

Standards for good transfusion practice guidelines

Feb-22

A . COMMON SECTION

PERSONNEL
Do you have qualified personnel and are they sufficient in number?
Do you have an organization chart of the blood service?
Do you have job descriptions?
Do staff members with responsibilities have replacements that possess the appropriate qualifications?
Do the personnel receive job-related theoretical and practical training?
Do you have a Continuous Medical Education program (CME)?
Do you have general hygiene and safety procedures for your blood service?
Is the laboratory entrance controlled? And limited to authorized personnel?
PREMISES
Do they respect the separation of circulation and operation areas?
Are the premises qualified?
Do you have a cleaning procedure for premises?
Do you have alarm system to monitor the storage areas of consumables, reagents?
Is the quarantine area clearly identified and restricted to authorized personnel?
Have you planned a storage area for biological samples?
EQUIPMENT
Do you have a list of critical equipment?
Do you have a qualification file for critical equipment?
Do you have a log book for each equipment?
In the event of the breakdown of an essential equipment do you have a documented back-up process?
DOCUMENTATION
Are all the procedures for a process documented?
Are the documents validated periodically?
QUALITY CONTROL (QC)
Have you established a quality control procedure?
Do you have a sampling plan?
What action have you established in case of a nonconformance on a blood/blood component, a consumable ... is detected?

B. BLOOD COLLECTION

PERSONNEL
Did they receive an appropriate training including the theoretical and practical aspects of blood collection?
PREMISES
Do the premises and mobile blood drives have: A reception area A suitable area for donor interviews and examinations that guarantee confidentiality A suitable area for collection An area to rest with a bed An area for snacks and refreshments
EQUIPMENT
Are the measurement, recording and monitoring equipment calibrated and checked at regular intervals?
Do you have the necessary material for the collection process (pre-donation interview ..)?
DOCUMENTS
Do you have a procedure for managing donor's information?
Is the collection form filled correctly?
INFORMATION, RECEPTION AND DONOR IDENTIFICATION
Do you have any educational materials that a donor can read before each donation?
Is the unique and non-reusable nature of the identifier guaranteed by the transfusion center?
SELECTION OF DONORS: PRE DONATION INTERVIEW AND PHYSICAL EXAMINATION
Is the pre-donation interview conducted under conditions that guarantee confidentiality?
Is there an SOP for the selection of prospective donors?
Are the personnel authorized to perform a physical examination?
Do you have an SOP that describes what should be done for collection of platelets by automated apheresis methods
COLLECTION
How do you prevent accidental contamination of the donations?
What precautions do you take to prevent donor reaction or accident?
Do you have a Standard operating procedure for collection?
How is the unique identifier ensured between the donation and the collection tubes?
Is there always a person in close proximity who is trained to handle emergency situations?
What measures do you take to avoid the risk of an identification mistake or an error between the donation number on blood bags and the blood samples?
REST AND SNACK
Are the phlebotomists trained to detect any sign of adverse reaction?
POST DONATION INFORMATION
Does the transfusion center ensure that post-donation information is always taken into account?

C. PREPARATION AND PROCESSING

PRINCIPLE
Do you have a detailed list and specifications of all processed blood/blood components?
PREMISES
Do you have a workflow plan for the preparation of blood/blood components?
Is the temperature of the blood reception area controlled?
PREPARATION
<i>GENERAL ASPECTS</i>
What measures do you take to prevent the risk of microbial contamination of blood/blood components?
Do you have standard operating procedures for the blood/blood component preparation?
Are the preparation methods for each blood/blood component validated?
When blood/blood components are transferred to a new bag, is traceability ensured prior to transfer of contents?
<i>COLLECTED BLOOD COMPONENTS</i>
For each blood/blood component did you document the collection date, transport and storage times and temperatures between the collection and the processing?
<i>CENTRIFUGATION</i>
Are all whole blood units prepared into components using appropriate centrifugation methods?
Have you established all safety conditions?
Were the centrifugation conditions validated for each blood/blood component?
<i>WEIGHING</i>
Are the scales checked at regular intervals?
<i>STERILE CONNECTION</i>
How do you guarantee sterile conditions?
How do you ensure that there is no leakage risk caused by the seal?
<i>FREEZING</i>
Do you have a standard operating procedure for the freezing of blood/blood components?
<i>BLOOD/BLOOD COMPONENT LABELING</i>
Do you have a standard operating procedure?
STORAGE
Are the blood/blood components stored according to the requirements specific for each blood component?

D. DONOR BLOOD TESTING

PERSONNEL
Is the personnel appropriately qualified?
Is training for the use of automated equipment or information systems provided?
PREMISES
Do you have a document that describes the flow of activities, reagents, waste and personnel movement?
Do you have storage areas that allow separate storage of various product types?
Is the temperature of the premises controlled?
Is there a temperature recorder?
Do you have alarms?
Do you have a waste management procedure?
AUTOMATION/COMPUTERIZATION
In the event of automation or computer system breakdown, do you have a specific procedures that details what should be done?
SAMPLE HANDLING
<i>GENERAL ASPECTS</i>
Is the sample identification performed using an automated bar code reader?
Is the connection of automated equipment to the laboratory information system validated?
<i>STORAGE CONDITIONS</i>
Are the samples stored at temperatures between + 2°C and + 8°C after collection?
BLOOD TESTING
<i>GENERAL CONCEPT</i>
Do you have Standard Operating Procedures for detection of transfusion-transmitted diseases?
What are the mandatory blood tests that are performed?
Are mandatory tests intended to prevent disease transmission by allogeneic donations done by appropriate immunoenzymatic automated methods?
Are there any decision-making algorithms? And how are they validated?
Does the algorithm take into account discrepancies in the results?
Do you have a standard operating procedure for blood typing?
Is ABO group determined for each collection by testing the red cells with anti-A and anti- B reagents and by testing the serum or plasma for expected antibodies with A1 and B reagent red cells.
If the screening results are repeatedly positive on 2 separate measurements , do you discard the blood unit and all its components?
Is there a procedure in case of donation-donor misidentification either in relation to the current donation or a previous donation?
<i>QUALITY CONTROL FOR ANALYTICAL REAGENTS</i>
For each blood test, is the reagent conformity verified using internal controls?
Do you participate in a proficiency testing program ?
Are the reagents stored according to the manufacturer's recommendations?
<i>ANALYTICAL VALIDATION</i>
Do you have an SOP for analytical method validation?
<i>BIOLOGICAL VALIDATION</i>
Do you have an SOP for biological validation?

E. DISTRIBUTION

PERSONNEL
Do you have the job description of the distribution manager ?
Are the personnel qualified?
Is the distribution activity organized in order to ensure its continuity?(number of personel)
PREMISES
Are the premises consistent with the requirements of "Principles of good transfusion practice"?
Are storage areas maintained at appropriate temperatures and regularly checked?
Do you have an alarm and temperature recording system in storage areas?
EQUIPMENT
Is the refrigeration storage equipment consistent with the requirements of "Principles of good transfusion practice"?
Are the refrigerators equipped with high and low temperature alarms and freezers with high temperature alarm?
Are platelets stored in a temperature-controlled closed device?
Are platelets stored in agitators to facilitate gas exchange through the bag?
Are all storage equipment validated?
Do you have a monitoring and maintenance log for all storage devices?
Are the blood/blood components delivered along with appropriate documents? Is this document consistent with the requirements of "Principles of good transfusion practice"?
PROCEDURES FOR ISSUING BLOOD
Is the activity of issuing blood/blood components computerized?
Are the blood/blood components issued after determining the ABO-RH1 blood group on two different blood samples?
Do you have a procedure that assures the correct selection and traceability of blood components as stated in the "Principles of good transfusion practice"?
Do you perform a crossmatch for all patients having one or multiple alloantibodies?
Are the water-baths used for plasma thawing validated?
Is the SOP for the control and release of blood components consistent with the requirements of "Principles of good transfusion practice"?
Does the SOP include actions that can be taken in case of emergency situations?
Do you have an SOP for return of conforming blood products?
Do you have an SOP that specifies how to deal with non-conforming blood products (expired, damaged or contaminated blood products)?
Do you have an SOP concerning blood/blood component recalls?
Have you established a means of communication between the health care facility and the transfusion center or the person who released or distributed the product?