DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
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IN REPLY REFER TO
BUMEDINST 6530.16
BUMED-M3
3 Jul 2018

BUMED INSTRUCTION 6530.16

From: Chief, Bureau of Medicine and Surgery

Subj: PATHOGEN REDUCTION TECHNOLOGY FOR APHERESIS PLATELETS

Ref: (a) DoD Armed Services Blood Program Office memo BPL 17-04 of 27 Jun 2017 (NOTAL)
(b) 21 CFR 606.145a
(c) NAVMED P-5120

1. Purpose. This instruction sets the policy that apheresis platelets collected by Navy Blood Program managed blood donor centers be processed using Food and Drug Administration (FDA) approved pathogen reduction systems as per reference (a). It also establishes the requirements to use pathogen reduced apheresis platelets in transfusion services FDA-licensed through the Navy Blood Program.

2. Scope and Applicability. Applies to all Navy medical treatment facilities (MTF) collecting and transfusing apheresis platelets.

3. Background. As seen in recent history with Zika Virus, Ebola, Chikungunya, Dengue, and Babesia, emerging pathogens continue to threaten the blood supply. Testing for emerging transfusion-transmitted diseases may not be sustainable given the time it takes to identify and assess emerging pathogens, and develop approved tests. Use of pathogen reduction technologies in routine component processing will place Navy Blood Donor Centers in a favorable position to preemptively address the risks due to emerging pathogens.

a. Per reference (b), blood collection centers and transfusion services must ensure the risk of bacterial contamination of platelets is adequately controlled using FDA-approved or cleared devices. This requirement can be met by treating the platelets with an FDA-approved pathogen reduction device.

b. Per reference (c), the use of FDA-approved pathogen reduction systems may be used to minimize the risk of microbial contamination in platelets. Additionally, AABB standards require blood banks and transfusion services have policies to reduce the risk of Cytomegalovirus (CMV) transmission in cellular components. The current FDA-approved pathogen reduction system satisfies both standards with robust inactivation of bacteria and CMV in platelets.

c. AABB reviewed the effectiveness of pathogen inactivation technologies and determined they would be as effective as traditional irradiation in preventing transfusion-associated graft-versus-host disease. AABB enacted new standards to allow the use of pathogen reduction systems as a method to prevent transfusion-associated graft-versus-host disease.

4. Policy

a. Navy Blood Donor Centers and transfusion services must use FDA-approved or cleared apheresis platelet collection devices to ensure the risk of bacterial contamination of platelets is adequately controlled.

b. All apheresis platelets collected by Blood Donor Centers managed by the Navy Blood Program must be processed using a pathogen reduction system approved by the FDA.

c. Apheresis platelets treated with FDA-approved or cleared pathogen reduction technologies are considered CMV-safe and effective in preventing transfusion-associated graft-versus-host disease.

5. Action. Navy Blood Donor Centers and transfusion services must implement the following measures:

a. All apheresis platelets collected in Navy Blood Donor Centers must be FDA-licensed and pathogen-reduced using an FDA-approved pathogen reduction system according to its instructions for use. Blood Donor Centers must implement this requirement no later than 31 December 2018. Implementation must be coordinated with the Navy Blood Program Office.

b. Navy transfusion services must use pathogen-reduced apheresis platelets to the greatest extent possible. If requests for apheresis platelets exceed available inventory, the blood bank may acquire non-pathogen reduced platelets from other suppliers to meet patient transfusion needs.

c. When irradiated apheresis platelets are requested for patient transfusion, Navy transfusion services may provide pathogen-reduced platelets in lieu of irradiated apheresis platelets. Likewise, when CMV-negative apheresis platelets are requested for patient transfusion, Navy transfusion services may provide pathogen-reduced platelets in lieu of CMV-negative platelets.

6. Records Management

a. Records created as a result of this instruction, regardless of media and format, must be maintained and dispositioned for the standard subject identification codes (SSIC) 1000, 2000, and 4000 through 13000 series per the records disposition schedules located on the Department of the Navy/Assistant for Administration (DON/AA), Directives and Records Management Division (DRMD) portal page at https://portal.secnav.navy.mil/orgs/DUSNM/ DONAA/ DRM/Records-and-Information-Management/Approved%20Record%20Schedules/ Forms/AllItems.aspx. For SSIC 3000 series dispositions, please refer to part III, chapter 3, of Secretary of the Navy Manual 5210.1 of January 2012.

b. For questions concerning the management of records related to this instruction or the records disposition schedules, please contact your local records manager or the DON/AA DRMD program office.

7. Review and Effective Date. Per OPNAVINST 5215.17A, the Bureau of Medicine and Surgery, Healthcare Operations (BUMED-M3) will review this instruction annually on the anniversary of its effective date to ensure applicability, currency, and consistency with Federal, Department of Defense, Secretary of the Navy, and statutory authority using OPNAV 5215/40 Review of Instruction. This instruction will be in effect for 5 years, unless revised or cancelled in the interim, and will be reissued by the 5-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.

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