Standards for the Collection and Processing of Blood and Blood Components and the Manufacture of Associated Sterile Fluids

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SNBTS DOCUMENT REQUEST No:

2011/00073

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INTRODUCTION

(i) These Standards were compiled by the Department of Health and Social Security in consultation with the Regional Transfusion Directors of England, Wales and Scotland, the Directors of the Blood Products Laboratory, Elstree and Protein Fractionation Centre, Liberton and the Scottish Home and Health Department. The Document has no statutory force and should not be regarded as an interpretation of the requirements of an Act, Regulation or Directive.

(ii) These Standards are intended to relate to those aspects of the collection and processing of blood and blood components and the manufacture of associated sterile fluids which may have a bearing on the *safety and quality of the final product*. Accordingly, the section dealing with donor selection should not be construed as comprehensive guidance in this matter since its main emphasis is on donor selection in relation to the safety of the *product* and not in relation to the safety of the *donor*.

(iii) This document does not deal with matters related to the safety of persons connected with the collection and processing of blood and blood components. It should not be interpreted as augmenting, or causing dispute with, any recommendations of the Health and Safety Executive.

1. The collection and processing of blood and blood components

1.1 Premises

1.1.1 Whether blood is collected by mobile teams or in centres built for the purpose the premises must be adequate for the safety of both the donor and the blood.

1.1.2 *Premises used by mobile teams*
They shall be of suitable size, construction and location with adequate heating, lighting and ventilation. The standard of maintenance and cleanliness of the building shall be such as to allow the following activities to be conducted without undue risk to donors:

1.1.2.1 Medical examination of individuals to determine their fitness as donors of blood and/or blood components.

1.1.2.2 Withdrawal of blood from donors and where applicable reinfusion of the components with a minimal risk of contamination and error.

1.1.2.3 The care of donors including the treatment of donors who suffer reactions.

1.1.3 *Purpose built transfusion centres*
They shall comply with 1.1.2 and provide for the following additional activities.

1.1.3.1 Storage of whole blood and blood components pending completion of processing and testing.

1.1.3.2 Laboratory testing of blood and blood components.

1.1.3.3 Orderly processing and distribution of blood and blood components in a manner which will prevent contamination and error.

1.1.3.4 Adequate and proper performance of all steps in pheresis procedures.

1.1.3.5 Orderly labelling, packaging and other finishing operations to prevent errors.

1.1.3.6 Storage of equipment.

1.1.3.7 Storage of finished products prior to distribution.

1.1.3.8 Documentation and recording of data on the donor, the donated blood and the ultimate recipient.

1.1.4 *Further requirements for transfusion centres*

1.1.4.1 The premises shall be constructed to prevent the entrance and harbouring of vermin, birds and pests.

1.1.4.2 The premises shall be maintained in a good state of repair and be kept in a clean and tidy condition in accordance with accepted rules of hygiene.

1.1.4.3 Waste materials should not be allowed to accumulate in the premises or the external surrounds of the buildings.

1.1.4.4 Filtered air is not required in rooms where donors are bled, but the buildings should be sited where environmental contamination will be at a minimum.

1.1.4.5 Rooms where blood is withdrawn from donors should be restricted to that activity while donation is taking place and not be used as a general thoroughfare for personnel or the movement of materials.

1.2 Equipment and Containers

1.2.1 Equipment used in the collection, processing, storage and distribution of blood and blood components shall be kept clean, maintained in good condition and checked regularly.

1.2.2 Equipment employed to sterilise materials used in blood or blood component collection or for the disposal of contaminated products shall ensure the destruction of contaminating micro-organisms. The equipment shall be installed, operated and maintained in accordance with Hospital Technical Memorandum No. 10 – Sterilisers.

1.2.3 Only containers which have been approved by the appropriate authority shall be used for taking blood donations.

1.3 Personnel

1.3.1 Transfusion directors shall be responsible for ensuring that employees are adequately trained and gain practical experience and that they are aware of the application of accepted good practices in their respective functions.

1.3.2 Transfusion directors shall have the responsibility of bringing to the attention of the appropriate authority any serious breaches of discipline

among employees in the handling, processing and testing of blood and blood components.

1.3.3 A registered medical practitioner shall be responsible ultimately for all medical decisions in the collection of blood and blood components.

1.3.4 Persons, if not medically qualified, who undertake the collection of blood and blood components must be responsible to the registered medical practitioner referred to in 1.3.3.

1.4 Selection of Donors

1.4.1 Donors should be healthy persons of either sex over 18 years of age and under 65. As a general rule new donors should not be accepted after 60 years of age.

The removal of 420–440 ml of blood from such healthy persons has in general no deleterious effect on health or resistance to disease, and only temporary effect, rapidly recovered from, on the circulation.

1.4.2 Interval between donations. Donor panels should be maintained at a size that will permit donors to be bled not more frequently than twice per annum.

1.4.3 The decision whether a person is fit to give blood rests finally with the doctor who is ultimately responsible for the collection of the blood.

1.4.4 Hazardous occupations. Special note should be taken by the registered medical practitioner of the occupation of the donor and any hazardous hobbies the donor might engage in and arrangements made or advice offered as to the timing of donations to avoid increasing any hazard.

1.5 Donors

The subject from whom blood is drawn must as far as can be ascertained after clinical and laboratory examination and the study of his medical history, be free from disease transmissible by blood transfusion and be in a state of health suitable for donation.

1.5.1 The following illnesses or conditions disqualify a person from acting as a donor

Anaemia (see para 1.6)
Brucellosis
Cancer
Diabetes
Filariasis
Heart Disease
Hypertension
Illicit drug taking
Jaundice or Hepatitis
(but see para 1.5.2)
Presence in the blood of hepatitis B
associated antigen
Kala-azar
Leptospirosis
Stroke

1.5.2 The following illnesses or conditions may lead to acceptance, deferment or disqualification as a donor

Allergy
Epilepsy
Glandular fever (Infectious mononucleosis) in the last two years
Goitre (Thyroid disease)
Jaundice or Hepatitis (in the last year or contact with a case within 6 months)
Kidney disease
Toxoplasmosis
Tropical diseases. Potential donors should be asked about visits abroad and should not be used as donors until 12 clear weeks after arriving from Africa. As a general guide special consideration needs to be given regarding malaria, trypanosomiasis and pyrexia of unknown origin which could be caused by a dangerous virus. A history of other tropical diseases does not necessarily debar.
Tuberculosis

1.5.3. The following illnesses, conditions or circumstances necessitate temporary deferment

Contact with infectious diseases if the donor has not had the disease
Dental extraction
Infections such as tonsillitis or boils. Persons who have recovered within the previous three months from chickenpox, herpes zoster, herpes simplex, measles, mumps, rubella or certain other acute infectious diseases may provide plasma for specific immunoglobulins.

Inoculations/vaccinations (the blood of donors recently vaccinated against certain diseases may be used for the preparation of specific immunoglobulins)
Major surgery or accident
Pregnancy and post-partum (with special exceptions)
Tatooing, acupuncture, ear-piercing within the last 6 months
Transfusion within the last 6 months
Treatment with certain drugs e.g. antihistamines, antibiotics but not oral contraceptives.

1.5.4 In all circumstances the decision to accept, defer or disqualify must rest with the registered medical practitioner. Recording of unusual cases and the decision reached may prove useful

1.6 Haemoglobin Estimation

The haemoglobin should be determined each time the donor presents himself. Female donors with less than 12.5 g haemoglobin per 100 ml or male donors with less than ~~37.2~~ g haemoglobin per 100 ml should not be bled. The type of test is left to the discretion of the transfusion directors, but the Phillips-Van-Slyke copper sulphate method (Reference: J. Biol. Chem. 1950 *183*–305), using a sample of blood obtained from the finger, is recommended for use as a screen test.

Donors whose haemoglobin is below the appropriate level should be informed that they are not fit to be bled at present. In those cases, if a screen test has been used it is recommended to take a venous sample of blood into sequestrene for an exact determination of the haemoglobin, microhaematocrit and red cell indices. If the results confirm the haemoglobin to be below the appropriate level the donor should be advised to consult his or her own doctor who should receive a report of the results.

1.7 Venepuncture technique

1.7.1 Good technique involves:

1.7.1.1 the use of carefully prepared sterile equipment.

1.7.1.2 sterilisation of the skin which should be carried out by a well-tried method, such as described in M.R.C. Memorandum No. 34 1957, H.M.S.O.

1.7.1.3 skilfully performed venepuncture which should be preceded by the injection of a local anaesthetic. Normally not more than 420–440 ml of blood should be withdrawn.

1.8 Plasmapheresis donors

1.8.1 The criteria for plasmapheresis donors shall be the same as those employed for donors of whole blood. In addition there shall be a serological test for syphilis and a serum protein electrophoresis or quantitative immuno-diffusion test for immunoglobulins to determine the immunoglobulin composition of the serum. Before the second and all subsequent donations by plasmapheresis in addition to meeting the requirements for whole blood donors, plasmapheresis donors shall be shown to have a total serum protein of not less than 6.0 g/dl.

1.8.2 The medical evaluation of plasmapheresis donors shall be repeated at regular intervals.

1.8.3 Whenever a laboratory value is found outside the established normal limits or a donor exhibits any relevant abnormalities on history or physical examination, the donor shall be temporarily excluded until the abnormal finding has returned to normal and the donor's physician has given approval to his or her resuming donation for plasmapheresis.

1.8.4 In the event that a plasmapheresis donor donates blood for a unit of whole blood or does not have the red blood cells returned from a unit taken during the procedure, further donations from the donor shall be deferred until the blood indices have returned to normal.

1.9 Pilot and laboratory samples

1.9.1 Pilot samples for cross matching, which may be integral with the container or separate, shall be provided with each unit of whole blood or of red blood cells.

1.9.2 Pilot samples shall be collected at the time of donation.

1.9.3 Tubes or other containers for pilot samples which are not integral, shall, immediately before being filled, be marked with the same number as that on the container into which the donation is collected, so that the pilot sample is identified with the donation to which it refers.

1.9.4 Any laboratory samples which are collected in addition to pilot samples should meet the above requirements.

1.10 Identification of Samples

1.10.1 Each container of blood, blood components, and pilot and laboratory samples shall be identified by a unique number or symbol so that they can be traced back to the donor and from the donor to the recipient. The identity of each donor shall be established at the time of determination of donor fitness as well as at the time of blood collection.

1.11 Transportation of blood and blood components from collection centres

1.11.1 Where blood is collected by mobile teams it shall be stored in cooled insulated transit containers or cool insulated vehicles for transport to the transfusion centre unless other conditions are specifically required.

1.12 Storage of blood at transfusion centres

1.12.1 Blood shall be stored at transfusion centres in the appropriate refrigerated rooms or cabinets.

1.12.2 Refrigeration at the temperature ranges appropriate for the products must be efficient, reliable and constantly monitored with an alarm system to B.S. 4376:1968.

2. Manufacture and control of sterile fluids and the separation of blood components

2.1 Manufacture and control of sterile fluids

2.1.1 Sterile fluids shall be manufactured and controlled in accordance with the requirements of the Guide to Good Pharmaceutical Manufacturing Practice 1977, both with respect to the general principles of the Guide and the specific requirements of Appendix II pages 36 to 47.

2.1.2 Fluids shall be sterilised in their final containers (terminal sterilisation) where possible and manufactured in clean, but not necessarily aseptic areas, as described in the Guide referred to in paragraph 2.1.1.

2.2 Separation of blood components

2.2.1 The separation of blood components can be undertaken in multiple plastics bag systems or in single plastics bags, bottles or other separate containers.

2.2.2 Multiple plastics bag systems for the separation of blood components minimise the risk of microbial contamination by providing completely closed procedures until the blood products are administered.

No special environmental standards of processing are required for closed systems other than the usual standards of laboratory cleanliness and accepted rules of hygiene.

2.2.3 The use of single plastics bags, bottles or other single containers for the separation, transfer and pooling of blood components involves broaching or venting the containers and the systems are thereby open to atmosphere.

The pooling of plasma from separate containers is an open system.

2.2.4 Blood components separation or pooling by open systems shall be carried out under strict aseptic conditions as specified in the Guide to Good Pharmaceutical Manufacturing Practice. The separation or pooling of blood components by means of plastics packs with integral transfer lines shall be carried out as stated in WHO/BS/77.1144 para B.7.1 page 19.

2.2.5 The timing and method of separation (centrifugation, undisturbed sedimentation or a combination of the two) depends upon the blood components prepared from the given donation. When platelets or coagulation factors are being prepared separation of the components shall be performed as soon as possible after withdrawal of the blood from the donor.

2.2.6 If platelet concentrates are to be prepared by the "warm" system from a whole blood unit, the blood shall be kept at a temperature as close as possible to 20°C to 24°C until the platelet rich plasma is separated from the red blood cells.

2.2.7 Separation of blood cells by centrifugation shall be done in a manner that will not increase the temperature of the blood. Cells may also be separated by sedimentation, or by accelerated sedimentation.

2.2.8 The Guide to Good Pharmaceutical Manufacturing Practice, page 39 paragraph 12.28 recommends that for aseptic processing, articles to be handled in aseptic areas should be sterilised, and passed into the aseptic areas through double ended sterilisers sealed into the wall or by a procedure which achieves the same ends. Containers of blood and blood products cannot be sterilised in this way but the outsides of the containers should be as microbiologically clean as possible. To meet this requirement methods of dipping or spraying the containers may be required.

3. Processing of transfer sets and other components and assemblies

3.1 Transfer sets and other equipment components used in the separation procedures and which are processed in the transfusion centres shall be prepared and assembled under clean conditions as defined in the Guide to Good Pharmaceutical Manufacturing Practice.

Printed in England for Her Majesty's Stationery Office by
Hobbs the Printers of Southampton
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