CRITERA FOR THE ACCREDITATION OF BLOOD TRANSFUSION SERVICES

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1. PURPOSE AND SCOPE

The purpose of this document is to define the general, technical and specific requirements to be met by laboratories in the field of Blood Transfusion Science requiring accreditation to ISO 15189.

2. ABBREVIATIONS

DAT: Direct Antiglobulin Test

EDTA: Eethylenediamine tetra-acetic acid

FFP: Fresh Frozen Plasma

FDA: Food and Drug Administration

3. GENERAL REQUIREMENTS

3.1 Collection of blood from donors

Selection of Donors

a) The facility's donor selection criteria must be based on international standards, national laws and regulations and local epidemiological data of transfusion transmissible infections, risk behavior and local customs that may have an effect on the safety of the donor or recipient.

b) The facility shall develop guidelines for the deferral of potential donors who do not meet the selection criteria

c) A donor must give written consent prior to each donation procedure. Donors shall be informed about the blood donation procedure, potential adverse reactions and post-donation care, the tests carried out on the donated blood, the process for notification of abnormal results and information that may be released to a third party.

d) Donor interviews and evaluation shall be done by registered nurse or medical practitioner.

e) Records of any medical conditions, medications, and screening procedure are kept secure

Donor Screening

a) A donor health history questionnaire shall be designed to obtain information about risk factors to the donor or patient. The questionnaire shall be evaluated, periodically updated and used in a confidential manner and shall be completed prior to all collections.

b) The donor questionnaire form or electronic equivalent shall allow space for inclusion of but not limited to the following:

   i. Donor identification, gender, date of birth, location/contact details of donor, donor number

   ii. Name of the attending health officers

   iii. Date and time (start and end) of collection

Instructions for collection activities

The instructions for collection shall include the following:

a) Positive donor identification checked prior to donation

b) Verification that donor meets donor selection criteria

c) Instructions for collection of laboratory specimens and blood units shall be developed to include the following:

   i. Blood collection device, sample containers, sample volume and additive solutions

   ii. The blood collection devices shall be sterile, pyrogen-free and for single-use, with a closed system of collection.

   iii. Prior to collection of blood, the container to be filled shall be inspected in a manner recommended by the manufacturer to ensure that the hermetic seal is intact, that there has been no leakage of the anticoagulant or preservative solution from the container and that the container is in all other respects suitable for use.

   iv. The venipuncture site shall be free from lesions and signs of infection that might create a risk of contaminating the donation.

v. The venipuncture site shall be disinfected so as to minimize the risk of microbial contamination by following a validated method and using a qualified material that will not adversely affect the blood collected.

vi. Blood shall be collected by single venipuncture and the flow of blood shall be continuous.

vii. During blood collection, blood shall be gently agitated to mix the blood and anticoagulant in a manner that prevents the formation of micro clots

viii. Maximum collection time for whole blood intended for production of labile components shall be no longer than 12 minutes for platelets and 15 minutes for cryoprecipitate and FFP.

ix. The blood specimens for laboratory tests shall be collected at the same time as the collection of blood, as part of the collection process.

x. The pilot tubing of the plastic blood bag shall be filled with anticoagulated blood and sealed in such a manner that it will be available for subsequent testing.

xi. Verification on potential medication status that may affect blood components e.g. Use of aspirin on functionality of platelets must be noted or checked.

xii. Instructions for labelling laboratory samples and blood units must be clear. Specimens shall be labeled before the collection begins and shall be re-identified with the blood container immediately before the collection of the specimens.

d) Recording of the identity of person collecting blood, collection date and time

e) Instructions of proper storage conditions before collected blood units and blood samples are delivered to the laboratory

f) Safe disposal of materials used in the collection

g) Adverse events related to the blood donation process shall be assessed, investigated and monitored.

3.2 Handling, Transportation and Storage

1. The facility shall have procedures to ensure that blood, blood components and specimen are handled, stored and transported in a manner that prevents damage, limits deterioration and meets specified requirements.

2. Following collection, blood shall be placed in a qualified container for a maximum of 24 hours. The transportation container shall have sufficient refrigeration capacity to cool the blood continuously towards the required temperature range.
3. Donations for platelet components: Shall be cooled towards +20ºC to +24ºC until arrival at the processing laboratory.
4. Donations for production into components other than platelets: Shall be cooled towards +2°C to +8°C until arrival at the processing laboratory.
5. Blood collected for processing into components other than platelets shall be placed in an environment with a temperature range of +2°C to +8°C within 24 hours of collection.
6. Blood collected for processing into buffy coat derived platelet components shall be placed in an environment with a temperature range of +20ºC to +24ºC within 24 hours of collection.
7. Blood collected for processing into platelet rich plasmas shall be placed in an environment with a temperature range of +20ºC to +24ºC within 8 hours of collection
8. Containers used for the transportation of blood and blood components shall be validated to ensure they are suitable for maintaining required temperatures. Use of portable thermometers is highly recommended.
9. The facility shall verify that the establishment receiving the containers of blood and blood components maintains a system for checking that such containers arrive at their destination within the stipulated temperature ranges.
10. Corrective action shall be taken by the receiving facility if the container did not arrive at the required temperature.

3.3 Testing of Donated Blood

General Requirements

a) Blood group serology and testing for infectious diseases shall be carried out on a specimen collected at the time of donation, on every unit of whole blood or apheresis unit collected including autologous specimens.

b) The facility shall have procedures for the appropriate segregation and quarantine of untested units or those waiting further testing.

c) Test methods shall be validated or verified before implementation.

d) Records of testing for blood groups shall be maintained.

e) When ABO and/or RhD groups on record do not concur with current test results an investigation to resolve the anomaly shall be undertaken. Units in which an anomaly remains unresolved shall not be transfused and should be referred to a specific department that clears the anomaly

f) Any discrepancies in test results shall be resolved before the unit is released from quarantine and made available for transfusion.

3.3.1 Blood Group Serology

Mandatory testing of blood donations

a) ABO and RhD blood grouping are mandatory tests required as part of the criteria for release of all blood donations and components for clinical use.

b) Blood groups shall be determined using reagents that are approved by international recognised institutions such as FDA or standard internal procedures

c) In house produced cells can be used that ensure that the quality control is checked.

ABO blood grouping

a) The ABO blood group must be determined on each blood donation.

b) The ABO group shall be determined for each collection by testing the red cells with anti-A and anti-B reagents and by testing the serum or plasma with A_1 and B cells for the detection of ABO antibodies.

c) For a donor whose ABO blood group is unknown to the test centre (e.g. a first-time donor), the ABO blood group must be determined by testing the plasma/serum with group A_1 and B red cells. The red cells of the donation must be tested twice with anti-A and anti-B as a minimum before transfusion. The ABO group can only be accepted if the results are in agreement.

Quality control of ABO blood grouping

- Quality control procedures recommended by reagent and equipment manufacturers should be followed.
- The following minimum test monitors are required for each batch of ABO blood grouping tests:
  - anti-A, anti-B (and anti-AB where used) must give appropriate reactions with A_1, B and O cells as per manufacture guidelines
  - reagent red cell samples must give appropriate reactions with anti-A, anti-B (and anti-A,B where used), as per manufacture guidelines

RhD grouping

a) The RhD blood group must be determined on each donation of blood.

b) The RhD type shall be determined with anti-D reagent.
   - If blood is initially typed as RhD negative it shall be further tested to detect weak D unless a monoclonal IgM Anti-D reagent stated by the manufacturer as able to detect weak D has been used.
   - When the test for weak D is positive, the unit shall be labeled as Rh positive and not to be given to Rh negative patients.
   - When the tests for RhD and weak D are negative, the unit shall be labeled as RhD negative.

Quality control of RhD grouping

- Quality control procedures recommended by reagent and equipment manufacturers should be followed.
- The following minimum test monitors are required for each batch of RhD grouping tests:
  - each series of RhD blood grouping tests must obtain appropriate reactions with R_1r red cells as a positive and with r'r or rr red cells as a negative
  - appropriate reactivity with red cell samples expressing weak D should also be assured as a minimum during verification.

Antibody Screening

- Group O donations shall be tested for high titre ABO antibodies.
- Whole blood and plasma containing high titre ABO antibodies shall be labeled 'High Titre'.
- Red cell concentrates need not be labeled high titre if the majority of the plasma is removed.
- Whole blood or plasma labeled as "High Titre" shall be transfused into patients of the same ABO group only.
- Serum or plasma from donors shall be tested for irregular red cell antibodies using a method known to detect antibodies of probable clinical significance. When these are detected, plasma from these units shall not be used for transfusion.

Donations found to have a positive direct anti-globulin test

a) Direct antiglobulin test (DAT) positive donations may be identified incidentally by testing laboratories when:

- the autologous/reference control is positive in ABO/RhD blood grouping
- the antibody screen is positive
- anomalies are identified in extended phenotyping tests.

b) Non-red cell components may be prepared and issued from DAT positive red cell donations. Red cell units may be prepared and issued from DAT positive red cell donations provided that:

- the ABO and RhD groups are confirmed
- red cell antibodies have been excluded

a. Donors who have been found incidentally to have a positive DAT at donation testing may remain as blood donors provided they continue to pass the health screening questionnaire and have normal haemoglobin

Automated testing

- An automated system as a minimum must accomplish the following:

- positive sample identification, reading and interpretation of results
- matching of results to sample identification
- electronic transfer of results.

- There should be documented contingency plans for the breakdown or total failure of automated testing systems. Protocol settings for automated systems must be documented and version controlled. Where possible, current versions of software and settings for automated systems should be backed up and readily available.

Manual testing

a) A manual testing system can be used when the minimum automated testing criteria have not been met.
b) Manual testing can be used to resolve anomalous results.
c) Measures should be taken to minimize the testing batch size to avoid the potential for errors.
d) Manual tests must be performed and controlled according to the manufacturer's instructions.
e) Test results must be recorded.
f) There must be a secure and validated method of entering results onto the host computer. Post result entry verification should be performed.

Samples

a) Samples may be ethylenediamine tetra-acetic acid (EDTA) or clotted.
b) Where equipment/reagent manufacturers have defined protocols for storage and preparation, then these must be followed.
c) In the absence of protocols or recommendations from manufacturers, then validated protocols for sample storage and preparation must be defined.
d) Visual inspection to determine the suitability for testing must consider the following in relation to the equipment methods and samples used:

- Haemolysis
- lipaemia
- clots

- volume
- an unusually high or low cell: plasma (serum) ratio
- buffy coat layer (note: a large buffy coat layer in the sample may give rise to erroneous results).

e) Labels should be examined for defective labelling.

f) Reconciliation of all samples to be tested should be completed prior to testing.

Reagents and test kits

a) Acceptance testing should be performed on each batch/delivery of reagents and test kits.

b) Reagents and test kits should be stored and used according to the manufacturer's instructions.

c) Reagents and test kits without these instructions must be validated.

d) Reagent antisera must be validated and assured for specificity and potency

- A system of inventory control must be in place that records, as a minimum, the reagent or test kit:
  - lot number
  - expiry date
  - supplier
  - stock levels.

a) Procedures should ensure the traceability of the batch number and manufacturer of reagents and kits and, if relevant, the serial number of equipment used to test every donation.

Reporting of results

b) The report must indicate the result of each and every test, by a system that provides positive sample identification.

c) Reporting a series of tests by an 'assumed negative' procedure is potentially dangerous and not acceptable.

d) The acceptance and release of test results will be the responsibility of designated personnel of proven competency.

e) Information must be archived.

3.3.2 Donation Testing- Transfusion Transmissible Infections

General Requirements

Safe and effective procedures must be in place to ensure that:

- all donations, any subsequent components and their laboratory samples are correctly identified by bar-coded and eye-readable numbers
- donations can be linked to their donor
- information about previous test results which would preclude issue of a subsequent donation cannot be automatically overridden by a subsequent negative test result
- donor samples are suitably stored under appropriate conditions of temperature and time to preserve the targets for which they will be screened
- the screening assays used are properly evaluated and validated
- tests are appropriately performed and controlled, and the results properly and accurately recorded, using validated procedures
- test results and other relevant test information are retained for the appropriate period, as set out in the national regulations
- appropriate confirmatory testing must be available to investigate screen reactivity
- relevant data relating to screening and confirmatory test results must be reported to a centralised surveillance system, allowing the monitoring of trends in screening test reactivity and confirmed positive results.

Tests for Infectious Diseases

- The following tests are mandatory:
  - Human Immunodeficiency Virus (HIV) - Minimum - antibodies to HIV-1 and HIV-2
  - Hepatitis B virus (HBV). Minimum - Hepatitis B surface antigen (HBsAg)
  - Hepatitis C virus (HCV). Minimum - antibodies to HCV
  - Syphilis (*Treponema pallidum*). Minimum - antibodies to *T. pallidum* or VDRL test or RPR test
- Only donations that are non-reactive for the markers listed above shall be transfused even in

autologous situations

- Initially reactive donations should be re-tested in duplicate by the same assay. A repeatedly reactive donation should not be used for transfusion and should be destroyed unless used for non-therapeutic purposes.
- Further confirmatory testing should be performed using a different platform on all reactive specimens according to the facility defined algorithm that shall not compromise the safety of recipients.
- Additional infectious disease testing shall be performed based on national health guidelines and local epidemiological conditions.
- The facility shall maintain algorithms for testing procedures and the rejection or re-entry of reactive donors.

Test reagents, kits and equipment

- All assays used must be CE/FDA marked and must have been assessed (in respect of sensitivity and specificity) and deemed suitable internally by the laboratory for the detection of the required markers in the donation types being screened.
- Unless specifically validated for alternative use/performance, test kits and reagents must be stored and used according to the manufacturer's instructions.
- Each new manufacturer's lot of each assay should be assessed prior to being accepted and put into use with the help of the IQC.
- Additionally, all testing laboratories must ensure that the expected standard of performance of the assays used is being achieved, by using appropriate assay batch pre-acceptance testing, delivery acceptance testing and statistical monitoring of test results on defined quality control samples.
- All test procedures must be documented and an inventory maintained of kits and reagents in stock, including supplier, batch number, expiry date, date of receipt, version number of product insert and record of pre-acceptance testing.
- Procedures must ensure the traceability of the batch number and manufacturer of kits and reagents and the serial number of equipment used to test every donation.
- Equipment must be validated, calibrated and maintained.

- Appropriate records for these activities must be made and retained as defined in current national regulations.
- Appropriate reactivity with manufacturers' and any external control samples must be demonstrated with every series of tests.

Recording and reporting of results

- The laboratory final output should indicate the result of every test performed, using a system that provides positive sample identification.
- Each test result should be recorded by a system that does not require transcription. If manual completion of screening is performed it must be thoroughly documented and controlled and the results handled electronically following the same basic principles applied to fully automated testing.

Release of tested components

- Standard procedures must ensure that blood and blood components cannot be released for issue until all the required laboratory tests (mandatory and additional) have been completed, documented and approved within a validated system of work. Compliance with this requirement may be achieved by the use of a computer program, or suite of programs, which requires the input of valid and acceptable test results for all the mandatory and additional laboratory tests before permitting, or withholding, the release of each individual unit.
- Where a computer-based system has failed, compliance may be achieved by the use of a system, which requires documented approval for the release of each unit, by a designated person.

3.4 Donor Notification and Referral

Donors found to be reactive during screening for one or more TTI shall be notified and provided with counseling and referral services

3.5 Patient Testing

Sample acceptance and labelling

a) Visual inspection to determine the suitability for testing should consider the following in relation to the equipment, methods and samples used:

- the presence of haemolysis
- the presence of lipaemia
- the presence of an atypically large buffy coat layer
- the presence of clots in an anticoagulated sample
- a low sample volume
- an unusually high or low cell: plasma (serum) ratio.

b) If any of the above is identified, then this should be documented and appropriate action taken.

c) All samples must be labelled with both bar-coded and eye-readable numbers.

d) Samples that are separated prior to referral to the laboratory should be clearly labelled and signed to indicate the person separating the samples. Accompanying documents should clearly state the nature of the samples, the person separating the samples, and the time and date of sample separation.

Compatibility Testing

- Each blood specimen submitted from a potential transfusion recipient shall be tested for ABO group, RhD type (it is not necessary to test for weak D variants) and for clinically significant unexpected antibodies.
- A specimen of the recipient's serum or plasma shall be compatibility tested with a specimen of the donor's red cells from an originally attached whole blood or red blood cell segment before being issued for transfusion. The compatibility testing procedure shall include a method that will demonstrate ABO incompatibility. If the recipient's serum was not screened for abnormal antibodies using standardised antibody screening cells, the compatibility test using the recipient's serum and the donor's red cells shall include an anti-human globulin procedure.

- There shall be a process to ensure that the patient's historical record(s) of ABO group, RhD type and clinically significant antibodies have been reviewed and compared to current records and that discrepancies have been investigated and appropriate action taken before a unit is issued for transfusion
- If clinically significant red blood cell antibodies are detected in the recipient, red cell-containing components lacking the corresponding antigens shall be compatibility tested by a method that includes an anti-globulin phase.
    - If antigen typing of donor blood is not possible, cross-match compatible blood shall be issued.
- A compatibility testing record shall be completed for each recipient and shall include all units of blood or blood components issued, indicating the following:
    - Recipient's name.
    - Hospital identification number if available. A second identifier (such as date of birth) shall be used if the hospital number is not available.
    - Recipient ABO group and RhD type
    - Donation unit or pool identification number
    - Donor ABO group and RhD type
    - Interpretation of compatibility tests, if performed
    - Name/signature of the individual who performed the compatibility testing
    - Date of issue for transfusion.

- A label shall be attached securely to each unit intended for transfusion. The following information shall appear on the label:

    - Recipient's name and surname
    - Hospital name and number if available, A second identifier (such as date of birth) shall be used if the hospital number is not available
    - ABO and RhD type of recipient
    - Date of compatibility test
    - Name and signature of individual who performed the compatibility testing

- If it is not possible to include the name and signature of the individual who performed the compatibility testing on the label of the unit, there shall be a method to associate that individual with the unit.

- The recipient's specimens shall be kept at +2 to +8ºC for a minimum of 5 days after the transfusion.

Issue of Blood Components for Transfusion

- At the time a unit is issued for transfusion, there shall be a final check of facility records against each unit of blood or blood component. Verification shall include:
  - Visual inspection of blood and blood component
  - Comparison with current records of the patient
  - The intended recipient's two independent identifiers (i.e. recipient's full name and hospital number or date of birth), as well as ABO group, and RhD type
  - The donation identification number, the donor ABO group, and, if required, the RhD type
  - The interpretation of compatibility testing, if performed
  - The date and time of issue
  - Name/signature of individual who releases the blood component
  - Name/signature of individual who takes delivery of the blood component
- In the case of an anomaly or error detected during the time of issue, the unit shall be withheld for further investigation and appropriate corrective and preventive action taken.

- **Massive Transfusion:**
  - The facility shall have a procedure regarding compatibility testing when, within 24 hours, a patient has received an amount of blood or blood components approximating or exceeding the patient's total blood volume.

- **Transfusion of infants aged 4 months or less:**
  - Only anti-A and anti-B reagents are required to determine the infant's ABO group.
  - The RhD type shall be determined as previously prescribed
    - ABO group compatible red blood cell components shall be issued
    - RhD compatible red blood cell components shall be issued

- The serum or plasma of the mother shall be used to perform the test for clinically significant antibodies and if unavailable, then the infant's specimen shall be used, where possible. If the screening test for red cell antibodies is negative, and the infant is to be transfused with group O blood, it is unnecessary to perform compatibility testing for the initial or subsequent transfusions
- If the initial antibody screen demonstrates clinically significant unexpected red cell antibodies, units shall be prepared for transfusion that either do not contain the corresponding antigen or are compatible during cross-matching which includes by indirect anti-globulin compatibility testing
- In the management of haemolytic disease of the new-born, the mother's specimen shall be used for compatibility testing. In the absence of maternal serum or plasma, infant's serum or plasma shall be used
- Blood units selected for compatibility testing shall be ABO and RhD compatible with both infant and mother
- If a non-group O infant is to receive group specific red cells that are not compatible with the maternal ABO group, the infant's specimen shall be used for compatibility testing. Test methods shall include an antiglobulin phase.

Blood transfused in cases of dire emergency:

- When a specimen from the patient is submitted for compatibility testing, but the blood is required prior to testing being completed due to the urgency of the situation, then segments from the units provided for transfusion shall be retained and the compatibility testing shall be completed after the blood is issued.
- When patient's ABO group is unknown, they are to receive group O red cells.

3.6 Hemovigilance

Adverse Transfusion Reactions

- A facility that collects blood and/or performs compatibility testing or administers blood shall educate its health care workers on the identification, recording, management and reporting of adverse events in transfusion recipients:

- When a suspected transfusion reaction happens, it must be reported to the blood bank immediately, at the same time the person administered the blood shall also investigate the adverse event.
- The specimens must be collected and send to the laboratory for investigations. At a minimum, the investigation shall include:
    - A clerical check of all relevant transfusion records
        - Visual inspection of blood or blood components transfused (if available), and of post-transfusion specimen for haemolysis.
        - Determination of ABO group and RhD type of both pre- and post-transfusion specimens and transfused units, if available
        - Compatibility testing using both pre- and post-transfusion specimens
        - Direct anti-globulin test on both pre- and post-transfusion specimens.
        - Urine specimen is mandatory to check on the free haemoglobin in urine
- The results of the evaluation shall be recorded in the transfusion record of the patient and shall be reported to the patient's doctor.

Investigation of a Suspected Transfusion Transmissible Infections:

- When transmission of an infectious disease is suspected to be the result of transfusion, the facility that transfused the blood shall report that information to the collecting facility.
- The collecting facility shall have procedures for investigating and deferring donors when such reports are received.
- The collecting facility shall have procedures to notify the hospital or doctor of recipient(s) of units from a blood donor who is subsequently found to be infected with Syphilis, HIV, HBV or HCV.
- The facility shall provide guidance to the administering facility (hospital or doctor) which shall act on the information in the best interests of the patient- look back policy

Clinical Interface

- A facility that transfuses blood shall develop or adopt clinical guidelines on the appropriate use of blood and blood components and to advocate for best transfusion practices, and promote

continuing education in transfusion practice for clinical personnel. The guidelines shall include information on the products and services offered by the facility.

- A blood bank shall have procedures to communicate with clinical personnel to inform and educate them on the availability of blood and blood components and their appropriate use.
- A blood bank shall have procedures in place to provide timely clinical consultation to clinical personnel, 24 hours a day and seven days a week.

4.0 REFERENCES

- ISO 15189: Medical Laboratories – Particular requirements for quality and competence
- Guidelines for the Blood Transfusion Services in the United Kingdom, 8th edition, 2013, London: TSO
- Africa Society for Blood Transfusion, 2018 - Step-Wise Accreditation Standards

APPENDIX - AMENDMENT RECORD

Revision Status	Change			Approved by	Effective Date
	Page	Clause/ Subclause	Description of Change		
Issue 1	-	-	-	CEO	2023-02-28