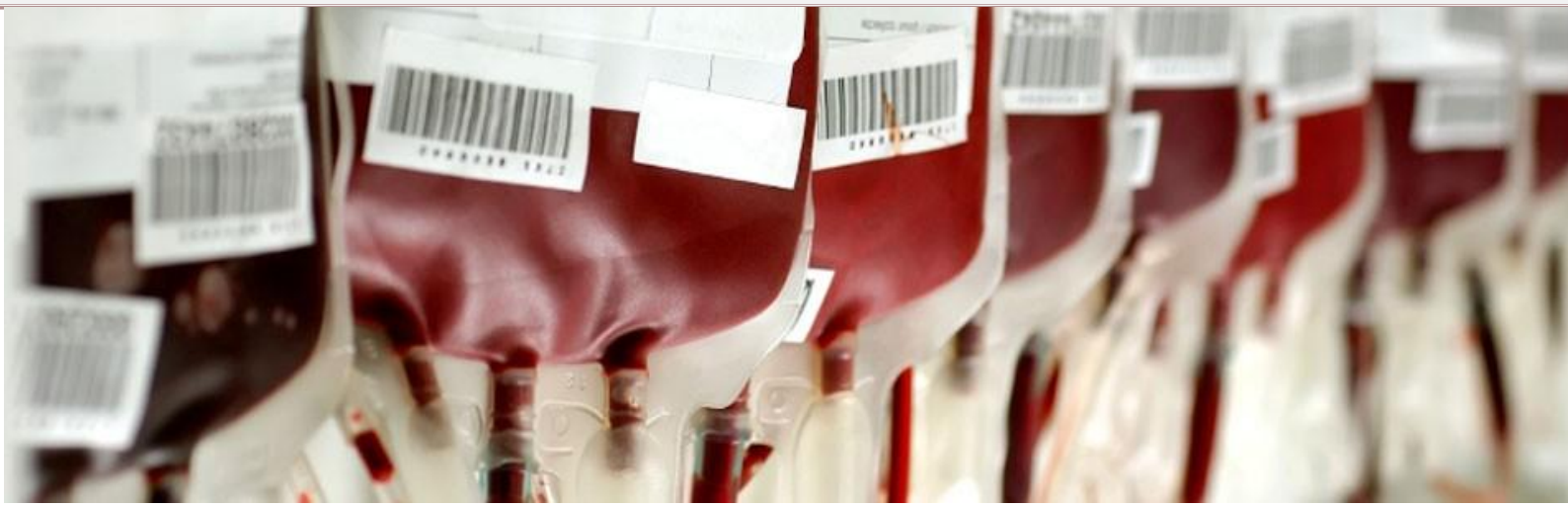
Punjab Blood Transfusion Authority

Government of the Punjab, Health Department

STANDARDS AND GUIDELINES FOR BLOOD ESTABLISHMENTS PUNJAB



PUNJAB BLOOD TRANSFUSON AUTHORITY

HEALTH DEPARTMENT

GOVERNMENT OF THE PUNJAB

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ACKNOWLEDGEMENT

Blood transfusion is an essential part of any health care system. Used correctly, it can save lives and improve health. Blood transfusion services in Pakistan are fragmented with a wide diversity in the quality and range of services provided. There has been growing awareness about quality in blood transfusion services, which has the objective of ensuring that only those blood components which fulfill the desired standards in terms of efficacy and safety are provided to patients. Keeping in view the vital importance of strict quality assurance at each stage of the vein to vein transfusion chain, the Punjab Blood Transfusion Authority has developed minimum standards and guidelines for blood establishments.

Originally prepared by GIZ Health Sector Support Program, the document has been adapted to the requirements and needs of the Punjab Blood Transfusion Authority. The Authority is indebted to GIZ and the Task Force (Col. Nuzhat Mushahid, Col (R) Farooq Khattaq, Prof. Fazle Raziq, and Dr.Sartaj Khan) for developing the original document. The Authority would also like to acknowledge the Technical Advisory Committee of the Punjab Blood Transfusion Authority for their efforts in reviewing and approving the document. In addition, the Authority would also like to extend its deepest gratitude to Dr. Saba Jamal and Dr. Javeria Aijaz for providing valuable suggestions for improving and adapting this document to the requirements of the Punjab Blood Transfusion Authority.

We sincerely hope that this document serves the purpose for which it was developed – standardization and quality in blood transfusion services in Punjab. While this document is developed to the best of the efforts and knowledge of the Authority, any suggestions for improvement, from any quarter, for future editions would be of utmost value.

Lahore, Punjab, June 2015

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PART I

1. DEFINITIONS

1.1 Blood Establishment: A ‘Blood Establishment’ is any registered body carrying out any of the processes in the vein-to-vein transfusion chain.

1.2 Vein-to-vein transfusion chain: All procedures from the selection of blood donors to the transfusion of blood are included in the vein-to-vein transfusion chain.

1.3 An ‘administrator’ is any person with the administrative responsibility for the operations of a blood establishment. An administrator may or may not be a medical doctor.

1.4 An ‘in-charge’ is a medical doctor appointed to supervise operations of the blood establishment.

2. INTRODUCTION

Standards are published documents that establish specifications necessary to ensure the reliability of the materials, products, methods, and services. In blood banking, standards are necessary to ensure blood safety. Adoption of standards may be voluntary or mandatory, depending on the circumstances. If adoption of standards is incorporated into law by the government, their implementation becomes obligatory. On the other hand, if not included in the law, a set of standards may be adopted for voluntary accreditation with certain organizations (e.g. ISO).

The standards included in this document provide a framework for the implementation of Blood Safety Laws in Pakistan. The document contains standards which are considered absolutely essential for licensing of blood establishments, and hence will be used by the Blood Transfusion Authorities to prepare inspection checklists, as well as evaluation and licensing criteria.[1]The primary intent of this document, therefore, is to define the essential criteria, all of which must be fulfilled if any Blood Centre is allowed to operate.As to Blood establishments, these general standards require that everyCentrehave policies, processes, and procedures to meet the specifications included in the document. Some guidelines, in this regard, are also elaborated with the standards, while chapter 4 of this document elaborates the essential documentation that all blood establishments must develop to meet the standards.

Since blood establishments in Pakistan are working at different levels in terms of the quality of services provided, this document, as already mentioned,lays down the minimum essentials for conducting basic blood banking operations with acceptable level of safety for donors and recipients. It is recognized that there are many state-of-the-art blood establishments in Pakistan participating in voluntary accreditation programmes with reputable international organizations. The intent, therefore, is not to reinvent the wheel but to develop standards which are considered as most essential and mandatory for blood safety, and hence compulsory for every blood establishment in Pakistan. Undeniably, any blood establishment with sufficient resources regarding infrastructure, equipment, reagents or human resource may target achieving any set of international standards, providing they add to and not deviate from these minimum standards for Pakistan. This will not only enhance blood safety in their settings, but will also help them to become model centres for rest of the country.

[1] The 'Functional Brief for Blood Transfusion Authorities' also includes a template inspection checklist.

3. REVISION OF STANDARDS-CHALLENGES & STRATEGIES

The Blood Transfusion Services in Pakistan are essentially fragmented with a wide diversity in the quality and range of services provided. According to estimates there are more than 1800 blood establishment in Pakistan. Most of these blood establishments are not regulated and are neither following any standards. Blood Banking and transfusion services are being offered by many public, armed forces, private and nongovernmental welfare organizations. Some coordination of public sector blood banking services structure is found in the province of Punjab only, which currently is unable to cater for the demand of all of the public sector blood establishments.

Under such circumstances, the documentation of standards is challenging. The target would be to achieve a balance between the capacities of the under-resourced establishmentswithout compromising the quality of the services provided. With this target ahead, the National Steering Committee[2], during its second meeting held in June 2010, decided to revise the existing National Standards and Guidelines and formulated a Task Force (1) for this purpose.

While lack of baseline national data limits the capacity to alter international standards and guidelines on the basis of objective evidence, an effort has been made to keep the local circumstances under consideration while revising guidelines. The experience of Task Force members in the field of blood banking and transfusion medicine in Pakistan was extremely valuable in this context.The existing set of National Standards and Guidelines[3] was used as a baseline for modifications, additions or deletions, as may be necessary.

For the Blood Establishments primarily involved with blood collection, only sections on the collection, labelling, record keeping and distribution of blood will apply whereas for some Blood Establishments involved in collection, processing and distribution of blood, all the relevant sections will apply. The standards pertaining to component preparation and storage apply only to establishments having facilities for these.

The qualification and relevant experience of staff entrusted with blood transfusion varies considerably between different blood transfusion services. Therefore, standards pertaining to the ‘immediate supervision’ of the facility have highlighted the need of supervision, without mentioning the qualification. The purposeis to make the initial implementation of minimum standards across the country possible. With the anticipatedimprovements in education, qualification and service structure of human resource associated with transfusion, addition to

[2]A National Steering Committee, headed by the Federal Secretary Health has been constituted to eliminate overlapping in the Safe Blood Transfusion programme activities and to oversee implementation of the programmes.*Source: Federal PC-1.*

[3]The first edition of the Standards and Guidelines for Blood Transfusion Services was published by the Ministry of Health, Government of Pakistan in August 1999. It was compiled by a team comprising senior members of Pakistan Society of Haematology, the programme managers of Blood Transfusion Services from all the provinces of Pakistan, officers of the National AIDS Control Programme and the WHO representative in Pakistan at that time. A major portion of the first edition of ‘National Standards and Guidelines for BTS in Pakistan’, was, however, adopted as such from the latest edition of ‘Guidelines for BTS in the UK’ at that time. The approved National Standards and Guidelines, despite being widely distributed, remained un-implemented. Lack of a reflection of the local perspective seems to be an important reason for their non-implementation, while there may also be organizational, systemic and regulatory issues.

these standardsin the form of required qualification and work experience of staff will be feasible.

The procurement of TTI screening kits procurement must be based on internationally accepted evaluation procedures.In view of the prevailing lack of proper TTI testing in most facilities, resulting in lack of blood safety, the section on the testing of blood donations has given a relatively comprehensive description of the procedures that must be in place for the purchase of screening kits. The implementation of these procedures will not only ensure that the evaluation of screening kits is carried out by qualified personnel but will also make the entire process transparent and simple for blood establishments.

Dearth of qualified and trained staff makes the use as well as the comprehension of existing guidelines difficult. To enhance the comprehension of these guidelines, the structure has been altered to separate the minimum essential standards, obligatory by the legislation of Pakistan, from the operational guidelines on the methods of achieving those standards which might be helpful but not obligatory by law.To enhance comprehension of the document, the language has also been simplified, wherever possible, by splitting long sentences into shorter phrases.

Financial limitations may prevent some centres from performing some of the procedures included in the existing standards and guidelines. Therefore, the standards in this document have included only the minimum essential standards, necessary for blood safety and obligatory by the legislation of Pakistan. Where appropriate, relevant international developments, occurring since the publication of the last guidelines, have also been included. In general, therefore, this document is intended to be simple, easily comprehendible and implementable.

4. STRUCTURE AND USE OF THE DOCUMENT

Each chapter of the document is divided into two sections. Section A states the minimum standards that have to be met by all centres on which these are applicable, irrespective of the scope and facilities available with them, whereas Section B comprises guidelines that clarify the intent of standards and include recommendations on how to implement technical requirements. In order to understand what is meant by standards and guidelines, these are defined so that authors and users are on the same page.

A “standard” is collection of system specific requirements that must be met by everyone under all circumstances. “Guidelines” are collection of procedure specific instructions/suggestions that may be used to meet the standards. These are not binding and any other procedures than those stated in the guidelines can be adopted to meet the standards. The standards have scientific basis and are sometimes based on the best judgment of experts. Inorder to keep the text brief, the explanation of the basis may not be given with each standard. There are many, easily and widely available text books on blood banking and transfusion medicine, explaining such scientific basis which may be used for reference.

There can be variety of procedures which can meet the standards e.g. for the standard that male donors should have hemoglobin of at least 13 g/dl before donating blood, there is no compromise on this minimum limit of hemoglobin, while taking routine donation from a male donor. The procedure adopted to ascertain the concentration of hemoglobin in the donor, however, can be chosen from any of following methods:

1. Cu SO4 solution based estimation based on the principle of specific gravity.
2. Photometric based methods like haemocue or other spectrophotometer methods which test cyanamethemoglobin.
3. Haematocrit based methods.
4. Automatic haematology analyzers using various principles of estimating hemoglobin.

The procedure adopted is left to the discretion of the user. Irrespective of the procedure adopted, however, the standard has to be met universally.The guidelines on the procedure details are usually found in many standard textbooks of the specialty along with the applicable quality control procedures for ensuring satisfactory test performance.

Every effort has been made to take all existing technologies into account. Under some circumstances, however, the manufacturer’s directions for the use of a device or the requirements for its use may be more proscriptive or even in conflict with the requirements contained in this document. In these cases, the device or material should be used in accordance with the manufacturer’s directions.

Since the standards and guidelines have been separated, the paragraphing and numbering scheme has been adapted to the structure of the document. The prefix ‘S’ has been added to the numbering of ‘standards’, whereas the prefix ‘G’ has been added to the numbering of guidelines. The standards are appropriately cross-referenced with the guidelines.

PART II

1. MANDATORY DOCUMENTATION AND GENERAL REQUIREMENTS

Section A

Section A states the minimum standards that have to be met by all centres on which these are applicable, irrespective of the scope and facilities available with them.

S.1.1 Each blood establishmentshall prepare documents pertaining to all operations of the blood establishment.

S.1.2 The mandatory documents include standard operating procedures (blood collection, production, TTI screening, grouping, cross-matching, issue protocols), forms (including donor history and examination form; worksheets used for various blood establishment procedures. e.g. blood grouping, cross-matching, blood request form, final disposition form, form for reporting of adverse transfusion reactions), list of blood establishment staff with qualifications and experience(including phlebotomists – blood collection staff, serology staff, and a medical doctor as a minimum), photocopies of educational credentials of the blood establishment staff, and adverse transfusion reaction record, duty roster of blood establishment staff, and minutes of meeting of Hospital Transfusion Committee (Hospital Transfusion Committees are only to be established in facilities where transfusions are taking place). All documents must be in conformance with standards prescribed by the Authority.The procedures manual must cover all activities in the establishment. [4]

S.1.3 A copy of the procedures manual shall be issued to all staff/sections involved in session's procedures. Measures should be instituted to ensure that procedures are regularly updated.

S.1.4 The blood establishment in-chargeis responsible for providing templates of all forms used in blood establishment operations. These should be revised whenever needed,in consultation with Hospital Transfusion Committees.

S.1.5 Procedures (Standard Operating Procedures) must be written in a manner that all staff in the establishment are able to understand and implement them.

S.1.6 The service area of a blood establishment must be capacious, neat and clean. Directional signs should be given for facilitation.

S.1.7 There must be designated areas for each process carried out in the blood establishment (e.g. donor management;testing of blood and processing of blood; storage of blood).

S.1.8 A blood establishment must be supervised by an appropriately qualified haematologist/blood bank specialist/pathologist,or medical doctor (MBBS or equivalent as recognized by PMDC) trained in blood transfusion services.

[4] Cf. guideline G.1

S.1.9 Donor selection shall be done by a medical doctor (MBBS or equivalent as recognized by PMDC).

S.1.10 All areas in a blood establishment shallbe manned by qualified and skilled staff(laboratory technologists or technicians).

S.1.11 The in-chargeof the blood establishment will take ultimate responsibility for all the procedures carried out in the establishment.

S.1.12 The blood establishment's administrator is responsible for procurement and provision of the mandatory equipment for all procedures carried out in the blood establishment.

S.1.13 The administrator is also responsible for ensuring that standard operating procedures covering all aspects are prepared and implemented in the establishment.

S.1.14 Relevant data from each blood establishment, as specified by the Blood Transfusion Authority, must be provided to the Authority at quarterly intervals. These data include:

(a) Number of blood collections/year
(b) Number and distribution by type of blood components produced/year
(c) Number and distribution by type of transfusion transmissible infections detected/year
(d) Number and distribution by type of adverse transfusion reactions/year in patients

S.1.15 The following mandatory equipment for each of the processes in a blood establishment must be available and in working order.

(a) Blood Collection: Mixer/scale for blood collection, tube sealer, tube stripper, weighing scale, equipment/reagents for Hb testing (copper sulphate, haematology analyser, haemoglobinometer), red cell transport box with eutatic plates (if blood collection is being done in camps, away from the blood establishment).
(b) Blood Testing: Equipment for testing of blood donations for the 5 mandatory transfusion transmissible infections, water bath/heat blocks, refrigerator (for kits, antisera storage), serofuge, agglutination viewer, bench top centrifuge.
(c) Blood Storage: blood bank cabinet

S.1.16 Blood establishments shall implement a system for the identification of every single blood donation, every single blood unit and components thereof, allowing full traceability to the donor as well as to the transfusion and its recipient.

S.1.17 The waste disposal practices at the blood establishment shall comply with the national laws, rules, regulations, and standards (available at http://environment.gov.pk/act-rules/rHWMRules2005.PDF, and other relevant).

S.1.18 Safety disposables and supplies (e.g gloves, bio-hazardous waste disposal containers) must be available and in use.

S.1.19 A needle stick injury protocol must be available.

Section B

Section B comprises guidelines that clarify the intent of standards and include recommendations on how to implement technical requirements.

G.1 The four tiers of documents and their examples are as follows:

G.1.1 First Tier Documents

G.1.1.1 These include the policy statements for blood establishments. Example: “blood centre“xyz” will undertake whatever is possible to collect blood while ensuring donor safety, and issue safe blood and blood components in timely and equitable manner to all the recipients having a rational, documented requirement of blood.”

G.1.2 Second Tier Documents

G.1.2.1 The second tier documents broadly outline the processes being carried out in blood centre. A process is a group of procedures, completing one activity. As an example, some of the ‘processes’ carried out in a blood centreare given below. The number of processes in any particular blood centremay be greater or lesser than what are enumerated, depending on its capacity, scope and need.

(a) Collection of Blood

(b) Component preparation and storage

(c) Donor testing

(d) Blood transfusion prescription

(e) Serologic testing (grouping, x-match, antibody screening)

(f) Issue of blood

(g) Blood administration and monitoring

(h) Adverse effects of transfusion and workup

(i) Staffing and procurement for blood centre and transfusion services

(j) Audit of transfusion practices by hospital transfusion committee

G.1.3 Third Tier Documents

G.1.3.1 Third tier documents are those that cover the comprehensive operational details to carry out procedures under each of the processes. The example of the “topics” of procedures that have to be written in detail are given below. These can also be used as training material before the induction of new staff in the blood centre.As an example, the procedure documents (SOPs) that may be required as per scope of the blood centre for three processes: donor management, collection of donation and transfusion transmissible infections screening are given below.

(a) Donor Management

i. Reception of donor
ii. Haemoglobin screening
iii. Pre-donation counseling
iv. Medical Interview
v. Physical Examination

(b) Collection of Donation

i. Inspection of blood bags and labelling
ii. Preparation of the venepuncture site
iii. Phlebotomy and collection of whole blood donation
iv. Collection of blood components through apharaesis
v. Collection of blood samples
vi. Post donation care/refreshments
vii. Management of adverse reactions
viii. Documentation of adverse reactions

(c) Transfusion Transmissible Infections Screening

i. Reception of blood samples
ii. Testing for HBs Ag
iii. Testing for HCV antibodies
iv. Testing for HIV antibodies
v. Malarial parasite detection
vi. Reporting of results

G.1.4 Fourth Tier Documents

These are the templates of actual forms/slips/chits etc. that are used while carrying out the transfusion processes.

2. SPECIFICATIONS OF DONOR SESSIONS AND SELECTION OF DONORS

Section A

Section A states the minimum standards that have to be met by all centres on which these are applicable, irrespective of the scope and facilities available with them.

S.1 GeneralConsiderations

S.1.1 Donor registration

S.1.1.1 All potential donors must be registered with the following information:

(a) full name (correctly spelt)

(b) age

(c) CNIC number. If the CNIC number is not available (e.g. in case of foreigners and refugees) any other appropriate identification number must be used.

(d) contact details (email address and/or mobile phone number and/or postal address)

S.1.1.2 A unique donor registration number should be generated for every donor, which will be unique for the life of the donor.

S.1.1.3 Each donation must be identified with a unique donation number which must appear on the blood bag and on the secondary sample tubes for laboratory testing.

S.1.2 Pre-donation education and consent of the donor

S.1.2.1 All prospective donors must be provided information,in a suitable language,about the natureof the donation process, the associated risks involved, the health check and other relevant medical information.

S.1.2.2 Donors must be made aware that recipients are at risk from transfusion if the donor has some high-risk behaviour.

S.1.2.3 It must be ensured that donors understand any information (e.g. pre-donation education material) and questionnaire presented to them.

S.1.2.4 Donor informed consent must be obtained in written form before donation.

S.1.3 Premises

The premises of blood donation sessions should be comfortable, clean, well-lit, airy and spacious.

S.2 Selection of donors

S.2.1 Application of donor selection criteria

S.2.1.1 The criteria for selection of blood donors apply equally tovoluntary donors of whole blood and to aphresis donors.

S.2.1.2 Replacement/directed donations shall be discouraged.

S.2.1.3Donations from paid/professional donors are prohibited by law.

S.2.2 General criteria of donor/donation selection

S.2.2.1 Donors who are drivers, heavy machine operators or aircrew must donate only on a non-working day.

S.2.2.2 Blood from patients referred for therapeutic venesection must be discarded.

S.2.2.3 The criteria for autologous donations should be decided between the treating clinician and the medical officer of the blood centrefor each individual patient and be documented.

S.2.2.4 During dengue epidemics, donors should have complete blood counts before donation. If the platelet count is low, they should be deferred for 4 weeks.

S.2.3 Medical assessmentof donors

S.2.3.1General Considerations

(a) A medical assessment of each donor must be carried out before donation.

(b) The medical assessment must include the relevant medical history, physical examination and haemoglobin estimation.

(c) Each blood centre/transfusion service must develop its donor history questionnaire and use the questionnaire to record findings.

(d) Donor privacy and confidentiality must be ensured during medical assessment.

(e) Only donors who appear healthy and well should be selected for donation.

(f) The person undertaking the medical assessmentmust be trained toutilize accepted guidelines on the selection of blood donors.

(g) The medical assessment record shall be signed by the doctor in-charge.

S.2.3.2 Medical history

(a) Donor deferral due to medical conditions

(i) Donors having a history of any of the following within the previous one year must be deferred for another one year:
   (a) jaundice
   (b) blood transfusion
   (c) major surgery
   (d) invasive dental treatment

(ii) Donors having a history of/suffering from any of the following must be permanently deferred:
   (a) Hepatitis B
   (b) Hepatitis C

(c) HIV
(d) Syphilis
(e) Cardiovascular diseases
(f) Central nervous system diseases
(g) Malignancy
(h) Insulin dependent diabetes mellitus
(i) Chronic respiratory diseases
(j) Chronic renal diseases

(iii) Pregnant and lactating women should not donate blood, unless there is a neonatal consideration.

(iv) All donors who are currently undergoing medical investigations or have been referred for a specialist opinion should be advised not to donate blood until investigations are complete.

(b) Donorson anti-platelet drugs

If the donor has taken drugs affecting platelet function (e.g. aspirin) within the last 5 days, the donations should not be used for the preparation of platelets. A list of all such drugs should be made available to staff at blood collection sessions by the In-charge of the blood centre.

(c) Inoculations and immunizations

The medical officer in-chargeis responsible for assessing the suitability of the donor, in accordance with the literature given with the vaccine.

(d) Age of donors

(i) The minimum age of donors is 18 years.

(ii) The upper age limit for first time donors is 60. There is no upper age limit for regular donors.

(e) Donation interval

The minimum interval between donations is 3 months for males and 4 months for females.

S.2.3.3 Weight of donors[5]

(a) The minimum weight of donors is 50 kg for a standard blood donation.

(b) Necessary blood volume calculation should be made for donors weighing less than 50 kg.

[5] Cf. guideline G.1

S.2.3.4 Haemoglobin estimation[6]

The haemoglobin of male donors must be at least 13.0 g/dL, of female donors at least 12.5g/dL.

S.2.4 Selection criteria for apheresis donors

S.2.4.1 For donors between 50 and 60 kg in weight, the extra-corporeal volume (ECV) must be calculatedand never exceed 15 % of the total blood volume.

S.2.4.2 The minimum pre-donation platelet count must be 150 x 10^9/Lthe predicted post procedure platelet count must not be less than 100 x 10^9/L.

S.2.4.3 For the collection of double units of red cells by apheresis, male andfemale donors must be greater than 70 kg in weight.

S.2.4.4 The haemoglobin level to donate double units of red cells must be 14.0 g/dL for both males andfemales.

S.2.4.5 A donor should not undergo a total of more than 24 plasma/plateletpheresis procedures per annum. There shouldnormally be a minimum of 2 weeks between plateletpheresis procedures.

S.2.4.6 Not more than 15 litres of plasma should be donated by one donor in a year.

S.2.4.7 Not more than 2.4 litres of plasma should be donated by one donor in any one-month period.

S.2.4.8 After a whole blood donation, or the loss of an equivalent number of red cells during an apheresis procedure,a donor should not normally donate plasma or platelets for a period of four weeks.

S.2.4.9 The inter-donation interval for regular donation of double red cells by aphaeresis should not be less than (6 months).

S.3 Collection of blood donation

S.3.1 Donor arm preparation procedure must be in place and internationally recommended disinfectants must be used.[7]

S.3.2 Blood collection shall be by aseptic techniques using a sterile closed system and a single venepuncture. The integrity of the system must be checked prior to use and measures must be taken to prevent unsterile air entering the system

S.3.3 It must be ensured that only intact, in date blood bags without any moisture when unpacked are used.

S.3.4 The maximum volume of whole blood collected from the donor must not exceed 450 ±45 ml (including the blood samples collected for mandatory testing) or 10 % of the calculated blood volume, whichever is less.

[6] Cf. guideline G.2
[7] Cf. guideline G.3

S.3.5 If a blood volume of less than 300 ml of whole blood is to be collected, it should be either be done in a paediatric collection bag or the necessary adjustment of anticoagulant and bag volume should be done.[8]

S.3.6 A standard equipment and method must be used to monitor the volume of donated blood which must not exceed that stated on the blood bag.

S.3.7 Appropriate equipment and procedure must be used for mixing blood and anticoagulant.[9]

S.3.8 Standard operating procedures and emergency tray with medications for post-donation care and management of adverse donor reactions must be in place.

S.3.9 It must be ensured that the donor is never left unattended during or immediately after donation and should be kept under observation throughout the phlebotomy.

S.3.10 The donor samples must be collected by a method that precludes contamination of the donor unit.

S.3.11 Donor segments prepared from the tube must be completely identifiable and be traceable to the primary bag.

S.3.12 The tube must be stripped by a stripper before segmentation.

S.4 Storage of blood after collection

S.4.1 Blood must immediately be placed in a blood establishment refrigerator(blood storage cabinet) if blood components are not to be prepared.

S.4.2 An ordinary refrigerator must NEVER be used for storage of blood.

S.4.3 If blood components are to be prepared by centrifugation, blood could be stored at ambient temperature for a maximum of 6 hours. The ambient temperature should be between 20-24^{o}C if platelets are to be prepared.

S.4.4 If there is offsite collection and processing, appropriate cold chain equipment must be used for transport of blood and blood components.

S.5 Donor session record and labelling

S.5.1 General considerations

S.5.1.1 Labelling should be performed in a quiet area to prevent disruption of the process and errors caused by distraction.

S.5.2.1 Labelling of donor session record, the primary and secondary collection packs and all the sample tubes used must be in a waythat avoids the possibility of errors.

S.5.3.1 Ensuring the appropriate labelling of blood bags and sample tubes is the responsibility of the doctor in-charge of the blood donation session.

[8] Cf. guideline G.1
[9] Cf. guideline G.4

S.5.2 Donation and donor identification

S.5.2.1 The use of a donation number links the donation to its donor. Donation numbers must be attached to all integral packs, sample tubes and corresponding record documents at the time of donation.

S.5.2.2 When component production requires the use of subsidiary packs which are not an integral part of the pack assembly e.g. filtration, freezing, a secure system must be in place to ensure that the correct donation number is placed on each additional pack used.

S.5.2.3 To ensure that all constituents of a component pool can be traced, the unique donation number of each constituent component must appear on the pack containing the component pool.

S.5.2.4 When a component is divided, a system must be in place to ensure that all sub batches can be traced.

S.5.2.5 The donation number must also appear on the secondary sample tubes used for laboratory testing.

S.5.3 Blood bag labels

The labelling of all blood bags (primary and secondary) must include the following:

(a) the unique donation identification number
(b) blood establishment's name
(c) name of the blood component
(d) the expiry date
(e) the ABO group
(f) the RhD group stated as positive or negative
(g) the composition and volume of the anticoagulant solution
(h) the temperature of storage
(i) any modification carried out (irradiation, leucocyte depletion, washing, sub division). Irradiated components' label must also include the date of irradiation and any reduction in shelf life.

S.5.4 Donor session records

S.5.4.1 A record of the session venue, the date, the donation number and the identity of all donors attending must be maintained.

S.5.4.2 For donors who are deferred, rejected or retired the full details must be recorded and the reason for the action taken.

S.5.4.3 All donations (successful and unsuccessful) must be recorded. In case of unsuccessful donations, the reason why they were unsuccessful must also be recorded

S.5.4.4 All adverse reactions must be recorded together with the action taken; full details of any other incidents, including those involving only staff must be recorded.

S.5.4.5 Batch number of the blood packs used should be recorded.

S.5.4.6 All records must be maintained for a period of 5 years.

S.6 Control of purchased material

S.6.1 Blood shall be collected into bags that have been registered by a competent national authority. Checking of this information is the responsibility of the blood establishment in-charge.

S.6.2 The blood bag label shall state the kind and amount of anticoagulant, the amount of blood that can be collected and the required storage temperature.

S.6.3 There should be no leakage from the blood bag, the anticoagulant used should be colourless and transparent.

S.6.4 Details of any defect (s) must be communicated to the vendor through the blood establishment administrator.

Section B

Section B comprises guidelines that clarify the intent of standards and include recommendations on how to implement technical requirements.

G.1 Volume calculation for donors weighing less than 50kg

G.1.1 In order to donate a standard unit (450 ± 45 ml if the blood bag contains 63 ml of anticoagulant, 500 ± 50 if the amount of anticoagulant is 70ml) the donor must weigh at least 50 kg. For donors weighing less than 50 kg the following blood volume calculation is to be made for donation.

$$\frac{\text{Donor's weight (kg)}}{50\ (\text{kg})} \times 450\ \text{ml} = \text{volume of blood (ml) to be collected from the donor}$$

G.1.2 If the volume of blood to be collected is less than 300 ml, the collection should be done in paediatric blood collection bags or the anticoagulant volume has to be adjusted according to the following formula:

$$\frac{\text{Donation volume (ml)}}{450\ (\text{ml})} \times 63\ (\text{ml}) = \text{volume of anticoagulant to be used with the donation}$$

G.2 Haemoglobin screening

G.2.1 Copper Sulphate haemoglobin screening

Aqueous copper sulphate, coloured blue, with a specific gravity of 1.053, equivalent to 12.5 gd/L haemoglobin is normally used to test female donors. Copper sulphate, coloured green, with a specific

gravity of 1.055, equivalent to 13.5 g/dL is normally used to test male donors. These stock solutions should be colour-coded and labelled accordingly.

G.2.2 Copper Sulphate storage

G.2.2.1 Stock solutions shall be stored at room temperature in tightly capped, dark glass containers to prevent evaporation and contamination.

G.2.2.2 Copper sulphate solutions must not be frozen or exposed to high temperatures.

G.2.2.3 The specific gravity of each batch in the stock solution should be checked at least weekly by designated staff with a calibrated hydrometer. The date, the result and the name of the individual who carried out the check must be recorded on the bottle.

G.2.3 Copper Sulphate for routine use

G.2.3.1 The solution shall be well mixed before dispensing the required amount of each solution into appropriately labelled, clean, drytubes or bottles.

G.2.3.2 These solutions shall be changed daily orafter 25 tests, depending on the volume of solution dispensed, otherwise contamination of the solution will affect the accuracy of the test.

G.2.3.3 Any usedsolution at the end of a session shall be discarded.

G.2.3.4 The calibrationtemperature of the copper sulphate must be that specified by the manufacturer to provide the correct specificgravity, e.g. cupric sulphate MAR, (material conforming to the AnalaR specification) has the correct specificgravity for haemoglobin estimations at 15.5 °C.

G.2.3.5 If kept chilled, the copper sulphate solutions must be given time towarm to ambient temperatures prior to use.

G.2.3.6 When dispensed or kept in plastic containers, care must betaken to avoid accumulation of electrostatic charge, as this can interfere with penetration by blood drops.

G.2.4 Spectrophotometric method for haemoglobin concentration screening

G.2.4.1 If a haemoglobin photometer (or other validated method) is used to provide a quantitative measurement of haemoglobin at the donor session, standard operating procedures for the use of the instrument must be available in the session procedures manual.

G.2.4.2 They should include a technique whereby the performance of the meter is validated by the regular use of appropriate working standards.

G.2.4.3 In addition, a system of regular and frequent assessment of the equipment performance, accuracy and precison must be established.

G.3 Disinfectants for venepuncture

The disinfectants used for cleaning the venepuncture site could either be iodoform compound in a concentration of 0.7% aqueous solution or isopropyl alcohol alone.

G.4 Blood donation

G.4.1 The blood and anticoagulant should be mixed gently and periodically (approximately every 30 seconds) during collection.

G.4.2 Mixing can be achieved by (1) manual inversion of the blood pack every 30 seconds, or (2) automatically by placing the blood pack on a mechanical agitator or (3) by using a rocking device.

3. BLOOD COMPONENT SPECIFICATIONS

Section A

Section A states the minimum standards that have to be met by all centres on which these are applicable, irrespective of the scope and facilities available with them.

S.1 Definitions

S.1.1 Closed system

A system in which the blood pack assembly is manufactured under clean conditions, sealed to the external environment and sterilized by an approved method. Apart from the act of blood collection (when a needle is exposed and enters the donor's arm) the integrity of this assembly must not be breached in any way.

S.1.2 Open system

A system which has been opened to the environment but every effort has been made to prevent microbial contamination by operating in a clean environment, using sterilized materials and aseptic handling techniques.

S.1.3 Whole blood

A unit of blood collected into an anticoagulant and not further processed.

S.1.4 Red cell concentrate

A component prepared by removing most of the plasma from whole blood after centrifugation.

S.1.5 Platelet-rich plasma

A component prepared from whole blood within 6 to 8 hours of venepuncture, containing platelets as the major cellular product.

S.1.6 Platelet concentrate

A component prepared by additional centrifugation and removal of most of the supernatant plasma from platelet-rich plasma.

S.1.7 Fresh frozen plasma

Fresh frozen plasma is plasma that has been obtained from whole blood and frozen (within 8 hours of venepuncture) to a temperature that will maintain the activity of labile coagulation factors.

S.1.8 Cryoprecipitate

Cryoprecipitate is the cold insoluble protein that precipitates when FFP is thawed to 1-6^{o}C. It contains FVIII, von Willebrand factor, fibrinogen, Factor XIII and fibronectin from a unit of fresh frozen plasma.

S.1.9 Cryosupernatant plasma

The supernatant plasma removed during the preparation of cryoprecipitate.

S.1.10 Red cells, washed

The red cell concentrate is washed with 0.9 % w/v sodium chloride to remove most of the plasma, leucocytes and platelets.

S.1.11 Red cells for exchange transfusion

A component for exchange transfusion of neonates prepared by removing a proportion of the plasma from fresh whole blood.

S.1.12 Components for neonatal use

Blood components meeting all the specifications outlined in this chapter but prepared by dividing the standard components into aliquots using a closed system.

S.1.13 Leucocyte depleted components

Cellular components containing less than 5 x 10^6leucocytes. Leucocyte depletion procedures shall not reduce red cell volume by more than 15%.In case of leucocyte depleted platelets, the volume of suspending medium must be sufficient to maintain the pH of the component throughout its shelf life.

S.1.14 Irradiated components

Cellular blood components irradiated by a standard method (X-Rays, Gamma-Rays) and dose to make the lymphocytes non-viable.

S.1.15 Calibration

Comparison of measurements performed by an instrument to those made by an accurate instrument (or standard) for the purpose of detecting, reporting and eliminating errors in measurement.

S.1.16 Process control

Activities intended to minimize variation within a process in order to produce a predictable output which meets specification.

S.1.17 Specification

Description of a set of requirements to be satisfied by a product, material or process including, if appropriate, the procedures to be used to determine whether the requirements are satisfied. Specifications are often in the form of written descriptions and drawings.

S.1.18 Ambient temperature

Ambient temperature is the temperature of the surrounding environment.

S.2 General specifications

S.2.1 Each component shall be visually inspected at each stage of processing and immediately prior to issue. The component must be withdrawn if there is leakage, damage to or fault in the container, excessive air, and suspicion of microbial or other colour change.

S.2.2 There must be a documented system available in each Blood Establishment/Transfusion Centre for the recall of any component(s) causing adverse effects and all other components linked with that component(s). Any recall of component(s) should lead to a thorough investigation to prevent recurrence.

S.3 Preparation of blood components

S.3.1 Detailed SOPs must be made available by the blood establishment in-charge to the component preparation section covering equipment operations, precautions and protocols of component preparation as per manufacturer's instructions and institutional policies.

S.3.2 All necessary equipment for component preparation should be regularly calibrated (e.g. table top centrifuges, refrigerated centrifuges) and its record maintained.[10]

S.3.3 The time limit for processing each component must be observed.

S.3.4 All units of blood collected and processed must be immediately placed in quarantine in a designated area until donor records have been reviewed and all laboratory testing has been complete.

S.3.5 Secure and exclusive quarantine storage should be available for known bio-hazardous material awaiting disposal.

S.3.6 Procedures should ensure that untested components are not quarantined with components which have produced reactive results in mandatory microbiological screening tests.

S.4 Mandatory statements at the time of issue

The following statements must appear on the blood bag label under the title 'CAUTION' at the time of issue:[11]

(a) Always check patient/component compatibility
(b) Do not use if there are signs of deterioration or damage
(c) Use a standard transfusion set
(d) Risk of adverse reaction/infection

[10] Cf. guideline G.1
[11] Cf. chapter 2, S.5, for additional details of labelling

S.5 Storage of blood components

S.5.1 All components must be stored within their recommended temperature for the stated shelf-life.[12]

S.5.2 After the component is taken out of its storage conditions (for transfusion), it must be transfused within the time limit set for that product.

S.5.3 Blood components prepared by an open system should be used as soon as possible. If storage is unavoidable, components with a recommended storage temperature of 22°C ± 2°C must be used within 6 hours. Components with a recommended storage temperature of 4°C ± 2°C are to be used within 24 hours.Components are rendered unsuitable for clinical use when breached and the requirements defined for an open system have not been observed.

S.5.4 When components are pooled, the maximum shelf life of the pool must not exceed the expiry date of the oldest constituent component.

S.5.5 Storage areas for blood and blood components must operate within a specified temperature range and should provide adequate space, suitable lighting and be arranged and equipped to allow dry, clean and orderly storage.

S.5.6 A current inventory must be maintained of components in each storage category.

S.5.7 A permanent, continuous record of storage temperature must be made and stored, and there must be documentation of verification of temperature storage equipment probes.

S.5.8 Alternative power supply (e.g. standby generators) and voltage stabilizers or regulators must be available for the blood establishment equipment required to maintain the cold chain (e.g. refrigerators, freezers, platelet incubators).

S.5.9 Backup cold chain equipment must also be available for use in case of equipment failure.

S.5.10 There must be a system of unit verification before bringing units into inventory from quarantine.

S.6 Transport of blood components

S.6.1 Whole blood & red cell concentrates

For Whole Blood/Red Cells the air temperature of transport containers for units must be maintained between 2°C and 10°C. Transport time should not exceed 12 hoursand if open processing has been used should be as short as possible. When the transport time exceeds 12 hours, appropriate battery charged transport containers must be used.

S.6.2 Platelets

Containers for transporting platelets must be equilibrated at room temperature before use. During transportation the temperature of platelets must be kept as close as possible to the recommended storage temperature of 22°C ± 2°C with continuous gentle agitation.

[12] Cf. guideline G.2

S.6.3 Fresh frozen plasma, cryoprecipitate & cryosupernatant

For FFP, cryoprecipitate and cryosupernatant every effort must be made to maintain the core storage temperature during transportation.

S.7 Quality control of blood components

S.7.1 General considerations

S.7.1.1 The sampling procedures forquality control must be carried out by trained personnel.The sampling procedure should ensure sterility of the components. It should also ensure that the properties of the component are not adversely affected.

S.7.1.2 A procedure must be in place to link the infectious disease screening results with each donation and all components prepared from the individual donation.

S.7.1.3 All components released to stock must be non-reactive for viral serology and transfusion transmissible infection screening tests. The components reactive for any one or more of these tests must be discarded in accordance with the national guidelines on safe disposal of biohazardous material.

S.7.2 Quality control

S.7.2.1 The frequency of quality control tests is 1% of the annual production of each component.

S.7.2.2 A minimum of 75% of the results of component monitoring (quality control) tests should achieve the specification.

S.7.2.3 For leucocyte depleted components, leucocyte counts are to be performed on all components. All leucocyte depleted components must meet the specified leucocyte count (<5 x 10^6/unit).

S.7.2.4 The quality control tests to be performed include the following:

Component	Volume[13]	Specifications
Whole blood	450ml ± 45 ml(excluding the anticoagulant volume)	Haemolysis <0.8 % of red cells Haemoglobin content of >40 g/unit
Red cell concentrate	280 ml ± 50 ml	Haematocrit 0.65-0.75 Haemolysis < 0.8% of red cells For washed red cells protein content should be <0.5g/unit
Platelet concentrate (random donor)	40-50 ml	Platelets 55 x 10^9/unit concentrate pH >6.2 at end of shelf life
Single donor platelets or apheresis platelets	200 ml-300ml	Platelet 300x10^9/unit Leukocytes <0.3x10^9/unit[14]

[13] Cf. guideline G.3
[14] Cf. guideline G.4

Fresh frozen plasma	125 ml ± 225 ml	Total proteins >50g/L Platelets <30x10^9/L (pre-freeze) Red cells < 6x10^9/unit leukocytes Factor VIII 0.7 IU/ml or 70 IU/100 ml
Cryoprecipitate	20-30 ml	Factor VIII >70 IU/ unit Fibrinogen >140 mg/dl

S.7.2.1 A procedure for statistical process control must be followed by the facility and records of the same must be available for inspection.[15]

S.7.2.2 Unacceptable quality control results must be investigated and corrective action must be implemented before repeating the procedure.

S.8 Discard of Non-Conforming Components

S.8.1 Components from donations that are reactive in mandatory microbiological screening tests are classified as bio-hazardous and must be appropriately discarded in compliance with national guidelines on disposal of bio-hazardous material.

S.8.2 Appropriate record of discard (bio-hazardous or otherwise non-conforming) must be maintained and include the following:

(a) the donation number
(b) the component identity
(c) the reason for discard
(d) the date of discard
(e) the identity of the person discarding the component

S.8.3 Secure and effective procedures must be in place to ensure that all components and samples from biohazard donations are retrieved and inactivated before their disposal.

S.9 Component Release

S.9.1 Standard procedures must ensure that blood and blood components cannot be released to stock until all the required laboratory tests, mandatory and additional, have been completed, documented and approved by a designated person in the blood establishment.

S.9.2 Documentation of satisfactory production and storage conditions must be ensured before release of components.

[15] Cf. guideline G.5

Section B

Section B comprises guidelines that clarify the intent of standards and include recommendations on how to implement technical requirements.

G.1 Refrigerated centrifuge calibration

G.1.1 Principle

Successful preparation of platelet concentrates requires adequate but not excessive centrifugation. The equipment used must perform in a consistent and dependable manner. Each centrifuge used to prepare platelets should be calibrated upon receipt and after adjustment or repair.

G.1.2 Calibration procedure for thepreparation of platelet-rich plasma (PRP)

G.1.2.1 Perform a platelet count on the pre-donation sample in EDTA. If the platelet count is below 150,000/µL, this donors blood should not be used for calibration

G.1.2.2 Calculate the number of platelets in the unit of whole blood i.e. platelets/µL×1000×mL of whole blood= number of platelets in whole blood.

G.1.2.3 Prepare platelet-rich plasma (PRP) at a selected speed and time. Place a temporary clamp on the tubing so that one satellite bag is closed off; express the PRP into the other satellite bag. Seal the tubing close to the primary bag and disconnect the two satellite bags. Do not remove the temporary clamp between the satellite bags until the next step.

G.1.2.4 Strip the tubing several times so that the tubing contains a representative sample of PRP.

G.1.2.5 Seal off a segment of the tubing and disconnect it, so that the bag of PRP remains sterile. Leave the PRP on bench for at least 01 hours before counting.

G.1.2.6 Perform a platelet count on the sample of PRP in the segment. Calculate the number of platelets in the bag of PRP i.e. platelets/µL×**1000**×mL of PRP = number of platelets in PRP. Calculate percent yield (% yield) as in following equation:

$$\text{Percent Yield} = \frac{\text{Number of platelets in PRP}}{\text{Number of platelets in whole blood}} \text{ X } 100$$

G.1.2.7 Repeat the above process three or four times with different donors, using different speeds and times of centrifugation, and compare the yields achieved under each set of test conditions. Select the shortest time and lowest speed that result in the highest percent of platelet yield but levels of red cell content should be very low.

G.1.3 Calibration procedure for the preparation of platelet concentrate (PC)

G.1.3.1 Centrifuge the PRP at a selected time and speed to prepare platelet concentrate (PC).

G.1.3.2 Express the platelet-poor plasma into the second attached satellite bag and seal the tubing, leaving a long section of tubing attached to the platelet bag.

G.1.3.3 Place the platelets on bench (not agitator) and leave them for at least 1 hour to ensure that they are evenly resuspended. Platelet counts performed immediately after centrifugation will not be accurate.

G.1.3.4 Strip the tubing several times, mixing its contents well with the contents of the platelet bag. Let the concentrate flow back into the tubing. Seal off a segment of the tubing so that the platelet bag remains sterile.Perform a platelet count on the contents of the segment.

G.1.3.5 Calculate the number of platelets in the concentrate: platelets/uL x**1000x**mL of PC= number of platelets in platelet concentrate

G.1.3.6 Calculate percent yield (% yield) with following formula:

$$\text{Percent Yield} = \frac{\text{Number of platelets in PC}}{\text{Number of platelets in PRP}} \times 100$$

G.1.3.7 Repeat steps G.1.3.1 though G.1.3.6 on PRP from different donors, using different speeds and times of centrifugation as shown in table 1 and compare the yields achieved under each set of test conditions.Select the shortest time and lowest speed that results in the highest percent of platelet yield in the platelet concentrate. The aim is to meet the QC criteria of having >55x 10^9 platelets/bag of random donor.

G.1.3.8 It is not necessary to recalibrate a centrifuge unless the instrument has undergone adjustment or repairs, or levels of platelet recovery fall below acceptable levels.

G.2 Storage of blood and blood components

G.2.1 Whole blood & red cell concentrates

Storage for a maximum of 35 days at a core temperature of 4° C ± 2° C must not be exceeded if the anticoagulant used is CPD-A1.

G.2.2 Platelets

G.2.2.1 Whole blood must not be refrigerated before preparation of the platelet component.

G.2.2.2 The ambient temperature of the room for preparing platelets should be 22°C ± 2°C.

G.2.2.3 Platelet-rich plasma must be separated from whole blood by centrifugation within 8 hours of venepuncture in case of CPD-A1 anticoagulant.

G.2.2.4 In a closed system, the maximum storage time for platelets is 5 days at a core temperature of 22°C ± 2°C.

G.2.2.5 Gentle agitation must be maintained throughout the storage period in appropriate equipment.

G.2.3 Fresh frozen plasma

G.2.3.1 The plasma must be placed under appropriate storage conditions within 8 hours of venepuncture.

G.2.3.2 Fresh frozen plasma should be stored at a core temperature of -18°C or below for a maximum of 12 months.

G.2.3.3 Once thawed, fresh frozen plasma must not be refrozen and should be used immediately. If the delay in transfusion is unavoidable, the component could be stored at ambient temperature, in which case it must be used within 30 minutes.

G.2.3.4 After thawing, fresh frozen plasma can be stored at 4 ± 2^{o}C for a maximum of 24 hours. In this case, however, it should not be used for replacing factor VIII deficiency.

G.2.4 Cryoprecipitate

G.2.4.1 Cryoprecipitate is obtained by thawing a single donation of fresh frozen plasma at 4°C ± 2°C.

G.2.4.2 After preparation cyroprecipitate should be used immediately or rapidly frozen (within 2 hours of preparation) to a core temperature of -18°C or below. The maximum storage time at this temperature is 12 months.

G.2.4.3 Once thawed, cryoprecipitate must not be refrozen and should be used immediately. If the delay in transfusion is unavoidable, the component could be stored at ambient temperature, in which case it must be used within 30 minutes.

G.2.4.4 G.2.4.4After thawing, cryoprecipitate can be stored at 4 ± 2^{o}C for a maximum of 4 hours.

G.2.5 Cryosupernatant

G.2.5.1 Cryosupernatant should be frozen to a core temperature of -18°C or below within 2 hours of separation from its cryoprecipitate. The maximum storage time at this temperature is 12 months.

G.2.5.2 Once thawed, cryosupernatant must not be refrozen and should be used immediately. If delay is unavoidable, the component should be stored at ambient temperature and used within 30 minutes.

G.2.6 Irradiated components

G.2.6.1 Except for use in IUT or exchange transfusion, red cell can be irradiated at any time up to 14 days after collection and be stored for up to 14 days after irradiation.

G.2.6.2 Red cells for use in IUT or exchange transfusion must be transfused within 24 hours of irradiation and should be less than 5 days old.

G.2.6.3 Platelets can be irradiated at any stage in their 5 day storage.Irradiated platelets can be stored up to their normal shelf life of 5 days after collection.

G.3 Calculation of blood component volume

Volume is generally calculated by dividing the component weight by its specific gravity. The following conventions should apply for calculating volume:

G.3.1 When whole blood is issued as a component, the volume given on the component label should include whole blood and anticoagulant.

G.3.2 For red cell components, volume is calculated by weighing the pack, deducting the weight of the pack assembly only and dividing the resultant weight by the nominal specific gravity 1.06. The weight of anticoagulant is not deducted when calculating the volume of red cell components.

G.3.3 For platelets and plasma components, volume is calculated by weighing the pack, deducting the weight of the pack assembly and dividing the resulting weight by the nominal specific gravity of 1.03.

G.4 Measurement of supernatant haemolysis

The supernatant haemolysis in plasma or platelet components can be measured by any one of the following methods: (1) Drabkin's method (2) Spectrophotometric method (3) Microplate method.

G.5 Measurement of total leucocyte count

The residual white-cell content of leukocyte- reduced (LR) whole blood and components can be determined using a large-volume hemocytometer. For red-cell-containing components, the red cells in the aliquot to be counted are first lysed. 0.01% Turk's solution is used to stain the leukocyte nuclei. The Nageotte counting chamber has a volume 56 times that of the standard hemocytometer. Accuracy of counting is improved by examin- ing a larger volume of minimally diluted spec- imen, compared with standard counting techniques.

4. TESTING OF BLOOD DONATIONS

Section A

Section A states the minimum standards that have to be met by all centres on which these are applicable, irrespective of the scope and facilities available with them.

S.1 Mandatory Testing of Blood Donations

S.1.1 Blood donations/donor screening for the following transfusion transmissible infections is mandatory:

(a) HBs Ag
(b) Anti-HCV
(c) Anti-HIV 1 & 2
(d) Syphilis (screening for syphilis must be by an antigen-based assay)
(e) Malaria

S.1.2 The mandatory red cell serological testing of blood donations includes ABO and RhD blood grouping, and cross-matching.

S.2 Screening for transfusion transmissible infections

S.2.1 General considerations

S.2.1.1 All blood establishments/transfusion services must strive to perform blood donations/donor screening with the most sensitive and specific reagents and methods available.

S.2.1.2 Screening by rapid (kit) methods should only be used when testing by more sensitive and specific methods is not feasible.

S.2.1.3 All donor samples testing reactive in the initial testing should be repeated on another sample obtained from the blood bag.

S.2.1.4 All cases in which the repeat sample is reactive should be informed about the result in a confidential manner and referred to a diagnostic laboratory for confirmation.

S.2.2 Blood donations/donor screening kits prequalification and evaluation

S.2.2.1 Responsibility

(a) The prequalification and evaluation procedure applies to the central purchasing authority (including personnel in the private facilities responsible for purchasing)/health authority.
(b) The purchaser of the screening kits will ensure that a procedure is in place for the qualification of vendors, distributors, suppliers and importers of blood donor screening kits.

(c) The purchaser will also be responsible for carrying out the procedure for evaluating the kit performance through a panel of professionals (including at least two pathologists, one of whom must be a virologist/microbiologist).
(d) The test evaluation protocol must be prewritten by the panel of professionals and vetted by the Health Secretary.
(e) The quality control procedures of the TTI screening tests will be carried out by the blood centre/transfusion service.

S.2.2.2 Essential elements of the pre-qualification procedure of TTI screening kits

(a) Ensuring that the kits selected are the ones specifiedby the manufacturer for use in the blood centre as donor screening kits. The kits for general diagnostic testing of HBsAg, anti-HCV, HIV and Syphilis must not be used in the blood centre.
(b) Ensuring that the kits are registered with well-known, reputable regulatory authorities like FDA, Pasteur Institute, Paul Erlich and International Consortium for Blood Safety and purchasing only the kits registered with these authorities.
(c) Ensuring that the sensitivity and specificity of kits along with the methods used for evaluating the sensitivity and specificity are documented on the kits. It is recommended that the minimum evaluated sensitivity and specificity levels of all assays used for blood screening should be as high as possible and preferably not less than 99.5%.. The procedure for evaluating the sensitivity and specificity must be a standard one (standard procedure by WHO).
(d) Obtaining and keeping in record the contact details of the manufacturer(s) of the kits.
(e) Ensuring that the distribution rights of the vendor are certified. The information about such certification must be communicated directly from the principal to the purchaser.
(f) Obtaining details about the infrastructure of the distributor in the country regarding storage, transportation and evaluation of the kits as per standards. These details must conform to the standards.

S.2.2.3 Evaluation of TTI screening kits/methods

(a) The kit performance protocol will include the following essential elements:
    (i) The standard procedure as recommended by WHO.
    (ii) The products that will be used to evaluate the sensitivity and specificity e.g sensitivity panel, performance panel etc. These are available from NIBSC UK and commercial vendors.
    (iii) The equipment that will be used for evaluation.
    (iv) The fitness criteria for each methodology. The criteria will not be at variance with the WHO or International Consortium of Blood Centres criteria.

(b) The purchaser will obtain the kits performance reports from the expert panel and may purchase the lowest priced kits/reagents which meet the performance criteria.
(c) The list of kits/reagents not meeting the fitness criteria will be maintained and made public by the purchaser for future reference and for the benefit of the public at large.

S.2.3 Quality control of blood donations/donor screening for transfusion transmissible infections

(a) Screening must be done with reagents/kits whose performance has been approved by the relevant purchasing authority.
(b) All efforts must be made to procure third party controls (e.g Biorad) for viral screening tests, to be run with each batch in order to determine the performance of the test being done.
(c) All efforts must be made to participate in external quality assurance programmes for blood donor screening tests.
(d) Batch testing is to be done in case of ELISA testing.
(e) The quality control procedures like maintaining LJ charts should be in place for ELISA testing.

S.3 ABO and RhD blood grouping[16]

S.3.1 General considerations

S.3.1.1 The ABO and RhD blood group must be determined on each blood donation at least twice.
S.3.1.2 ABO blood group must be determined at least once by both the forward and reverse blood grouping.
S.3.1.3 With the monoclonal reagents currently in use, testing for weak D (D^u) by the indirect antiglobulin test is not necessary. Testing for weak D (D^u) is, however, essential for donors case of a blood group discrepancy. When in doubt, the blood group should be considered as RhD positive in donors.
S.3.1.4 The reagent used for RhD testing of donors must detect D^{IV}.
S.3.1.5 Standard operating procedures for ABO and RhD blood grouping must be made available by the blood centre in-charge to the staff performing the procedure. The standard operating procedure must be in accordance with acceptable international guidelines for ABO and RhD grouping (e.g AABB guidelines).The standard operating procedure must also include the appropriate use of controls.
S.3.1.6 The primary blood bag and all the secondary blood bags must be clearly and legibly labelled with the ABO and RhD blood group.

[16] Cf. guidelines G.1 and G.2

S.3.2 ABO and RhD blood grouping reagents' prequalification and evaluation

S.3.2.1 Responsibility

(a) The purchaser of the reagents will ensure that a procedure is in place for the qualification of vendors, distributors, suppliers and importers of blood donor screening kits.
(b) The prequalification and evaluation procedure applies to the central purchasing authority (including personnel in the private facilities responsible for purchasing)/health authority.
(c) The procedures for evaluating the reagents performance will also be carried out by the purchaser through a panel of professionals (including at least two pathologists, one of whom must be a haematologist).
(d) The reagent evaluation protocol must be prewritten by the panel of professionals and vetted by the Health Secretary.

S.3.2.2 Essential elements of the pre-qualification procedure of ABO and RhD blood grouping reagents

(a) Ensuring that the reagents are registered with well-known, reputable regulatory authorities like FDA, Pasteur Institute, Paul Erlich and International Consortium of Blood Centres and purchasing only the kits registered with these authorities.
(b) Ensuring that the potency and avidity of the reagents along with the methods used for evaluating the potency and avidity are documented. The potency and avidity of the reagents must be as recommended by WHO. The procedure for evaluating the potency and avidity must be a standard one. WHO documents, WHO/BS/06.2053 and WHO/BS/04.2000, provide the relevant details.
(c) Obtaining and keeping in record the contact details of the manufacturer(s) of the reagents.
(d) Ensuring that the distribution rights of the vendor are certified. The information about such certification must be communicated directly from the principal to the purchaser.
(e) Obtaining details about the infrastructure of the distributor in the country regarding storage, transportation and evaluation of the reagents as per standards. These details must conform to the standards.

S.3.2.3 Evaluation of ABO and RhD blood grouping reagents

(a) The reagents' performance protocol will include the following essential elements:
  (i) The standard procedure as recommended by WHO.
  (ii) The products that will be used to evaluate the potency and avidity.
  (iii) The equipment that will be used for evaluation.

(iv) The fitness criteria for each methodology. The criteria will not be at variance with the WHO criteria.

(b) The purchaser will obtain the reagents performance reports from the expert panel and may purchase the lowest priced reagents which meet the performance criteria.

(c) The list of reagents not meeting the fitness criteria will be maintained and made public by the purchaser for future reference and for the benefit of the public at large.

S.3.3 Quality control of ABO blood grouping by the blood centre

Daily quality control must include:

(a) Obtaining appropriate reactions with A, B and O cells for reagent anti-sera (anti-A and anti-B);

(b) Obtaining unequivocal, appropriate reactions with anti-A and anti-B for reagent red cell samples.

S.4 Cross-matching

Cross-matching must be done by the standard method which includes three phases: saline, albumin, and coomb's.

Section B

Section B comprises guidelines that clarify the intent of standards and include recommendations on how to implement technical requirements.

G.1 General guidelines for serological tests

G.1.1 Test tubes

For manual tube tests, unless otherwise stated 10-12mm (diameter) x 75mm glass tubes should be used.

G.1.2 Optimum centrifugation

G.1.2.1 Various RCF and times satisfactory for spin-tube tests are as follows:

RCF (g)	110	200-220	500	1000
Time (s)	60	25-30	15	8-10

G.1.2.2 The following formula is used for the conversion of RPM (revolutions per minute) of centrifuges into the G-force (centrifugal force):

RCF or G-force= 1.12 x R (mm) x (RPM/1000)²

G.1.3 Grading system of agglutination for manual tube tests.

G.1.3.1 The following table gives the grading system for manual tube serological testing. If a cumulative (titration) score is required to assess the characteristics of a blood grouping reagent in a titration, then the score as indicated should be used.

Grade	Description	Score
5	Cell button remains in one clump or dislodges into a few large clumps, macroscopically visible.	12
4	Cell button dislodges into numerous large clumps, macroscopically visible.	10
3	Cell button dislodges into many small clumps, macroscopically visible.	8
2	Cell button dislodges into finely granular but definite, small clumps, macroscopically visible.	5
1	Cell button dislodges into fine granules, microscopically visible.	3
0	Negative result	0

G.1.3.2 Unless otherwise stated, an unequivocal tube manual reaction is defined as a grade 3 or greater.

G.1.4 Reading serological tests

G.1.4.1 Haemolysis

Haemolysis should be determined by the visual detection of haemoglobin in the supernatant fluid.

G.1.4.2 Agglutination

(a) A 'Shake' reading technique should not be used. Its over-vigorous action disrupts agglutination and is responsible for false negative tests in blood group serology.

(b) Any of the following reading techniques may be used:

(i) Pipette transfer of cell button to microscope slides. The tube is not agitated at any stage. The transfer pipette is clean and has a 1.5-2.0 mm internal diameter bore and the tip is free from any irregularities. The cell button is drawn, by the minimum suction possible, into the stem of the clean pipette, then gently ejected onto a slide and simultaneously drawn out over an area of some 2cm_2 • The angle of the pipette above the horizontal controls the width of the spread. The test is observed macroscopically and microscopically if required.

(ii) Tip and roll. The tube is held almost horizontally (70-80° to the vertical) between the thumb and the first two fingers and slowly rotated without any shaking or agitation, until the cell button is dislodged from the tube. The free cell button /agglutinates are only allowed to move a maxim of 1cm down the tube. The test is read macroscopically with the tube held horizontally over an illuminated light source. A x5 or x6 magnifying mirror, or a x6 hand lens can be used. Reading can then be obtained by examination of the tube placed horizontally on the stage of an inverted microscope.

(iii) Gentle agitation. The tube is held almost vertically between the thumb and first two fingers and gently agitated using a trembling or vibrating movement. The test is read as described above.

G.1.4.3 Reading of slide tests

(a) The reagents are mixed thoroughly by rocking the slide for approximately 30 seconds with occasional further mixing during the incubation period.

(b) The test is observed macroscopically, and if required microscopically, for agglutination. This may be facilitated by reading over diffuse light resource.

G.2 ABO and RhD blood grouping

G.2.1 Red cells should be tested against monoclonal anti-A and anti-B blood grouping reagents.

G.2.2 Plasma or serum should be tested against group A and B reagent cells. The reverse group should include a negative control, e.g the person's own red cells or group O

cells, to exclude reactions with A and B cells due to cold antibodies in the patient's sample other than anti-A or anti-B.

G.2.3 Each sample must be tested in duplicate with IgM monoclonal anti-D blood grouping reagents.

G.2.4 Documentation errors may occur during the manual reading and interpretation of ABO and RhD groups. The risk of error can be minimized by:

G.2.4.1 separating the procedure into distinct tasks and using different members of staff to perform each task.

G.2.4.2 separating the documentation of reaction patters from the final interpretation.

G.2.4.3 separating the interpretation and documentation of the forward and reverse ABO blood groups.

G.2.5 The ABO and RhD group must, wherever possible, be verified against previous results (if available). Any discrepancies must be resolved prior to transfusion of whole blood, red cells and red cell contaminated components.

G.2.6 ABO and RhD groups must be repeated when a discrepancy is found. Repeats should be performed using washed cells. To prevent the perpetuation of mistakes, the cells should be taken from the original sample, rather than from a suspension made previously. An autocontrol should be included.

G.2.7 Repeatably anomalous results may require a fresh sample or referring to a reference laboratory.

5. PRE-TRANSFUSION TESTING

Section A

Section A states the minimum standards that have to be met by all centres on which these are applicable, irrespective of the scope and facilities available with them.

S.1 ABO and RhD blood grouping of recipients[17]

S.1.1 ABO and RhD grouping must be performed on every recipient. The only exceptional circumstances sometimes arise in case of emergency pre-transfusiontesting which are dealt in section S.4.

S.1.2 Both forward and reverse grouping must be done on the recipient sample (except in case of infants less than 6 months of age when only forward ABO blood grouping is done).

S.1.3 The indirect antiglobulin test must not be used to detect weak D in recipients. When in doubt, the sample should be considered as RhD negative.

S.1.4 The reagent for RhD testing of recipients must not detect D^{IV}.

S.1.5 Standard operating procedures for ABO and RhD blood grouping must be made available by the blood centre in-charge to the staff performing the procedure. The standard operating procedure must be in accordance with acceptable international guidelines for ABO and RhD grouping (e.g AABB guidelines).The standard operating procedure must also include the appropriate use of controls.

S.2 Selection of blood for recipients

S.2.1 Whole blood and red cell components of the same ABO and RhD group as the patient must be selected for transfusions. The only exceptional circumstances sometimes arise in case of emergency issue of blood which are dealt in section S.4.

S.2.2 Platelet concentrates from donors of the identical ABO group as the patient are the components of choice and should be used as far as is possible.Administration of ABO non-identical platelets is acceptable transfusion practice in particular, when platelet concentrates are in short supply. Group O platelets should, however, be transfused to group O patients only. RhD-negative platelet concentrates should be given, where possible, to RhD-negative patients, particularly to women of reproductive age group.

S.2.3 Group O FFP must only be given to group O recipients. AB plasma, suitable for patients of any ABO group, is often in short supply. The principles of selection of FFP according to donor and recipient ABO blood group are given below.

[17] Cf. chapter 4, section S.3.2 for prequalification and evaluation of blood grouping reagents.
Cf. chapter 4, section S.3.3 for quality control of ABO and RhD blood grouping reagents.
Cf. chapter 4, guidelines G.1 & G.2 for guidelines on ABO and RhD blood grouping.

Recipient Group	O	A	B	AB
1st choice	O	A	B	AB
2nd choice	A	AB	AB	A
3rd choice	B	B	A	B
4th choice	AB	-	-	-

The RhD status of FFP or cryoprecipitate is unimportant, and RhD positive FFP can be given safely to RhD negative recipients – even women of child bearing age.

S.3 Cross-matching[18]

S.3.1 Cross-matching of the patient's serum against donor red cellsmust be performed by the indirect antiglobulin method to confirm donor-recipient. The only exceptional circumstances arise in case of emergency issue of blood which aredealt in section S.4.

S.3.2 A standard operating procedure for cross-matching by the indirect antiglobulin method must be prepared by the blood centre in-charge and made available to the staff performing the procedure.

S.3.3 A suitable polyspecific AHG reagent should contain a potent anti-IgG and an adequate anti-complement reagent, or a satisfactory monoclonal anti-C3d that gives equivalent sensitivity.

S.3.4 The reagent must not give false positive reactions in tests with fresh serum incubated with red cells from the segment lines of CPD-A1 donor packs 10-28 days old.

S.3.5 It must be remembered that in addition to agglutination, haemolysis is also a sign of incompatibility.

S.4 Antibody screening

S.4.1 Antibody screen of the recipient, or mother in the case of neonatal transfusion, is strongly recommended in every recipient.

S.4.2 In the event of a positive antibody screen, antibody identification should follow.

S.4.3 The patient's serum should be tested against at least two red cell suspensions, used separately and not pooled.

[18] Cf. guideline G.1

S.5 Emergency issue of blood

S.5.1 A written request for emergency issue of blood must be made by the treating physician.

S.5.2 An EDTA and a clotted sample should be obtained from the patient before the administration of intravenous colloids, such as Dextran and HES.

S.5.3 If it is not possible to obtain the minimum patient identification specified in section S.6 from trauma or unconscious accident and emergency patients, there must be at least one unique identifier, usually the hospital registration number, and the sex of the patient. The sample should be taken and labelled and the form and sample signed by the prescribing medical doctor as one continuous procedure.

S.5.4 If blood is urgently required by the recipient, ABO and RhD blood grouping may be performed by rapid techniques. Under these circumstances, cross-matching may also be reduced to a rapid 2-5 min cross-match to exclude ABO incompatibility.If this procedure is followed, it should seldom be necessary to resort to group O RhD negative blood.

S.5.5 In a life-threatening situation, group O blood must be issued until ABO blood grouping has been done on a suitably labelled sample. If the patient is a premenopausal female, group O, RhD-negative blood should be given.

S.5.6 If ABO and RhD identical blood group in not available, a different blood group red cell component may be issued only under the following circumstances:

S.5.6.1 Group O red cell component may be issued to all recipients, provided it is plasma depleted.

S.5.6.2 Group AB red cell component should be used for AB patients but if it is not available, group A or B blood may be used provided it is plasma depleted.

S.5.6.3 When supplies of RhD-negative blood are limited, RhD-positive blood may be selected for RhD-negative recipients. It is important that RhD-positive cellular components are not issued to RhD-negative pre-menopausal females.

S.5.7 In the massive transfusion situation, where the number of units transfused in any 24 hour period exceeds the recipient's blood volume, compatibility testing may be reduced to checking the ABO/RhD groups of the transfused units.

S.5.8 After the emergency has been dealt with, retrospective cross-matching should be undertaken with the pre-transfusion sample.

S.5.9 Donor units that have not been tested, or not fully tested, against the patient's serum should be clearly labelled, e.g. 'Selected for patient …, but not cross-matched'.

S.6 Samples and documentation

S.6.1 Transfusions must be prescribed by a medical doctor.

S.6.2 The request form must include the final disposition form which is sent with the blood bag to the ward (and includes the baseline pulse, temperature, blood pressure, etc. of the patient along with the identification details). The request form and the sample must

contain the following minimum patient identification. Emergency samples and documentation are dealt in section S.4:

(c) Full name (correctly spelt first name(s) and surname)
(d) Hospital registration number
(e) Plus at least one of the following unique identifiers:
(i) Date of birth (not age or year of birth)
(ii) CNIC number or, in case of foreigners and refugees, any other unique identification number

S.6.3 The sample must be labelled and signed by the person taking it.

S.6.4 A standard operating procedure should be in place for dealing with inadequately labelled samples.

S.6.5 Immediately on receipt, laboratory staff must confirm that the blood sample is appropriately labelled and that the information on the sample and the request form is identical.

S.6.6 If the patient has been transfused since the date of collection of the sample, and if that transfusion was given more than 3 days ago, a new blood sample is required for cross-matching to detect the emergence of any new antibodies.

S.6.7 Standard blood request forms must be prepared by blood establishments and make available to the clinical staff requesting blood/blood components.

S.6.8 The standard blood request form must contain the following information:

(a) Date and time on which the blood/blood component is required
(b) The number and type of component required
(c) The clinical indication for transfusion

S.6.9 Duplicate records must be avoided. It is necessary, at the time of request, to identify and link separate records that exist for each patient.

S.6.10 The laboratory worker performing the compatibility procedure must double check the identity of the patient's sample with the request form and with the compatibility label on the donor units before issuing the blood.

Section B

Section B comprises guidelines that clarify the intent of standards and include recommendations on how to implement technical requirements.

G.1 Cross-matching

G.1.1 Sensitization of red cells

G.1.1.1 The tubes should be shaken to mix the reactants (patients' serum, donor red cells and potentiator in appropriate ratios).

G.1.1.2 The incubation is to be done at 37^{o}C in a waterbath for a minimum incubation time of 45 minutes if albumin is used as a potentiator. The incubation time is reduced to 15 minutes if LISS is the potentiator used.

G.1.2 Washing the tests

G.1.2.1 to 4 washes are recommended for washing

G.1.2.2 The essentials for efficient washing are thorough mixing of the cells, followed by a vigorous injection of the saline wash to mix the cells and serum thoroughly throughout the tube, and then removal of as much of the supernatant as possible at the end of each washing cycle.

G.1.2.3 Saline solutions produced commercially for in-vivo irrigation/injection, and stored in plastic containers, should not be used for washing.

G.1.3 Quality control of the whole test by the addition of sensitized cells (check cells) to negative AHG tests

G.1.3.1 R_1r cells sensitized with a 'control' anti-D (check cells) to give ++/+++ reaction in a spin test should be added to negative tests. These cells should give detectable reactions from '+' to '+++'.

G.1.3.2 The absence of a reaction suggests a washing deficiency and demands corrective action and a repeat test. More strongly sensitized '++++' cells should not be used as they give an illusion of safety by still reacting strongly with a partially neutralized AHG reagent that would miss +/++ reactions.