Autologous Blood and Blood Components (3/15/89)

Date : March 15, 1989

From: Director, Center for Biologics Evaluation and Research

Subject: Guidance for Autologous Blood and Blood Components

To: All Registered Blood Establishments

I. INTRODUCTION

The safety of blood and blood components continues to be one of the Food and Drug Administration's primary concerns. Because autologous blood collections are occurring with increased frequency, there is a heightened need for definitive guidance in this area. The guidance for collecting, testing, labeling, storing and distributing blood and blood components from autologous donations as described in this document was reviewed by the Blood Products Advisory Committee on November 18, 1988.

II. LICENSING AND REGISTRATION

1. Establishments collecting autologous blood must register annually with the FDA as required by 21 CFR Part 607.

2. Establishments collecting autologous blood or blood components for transfusion that are routinely shipped in interstate commerce must be licensed in accordance with the provisions of Section 351 of the Public Health Service Act. Unlicensed blood or blood components for autologous use should not be shipped in interstate commerce except in the unusual circumstance that the place of surgery is unexpectedly changed to another state.

3. Autologous blood collected without predetermined medical need at the time of collection should be licensed because requests for interstate shipments are expected to occur.

III. TESTING OF AUTOLOGOUS BLOOD

1. All FDA required tests in 21 CFR 610.40 (HBsAg), 610.45 (anti-HIV-1) and 640.5 (syphilis) should be performed on a sample obtained at the time of collection and prior to labeling and distribution. If the donor is confirmed to be anti-HIV-1 positive or confirmed to be HBsAg reactive, CBER recommends that the blood or blood components not be used. However, the products may be distributed only for autologous use by the collecting facility provided that a written, signed and dated request for the use of confirmed anti-HIV-1 positive and HBsAg reactive products is received from the patient's physician. If

distributed on a common carrier not under the direct control of the collecting facility, the product is to meet the provisions for shipping an etiologic agent pursuant to 42 CFR 72.3. If not used, all components, including recovered plasma, should be quarantined and destroyed. Donors who are repeatably reactive for anti-HIV-1 or HBsAg, whether confirmed or not, must bepermanently deferred as donors of blood for homologous use pursuant to 21 CFR 606.160 (e).

2. Frozen autologous components, including those currently in storage, should meet the same testing requirements. Previously frozen units from donors with rare blood group phenotypes may be used in emergencies. Whenever possible, donors of units currently in frozen storage should be requested to provide a current sample for testing before untested units are used. For future donations, CBER recommends that a plasma/serum sample collected at the time of donation be frozen with the unit to accommodate the possible addition of new tests during the storage period.

IV. LABELING OF AUTOLOGOUS BLOOD

1. All blood components suitable only for autologous use at the time of collection should be permanently labeled with a special message label as prescribed in 21 CFR 606.121(i)(4) and in the current Guideline for the Uniform Labeling of Blood and Blood Components.

2. Blood or blood components that test positive for anti-HIV-1 or are reactive for HBsAg as defined in Section III.1. should be permanently labeled at the time of distribution with a special BIOHAZARD label as provided in the current Guideline for the Uniform Labeling of Blood and Blood Components.

3. If time does not permit confirmation of repeatedly reactive tests for HBsAg or anti-HIV-1 prior to distribution, the labeling recommendations of Section IV, 1. and 2. apply.

4. The donor classification statement, "AUTOLOGOUS DONOR" should be permanently affixed in addition to "VOLUNTEER DONOR" or "PAID DONOR". It is the intent of the Agency to amend 21 CFR 606.121 (c)(5) to require the autologous donor classification.

V. RELEASE OF AUTOLOGOUS BLOOD FOR HOMOLOGOUS USE

1. Only blood and blood components collected from donors who meet all suitability requirements as defined in 21 CFR 640.3 and the testing requirements of 21 CFR 610.40, 610.41 and 610.45 may be

distributed for homologous use or for further manufacture.

2. AIDS educational information should be provided to donors and confidential unit exclusion procedures should be applied at the time of donation.

3. Labeling of autologous blood and blood components for homologous use must follow the requirements of 21 CFR 606.121(i)(4) and (5) and should also include the donor classification statement, "AUTOLOGOUS DONOR".

VI. INTRAOPERATIVE OR POSTOPERATIVE RED BLOOD CELL SALVAGE

1. The intraoperative or postoperative salvage of red blood cells for immediate return to the same patient generally is considered a part of the practice of medicine. When salvaged units are held and stored in the blood bank after surgery before return to the patient, the labeling, quarantine, storage and recordkeeping requirements of 21 CFR Part 606 should be met.

2. Because of the increased risk of bacterial contamination in autologously collected salvaged red blood cells, the storage period at 1 - 6 degree Celsius should not exceed 6 hours after which the unit(s) should be destroyed.

3. Because of the brief storage period of such products, testing for HBsAg and anti-HIV-1 may be waived, but products should be stored in a quarantine area and conspicuously labeled for autologous use only.

Please refer technical questions to the Division of Blood and Blood Products, HFB-400, Bethesda, MD 20892 or call (301) 496-0952 or 496-4396- Application forms for registration or licensure may be obtained from the Division of Product Certification, HFB-240, 5600 Fishers Lane, Rockville, MD 20857 or by calling (301) 443-5433.

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