Guideline on Plasma Donation for Plasma Derived Medicinal Products

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Guideline on Plasma Donation for Plasma Derived Medicinal Products

Draft

Saudi Food & Drug Authority
Drug Sector

Please send your comments or suggestions before 19 April 2020 to:

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1. INTRODUCTION
Human plasma for fractionation is the starting material for the manufacture of a range of medicinal products, which are obtained by a combination of large-scale processing steps known as “fractionation”. These products are used for the treatment of a variety of life-threatening injuries and diseases.

Human plasma for fractionation may be obtained by separation of plasma from whole blood, or by apheresis.

Apheresis plasma is obtained by a procedure in which anticoagulant-treated blood is removed from the donor, the plasma is separated from the formed elements, and at a minimum, the red cells are returned to the donor.

1.1. Objective
The present recommendations are intended to provide guidance on the donation of plasma by plasmapheresis (apheresis).

1.2. Scope
This guidance document addresses only human plasma sourced for the manufacture of plasma derivatives, and does not cover plasma for clinical use.

1.3. Related guidelines
- Guideline on Blood Products (Plasma Derived Medicinal Products)
- Guideline on the Scientific Data Requirements for Plasma Master File (PMF)
- Good Manufacturing Practice for Blood Establishments
2. PLASMAPHERESIS

2.1. Definition
A procedure in which, during a single visit to the establishment, blood is removed from a donor, the plasma separated from the formed elements, and at least the red blood cells returned to the donor.

2.2. Requirements
1. The donor’s weight at the time of plasmapheresis must not be less than 50 Kilograms.
2. A sample of blood from each donor is to be drawn on the day of the initial physical examination (Annex I) and at least every 4 months thereafter. A serologic test for syphilis, a total plasma or serum protein determination, and a plasma or serum protein electrophoresis or quantitative immuno-diffusion test or an equivalent test to determine immunoglobulin composition of the plasma or serum shall be performed on the sample.
3. A repeat donor that fails to give a sample for testing for a period of 4 months or more shall be treated as a new donor.
4. Conditions for Donor Deferral:
A) To determine whether the donor should be deferred from further donation, the following have to be reviewed by the appointed physician within 14 calendar days after the sample is drawn:
   • Accumulated laboratory data, including any tracings of the plasma or serum protein electrophoresis pattern.
   • Calculated values of the protein composition of each component, and the collection records.
If a determination is not made within 14 calendar days, the donor must be deferred until a determination is made and the appointed physician signs the review.
B) The donor must be deferred from donation until the protein composition returns to acceptable levels:

- If the protein composition is not within normal limits established by the testing laboratory; or
- If the total protein level is less than 6.0 grams per deciliter or more than 9.0 grams per deciliter in a plasma sample or serum sample.

Reinstatement of the donor into the plasmapheresis program must be approved by the appointed physician.

C) A donor with a reactive serologic test for syphilis shall not be plasmapheresed again until the donor's serum is tested and found to be nonreactive to a serologic test for syphilis.

D) A donor blood loss of more than 200 milliliters of red blood cells during a plasmapheresis procedure causes deferral of the donor for eight weeks.

5. A donor identification system shall be established that positively identifies each donor and relates such donor directly to his blood and its components as well as to his accumulated records and laboratory data. Such system shall include either a photograph of each donor which shall be used on each visit to confirm the donor's identity, or some other method that provides equal or greater assurance of positively identifying the donor.

6. Volume of donation:

A) No more than 500 milliliters of whole blood shall be removed from a donor at one time, unless the donor's weight is 79 kilograms or greater, in which case no more than 600 milliliters of whole blood shall be removed from the donor at one time.

B) The maximum amount of whole blood, not including anticoagulant, removed from a donor during a manual plasmapheresis procedure is 1,000 milliliters. However, if the donor's weight is 79 kilograms or greater, the maximum amount of whole blood, not including anticoagulant, removed from the donor during a manual plasmapheresis procedure is 1,200 milliliters. The
maximum amount of whole blood, not including anticoagulant, removed from a donor in a 2-day period is 1,000 milliliters. However, if the donor's weight is 79 kilograms or greater, the maximum amount of whole blood, not including anticoagulant, removed from the donor in a 2-day period is 1,200 milliliters.

C) The maximum amount of whole blood, not including anticoagulant, removed from a donor during a manual plasmapheresis procedure within a 7-day period is 2,000 milliliters. However, if the donor's weight is 79 kilograms or greater, the maximum amount of whole blood, not including anticoagulant, removed from a donor during a manual plasmapheresis procedure within a 7-day period is 2,400 milliliters.

D) Not more than 15 liters of plasma should be donated by one donor in a year.

7. The plasma shall be separated from the red blood cells immediately after blood collection. The maximum feasible volume of red blood cells shall be returned to the donor before another unit is collected.

8. The volume of plasma collected during an automated plasmapheresis collection procedure shall be consistent with the volumes specifically approved by the Saudi Food and Drug Authority, and collection shall not occur less than 2 days apart or more frequently than twice in a 7-day period. Collecting from donors in less than 48 hours is acceptable if the donations are two calendar days apart.

9. Eight weeks must elapse after whole blood donations or after plasma donations when cells are not returned.

10. Infrequent Source Plasma donors may donate once in four or more weeks. An infrequent donor is a donor who returns for plasmapheresis in four weeks.
3. ANNEX 1

Recommendations on the minimum procedures be included in the physical examination before plasma donation:

1. Heart and lung sounds should be determined on bare skin, both front and back, and with several intakes of air during the evaluation.

2. Abdominal examination is performed at some centers to determine enlargement of the liver, spleen, or lymph nodes. The donor should be relaxed, possibly with knees bent, and the physician should gently but firmly press deeply into the abdomen on both right and left upper abdominal areas. Although not required, some centers include palpation of the inguinal (groin) area for lymph node enlargement as part of the exam.

3. Neurological examination may consist of reflex assessment using a reflex hammer on knees and possibly elbows, ankles, wrists, or other points. Coordination and sensory examinations may also be made, including touch and balance evaluations.

4. Examination of the urine for sugar and protein should be conducted.

5. The lymph node examination should include the neck from the jaw down towards the shoulders, angling forward from the angle of the jaw and nearly straight down from behind the ears. Other areas that may be evaluated include under the arms, at the elbows and the groin region.

6. The skin should be examined for irregular patches that are reddish to maroon-blue in color and may be slightly raised. These patches can occur inside the mouth or nose as well as other skin surfaces.

7. The mouth should be carefully checked for irregular cottony-appearing white blotches.

8. It is also important to check under the tongue, arms, and some centers also check legs for needle tracks.
4. REFERENCES:

- Guidelines for the Blood Transfusion Services in the United Kingdom (7th Edition)