Volume Limits - Automated Collection of Source Plasma (11/4/92)

Date: 4 November 1992

From: Director, Center for Biologics Evaluation and Research

Subject: Volume Limits for Automated Collection of Source Plasma

To: All Registered Blood Establishments

The increased number of automated plasma collection devices with varying capacities for tailoring each collection to the specific donor has resulted in the existence of multiple Food and Drug Administration (FDA) approved nomograms which specify, for each piece of equipment, the maximum volume of plasma to be harvested from each donor category. Current considerations in determining the volume of plasma to be collected include sex, height, weight, hematocrit, and in some centers, the length of time in process or the number of cycles. Because multiple equipment types commonly coexist in a location, the potential for error due to application of an inappropriate nomogram is significantly increased. The use of various anticoagulant solutions, differing concentrations of the anticoagulant, and a range of anticoagulant to plasma ratios, additionally complicates some schema and creates additional opportunity for error.

The experience to date with all of the approved equipment indicates that there is no discernible impact on donor safety or product quality with the use of any of the current limits in preference to any other. Some Source Plasma manufacturers have requested and received approval for simplified nomograms. The FDA supports this type of process change which potentially improves the consistency of procedures for manufacturing and minimizes the opportunity for staff error.

To promote rapid implementation of such simplified schema, the Center for Biologics Evaluation and Research is informing all manufacturers that the following limits may be adopted without further notice. The anticoagulant volume is included in the third column below. This volume is based on a 1:16 (0.06) ratio of anticoagulant to anticoagulated-blood.

| Donor Weight | Plasma Volume or Weight | Collection Volume |
|---|---|---|
| 10-149 lbs | 625 mL (640 g) | 690 mL (705 g) |
| 150-174 lbs | 750 mL (770 g) | 825 mL (845 g) |
| 175 lbs & up | 800 mL (820 g) | 880 mL (900 g) |

It has been determined that the use of this simplified nomogram does not constitute a significant change in manufacturing and, therefore, does not require advance approval of amendments to licenses. However, it should be noted that the nomogram is intended to be adopted as a complete set of limits. The simplified nomogram and the equipment manufacturer's nomogram should not be used simultaneously in the same center. Portions of the table should not be selectively applied in combination with some other system of limits. Variations will require advance approval of license amendments based on supporting documentation including evidence that the chance of error is not increased.

To monitor potential adverse reactions and ensure that no increased frequency of reactions is observed with this change in the volume of plasma collected, it is requested that any reactions observed for the first 1,000 procedures done under your license be reported to the FDA. If plasma from 1,000 donors has not been collected during the first three months after implementation of the new nomogram, please provide an interim report of any reactions occurring during the first three months. For your convenience we have provided a format for reporting of the desired information on adverse reactions.

Kathryn C. Zoon, Ph.D.

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Addendum to FDA Memorandum
Suggested Format for
Experience Report On Plasma Collection Adverse Events

Automated device used for collection:

Anticoagulant used:

Anticoagulant to anticoagulated-whole blood ratio used during this collection procedure:

Weight of donor:

Height of donor:

Donor number and sex of donor:

Hematocrit prior to collection:

Total protein prior to collection:

Amount of plasma collected when reaction occurred:

Amount of anticoagulant used before reaction occurred:

Amount of saline administered before reaction (if any):

Type of reaction and severity (mild, moderate, severe, life-threatening):

Signs/symptoms of reaction:

Blood pressure at time of reaction:

Was physician notified?:

Treatment of donor:

Any operator error detected?

If yes, please provide additional details in accordance with FDA memorandum, March 20, 1991: Responsibilities of Blood Establishments Related to Errors & Accidents in the Manufacture of Blood and Blood Components.

Other comments:

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