D.PHARM • SECOND YEAR

Pharmacy Law & Ethics

CHAPTER 15

Blood Bank



ENGLISH CHAPTER NOTES

DIPLOMA IN PHARMACY

BLOOD BANK – BASIC REQUIREMENTS AND FUNCTIONS

MEANING

- A Blood Centre (traditionally called a blood bank) is a licensed medical facility that collects, tests, processes, stores and issues human blood and blood components for transfusion.
- It supports emergencies, surgery, trauma and treatment of anaemia, cancer, haemophilia and other conditions.
- Blood is given only for clinical need; voluntary non-remunerated donation is preferred.

REGULATORY FRAMEWORK — INDIA

- Human blood and blood components are regulated under the Drugs and Cosmetics Act, 1940 and the Drugs Rules, 1945.
- Schedule F, Part XII-B gives requirements for the functioning and operation of a Blood Centre and preparation of components.
- A valid licence and compliance with approved premises, staff, equipment, testing and records are essential.

CORE FUNCTIONS — DONOR TO RECIPIENT

Donor



Voluntary non-remunerated donation preferred.

1 DONOR COUNSELLING & SELECTION



information, consent, history, examination and haemoglobin check.

2 COLLECTION



safe collection in a sterile blood bag by trained staff.

3 TESTING



blood group, compatibility-related testing and mandatory infection screening.

4 COMPONENT PREPARATION



red cells, plasma, platelets and cryoprecipitate when facilities are licensed.

5 CONTROLLED STORAGE



correct temperature, quarantine, alarms and inventory control.

6 ISSUE / DISTRIBUTION



correct unit to the correct patient with documentation and traceability.

Patient



For clinical need.

QUALITY CONTROL + RECORDS | QUALITY CONTROL + RECORDS protect every step.

BASIC REQUIREMENTS FOR A BLOOD BANK

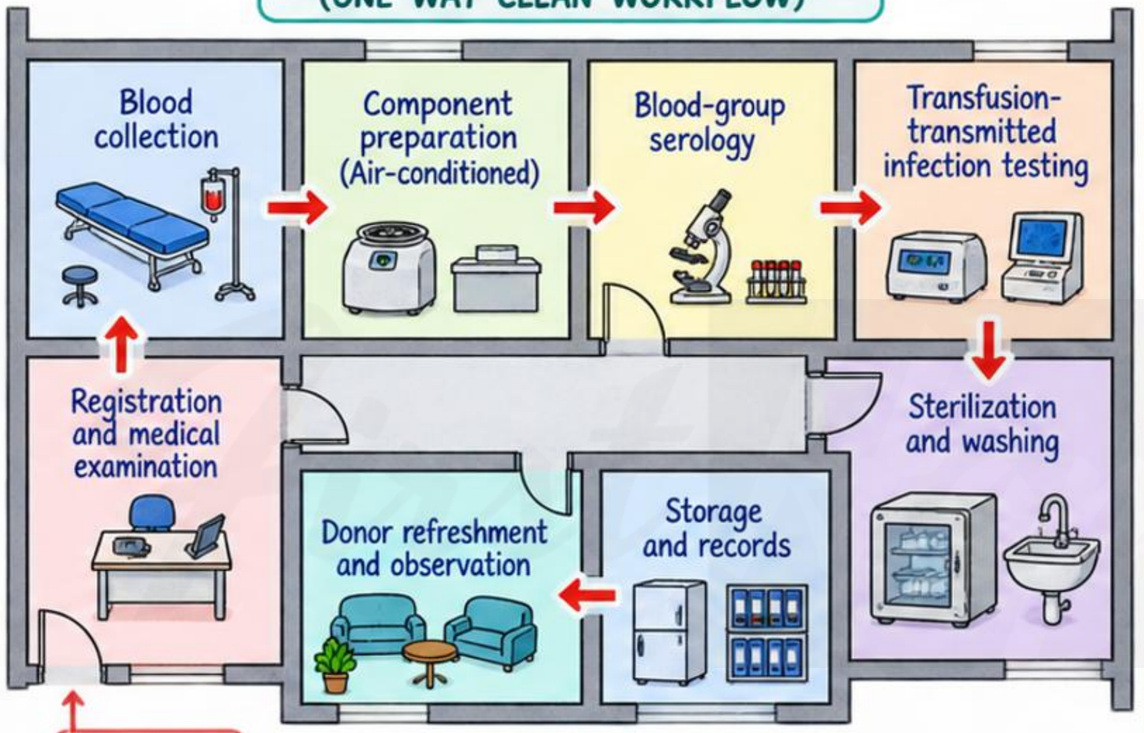
1 PREMISES & ZONES

- Clean, hygienic, well lit and ventilated premises; restricted entry and washable work surfaces.
- Separate areas for: registration and medical examination • blood collection • component preparation • blood-group serology • transfusion-transmitted infection testing • sterilization and washing • donor refreshment and observation • storage and records.
- Component-preparation area is air-conditioned; workflow should reduce mix-ups and contamination.

3 COMPETENT PERSONNEL

- Qualified Medical Officer / Transfusion Medicine specialist directs medical, technical and administrative services.
- Trained blood-bank technicians perform grouping, compatibility testing, screening and component work.
- Registered nurses support donor care; a qualified technical supervisor is required where components are prepared.
- Pharmacists may support storage, labelling and inventory of consumables and reagents within their authorised role.

BLOOD BANK FACILITY LAYOUT (ONE WAY CLEAN WORKFLOW)



BLOOD BANK TEAM



2 ESSENTIAL EQUIPMENT

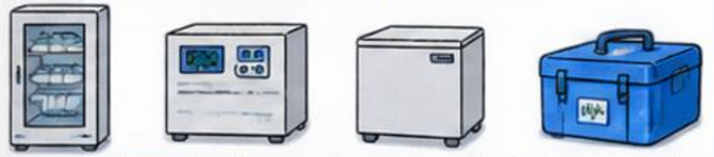
- Donor couch, weighing balance, blood mixer / collection monitor and tube sealer.



- Haemoglobinometer, centrifuge or refrigerated centrifuge, microscope and serology equipment.



- Blood-bank refrigerator with continuous temperature record and alarm; platelet incubator-agitator; plasma freezer and validated transport boxes.



- Approved TTI-testing equipment, water bath, autoclave, calibrated thermometers and reliable backup power.



- Equipment must be validated, calibrated, maintained and recorded.

SAFETY BASE: sanitation • PPE • SOPs • restricted access • pest control • emergency power

BASIC REQUIREMENTS FOR A BLOOD BANK

GATE 1 ELIGIBILITY



- Whole-blood donor: **18–65 years.** A first-time donor should not be over **60 years**; a repeat donor may donate up to **65 years**.
- Apheresis donor: **18–60 years.**
- Other medical criteria, weight, vital signs and deferral rules must also be satisfied.

GATE 2 INFORMED CONSENT



- Give understandable information, protect privacy and obtain written consent before collection.
- Consent includes screening of the donated blood and whether the donor wishes to be informed of abnormal results.

GATE 3 HEALTH CHECK



- Donor questionnaire + medical history + limited physical examination + haemoglobin test.
- Minimum haemoglobin for routine whole-blood donation: **12.5 g/dL.**

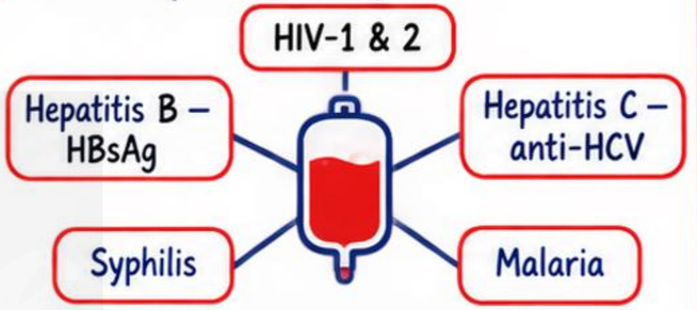
GATE 4 SAFE COLLECTION



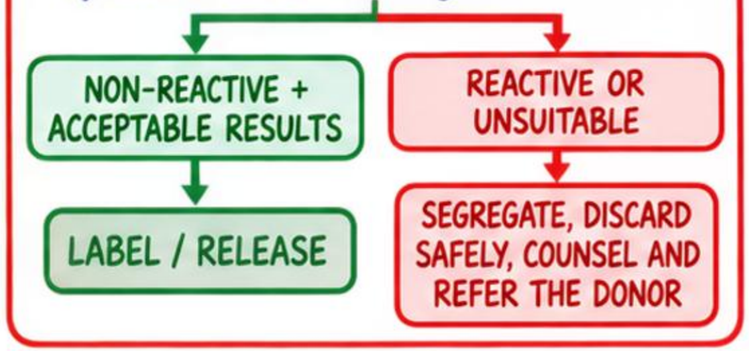
- Collect only through a licensed Blood Centre using a sterile, pyrogen-free, disposable closed blood-bag system under trained supervision.

GATE 5 TEST EVERY UNIT

- Confirm ABO and Rh(D) group and perform required compatibility-related testing.
- Mandatory TTI screening:



- Use approved validated methods. NAT can reduce the window period and is recommended, but it does not remove other required screening.
- Screening is for blood safety; a reactive screening result requires proper donor follow-up and is not by itself a final clinical diagnosis.



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