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Essentials of Blood Banking & Transfusion Medicine

A Handbook for Students of Blood Banking and Clinical Residents

SR Mehdi

3rd Edition

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CHAPTER 18

Standards for Blood Banks

Based on the Guidelines of National AIDS Control Organization (NACO) of Ministry of Health, Government of India



Ministry of Health and Family Welfare
Government of India

NACO

NACO STANDARDS DGHS STANDARDS

Donor Selection

1.0 Donor Recruitment

1.1 Blood should be accepted only from voluntary, nonremunerated, low risk, safe and healthy donors.

1.2 Efforts should be directed towards encouraging and retaining adequate numbers of repeat donors. Donors should be appropriately recognized and felicitated for their contribution.

1.3 The blood bank should educate donors prior to collection of blood regarding the risk of transfusion transmissible infections.

2.0 Donor Selection

2.1 Predonation counseling by trained staff should be made available while maintaining privacy and confidentiality. Predonation information should include:

- Modes of transmission leading to risk behavior and self exclusion for patient's safety.
- Alternative testing site
- Tests carried out on donated blood
- Confidentiality of test results
- Need for honest answers in view of window period.

2.2 A questionnaire should be prepared in English and local languages which is simple and easy to understand to be answered by the donor.

2.3 For donors who are illiterate, assistance should be given by donor registration staff.

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2.4 Medical officer with MBBS qualification should be responsible for reviewing the donor's health conditions and performing physical examination of the donor.

2.5 Demographic details such as name and address of donor, date and time of donor selection and donation should be registered.

2.6 Consent should be obtained in writing from the donors after explaining the procedure, potential adverse reactions as well as the tests carried out on the donated blood.

3.0 Criteria for Selection of Donors

Following guidelines should be observed in order to determine that the blood donation will not be detrimental to the donors/recipients.

3.1 Physical Examination

A medical officer should certify the donor fit for blood donation.

3.1.1 General appearance: The prospective donor should appear to be in good health.

3.1.2 Age: Donors should be between the age of 18 and 65 years.

3.1.3 Hemoglobin or packed cell volume (hematocrit): The hemoglobin should be not less than 12.0 g/dL or the packed cell volume (hematocrit) should be not less than 36%. The screening should be carried out by using any appropriate and validated methodology. A more sensitive method of hemoglobin testing should be available as a reference or control.

3.1.4 Weight: Blood collection from donors weighing 45–55 Kg should be 350 mL blood and from those weighing 55 Kg and above should be 450 mL.

3.1.5 Blood pressure: The systolic blood pressure should be between 100 and 160 mm of mercury and the diastolic pressure should be between 60–90 mm of mercury.

3.1.6 Temperature: Temperature should not exceed 37.5°C/99.5°F

3.1.7 Pulse: Pulse should be between 60 and 100 beats per minute and regular.

3.1.8 Donor skin: The skin at the venipuncture site should be free of any skin lesion or scar indicative of addiction to narcotics or infection as well as marks of repeat venipuncture.

3.1.9 Examination of respiratory system, cardiovascular system and abdomen should be carried out if necessary.

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3.2 Medical History

3.2.1 Conditions that affect safety of donors: Before each donation questions should be asked to determine that the donor is in normal health and has not suffered or is not suffering from any serious illness, e.g., malignant disease, epilepsy, bronchial asthma, diabetes, excessive menstrual bleeding, cardiovascular conditions, renal disease, allergic diseases, abnormal bleeding tendency.

3.2.2 Pregnancy: Prospective donor should not be accepted during period of pregnancy and till 12 months after full term delivery and also during lactation. Donors who have abortions should be deferred till 6 months after 2nd and 3rd trimester abortion. Menstruation in itself should not be a cause for deferral.

3.2.3 Any donor who appears to be under the influence of alcohol or any drug abuse and who does not appear to be providing reliable answers to questions on their medical history should not be accepted.

3.3 Conditions that Affect Safety of Recipients

3.3.1 Any donor on antibiotic therapy or other medications should be deferred after evaluating his/her suitability as donor.

3.3.2 Infectious disease

3.3.2.1 Donors with a history of malaria should be accepted after 3 months.

3.3.2.2 Donors having history of jaundice should be deferred up to 1 year.

3.3.2.3 Donors having history of being HIV, HBsAg/HCV antibody positive should be permanently deferred.

3.3.2.4 Donors having intimate contact with HIV, HBsAg/HCV antibody positive individual should be deferred for 1 year.

3.3.2.5 Donors having history of measles/mumps/chickenpox should be deferred for 8 weeks.

3.3.2.6 Donors having history of influenza and upper respiratory tract infections (URTI) should be deferred till 1 week after treatment. Donors having history of diarrhea in preceding week particularly if associated with fever should be deferred.

B.3.3.2.7 For emerging potential transfusion transmissible infections, the guidelines published from central health authorities should be followed.

B.3.3.2.8 Private interview of each donor is essential to assess the risk of HIV infection due to high risk sexual behavior and unsafe sexual practice.

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B.3.3.2.9 Donors who give history suggestive of HIV infection such as; swollen glands persistent cough unexplained weight loss night sweats/ fever skin rashes and skin infections and prolonged diarrhea should be deferred permanently.

3.3.3 Vaccinations

3.3.3.1 Individuals who have taken vaccination against TAB/TT/ CHOLERA/HEPATITIA—should be accepted if free of symptoms. Those who have received hepatitis B vaccination should be accepted after 7 days of vaccination.

3.3.3.2 Yellow fever/measles/polio—should be deferred for 2 weeks

3.3.3.3 Rabies vaccination—should be deferred for 1 year. Those bitten by any animal should be deferred for 1 year.

3.3.3.4 Hepatitis B immunoglobulin—should be deferred for 1 year.

B.3.4 Aspirin Ingestion

B.3.4.1 Ingestion of aspirin or any-related medicine within 3 days prior to donation should preclude use of donor as a source of platelet preparation.

B.3.5 Surgical Procedures

B.3.5.1 Donors should be accepted 1 year after the recovery from major operations and 6 months after recovery from minor operations including acupuncture, tattooing and scarification.

3.5.2 Donors having history of receiving transfusion of blood or blood products should be deferred for 12 months DONATION INTERVAL. The interval between two blood donations should be at least 12 weeks. At least 48 hours must elapse after plasma pheresis or cytapheresis before whole blood is collected from a donor. Apheresis should be done only after 90 days of whole blood collection or in an event when red cells are not returned at the end of pheresis.

5.0 Information Provided to the Donors

5.1 Requirement of consent prior to blood donation, the consent of the donor should be obtained in writing with donor's signature or thumb impression after the procedure is explained and the donor is informed regarding testing of blood for all mandatory tests for safety of recipients. The donor should be provided an opportunity to ask questions and refuse consent.

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5.2 Postphlebotomy advice Donors should be given advice regarding postphlebotomy care and cautioned as to possible adverse reactions. This should also be displayed in the blood collection/observation room.

5.3 Information of Test Results

The medical officer of blood bank should inform the donor about any sero-reactive result of transfusion-transmitted infection (TTI).

Donors who are HIV sero-reactive should be referred to an integrated counseling and testing centre (ICTC) for postdonation confirmation and counseling.

5.4 Counseling and Referral

5.4.1 For ensuring blood safety, the blood banks should provide pre and postdonation counseling services.

5.4.2 All blood banks should train their donor organizers/medical officers to undertake counseling, besides appointing a donor counselor.

5.4.3 Donors should be referred to appropriate medical services for follow up and treatment whenever necessary.

5.4.4 For postdonation counseling on HIV, blood banks should have facilities of counseling in major blood banks, while other district level blood banks will avail the service of ICTC in their area. All blood banks should procure a list of ICTC from their respective state AIDS control societies.

Collection of Blood from Donors

1.0 Blood should be collected only by a licensed blood bank. Blood should be drawn from the donor by a qualified physician or under his/her supervision by assistants trained in the procedure. A physician should be present on the premises when the blood is being collected. Blood should be collected by single venipuncture and flow of blood should be continuous.

1.1 The blood donor area should be clean, congenial, comfortable and conveniently approachable. As the temperatures vary widely in different seasons, it is mandatory to have air-conditioned rooms to make the donor comfortable and to minimize chances of contamination.

2.0 Method

A strict standardized procedure should be in use to achieve surgical cleanliness for preparing venipuncture site to provide maximum possible assurance of sterile product.

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3.0 Equipment

The blood bags for collection of blood should be sterile, pyrogen free and disposable, with a closed system of collection as per standards provided by ISO/ISI. Multiple interconnected plastic bags should be used for blood component preparation (closed system). Venting of any container should be done under laminar airflow bench and such container should be used within 24 hours. To avoid venting in case of pediatric use, multiple interconnected closed containers should be used.

4.0 Anticoagulant Solutions

The anticoagulant solution should be sterile and pyrogen free. One of the following solutions should be used in the indicated volumes.

4.1 Citrate-phosphate-dextrose (CPD) solution: 14 mL of the solution is required for 100 mL of blood.

4.2 Citrate-phosphate-dextrose-adenine (CPD1) solution: 14 mL of the solution is required for 100 mL of blood.

4.3 100 mL SAM/ADSOL or any approved additive solution containing saline adenine and glucose (or with mannitol) is added to packed cells after separation of plasma for storage.

5.0 Volume of Blood

Volume of blood collected should be proportionate to the volume of anticoagulant, with ±10% variation and should not exceed 10 mL/kg body weight limited to a volume of 500 mL. Units of blood where volume collected is out of the permitted limits should not be used for transfusion. No attempt should be made to collect blood from such donor during the same session.

6.0 Samples for Laboratory Tests

The blood samples in the pilot tubes (clotted and anticoagulated) should be collected at the time of collection of blood by the same person who collects blood. They should be marked before collection to be identified with the unit of blood. The integral donor tubing of plastic bag should be filled with anticoagulated blood and sealed in such a manner that it will be available with segment numbers for traceability for subsequent compatibility tests.

7.0 Identification

Each container of blood/blood components/pilot tubes should be identified by a numeric or alpha numeric at the time of collection of blood,

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so that it can be traced back to the donor and also to the recipient. The segment number printed on the integral donor tubing should be recorded.

8.0 Temperature

Immediately after collection, the blood should be placed at 4–6°C + 2°C except if it is used for component preparation it will be stored at 22°C + 2°C until the platelets are separated.

9.0 Donor Reaction

Necessary drugs and equipment should be available for treatment of donor reaction if any. Donor collection staff should be trained in identification and management of donor reactions.

10.0 Therapeutic Phlebotomy

Therapeutic phlebotomy should be done only on the request of the patient's physician. The blood bank physician must decide whether to accept the responsibility of the patient. The blood collected in such circumstance should not be used for transfusion.

11.0 Outdoor Blood Donation Camps

11.1 Blood donation camps should be organized to augment blood stocks. Donor organizer/medical social worker of the blood bank should contact offices, institutions, industries, social and religious organizations, colleges and schools to collect need-based volume of blood from targeted group of donors located at a particular venue at regular intervals.

11.2 Adequate publicity and IEC material should be made available to the organizations.

11.3 The number of blood units collected should be commensurate with the actual requirement of blood units rather than by social or emotional pressures.

11.4 The donation site should be inspected prior to the day of blood collection to ensure availability of all facilities as prescribed by drugs and cosmetics rules.

11.5 The outdoor camp should be organized in an environment which is conducive and comfortable. The area should be cleaned before and after the blood collection.

11.6 Blood bank should maintain quality at each step from donor recruitment, selection and collection to the final product. The method of

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blood collection and management of donors should be the same as at fixed sites.

11.7 Blood and its components could contain infectious agents and hence these should be handled with precautions.

11.8 Large Camps: The large camps organized on a day should be planned as per criteria laid down by the Drugs and Cosmetics Act. All quality measures and predonation counseling procedures should not be compromized.

Testing of Donated Blood

1.0 Determination of ABO Group

ABO group should be determined by testing red cells with anti-A, anti- B, anti-AB reagents (by tube or microplate method or gel technology by any validated manual or automated methods) and by testing serum or plasma for expected and unexpected antibodies with known type A, B and O pool cells/panel cells if available. For each group a pool of three different cells should be used. The blood should not be released until any discrepancy, if found, is resolved.

2.0 Determination of Rh(D) Type

The Rh(D) type should be determined with anti-D reagent from two different sources using a validated method. It is preferable to use one IgM and other a blend, i.e., IgM + IgG. If blood is typed as negative it should be tested to detect 'Du'/weak D using IAT method. When the test for D or 'Du' is positive, the label should read 'Rh(D) positive. When the test for D and 'Du' is negative, the label should read 'Rh(D) negative'. Testing with anti-CDE should not be routinely required.

3.0 Previous Records

A donor's previous record of ABO and Rh(D) type should not serve as identification of units of blood subsequently given by the same donor. New determination should be made for each collection. Discrepancy with previous record should be investigated and resolved.

4.0 Tests for Detecting Unexpected Antibodies in Serum

Serum or plasma from donors should be tested for unexpected antibody/ies with pooled O Rh(D) positive cells or preferably screening cell panel using albumin/enzyme/indirect AHG test which can identify clinically significant antibodies.

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4.1 Blood in which such antibody/ies are found, should be used as packed cells only.

4.1.1 Any component with cold antibody should be transfused only with special instructions to warm before transfusion.

4.1.2 If warm allo-antibody is present only packed cells should be used for transfusion under observation.

4.1.3 In case when warm auto-antibody is present least incompatible blood should be used, depending on patient's clinical condition, necessitating transfusion.

5.0 Laboratory Tests for Infectious Diseases

All mandatory tests should be carried out on blood samples in pilot tubes taken at the time of collection. The whole blood or components from any unit that tests positive should be discarded.

5.1 Test for syphilis each donation of whole blood should be subjected to a serological test for syphilis by VDRL/RPR Method/TPHA.

5.2 Test for viral hepatitis A test for hepatitis B (HBsAg) and hepatitis C (anti-HCV) by ELISA/Rapid test which is a validated method should be done on each unit of blood. Any technology with similar or higher sensitivity may be used additionally to improve blood safety.

5.3 Screening for HIV antibodies: All blood units collected should be tested for HIV-1 and HIV-2 antibodies using ELISA/Rapid, which is a validated method. Any alternative technology with similar or higher sensitivity may be used.

5.4 Test for malaria: All blood units should be tested for malarial parasites using a validated and sensitive antigen test.

6.0 Quarantine Storage

The whole blood or components should not be issued for transfusion, till the mandatory tests are completed and reported as nonreactive. In order to ensure this procedure, the untested blood should be kept in quarantine storage. The units which test reactive in any test should be segregated immediately and kept in a separate quarantine area till sent for disposal. It is preferable to use biohazard labels.

7.0 Sterility

Each donation of whole blood or its component intended for transfusion constitutes a single batch. The sterility of the blood should be checked on

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1% of the blood units collected or 4 per month whichever is higher. The sterility test should not be done by a method that entails breaching the final container before the blood is transfused. The blood sample from the tubing attached to the container should be used for sterility testing, i.e., culture at 4°C, 22°C and 37°C.

8.0 The blood bank should establish a procedure to identify a recipient of a transfusion of blood from a donor who is subsequently found to have been infected with transfusion transmissible infection. In case this happens the blood bank should inform the patient's physician. Appropriate record of such events should be kept. The unused components from this unit should be discarded.

Preparation of Blood Components

1.0 General Principles

1.1 Sterility: The sterility of all components should be maintained during processing by the use of aseptic methods and sterile pyrogen free disposable bags and solutions.

1.2 Seal blood bags that allow transfer of component without breakage of the seal (closed system) should be recommended. If the seal is not broken, the viability and stability of the component is assured. The seal will not be considered broken if a sterile connection device is used resulting in a closed system.

1.2.1 If the seal is broken during processing, components stored between 4°C + 2°C must be transfused within 24 hours and component stored between 22°C + 2°C should be transfused as early as possible and not beyond 6 hours.

1.2.2 Once the frozen components are thawed, these should be transfused at the earliest and positively within 6 hours.

1.2.3 At the time of preparation of the final components the integrally connected tubing should be filled with aliquot of the components and sealed in such a manner that it should be available for subsequent compatibility and assay testing if needed.

1.3 A process of feedback should be in place with the clinician in order to periodically assess the efficacy of all blood components.

2.0 Red Blood Cell Components

2.1 Red blood cells: Red blood cell concentrate should be prepared from the whole blood collected in plastic bags, preferably in double or multiple

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plastic bags system. Plasma is separated from red blood cells following either centrifugation or undisturbed sedimentation at any time before the expiry date of blood. If closed system is in use, the expiry date of red cells should be the same as whole blood. The hematocrit of packed cells should be adjusted so that it is not more than 70%.

2.2 Washed red cells: Red blood cells should be washed with normal saline by automatic cell washer or manually by centrifugation. The cells should be washed 2–3 times with normal saline by centrifuging at 4°C ±2°C. A laminar bench that is validated from time to time should be used. Closed system of washing is recommended.

2.3 Leukocyte depleted red blood cells: Leukocyte depleted red blood cells concentrate should be prepared by a method known to reduce leukocytes in the final component to less than 5×10^8 when intended to prevent febrile reactions and to less than 5×10^6 when it is required to prevent alloimmunization or CMV infection. For achieving a level 5×10^6, use of leukocytes filter is necessary.

2.4 Frozen and deglycerolized red blood cell concentrate: Red cells should be stored frozen continuously at low temperature of -80° to -196°C in the presence of cryoprotective agent. The red cells should be washed to remove the cryoprotective agent prior to transfusion.

2.4.1 The method of preparation, storage, thawing and washing should ensure a recovery of at least 80% of original red cells or larger depending on the procedure in use.

2.4.2 Red blood cells should be ordinarily frozen within 6 days of collection of blood and can be kept frozen up to 10 years.

2.4.3 The cryoprotective agent in most common use is glycerol. The concentration of glycerol used should depend on the storage temperature.

3.0 Platelet Concentrate (Random Donor Platelets)

Platelet concentrate should be prepared by centrifugation of a single unit of whole blood collected with a smooth venipuncture and a continuous flow of blood.

3.1 Platelet concentrate should be separated from whole blood within 8 hours of collection by centrifugation at 22°C + 2°C using either platelet rich plasma (PRP) or buffy coat (BC) method, which is validated.

3.2 Platelet concentrate prepared from whole blood (450 mL) should contain a minimum 4.5×10^{10} platelets and from 350 mL whole blood minimum of 3.5×10^{10} platelets in at least 75% of units tested on storage from 1% of total prepared or 10 units every month whichever is

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higher. It is recommended that only 450 mL bags are used for platelet separation.

3.3 Platelets should be suspended in approximately 50 mL of plasma and stored at 22°C + 2°C. The pH at storage temperature should not be lower than 6.0 at the end of storage period.

3.4 Continuous gentle agitation (60–70 oscillations/per min) using horizontal agitator or a rotor with 5–10 cycles/minute should be maintained throughout the storage period varying from 3–5 days depending on the nature of plastic of the bag in use considering day of blood collection as day zero.

3.5 There should be no grossly visible platelet aggregates during the storage. Swirling phenomenon should be checked before issue.

3.6 The concentrate prepared should not be contaminated with red cells. The degree of reddish tinge of the concentrate indicates red cell contamination. The units contaminated with red cells should be used as group specific.

3.7 1% of all platelet concentrates prepared should undergo tests for bacterial detection by a validated method as part of routine quality control.

3.8 Leukocytes reduced platelets: Platelets prepared by buffy coat method should contain 5×10^8 leukocytes. To achieve a level of d" 5×10^6 leukocytes, platelets should be filtered using leukocyte filters.

4.0 Granulocyte Concentrate

4.1 Use of unit of granulocytes prepared by use of cell separator should have 1×10^{10} leukocytes and should be kept at 22°C+ 2°C for a maximum period of 24 hours.

5.0 Plasma

5.1 Single donor plasma: Plasma should be separated from whole blood at any time up to 5 days after the expiry of the whole blood. The plasma separated after 5 days of expiry date will be used only for fractionation.

5.2 Fresh frozen plasma: Fresh plasma should be separated from the whole blood not later than 6–8 hours of collection and frozen solid at –30°C or lower as early as possible. Prior to infusion the frozen plasma should be thawed rapidly at 30–37°C in a water bath with shaker. Once thawed it should be used within 6 hours.

5.2.1 Fresh plasma should contain a minimum of 0.7 IU of F VIII per mL in at least 90% of units tested (1% of total manufactured) or 10 units/month whichever is higher.

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Essentials of Blood Banking & Transfusion Medicine

Salient Features

- This 3rd edition has been thoroughly revised and updated with inclusion of MCQs at the end of every chapter, which is a must to refresh the knowledge of the students.
- Those who are planning to establish a blood bank or are already in this business shall find the guidelines in the chapter on standards of blood bank, incorporated from NACO, which is a boon for them.
- The dedicated chapters of Obstetrics and Gynecology and Pediatrics are an asset to the residents as it has been observed that the residents of these specialties find it very challenging to advise the proper blood product to their patients.
- For the UG and PG students of Pathology, the blood banking is almost a neglected subject, completely overshadowed by Histopathology, Cytology, and Hematology. This edition shall definitely enhance the knowledge of theory and practical of blood banking of these students.
- The technicians are the backbone of the blood bank. They must be updated with the latest equipment and techniques. They pick up their knowledge and skill of the subject during their teaching and training of DMLT and BMLT. Their theory and practical examination in blood banking are more comprehensive and exhaustive than the students of MBBS. The book is designed keeping in mind the students of these technical courses as well.
- The other advantage is that the book is very handy and can be used as a manual of blood banking and transfusion medicine.

SR Mehdi pursued his UG and PG degrees from Jawaharlal Nehru Medical College (JNMC), AMU Aligarh, Uttar Pradesh, which consistently remains one of the top medical colleges of India. Subsequently, he joined the Department of Pathology of JNMC as faculty where he was assigned the duty of in-charge of the Blood Bank. Because of his own interest in the subject and encouragement from the administration in the early 90s, he took the responsibility of upgrading the blood bank of JNMC. He had to make several visits to the offices of the Ministry of Health (MOH) and National AIDS Control Organisation (NACO) at New Delhi. By the virtue of being the in-charge of the blood bank, Dr Mehdi attended many training sessions and workshops organized by Uttar Pradesh State Aids Control Society (UPSACS), at different places. He was also appointed as the coordinator of the Training of Trainers (TOT) program of UPSACS on AIDS. His job was to train the physicians of the district hospitals of the western UP in workshops on Blood Banking and AIDS. During his stay in Saudi Arabia, being the in-charge of a very advanced blood bank of a teaching hospital, Dr Mehdi had an opportunity to learn the latest techniques on the state-of-the-art equipment. There he was exposed to the Apheresis technique. After joining the Era Medical College, Dr Mehdi applied his experience of blood banking in imparting the knowledge to the UG and PG students of Pathology and on training the technicians. He brought an Apheresis Machine in the Era's blood bank and trained his PG students on Apheresis. During this period, Dr Mehdi had published the first two editions of this title which got good response from students not only in India but also in Saudi Arabia. The broad coverage and circulation of Jaypee Brothers Medical Publishers was instrumental in the circulation of the book.

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