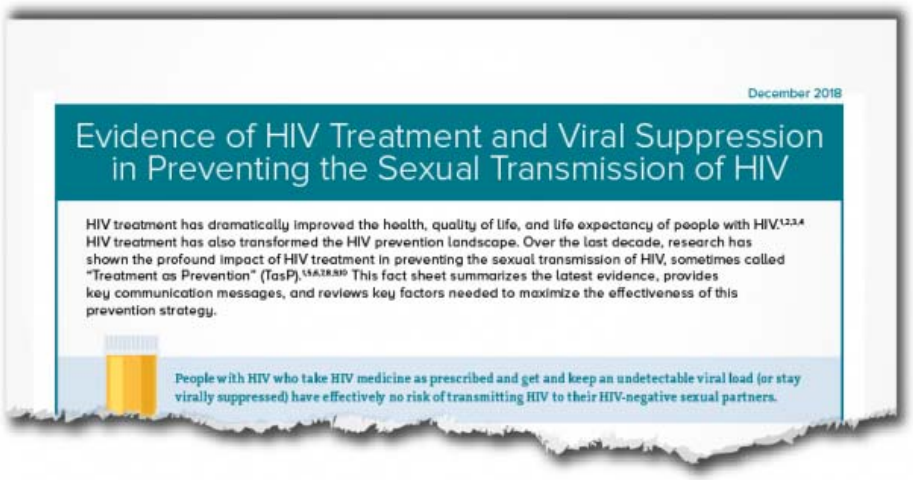

Download technical fact sheet.

Get Tested

Find an HIV testing site near you.

Enter ZIP code or City Go

Follow HIV/AIDS

- CDC HIV (http://www.facebook.com/cdchiv)
- CDC HIV/AIDS (https://twitter.com/CDC_HIVAIDS)
- See RSS (http://tools.cdc.gov/api/v2/resources/media/342776.rss) | Subscribe to RSS (http://tools.cdc.gov/api/v2/resources/media/342776.rss)
- Get Email Updates on HIV (https://www.cdc.gov/Other/emailupdates/)
- Syndicated Content
- Website Feedback

File Formats Help:

How do I view different file formats (PDF, DOC, PPT, MPEG) on this site? (https://www.cdc.gov/Other/plugins/)

(https://www.cdc.gov/Other/plugins/#pdf)

Page last reviewed: December 18, 2018

Page last updated: December 18, 2018

Content source: Division of HIV/AIDS Prevention (/hiv), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (/nchhstp), Centers for Disease Control and Prevention (/)

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EXHIBIT 52

CDC, Dear Colleague Letter September 27, 2017

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Dear Colleague: September 27, 2017

Dear Colleague

INFORMATION FROM CDC'S DIVISION OF HIV/AIDS PREVENTION

September 27, 2017

Dear Colleague,

Today is National Gay Men's HIV/AIDS Awareness Day. On this day, we join together in taking actions to prevent HIV among gay and bisexual men and ensure that all gay and bisexual men living with HIV get the care they need to stay healthy. Gay and bisexual men are severely affected by HIV. More than 26,000 gay and bisexual men received an HIV diagnosis in 2015, representing two-thirds of all new diagnoses in the United States, and diagnoses increased among Hispanic/Latino gay and bisexual men from 2010 to 2014.

However, recent trends suggest that prevention efforts are slowing the spread of HIV among some gay and bisexual men. From 2010 to 2014, HIV diagnoses fell among white gay and bisexual men and remained stable among African American gay and bisexual men after years of increases.

Scientific advances have shown that antiretroviral therapy (ART) preserves the health of people living with HIV. We also have strong evidence of the prevention effectiveness of ART. When ART results in viral suppression, defined as less than 200 copies/ml or undetectable levels, it prevents sexual HIV transmission. Across three different studies, including thousands of couples and many thousand acts of sex without a condom or pre-exposure prophylaxis (PrEP), no HIV transmissions to an HIV-negative partner were observed when the HIV-positive person was virally suppressed. This means that people who take ART daily as prescribed and achieve and maintain an undetectable viral load have effectively no risk of sexually transmitting the virus to an HIV-negative partner.

However, according to a recent *Morbidity and Mortality Weekly Report* (https://www.cdc.gov/mmwr/volumes/66/wr/mm6637a2.htm?s_cid=mm6637a2_e), too many gay and bisexual men living with HIV are not getting the care and treatment they need. Among gay and bisexual men living with diagnosed HIV, 61% have achieved viral suppression, more than in previous years, but well short of where we want to be. More work is needed to close this gap and to address the barriers that make it more difficult for some gay and bisexual men, including African American and Hispanic/Latino men, to get HIV care and treatment. For example, socioeconomic factors such as lower income and educational levels and cultural factors such as stigma and discrimination may affect whether some gay and bisexual men seek and are able to receive HIV treatment and prevention services.

Some of the Centers for Disease Control and Prevention's (CDC) activities to reduce new HIV infections among gay and bisexual men, increase testing, improve treatment outcomes, and reduce HIV-related disparities include:

- Funding health departments and community-based organizations (CBOs) to support HIV prevention services for gay and bisexual men. For example, under current cooperative agreements, CDC has awarded at least $330 million per year to health departments for HIV prevention among the most affected populations and is awarding nearly $11 million per year to CBOs to provide HIV testing to young gay and bisexual men of color and transgender youth of color.
- Supporting biomedical approaches to HIV prevention such as PrEP and post-exposure prophylaxis (PEP).

- Supporting projects to identify promising prevention strategies, such as Project PrIDE (PrEP, Implementation, Data to Care, and Evaluation), which is helping health departments implement PrEP and Data to Care demonstration projects for gay and bisexual men of color.
- Providing gay and bisexual men with HIV prevention and treatment messages through *Act Against AIDS*. For example, *Doing It* (http://www.cdc.gov/actagainstaids/campaigns/doingit/index.html), which encourages all adults to get tested for HIV, includes many resources for gay and bisexual men. *Start Talking. Stop HIV.* helps gay and bisexual men communicate about HIV prevention, and *HIV Treatment Works* provides resources to help people live well with HIV.

CDC encourages public and private stakeholders to implement interventions that increase retention in HIV care and viral suppression. In addition, partners such as health departments, CBOs, and others can help address stigma and discrimination—using the resources of the *Act Against AIDS* campaign *Let's Stop HIV Together*, for example—and extend the reach of their HIV prevention and testing services that focus on gay and bisexual men. Learn more about how CDC can support your prevention programs.

Thank you for your contributions to HIV prevention efforts for gay and bisexual men. With your help, we have made tremendous strides over the decades. And while there is still much work to do, today we have powerful prevention and treatment tools that can dramatically reduce HIV infections among gay and bisexual men and move us closer to a future free of HIV.

Sincerely,

/Eugene McCray/

Eugene McCray, MD
Director
Division of HIV/AIDS Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention
www.cdc.gov/hiv

/Jonathan Mermin/

Jonathan H. Mermin, MD, MPH
RADM and Assistant Surgeon General, USPHS
Director
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention
www.cdc.gov/nchhstp (https://www.cdc.gov/nchhstp)

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EXHIBIT 53

Armed Services Blood Program
Educational Campaign Factsheet

GIVE TO THE RED WHITE & BLUE

militaryblood.dod.mil

GIVE TO THE RED WHITE & BLUE

How do you know your blood is going to the troops?

Give to the red, white and blue

WHAT IS THE ARMED SERVICES BLOOD PROGRAM?

The ASBP is the official military provider of blood products to U.S. armed forces. Service members are often confused and erroneously believe that a civilian collection agency provides blood products to the military community. That is not true. The ASBP is one of four organizations that ensure our nation has a safe, potent blood supply. We work closely with our civilian counterparts in times of need. However, the ASBP is the official blood collection, manufacturing, transport and transfusion program for the U.S. military.

MISSION

The mission of the ASBP is to provide quality blood products and services for all customers in both peace and war. It is tasked with the collection, processing, storage and transportation of blood and blood products to ill or injured service members, veterans and their families worldwide.

WHO IS THE ARMED SERVICES BLOOD PROGRAM?

Tri-service organization benefiting all major services

As a tri-service organization, the ASBP represents all three branches of service – Army, Navy and Air Force. As a joint operation among the military services, the ASBP has many components working together to collect, process, store, transport and transfuse blood worldwide.

Begun in 1952 and a fully-operational, distinct program by 1962

The ASBP was begun by President Harry Truman in 1952. It has been a fully-operational, distinct blood program since 1962. After the Korean War, the ASBP took over collecting, processing and transporting blood products for the military community from the American Red Cross.

Governed by the FDA to maintain safety and quality

Like civilian collection agencies, the ASBP is governed by strict Food and Drug Administration guidelines to maintain safety and quality of blood and blood products. The ASBP follows the standards, procedures, recommendations and guidelines of the AABB, formerly known as the American Association of Blood Banks.

We are not the same organization as the American Red Cross

But we do work closely in times of need, as we do with all civilian blood agencies: America's Blood Centers, Blood Centers of America and other local hospital organizations. Blood cannot be donated to the ASBP through a civilian organization. When civilian agencies collect blood on a military installation, an agreement is made to ensure that for every certain number of units collected, a certain number of credits are set aside to be used upon request by the ASBP. In fact, many service members who are treated at civilian hospitals receive blood from civilian agencies. The ASBP collaborates with and provides blood to civilians during emergencies at home or globally, during humanitarian missions. Sharing donors is part of how we all work together to save lives.

WHERE IS THE ARMED SERVICES BLOOD PROGRAM?

Blood for the battlefield is transported by the ASBP

The ASBP is responsible for providing blood and blood products to deployed service members on the battlefield, on board Navy casualty receiving treatment ships, hospital ships and aircraft carriers. Anyone receiving blood or blood products in a combat area will receive blood through the ASBP. The only way to know your donation will definitely go to the ASBP, directly

ARMY BLOOD DONOR CENTERS	NAVY BLOOD DONOR CENTERS	AIR FORCE BLOOD DONOR CENTERS
Fort Benning, Ga.	Bethesda, Md.	Keesler AFB, Miss.
Fort Bliss, Texas	Camp Lejeune, N.C.	Lackland AFB, Texas
Fort Bragg, N.C.	Great Lakes, Ill.	Wright-Patterson AFB, Ohio
Fort Gordon, Ga.	Okinawa, Japan	
Fort Hood, Texas	Portsmouth, Va.	
Landstuhl, Germany	San Diego, Calif.	
Fort Leonard Wood, Mo.	U.S. Naval Hospital, Guam	
Joint Base Lewis-McChord, Wash.		
Pentagon, Arlington, Va.		
Fort Sam Houston, Texas		
Tripler Army Medical Center, Hawaii		

supporting service members on the battlefield is to look for the flag blood drop, most commonly depicted as a red, white and blue drop.

More than 20 blood donor centers worldwide

There are more than 20 ASBP blood donor centers in the U.S. and around the globe. Each service operates multiple blood donor centers. Others, known as Armed Services Blood Bank Centers, are operated with tri-service support, which means, that personnel from all three services are working in the center.

We do it all: collect, test, transport and transfuse

Blood is collected and processed at supporting installations and ASBP blood donor centers. All of the ASBP blood donor centers send blood collected at their sites to one of two Armed Services Whole Blood Processing Laboratories, or ASWBPLs. The ASWBPLs then send blood into theater either by pre-positioning frozen blood at Blood Product Depots or by sending blood and blood components to Expeditionary Blood Transshipment Systems, which then forward the blood products to Blood Supply Units. The blood will go from there to forward deployed surgical units, theater hospitals, U.S. Navy ships, enroute care, Force Service Support Groups or Allied/Coalition hospitals. Forward deployed surgical units and theater hospitals will then provide blood and blood products to first responders at the unit level.

Army Lt. Nicholas Vogt

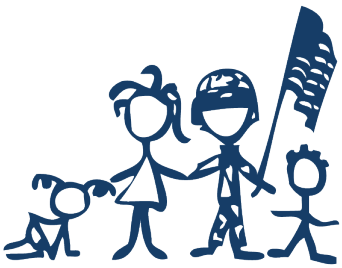
1st Lt. Nicholas Vogt received more than 500 units of donated blood after being injured by a roadside bomb while deployed to Afghanistan. In Kandahar alone, he received 404 units of blood. After a call when out to his brothers and sisters in arms in Afghanistan, more than 300 fellow service members rolled up their sleeves to donate blood after hearing about the severity of his injuries. To date, Vogt has received more blood than any other survivor in combat history.

Marine Cpl. Mark Fidler

Like Vogt, Cpl. Mark Fidler was also severely injured after being struck by a roadside bomb in Afghanistan. On the first day after his injuries, Fidler received 120 units of blood. The day after, he received another 68 units. Every time he went into surgery the hospital prepared 20 units of blood for his use. Although he lost both legs, Fidler survived and has been able to accomplish some of his dreams – like fishing on Jimmy Buffet's boat – as he continues to recover from his wounds.

WHY IS AN ARMED SERVICES BLOOD PROGRAM NEEDED?

We support them all: active duty, retirees and military families



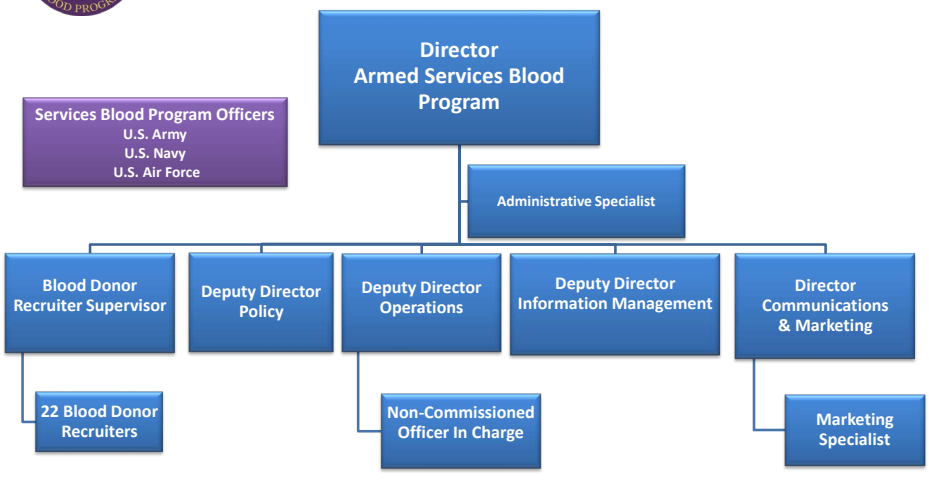
Blood and blood products are used for military patients of all ages for many reasons. Whether blood is needed to treat cancer patients, surgical patients or battlefield injuries, service members depend on blood donors every day. Each unit is critical when you consider:

- 40 or more units of blood may be needed for a single trauma victim.
- 8 units of platelets may be required daily by leukemia patients undergoing treatment.
- A single pint of blood can sustain a premature infant's life for two weeks.

Since the ASBP's inception over 60 years ago, more than 1.5 million units of blood have been provided to treat battlefield illnesses and injuries. While ASBP blood recipients are most often thought of as deployed service members injured in the line of duty, the ASBP also supports the peacetime needs of military personnel and their families. Blood must be available to military hospitals for scheduled and emergency procedures.

Additionally, the ASBP's recipient base extends beyond the military community. In cases of natural disasters or other catastrophes, the ASBP is called upon to serve civilians in need, not only here at home but globally during humanitarian missions. Anyone receiving blood products in a combat area will receive blood through the ASBP.

The Armed Services Blood Program (ASBP) Leadership & Organization



FOR MORE INFORMATION

To learn more about the ASBP, please visit us online at www.militaryblood.dod.mil
To interact directly with our staff, see more photos or to get the latest news, follow @militaryblood on Facebook, Twitter, Flickr, YouTube and Pinterest.

Tri-service organization
Benefits all major services

Stood up in 1952. Fully operational distinct program by 1962

Blood for the battlefield is transported by the ASBP

We do it all: collect, test ship and transfuse

Over 20 blood donor centers worldwide

ASBP

THE ARMED SERVICES BLOOD PROGRAM

We support them all: active duty retirees and military families

Governed by the FDA to maintain safety and quality

We are not affiliated with the Red Cross, but we work closely in times of need

ASBP

militaryblood.dod.mil

EXHIBIT 54

Excerpts from the March 1, 2019 Deposition of Audra Taylor

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

- - - - - - - - - - - - - - - - - - x
NICHOLAS HARRISON and OUTSERVE-SLDN, INC., : Plaintiffs, : vs. : No. 1:18-cv-00641 JAMES N. MATTIS, In His Official Capacity As Secretary of Defense; MARK ESPER, In His Official Capacity As the Secretary of the Army; and the UNITED STATES DEPARTMENT OF DEFENSE, : Defendants. :
- - - - - - - - - - - - - - - - - - x
RICHARD ROE, VICTOR VOE, and and OUTSERVE-SLDN, INC., : Plaintiffs, : vs. : No. 1:18-cv-01565 JAMES N. MATTIS, In His Official Capacity As Secretary of Defense; HEATHER A. WILSON, In Her Official Capacity as Secretary of the AIR FORCE; and the UNITED STATES DEPARTMENT OF DEFENSE, : Defendants. :
- - - - - - - - - - - - - - - - - - x

VIDEOTAPED 30(b)(6) DEPOSITION OF DEFENDANTS
GIVEN BY AUDRA L. TAYLOR

DATE: Friday, March 1, 2019
TIME: 10:17 a.m.
LOCATION: Winston & Strawn
1700 K Street, N.W.
Washington, D.C.

and AB.

Q I'm sorry. I want to go back to the question before for just a moment. Can you give me some examples of transfusion-transmitted diseases?

A Hepatitis -- hepatitis C, hepatitis B, HIV, HTLV, West Nile virus, Zika, T. Cruzi, Chagas -- or Chagas. Syphilis.

Q And I understand that's not necessarily an exhaustive list. There may be others. Or is that the exhaustive list?

A I think I didn't mention -- I think -- I don't think I said hepatitis B surface antigen. So you could have hep B core or hep B surface antigen. And I think that's the rest of them.

Q Which blood type is the universal donor blood type?

A For which product?

Q For whole blood.

A O. How --

Q What -- go ahead.

A But only if it's a low titer O.

Q What additional testing must be done to type O blood to minimize the risk of adverse reactions in the recipient?

me see here when might be a good time to do that. I think I've only got another, like, four or five minutes. Can we do that?

MR. ABBUHL: Of course.

BY MR. SCHOETTES:

Q What pre-screening process is used for donors of fresh whole blood?

A In theater?

Q Yes.

A In theater, they would fill out a donor history questionnaire, a 572, and the tubes would be drawn. The tubes would then be shipped back to the United States for testing of the TTDs.

Q But the blood would be used prior to the results of those tests, correct?

A So you said screening. So if a screening process occurs, they're just filling out the card and just collecting the tubes to screen to be part of the walking blood bank.

Q I understand. So what you were describing is the process by which an individual in a deployed environment would be processed to become a donor in the walking blood bank at a subsequent time?

A Yes.

Q When that individual in the walking blood bank is then asked to donate blood, what screening process is used at that point?

A The same, to the greatest extent possible. So if it's a -- if you can see it coming, if you're at a facility with more comprehensive care and you have the time and the personnel, your goal is always to screen the donor on the date of donation. So another card would be filled out, if there's time for that, to screen them that day to make sure they're feeling well and healthy or nothing else has come up. The unit would be collected along with the tubes.

The unit would get ready for transfusion. The tubes would -- they would do what they need to to make sure everything is labeled. They would perform the rapid testing, if they have that available, and then to get the unit ready for transfusion.

Q So besides for sending the tubes to the United States for testing for TTDs and conducting rapid testing, is the process any different than the process used at a donor center?

A Yes.

Q How is it different?

THE VIDEOGRAPHER: The time is 11:52 a.m. We are going off the record.

(Whereupon, a short recess was taken.)

THE VIDEOGRAPHER: The time is 11:59 a.m. We are back on the record. Please proceed, Counsel.

BY MR. SCHOETTES:

Q Which donors among those who are participating in the walking blood bank as pre-screened donors are given priority in terms of collecting blood for transfusion?

A Which donors? Any donor that's been pre-screened would be -- is the priority.

Q Is there a time frame on the pre-screen that makes some donors higher priority than others?

A Yes.

Q What is the time frame for pre-screening of the highest priority donors?

A I believe 120 days.

Q Which donors are next in priority in terms of amount of time since their screening, pre-screening?

A Any donor who has been screened, but maybe not within the suggested time frame.

Q Understood.
A Does that make sense?
Q It does. So the program for LTOWB is new enough that it has not been fully implemented across the different branches?
A Correct.
Q It has been fully implemented, however, among special forces?
A Yes.
Q So when it is fully implemented, type O donors would be chosen first to donate blood as a part of the walking blood bank?
A Yes. Type O donors that are low titer.
Q Once it is fully implemented, when will type A and type B pre-screened donors be called upon to give blood?
A They would be called upon when necessary. So even though the preferred donor is the low titer group O donor, there are only so many of those in the population. And in preparation for future battles, you do not want -- we do not want to limit ourselves to just group O low titer.
If we're in a certain area for an extended period of time, we want to know the status of all available donors so that we have

that flexibility and a larger donor population.

Q And not just the type of blood for those donors, but also that they've been pre-screened in terms of TTDs, correct?

A Correct. Correct.

Q So it would be when the supply of LTOWB has been diminished that, then, potentially a type A or type B donor would be called upon to donate as part of the walking blood bank?

A Correct.

Q Is a person's blood type included on their dog tags?

A Yes.

Q Is dog an acronym in dog tags?

A I don't know.

Q That makes -- that makes two of us.

MR. ABBUHL: Objection. Outside the scope of the 30(b)(6) deposition.

BY MR. SCHOETTES:

Q What other information is included on a persons dog tags in addition to their blood type?

A I believe name, last name, middle -- last name, first name, middle initial, religion, blood type, and the unknown is if they're still using social or DODID. It could be --

recruitment. And then it says, "When emergency whole blood collections are" --

MR. ABBUHL: Counsel, where are you?

THE WITNESS: I'm sorry. Where are you?

BY MR. SCHOETTES:

Q I'm sorry.

A Oh, I see. Down at the bottom?

Q Yes. So in donor recruitment, we're on page 22.

MR. ABBUHL: Just let the record reflect the number 2 appears multiple times on this page.

BY MR. SCHOETTES:

Q I'm sorry. I'm, of course, looking at the one I'm looking at, so I think I'm good to go.

So under 4.0, procedures, there's a paragraph 2.

A Got it.

Q And it's called, "Donor recruitment." And it says, "When emergency whole blood collections are required, donors will be selected in the following order in descending priority." And then it lists the first one as, "Donors who have been pre-screened within the last 90 days with the full panel of FDA-licensed donor infectious disease tests and found to be negative

for all tests."

Does that -- do you want to alter the answer you gave earlier where you said it was 120 days?

A Yes.

Q So indeed it's 90 days, correct?

A Yes.

Q And then the next group it says here would be, "Donors who have been pre-screened 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."

Is that correct?

A Yes.

Q Then what is the next group that is identified in priority order?

A It says, "Donors who report being repeat blood donors in the past and have not been deferred for transfusion-transmitted disease."

Q So these would be individuals who have not been pre-screened --

A Correct.

Q -- but you would look for people, service members who had been --

A Who had donated --

Q -- donors in the past multiple times and not deferred during any of those donations because they had a transfusion-transmitted disease, correct?

A Correct.

Q And then it talks about the final group of donors which are "donors who have not been pre-screened with FDA-licensed tests nor have been blood donors in the past," correct?

A Correct.

Q And that's the group that you go to last?

A Correct. So I may need to alter another answer --

Q Go ahead.

A -- because I think I mentioned that group as being third previously.

Q So -- yes, and we just established, right, that before that group would be donors who are repeat donors --

A Yes.

Q -- who have not been deferred?

A Yes.

Q Okay. And there are no other groups beyond that that would be used --

MR. ABBUHL: Objection. Vague.

BY MR. SCHOETTES:

Q -- correct? Let me ask my question a different way. If a donor has a permanent deferment, they're not going to be recruited to donate blood, correct?

A Correct.

Q You said something earlier about voluntary donors. Can you explain the distinction you were drawing between voluntary and whatever the other category would be?

A Right. So the donation process is voluntary. Alginate (phonetic) donors are volunteer donors. And that's an industry standard. So we would still stay true to that even in this setting. So they will recruit and -- would you like to participate in the walking blood bank?

Q Blood is never taken from anyone against their will?

A No.

Q I apologize if I've asked this question, but what rapid screening tests are performed on fresh whole blood collected through the walking blood bank?

A The HIV rapid test, the HCV rapid test,

Q So they may or may not be allowed to donate blood?

A It depends on the time frame.

Q Where does it ask on this form when the individual was -- or does it ask on this form when the individual was pregnant?

A No. The interviewer would ask and they would write it down there in the comment section.

Q And that's how they decide whether or not the donor could donate blood on that day?

A Correct.

Q The next question asks of female donors if they've ever had sexual contact with a man -- a male who had sexual contact with another male in the past 12 months.

If a donor answers yes to that question, are they allowed to donate blood that day?

A No, because it would be within the past 12 months.

Q The next question is for male donors, and it asks, "In the past 12 months, have you had sexual contact with another male?" Correct?

A Correct.

Q And if you answer yes to that question, is that donor allowed to donate blood that day?

A No.
Q The next question asks, "Are you currently taking malaria prophylaxis?" Correct?
A Correct.
Q If a donor answers yes to that question, are they allowed to donate blood that day?
A I would have to look. I don't remember.
Q Question 15 asks, "Have you had physical contact with someone who was vaccinated for smallpox in the past eight weeks?" Correct?
A Correct.
Q And if a donor, potential donor, answered yes to that question, would they be allowed to donate blood?
A I would have to look further on that one as well. I don't recall off the -- because it's a live vaccine. I would have to confirm the time frame. But if it's eight weeks, then, no.
Q So if they answered yes, that they [sic] had been vaccinated within the past eight weeks, they would not be allowed to donate blood?
A I would investigate further.
Q Okay. What about question 18, "In the past 12 months, have you lived with or had sex with a person who has hepatitis" -- is what it

not. So it would be in that plasma suite of products that would be available.

Q I guess what I'm trying to ask is, when you said augmented, it isn't that you would use freeze-dried plasma to augment a unit of fresh frozen plasma. It is that you're augmenting the supply?

A Yes. Yes.

Q What specific infections would be tracked in terms of transfusion-transmitted infections that have resulted through the walking blood bank?

A Any of the -- any of the tests that we screen the supply for would be tracked.

Q So HIV, HBV, HCV --

A Correct.

Q -- et cetera?

A Correct.

Q Have there been any documented transmissions of HIV through the Armed Services Blood Program blood supply in the past ten years?

A Not that I'm aware of.

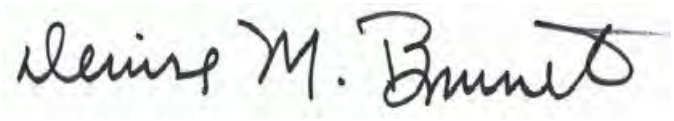
Q In the past 20 years?

A I don't know.

Q What about HBV? Have there been any transmissions of HBV through the Armed Services

CERTIFICATE OF NOTARY PUBLIC

I, Denise M. Brunet, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was sworn by me; that the testimony of said witness was taken by me stenographically and thereafter reduced to print by means of computer-assisted transcription by me to the best of my ability; that I am neither counsel for, related to, nor employed by any of the parties to this litigation and have no interest, financial or otherwise, in the outcome of this matter.



Denise M. Brunet
Notary Public in and for
The District of Columbia

My commission expires:
December 14, 2022

Exhibit 3 to Deposition of Audra Taylor

Joint Trauma System Clinical Practice Guideline

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

TABLE OF CONTENTS

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.

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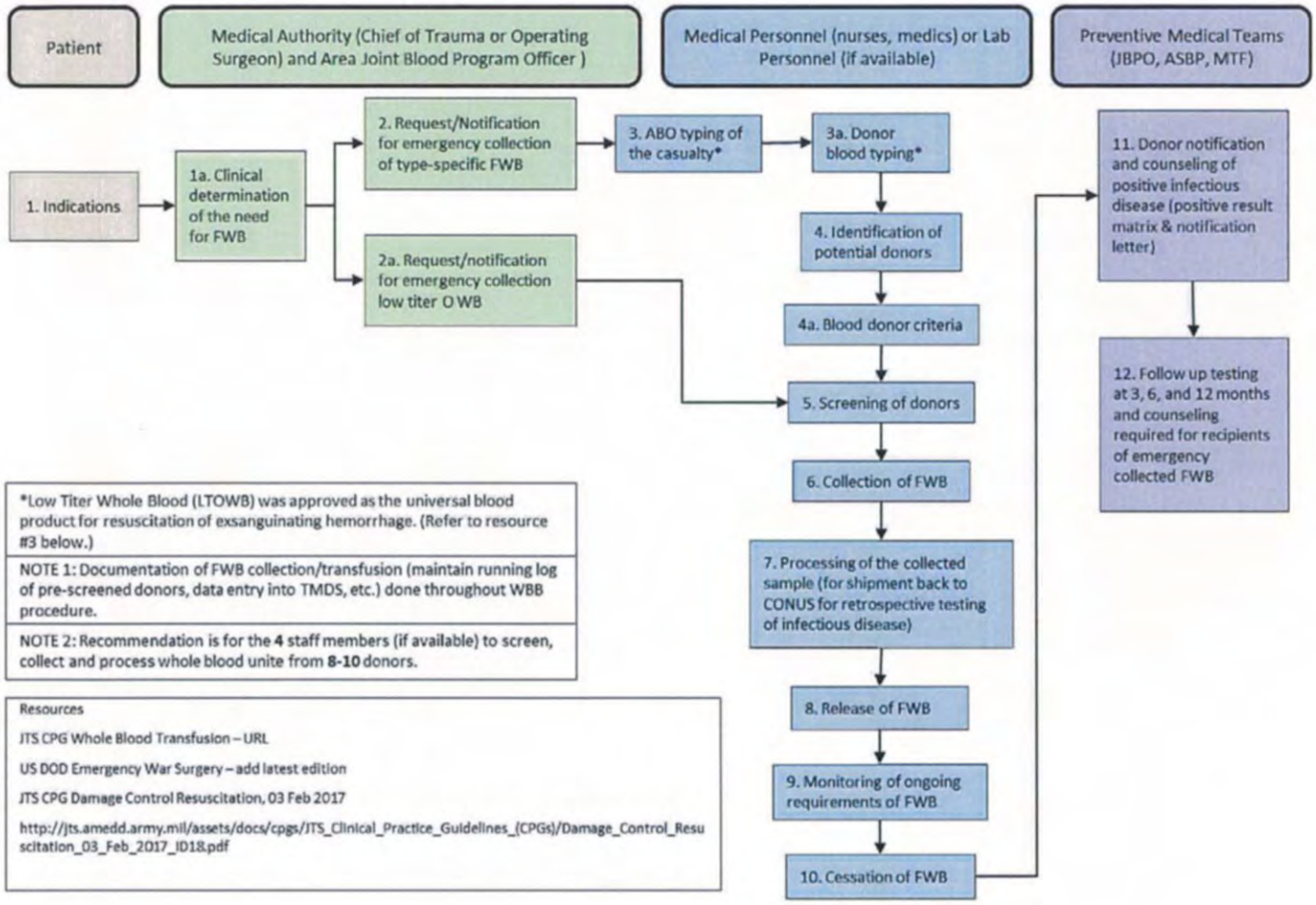
APPENDIX A: WALKING BLOOD BANK PROCESS MAP



*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

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

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.

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)

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

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)

		Y	N			Y	N
9	Are you feeling healthy and well today?			18	In the past 12 months, have you lived with or had sex with a person who has hepatitis?		
10	Female donors: Have you ever been pregnant or are you pregnant now?			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)?		
11	Female donors: Have you had sexual contact with a male who had sexual contact with another male in the past 12 months?			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?		
12	Male donors: In the past 12 months, have you had sexual contact with another male?			21	In the past 12 months, have you come into contact with someone else's blood?		
13	Are you currently taking malaria prophylaxis?			22	In the past 12 months, have you had an accidental needle-stick?		
14	Are you currently taking any medications for an infection?			23	In the past 12 months, have you had a blood transfusion?		
15	Have you had physical contact with someone who was vaccinated for smallpox in the past 8 weeks?			24	In the past 12 months, have you had sexual contact with anyone who takes money or drugs or other payment for sex?		
16	In the past 48 hours, have you taken aspirin or anything that has aspirin in it?			25	In the past 12 months, have you had or been treated for syphilis or gonorrhea?		
17	In the past 8 weeks, have you donated blood, platelets, or plasma?			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?		

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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	+ =	+ =	+ =	+ =			
	+ =	+ =	+ =	+ =			
	+ =	+ =	+ =	+ =			
	+ =	+ =	+ =	+ =			
	+ =	+ =	+ =	+ =			
	+ =	+ =	+ =	+ =			
	+ =	+ =	+ =	+ =			
	+ =	+ =	+ =	+ =			

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.

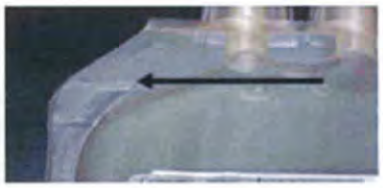
   NOTE: *It is not necessary to use the entire amount of the solution in the applicator*
6. Set up the whole blood collection bag.
   - Ensure that the donor's ISBT Label or ID has been recorded in the Unit Number field on the CPD Whole Blood Collection bag if not previously performed.
   - Ensure date 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 #:	
	Exp:			Exp:			Exp:			Exp:			Exp:	
Assigned Unit #	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 7540-00-634-4156

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 [redacted]

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.	TEST INTERPRETATION: ANTIBODY SCREEN	TEST INTERPRETATION: CROSSMATCH	PREVIOUS RECORD CHECK: ☐ RECORD ☐ NO RECORD
				SIGNATURE OF PERSON PERFORMING TEST [redacted]
DONOR: ABO / Rh	RECIPIENT: ABO / Rh	☐ CROSSMATCH NOT REQUIRED FOR THE COMPONENT REQUESTED		DATE
		REMARKS:		

SECTION III - RECORD OF TRANSFUSION

PRE-TRANSFUSION DATA			POST-TRANSFUSION DATA			
INSPECTED AND ISSUED BY *(Signature)* [redacted]			AMOUNT GIVEN	TIME/DATE COMPLETED/INTERRUPTED		
			REACTION ☐ NONE ☐ SUSPECTED	TEMPERATURE	PULSE	BLOOD PRESSURE
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.

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.

1st VERIFIER *(Signature)* [redacted]

2nd VERIFIER *(Signature)* [redacted]

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

PRE-TRANSFUSION

TEMP. | PULSE | BP

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

DATE OF TRANSFUSION | TIME STARTED

SIGNATURE OF PERSON NOTING ABOVE [redacted]

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.

EXHIBIT 55

Transfusion-Transmissible Infections Among U.S. Military Recipients of Emergently Transfused Blood Products, June 2006–December 2012

Transfusion-Transmissible Infections Among U.S. Military Recipients of Emergently Transfused Blood Products, June 2006–December 2012

Timothy Ballard, MD (Lt Col, USAF); Patricia Rohrbeck, DrPH, MPH (Maj, USAF); Mindy Kania; Lucas A Johnson, MD, MTM&H (LCDR, USN)

In austere deployment environments, transfusion of freshly collected blood products from volunteer donors is sometimes necessary to save wounded service members' lives. Because these blood products may have an increased risk of transmitting bloodborne pathogens, recipients are administratively tracked and offered serial serologic testing by the Blood Look Back (BLB) program. This study evaluates the frequency of transfusion-transmissible infections (TTIs) in U.S. service member (SM) recipients of non-FDA-compliant blood products from 1 June 2006 through 31 December 2012. Routine BLB program efforts identified and evaluated 1,127 SM recipients for evidence of seven TTIs for 12 months following transfusion. The Defense Medical Surveillance System was then queried for evidence of provider-diagnosed TTIs and the results were compared. A single, previously reported incident case of human T-lymphotropic virus (rate of 1.3 per 1,000 persons) was the only TTI identified during the study period. Screening of recipients identified two (rate of 1.9 per 1,000 persons) prevalent (pre-transfusion) cases of chronic hepatitis B virus (HBV) infection, 16 (rate of 15.5 per 1,000 persons) prevalent cases of naturally acquired immunity to HBV and seven (rate of 6.8 per 1,000 persons) prevalent cases of hepatitis C virus infection. No cases of infection with human immunodeficiency virus, syphilis, *Trypanosoma cruzi*, or West Nile virus were identified.

The U.S. Food and Drug Administration (FDA) develops procedures to reduce the inherent risk of communicable disease in the blood supply. U.S. Code of Federal Regulations Title 21 requires all donated blood (including leukocyte-rich cells) to be tested for human immunodeficiency virus (HIV) types 1 and 2, hepatitis B virus (HBV), hepatitis C virus (HCV), human T-lymphotropic virus (HTLV) types I and II, and syphilis.[1] In November 2009, following 30 documented cases of West Nile virus (WNV) infection acquired from blood transfusion, and in December 2010 after seven transfusion reported cases of *Trypanosoma cruzi* infection, the FDA recommended screening of all donated blood for WNV[2] as well as one-time donor testing for *T. cruzi*.[3]

In the early, resuscitative care of combat casualties, the transfusion of blood products, often in large amounts, has proven to be crucial to improving survival in the wounded. In forward areas of combat zones where conditions are austere and resupply is intermittent, supplies of pre-positioned FDA-compliant blood products may be limited, and may be quickly exhausted. Under such circumstances, transfusion with freshly collected blood products is sometimes used to save lives.[4] When such blood products are transfused, Department of Defense (DoD) policy requires recipients to be offered testing for transfusion-transmissible infections (TTIs) at intervals of 3, 6, and 12 months after transfusion. This testing is tracked by The Armed Services Blood Program (ASBP) office via the Blood Look Back (BLB) program. BLB program personnel also ensure that recipients of non-FDA-compliant products have been counseled regarding the reason for their emergent transfusion and understand the importance of laboratory follow-up testing. Program personnel then coordinate with patients, case managers, and medical providers to ensure that transfusion recipients receive follow-up laboratory testing at Clinical Laboratory Improvement Amendments–certified laboratories. When possible, testing is performed at military treatment facilities, or Department of Veterans Affairs (VA) hospitals; however, testing is sometimes performed at civilian facilities as well. Laboratory testing results are transmitted to the BLB, verified by the ASBP, and recorded in the service member's (SM's) medical record. If a recipient demonstrates serologic evidence of a TTI, BLB personnel interview the SM, perform a comprehensive review of the medical records, review the results of blood samples taken from the donor at the time of donation, and in some cases, request testing of the donors' pre-deployment serum.[5] The BLB program routinely tests for HIV types 1 and 2, HTLV types I and II, HBV, HCV, syphilis, WNV and *T. cruzi* (WNV and *T. cruzi* testing were added in May 2013).

Previous research suggests TTIs among SMs transfused in combat with freshly collected blood products are rare. A study by Hakre et al. tested SMs who received non-FDA-compliant blood products from March 2002 through September 2007. Of the 761 recipients of emergently transfused blood products, pre- and post-transfusion sera were tested for HIV (472 recipients), HBV (469 recipients), and HCV (475 recipients). A single case of transfusion-transmitted HCV infection was identified (incidence rate of 2.1 per 1,000 persons). Additionally, the study

identified two cases of prevalent (pre-transfusion) chronic HBV infection (4 per 1,000 persons), nine cases of prevalent natural immunity to HBV (19 per 1,000 persons), and four prevalent cases of HCV infection (8 per 1,000 persons).[6]

This study updates the current body of knowledge by determining the incidence and prevalence of seven TTIs among SMs who received non-FDA-compliant blood products from 1 June 2006 through 31 December 2012. Furthermore, this study examines whether the addition of a passive surveillance system, the Defense Medical Surveillance System (DMSS), detected any SMs diagnosed with TTIs, including *T. cruzi* or WNV prior to routine screening in 2013. Finally, this study explores the use of the DMSS as a potential tool to augment current BLB programmatic surveillance efforts.

METHODS

A retrospective cohort study was designed using pre-existing data routinely collected by the BLB program as well as ICD-9 diagnostic information routinely captured from SM electronic health records in the DMSS. Maintained by the Armed Forces Health Surveillance Center, DMSS records document provider diagnoses recorded during outpatient encounters and inpatient hospitalizations of active component SMs in fixed military and civilian (if reimbursed through the Military Health System [MHS]) treatment facilities.[7] The cohort consisted of active-duty SM recipients of non-FDA-compliant blood products identified by the BLB program. The primary outcomes of interest were the presence of laboratory-confirmed TTIs within 12 months of receiving a non-FDA-compliant blood transfusion. The exposure period was 1 June 2006 through 31 December 2012, and the total surveillance period was 1 June 2006 through 31 December 2013. SMs were followed for at least 12 months after date of transfusion; until completion of follow-up laboratory testing; or until completion of the study surveillance period. To account for patient noncompliance with BLB program–recommended follow-up, as well as the introduction of WNV and *T. cruzi* laboratory testing after the study exposure period, SM medical records were also queried in the DMSS for evidence of provider-diagnosed TTI during the 12-month surveillance period following transfusion. Case definitions for DMSS-diagnosed TTIs were based on standardized, previously published criteria.[8] This project was reviewed and approved by the Uniformed Services University of the Health Sciences Offices of Research and determined to be exempt from Institutional Review Board review.

Demographic characteristics and primary outcome of the study cohort were reported using descriptive statistics. Rates were calculated and expressed as rates per 1,000 persons. All statistical analysis was completed in Stata/IC 12.1.[9]

RESULTS

BLB data initially identified 1,206 recipients during the study exposure period **(Figure 1)**. Despite initially surviving their injuries and transfusion, 31 SMs succumbed to their injuries prior to completion of follow-up and were excluded from analysis. Another 48 recipients were later identified as civilians at the time of their transfusion and were excluded from the analysis because they did not meet the criteria for inclusion into the study because no health information was available on DoD civilians through DMSS. The remaining 1,127 SMs were then matched to DMSS diagnostic data in accordance with the standardized case definitions. A total of 97 SMs had no documentation of completing any laboratory follow-up testing. The remaining 1,030 SMs received at least some follow-up laboratory testing for TTIs. A total of 778 SMs completed all required follow-up serologic tests; an additional 252 SMs had incomplete follow-up, defined as missing documentation of at least one or more required laboratory tests.

The typical recipient of non-FDA-compliant blood was a junior enlisted soldier, aged 20–24 years **(Table 1)**. The Army and Marine Corps combined represented 96% of those who received non-FDA-compliant blood, while the Air Force and Navy each represented only 2%.

FIGURE 1. Selection of the study population

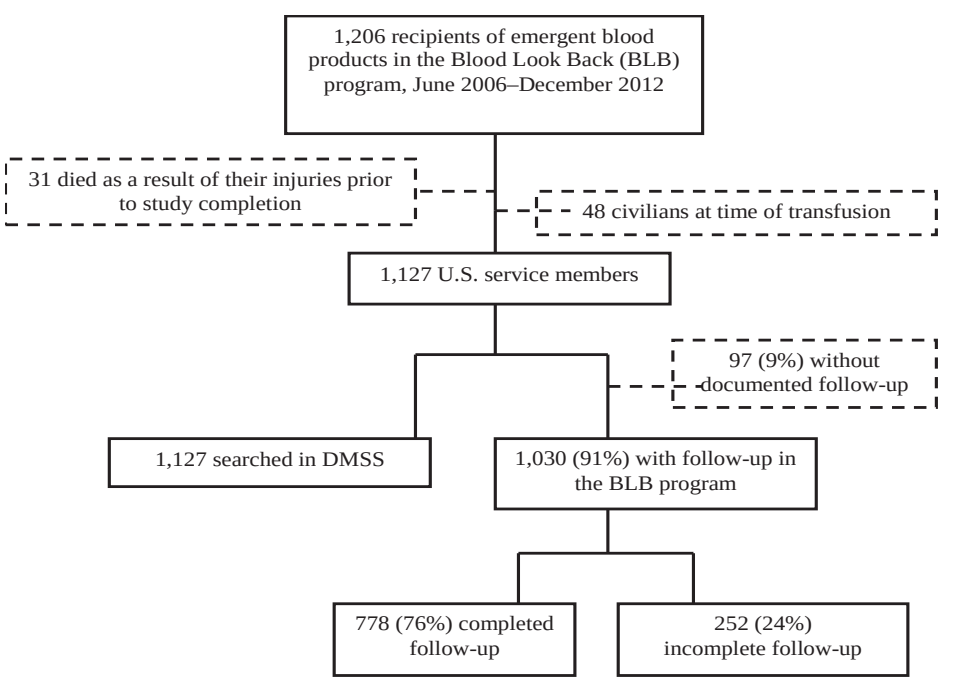


TABLE 1. Demographic characteristics of U.S. service member recipients of non-FDA-compliant blood products, June 2006–December 2012

	No.	%
Total	1,127	
Age		
<20	59	5.0
20–24	576	51.0
25–29	297	26.0
30–34	115	10.0
35–39	47	4.0
40+	33	3.0
Service		
Army	762	68.0
Air Force	24	2.0
Marine Corps	320	28.0
Navy	21	2.0
Rank		
E1–E4	659	58.0
E5–E9	385	34.0
O1–O9, WO	83	7.0
Year of transfusion		
2006	136	12.0
2007	203	18.0
2008	94	8.0
2009	82	7.0
2010	205	18.0
2011	252	22.0
2012	155	14.0

FDA=U.S. Food and Drug Administration

TABLE 2. Non-FDA-compliant blood products transfused to U.S. service members, June 2006–December 2012

Blood product	No. of recipients	No. of units	Minimum-maximum units per recipient
Whole blood	253	2,116	1–57
Platelets	1,022	2,712	1–26
Fresh frozen plasma	15	29	1–9
Total	1,127[a]	4,857	

[a]Some recipients were transfused multiple types of blood products.

FDA=U.S. Food and Drug Administration

Blood products

A total of 4,857 units of non-FDA-compliant blood products were transfused to 1,127 SMs during the study period **(Table 2)**. Apheresis platelets were the most utilized product (2,712 units transfused to 1,022 personnel) followed by whole blood (2,116 units transfused to 253 personnel). These values represent only the quantity of non-FDA-compliant blood products because the BLB database does not systematically record type and volume of FDA-compliant banked blood products. According to the Armed Services Blood Program (AFBP), the U.S. military transfused 237,100 units of blood products between June 2006 and December 2012. Thus, the 4,857 non-FDA-compliant units represented approximately 2% of the total blood products.

Transfusion-transmitted infections

Between June 2006 and December 2013, there was a single occurrence of the primary outcome of interest: an incident laboratory-confirmed case of HTLV infection (rate of 1.3 per 1,000 persons) among the 778 individuals who completed all required testing **(Table 3)**.

Hepatitis B virus

The BLB program identified 16 recipients (rate of 15.5 per 1,000 persons) who were repeatedly reactive for HBV core antibody (HBcAb) and HBV surface antibody (HBsAb) but were negative for HBV surface antigen (HBsAg). These recipients were identified as having a history of exposure to HBV and natural immunity. Two recipients (rate of 1.9 per 1,000 persons) were HBcAb repeat reactive with HBsAg positivity and were identified as having chronic HBV infection.

By using the standardized surveillance case definitions, DMSS records were identified for three transfusion recipients as having been diagnosed with HBV infection. Two of these recipients corresponded to SMs previously identified by the BLB program as having a history of HBV prior to receiving a transfusion. The third individual had completed all follow-up laboratory testing and was serologically negative for evidence of HBV infection.

Hepatitis C virus

Within the BLB program, seven transfusion recipients (rate of 6.8 per 1,000 persons) were anti-HCV positive, confirmed by either recombinant immunoblot assay or nucleic acid amplification testing. All seven transfusion recipients were determined to have a history of HCV prior to transfusion by a combination of medical record review, patient report, or serologic analysis of pre-transfusion aliquot for HCV.

DMSS records were identified for five transfusion recipients as having been diagnosed with HCV infection. Three of these records corresponded to recipients previously identified by the BLB program as having a history of HCV prior to transfusion. One record was for a recipient determined to have an initial false-positive test for HCV infection, and later serologically confirmed to be HCV negative. The final recipient completed all follow-up laboratory testing and was serologically negative for evidence of HCV infection.

HIV, syphilis, *T. cruzi*, and WNV

No cases of HIV, syphilis, *T. cruzi*, or WNV infection were identified by either the BLB program or the DMSS.

EDITORIAL COMMENT

This study confirms and reaffirms a previously reported 2010 case of HTLV type I[10] as the only incident case of a TTI identified to date in this cohort of 1,127 SMs receiving non-FDA-compliant blood products from 1 June 2006 through 31 December 2012. The addition of DMSS as a passive surveillance tool did not identify additional positive cases of TTIs among

TABLE 3. Incidence and prevalence of potential TTIs by data source

	Blood Look Back program		DMSS
	No. of cases (rate)[a]	No. of cases (rate)[a]	No. of cases[d]
TTI	Incidence[b]	Prevalence[c]	
HIV	0	0	0
HBV/chronic	0	2 (1.9)[a]	3
HBV/naturally acquired immunity	N/A	16 (15.5)[a]	N/A
HCV	0	7 (6.8)[a]	5
HTLV I and II	1 (1.3)[a]	0	1
Syphilis	0	0	0
WNV	Not tested	Not tested	0
Trypanosoma cruzi	Not tested	Not tested	0

[a]Cases per 1,000 persons

[b]Rate derived from 778 service members who completed all laboratory testing.

[c]Rate derived from 1,030 service members at risk of outcome; includes incomplete follow-up.

[d]DMSS recorded both incident and prevalent cases derived from 1,127 service members searchable in the DMSS.

DMSS=Defense Medical Surveillance System; HBV=hepatitis B virus; HCV=hepatitis C virus; HTLV=human T-lymphotropic virus; TTI=transfusion-transmissible infection; WNV=West Nile virus

SMs with incomplete follow-up or among those who may not have received laboratory testing for WNV and *T. cruzi* by the BLB program.

The incidence rate of a TTI in this population was one case out of 1,127 (0.9 per 1,000 persons). Confining incidence estimates to the most conservative denominator (778 recipients who completed 12 months of laboratory testing) yields an incidence rate of 1.3 per 1,000 persons. This rate is below the previously reported incidence rate of 2.1 per 1,000 transfusions among 475 recipients from 2002 to 2007.[6]

The BLB program data identified 16 recipients (rate of 15.5 per 1,000 persons) with evidence of HBV from a natural infection prior to transfusion and two (rate of 1.9 per 1,000 persons) recipients chronically infected with HBV with evidence of infection prior to transfusion. These prevalence results are less than the rates reported in the 2002–2007 transfusion cohort (19 per 1,000 persons and 4 per 1,000 persons, respectively).[6] The observed rate of SMs with chronic HBV was substantially higher than the rate of 0.095 per 1,000 persons reported in a 2011 study of all active component SMs from 2000 through 2010.[11] The existence of undiagnosed, chronic HBV infection may result from lack of a servicewide systematic screening process for HBV, as well as potential patient disclosure issues, because chronic hepatitis and hepatitis carrier state are grounds for rejection from appointment, enlistment, or induction in military service.[12] Methodologic differences may also account for the observed differences in reported prevalence. The study design for the report utilized both laboratory and diagnostic criteria, an approach that is likely more sensitive than the diagnostic only estimate provided by the 2011 study.

The BLB program identified seven recipients (rate of 9 per 1,000 persons) with evidence of HCV prior to transfusion, similar to the prevalence of HCV in the 2002–2007 cohort of 8 per 1,000 persons,[6] but also substantially higher than the prevalence of chronic HCV (0.17 per 1,000) reported in the U.S. Armed Forces from 2000 through 2010.[13] Methodologic differences likely account for these differences as 91% of this study cohort was serologically screened for HCV as compared to an unknown, but presumably low, percentage of individuals receiving actual serologic screening in the previous study.[13]

This study utilized DMSS records to augment routine BLB program follow-up by identifying transfusion recipients who received a diagnosis of a TTI by a healthcare provider. Additionally, DMSS records were searched for evidence of diagnoses of WNV and *T. cruzi* infection because routine laboratory testing for these conditions was not introduced until after the exposure period of this study. By using standardized case definitions, DMSS records enabled the correct identification of the two prevalent cases of HBV identified through routine BLB program laboratory testing. One SM serologically proven to demonstrate no serologic evidence of HBV infection had a healthcare provider diagnosis of HBV in the medical record and thus was incorrectly identified as a case by using the standardized case definition. Standardized case definitions applied to DMSS records allowed for the correct identification of three out of seven individuals with HCV; however, two SMs whose DMSS records contained diagnoses of HCV infection were serologically proven to demonstrate no evidence of HCV infection. Despite these limitations, approximately one-quarter of the cohort did not complete all recommended laboratory follow-up for a variety of reasons; the ability to continue tracking these individuals through a passive surveillance tool is a valuable practice that should be further investigated.

Interpretation of this study is subject to several limitations. First, despite robust administrative support and coordination with case managers across the spectrum of the MHS, the VA, and civilian care, nearly one-quarter of the cohort did not complete all recommended laboratory testing. Second, some infectious conditions monitored by the BLB program (particularly HCV and *T. cruzi*) can demonstrate long latency periods prior to an individual becoming symptomatic. SMs who are non-compliant with laboratory follow-up may require greater than 12 months of follow-up prior to experiencing symptoms that may result in a provider diagnosis if indeed infected with a TTI. Third, while inclusion of the DMSS data may help compensate for incomplete BLB program follow-up, diagnostic information resulting from care provided to SMs outside of the MHS or care that is not reimbursed by the

MHS (e.g., care provided out-of-pocket or for free at a public health department clinic) will not be captured in DMSS. Fourth, despite use of standardized surveillance case definitions, DMSS data still depend on individual providers entering correctly coded diagnoses into the medical record. If providers misdiagnosed a condition (e.g., if a case of meningitis was secondary to WNV, the diagnosis may only be recorded as meningitis), this would result in under-reporting and an underestimate of frequency of infection. Finally, the study design resulted in differential follow-up because SMs enrolled in the cohort earlier in the study period were necessarily followed for a greater amount of time compared to those enrolled in later years.

This study has several strengths: first, the sample size of 1,127 makes this the largest exploration of data about SM recipients of non-FDA-compliant blood products to date. Second, vetting the BLB program data against DMSS data improves the sensitivity of this study's ability to identify a TTI as well as provide a means to potentially identify two diseases for which no laboratory testing was performed at the time of transfusion (*T. cruzi* and WNV). Additionally, DMSS aids in this study's ability to identify and track individuals who did not complete BLB program recommended follow-up. Third, standard procedure within the BLB program was to rigorously follow and confirm potential positive laboratory tests. This practice frequently involved testing for the presence of the infectious agent's DNA or RNA. Additionally, donor serums could be screened for TTIs if recipients declined to complete recommended follow-up. In the case of the recipient identified as an incident case of HTLV, viral DNA sequencing of the donor and recipient allowed for a very high level of evidence for the route of viral transmission. Fourth, whenever possible, standardized disease case definitions were used to allow for more direct comparisons between this study, previously published literature, and potential future research.

One incident case of HTLV was identified in this review, representing a rare outcome of a life-saving measure. Prevalent cases of HBV and HBC were identified, which are a potential concern as they represent the presence of undiagnosed infectious agents in a cohort who themselves may become non-FDA-compliant blood product donors to others. The use of DMSS as an additional passive surveillance tool did not identify additional true positive cases of TTIs potentially validating current BLB programmatic efforts. Considering the substantial numbers of SMs who do not complete all recommended laboratory follow-up after receiving non-FDA-compliant blood products, further evaluation of the DMSS as an additional surveillance tool may be warranted.

Disclaimer: The views expressed are those of the author(s) and do not necessarily reflect the official views of the Uniformed Services University of the Health Sciences, the U.S. Air Force, the U.S. Navy, or the Department of Defense.

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