OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

MAR 19 2010

MEMORANDUM FOR SECRETARY OF THE ARMY
SECRETARY OF THE NAVY
SECRETARY OF THE AIR FORCE
COMMANDERS OF THE COMBATANT COMMANDS
DIRECTOR, JOINT STAFF

SUBJECT: Policy on the Use of Non-U.S. Food and Drug Administration Compliant Blood Products

This policy memorandum provides guidance on the use of and protocol for follow-up regarding non-U.S. Food and Drug Administration (FDA)-compliant blood products that are transfused overseas. This policy replaces the Assistant Secretary of Defense (Health Affairs) memorandum, "Policy on the Use of Non-U.S. Food and Drug Administration Licensed Blood Products," Policy 01-020, dated December 4, 2001, which is hereby rescinded.

The Department of Defense healthcare policy requires that beneficiaries receive medical treatment that meets or exceeds the established "standard of care." In regard to blood transfusion, this means that all transfused blood products must be FDA-compliant. Since U.S. personnel are deployed around the world and banked blood is perishable, it is not always possible to provide transfusion centers with FDA-compliant blood products. 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. When non-FDA-compliant blood must be transfused, it carries the risk of transmitting infectious diseases. To mitigate this risk, proper controls must be applied to ensure every blood product collected in an emergency is retrospectively tested and proper follow-up of the blood recipient is accomplished. Patient follow-up also applies to U.S. patients transfused in host-nation healthcare facilities.

The policy set forth in this memorandum is limited to medical emergency situations for which FDA regulation (21.C.F.R.610.40(g)) permits the release of blood products, properly labeled, prior to the completion of required testing. Such products must be labeled "For Emergency Use Only".

Management of Blood Donors:

a. When emergency blood collections are required, donors will be selected from among the following groups, in order:

(1) Donors who have been prescreened within the last 90 days by a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory using all the current FDA-required blood donor infectious disease screening tests.

(2) Donors who report being repeat blood donors in the past and have not been deferred for a transfusion-transmitted disease. (Donation cards may serve as evidence of past blood donation.)

(3) Donors who have not been prescreened with FDA-licensed tests, nor have been a blood donor in the past.

b. To the maximum extent possible, DoD Military Treatment Facilities (MTFs) and U.S. Navy vessels where appropriate will establish and maintain rosters of prescreened donors, and repeat the screening at regular intervals (not to exceed 90 days). Retrospective testing following an emergency blood donation may serve as a prescreen for a subsequent donation.

c. To the maximum extent possible, blood will only be collected from U.S. personnel: military, Department of Defense (DoD) civilians, DoD contractors, or beneficiaries (non-theater donation).

d. To the maximum extent possible, prospective donors will be screened for eligibility on the day of donation using Armed Services Blood Program (ASBP)-approved donor history screening protocols and infectious disease rapid screening test kits approved by the ASBP Office (ASBPO) or Combatant Command. NOTE: The use of infectious disease rapid- screening test kits is not equivalent to testing with FDA-licensed screening tests for donor eligibility.

e. Specimen sample tubes will be collected and labeled with a unique International Society of Blood Transfusion (ISBT) donor identification number at the time of blood donation and sent to a designated CLIA-certified donor testing laboratory for retrospective testing. Results of all prescreening and retrospective testing will be provided to the Combatant Command Theater Joint Blood Program Office (JBPO).

f. Donor collection information will be submitted to the Combatant Command Theater JBPO within 48 hours of collection. The required information will be determined by the Combatant Command JBPO but should, at a minimum, include: the donor's full name, unique identifier/Social Security number, unique donation

identification number, organizational unit assigned, date of donation, location of donation, unit disposition (transfused, destroyed), unit disposition date, and any testing results (rapid or retrospective) available.

g. All records of emergency blood donation must be maintained in accordance with ASBP, Military Department and/or Combatant Command policies.

h. Follow-up notification and counseling will be provided to any donor who tests positive on either the prescreen, rapid, or retrospective test panels, as follows:

(1) Document, track, and follow-up blood donors with positive infectious disease testing 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) 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 (i.e., notification, counseling, and treatment referrals).

Management of 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, that non-FDA-compliant blood products will be or were given, of the reason for the transfusion, and of the necessary patient follow-up required. The notification will be documented in the patient's medical record and, if available, in a centralized electronic patient medical record or tracking system.

c. 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.

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

Responsibilities:

a. Military Department Surgeons General:

(1) Will assign responsibility for performance and oversight of the requirements of this policy to the appropriate subordinate agencies.

(2) Will ensure all Military Department medical elements comply with the provisions of this policy memorandum.

(3) Will ensure, to the maximum extent possible, the continuity of follow-up testing if patient care transitions to a civilian or Veterans Affairs Medical Center.

b. Combatant Commands:

(1) Will formulate policy and procedures regarding transfusion of non-FDA-compliant blood products for use within their respective Combatant Command.

(2) To the maximum extent feasible, notify and offer counseling to blood donors collected in theater who test positive on either prescreen, rapid, or retrospective infectious disease testing.

(3) To the maximum extent feasible, notify transfusion recipients when non-FDA-compliant blood products are transfused.

(4) Combatant Command policy and procedure must include all elements described in this memorandum, and should be staffed through the ASBPO to ensure coordination of efforts.

(5) The Combatant Command JBPO should coordinate with the ASBPO for technical and quality assessments of host-nation blood supplies to determine FDA compliance.

c. ASBPO

(1) Will establish international agreements with allies and coalition forces to share medical information, where applicable, to ensure:

(a) Notification to the appropriate foreign medical authority regarding any non-U.S. patient who receives non-FDA-compliant blood products in a U.S. MTF.

(b) Notification to the appropriate foreign medical authority regarding positive donor test results and/or post-donation information involving non-U.S. recipients.

(c) Notification to the Combatant Command JBPO regarding any U.S. citizen who receives a blood transfusion in a host-nation healthcare facility.

(2) Will work with Combatant Command JBPOs to ensure coordinated interface of ASBPO and Combatant Command efforts to track and manage non-FDA-compliant blood product transfusions.

(3) Will determine screening/and testing qualifications of foreign blood supplies with approval of the Assistant Secretary of Defense for Health Affairs. Any blood product brought into a Theater of Operations by the North Atlantic Treaty Organization or other Allied countries, whose donor screening/and testing processes have been reviewed by ASBPO and are deemed comparable to U.S. standards, may to the extent authorized by FDA regulations, be declared exempt from notification and follow-up infectious disease testing as defined in this policy.

These guidelines shall be implemented within 90 days of the date of publication of this memorandum. Provide implementation documents to the Director, Armed Services Blood Program Office, 5109 Leesburg Pike, Falls Church, Virginia 22041-3258. The point of contact for this policy is Colonel Francisco Rentas, Director, Armed Services Blood Program, who may be reached at 703-681-8027, DSN 761-8027, or Francisco.Rentas@amedd.army.mil.

Charles L. Rice, M.D.
President, Uniformed Services University
of the Health Sciences
Performing the Duties of the
Assistant Secretary of Defense
(Health Affairs)

cc:
Surgeon General, U.S. Army
Surgeon General, U.S. Navy
Surgeon General, U.S. Air Force
Joint Staff Surgeon
COCOMS/COCOM SURGEONS