DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
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IN REPLY REFER TO
BUMEDINST 6530.18
BUMED-M3
29 Sep 2020

BUMED INSTRUCTION 6530.18

From: Chief, Bureau of Medicine and Surgery

Subj: USE OF NON-UNITED STATES FOOD AND DRUG ADMINISTRATION COMPLIANT BLOOD PRODUCTS

Ref: (a) OASD (HA) Policy 10-002 of 19 Mar 10
(b) 5 U.S.C. §3109
(c) NAVMED P-6530

Encl: (1) Definitions
(2) Guidelines for the Collection and Transfusion of Non-Food and Drug Administration Compliant Blood Products

1. Purpose. Per reference (a), to establish guidelines for the Navy Medicine enterprise regarding the collection and transfusion of non-U.S. Food and Drug Administration (FDA) compliant blood products.

2. Scope and Applicability. This instruction applies to Navy Medical Department personnel defined as active duty and Reserve Component officers and enlisted Service members, civilian personnel, contractors, Intergovernmental Personnel Act appointees, and experts and consultants employed per reference (b).

3. Background. Over the last few years, the use of whole blood for the management of hemorrhagic shock has significantly increased in the military. This has led to increased collections and transfusions of whole blood for deployed forces. In deployed environments, the inability to supply blood components due to logistical constraints has led to the use of whole blood collected onsite from walking blood banks. These blood products are not prospectively tested for infectious diseases and are therefore non-compliant with FDA regulations. As a result, per reference (a), recipients of these blood products must be tested at 3, 6, and 12 months post-transfusion to monitor for disease transmission.

a. Reference (a) established policy requiring all transfused blood products to be compliant with the FDA. However, this policy recognizes that the use of non-FDA compliant blood is sometimes necessary to save lives and may be the only alternative during combat operations or

mass casualty events. Additional guidance on the use of non-FDA compliant blood products can be found in reference (c), Armed Services Blood Program Joint Program Handbook, appendix G, section G-1, available at Web site, https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/ARN18580_tm8_227_12_FINAL.pdf.

b. Definitions are described in enclosure (1). Guidelines for activation of emergency non-FDA compliant blood product collections and requirements for managing transfusion recipients of non-FDA compliant blood products are provided in enclosure (2).

4. Policy. Navy Medical Department personnel must follow the guidelines provided in enclosure (2) when collecting and transfusing non-FDA compliant blood products.

5. Records Management

a. Records created as a result of this instruction, regardless of format or media, must be maintained and dispositioned per the records disposition schedules located on the Department of the Navy (DON) Directorate for Administration, Logistics, and Operations, Directives and Records Management Division portal page at https://portal.secnav.navy.mil/orgs/DUSNM/DONAA/DRM/Records-and-Information-Management/Approved%20Record%20Schedules/Forms/AllItems.aspx.

b. For questions concerning the management of records related to this instruction or the records disposition schedules, please contact the local records manager or the DON Directorate for Administration, Logistics, and Operations, Directives and Records Management Division program office.

6. Review and Effective Date. Per OPNAVINST 5215.17A, Healthcare Operations (BUMED-M3) will review this instruction annually around the anniversary of its issuance date to ensure applicability, currency, and consistency with Federal, DoD, Secretary of the Navy, and Navy policy and statutory authority using OPNAV 5215/40 Review of Instruction. This instruction will be in effect for 10 years, unless revised or cancelled in the interim, and will be reissued by the 10-year anniversary date if it is still required, unless it meets one of the exceptions in OPNAVINST 5215.17A, paragraph 9. Otherwise, if the instruction is no longer required, it will be processed for cancellation as soon as the need for cancellation is known following the guidance in OPNAV Manual 5215.1 of May 2016.

G. D. SHAFFER
Acting

Releasability and distribution:
This instruction is cleared for public release and is available electronically only via the Navy Medicine Web site, https://www.med.navy.mil/directives/Pages/BUMEDInstructions.aspx

DEFINITIONS

1. FDA Licensed Donor Test. A test licensed, approved, or cleared by the FDA for use as a donor screening test. These tests are typically reserved for blood donor testing only. FDA licensed donor tests are listed on the FDA Web site, https://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/BloodDonorScreening/InfectiousDisease/ucm080466.htm.

2. Non-FDA Compliant Blood Products. Blood products that do not meet FDA regulatory standards. Non-FDA compliant blood products must only be used when necessary to save lives and is the only alternative during combat operations or mass casualty events. Non-FDA compliant blood carries heightened risk of transmitting infectious diseases.

3. Pre-screening. Used interchangeably with screening. A procedure used to qualify prospective emergency whole blood donors prior to the day of donation. Standard operating procedures for pre-screening can be found in the joint trauma system whole blood transfusion clinical practice guideline pre-screening which includes:

a. Collection of the prospective donor's medical history. This will include an interview of the prospective donor. The interview must be performed by trained medical personnel.

b. Testing.

c. Registration in Theater Data Medical Stores (TMDS). It is the responsibility of Navy medical personnel attached to the deploying unit to register and enter donor demographics and testing results in TMDS.

4. Testing. The assays listed in subparagraphs 4a through 4d must be performed when pre-screening a prospective theater blood donor. Results must be entered in TMDS.

a. Blood group agents (ABO) and Rhesus (Rh) including weak-D testing for those who initially test as Rh negative.

b. Testing for unexpected antibodies to red cell antigens.

c. Assays for infectious agents. Pre-screen infectious disease testing may be performed using either FDA-licensed donor testing or diagnostic laboratory testing.

(1) Hepatitis B Virus nucleic acid assays.

(2) Hepatitis B surface antigen.

(3) Anti-hepatitis B core antigen.

(4) Anti-hepatitis C virus encoded antigen.

(5) Hepatitis C virus nucleic acid assay.

(6) Anti-human immunodeficiency virus (HIV) types 1 and 2.

(7) HIV-1 nucleic acid assay.

(8) Anti-human t-lymphotropic virus types I and II.

(9) West nile virus nucleic acid assay.

(10) Anti-trypanosoma cruzi.

(11) Zika nucleic acid assay.

(12) Syphilis by serologic test.

(13) Babesia nucleic acid assay (required only when blood is collected in Connecticut, Delaware, Maine, Maryland, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, Wisconsin, and District of Columbia).

d. Anti-A and anti-B titers for group O donors.

5. FDA Compliant Blood Products. Blood products that meet FDA regulatory standards and are collected by FDA licensed blood establishments. These products pose the least infectious risk to the transfusion recipient.

6. Walking Blood Bank. Emergency blood collection procedure in which non-FDA compliant blood products are collected and manufactured during combat operations or mass casualty events.

GUIDELINES FOR THE COLLECTION AND TRANSFUSION OF NON-FOOD AND DRUG ADMINISTRATION COMPLIANT BLOOD PRODUCTS

1. Activation of Emergency Non-FDA Compliant Blood Product Collections

a. The collection of whole blood and other non-FDA compliant blood products (e.g., apheresis platelets) in the deployed environment is limited to situations where non-FDA compliant blood products are necessary to save lives and are the only alternatives during combat operations or mass casualty events. This decision can only be made by the senior medical department representative.

b. When emergency blood collections are required, donors must be selected in descending priority:

(1) 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. (Note**:** Any donor with a positive test result will not be listed as an approved pre-screened donor and must not be collected.)

(2) 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.

(3) Donors who report being repeat blood donors in the past and have not been deferred for transfusion-transmitted disease.

(4) Donors who have not been pre-screened with FDA-licensed tests nor have been blood donors in the past.

c. To the maximum extent possible:

(1) Blood will only be collected from U.S. personnel to include Service members, DoD civilians and contractors, or beneficiaries.

(2) On the day of donation, prospective donors will be screened for eligibility using approved donor history screening protocols and will be tested for infectious diseases using Armed Services Blood Program approved rapid screening tests. As much as possible, rapid screening tests should be performed before issuing the product. Blood donor screening procedures are provided in the Joint Trauma System Whole Blood Transfusion Clinical Practice Guideline.

d. Collect whole blood following procedures provided in the Joint Trauma System Whole Blood Transfusion Clinical Practice Guideline.

e. Each unit and its corresponding infectious disease samples must be labeled with a unique donation identification number. The identification number should be International Society of Blood Transfusion compliant, if possible. Products must be labeled "For Emergency Use Only."

f. The blood samples must be sent to a FDA-licensed donor testing laboratory for retrospective testing.

g. Donor information must be submitted to the combatant command theater joint blood program officer (JBPO) within 48 hours of collection or as early as possible depending on availability of communications. The required information will be determined by the combatant command JBPO but should, at a minimum, include:

(1) Donor full name.

(2) Donor unique identifier (e.g., DoD identification number).

(3) Unique donation identification number.

(4) Organizational unit assigned.

(5) Date of donation.

(6) Location of donation.

(7) Blood product disposition (e.g., transfused or destroyed).

(8) Blood product disposition date.

(9) Any testing results (rapid or retrospective) available.

h. Follow-up notification and counseling will be provided to any donor who tests positive or reactive on either a rapid or retrospective infectious disease test, as listed in subparagraphs 1h(1) through 1h(3):

(1) Document, track, and follow-up blood donors with positive infectious disease test results, regardless of whether the unit was transfused.

(2) The donor will be deferred from subsequent blood donations, notified of the test results, and offered counseling.

(3) The JBPO will ensure that a preventive medicine or infectious disease agency will be used to ensure all donors have been notified of their retrospective test results and the appropriate follow-up is completed (e.g., notification, counseling, and treatment referrals). If the donor has re-deployed, the armed services blood program office should be notified to assist with donor tracking and ensure the donor is notified.

2. Requirements for Managing Non-FDA Compliant Blood Product Transfusion Recipients

a. To the maximum extent feasible, a pre-transfusion blood specimen will be collected to establish a baseline for each of the current FDA-required blood donor infectious disease screening tests. If a pre-transfusion specimen cannot be obtained, a baseline blood sample should be collected as soon as possible post-transfusion.

b. Recipients will be notified prior to transfusion, if feasible, or as soon thereafter as possible:

(1) Non-FDA-compliant blood products will be or were given.

(2) Of the reason for the transfusion.

(3) Of the necessary patient follow-up required.

c. The notification and subsequent transfusion will be documented in the patient's medical record and, if available, in a centralized electronic patient medical record or tracking system.

d. Transfusion recipient information will be submitted to the combatant command theater's JBPO within 48 hours of transfusion or as early as possible depending on availability of communications. The required information will be determined by the combatant command theater's JBPO but should, at a minimum, include:

(1) Patient full name.

(2) Unique identifier (e.g., DoD identification number).

(3) Unique donation identification number(s) of the blood products transfused.

(4) Organizational unit assigned.

(5) Date of transfusion.

(6) Location of transfusion.

(7) Any recipient testing results (rapid or retrospective) available.

e. Follow-up infectious disease testing of U.S. patients will be conducted at intervals of 3, 6, and 12 months after transfusion. A preventive medicine or infectious disease agency will be used to ensure recipients have been notified and appropriate follow-up is completed (i.e., notification, counseling, and treatment referrals). Non-U.S. patients will be followed according to their respective medical policies.

f. Baseline and follow-up infectious disease testing samples must be sent to a FDA-certified laboratory. Results will be documented and maintained in the patient medical record and, if available, in a centralized electronic patient medical record or tracking system.