Reference Manual for
Health Care Facilities with Limited Resources

Infection Prevention and Control.

Module 8. Laboratories and Blood Banks

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Module 8. Laboratories and Blood Banks

Chapter 1. Clinical Laboratory Biosafety

Key Topics

- Common routes of exposure to laboratory-acquired infections
- Practices for all laboratories receiving clinical samples
- Practices for laboratories performing microbiology on clinical samples
- Additional practices for laboratories working with potentially hazardous material
- Administrative support for biosafety
- Infection control practices for specific laboratory procedures
- Prions

Key Terms

- **Biosafety** involves containment principles, technologies, and practices implemented in the laboratory to prevent unintentional exposure of staff or the community to pathogens and toxins or their unintentional releases.
- **Biosafety cabinet (BSC)** is an piece of laboratory equipment shaped like a cabinet that includes ventilation and is designed to provide protection to personnel, the environment, or a product being worked with (bacteria, viruses, human or animal tissues, or vaccine samples). Procedures are conducted in a workspace within the cabinet where the structure and airflow cabinet provide protection. This protection relies upon all recommended practices and procedures being followed. There are three types of safety cabinets:
    - **Class I** BSCs are open-fronted, negative-pressure cabinets. They provide personnel and environmental protection but not product protection. Exhaust air passes through a high-efficiency particulate air (HEPA) filter.
    - **Class II** BSCs are vertical, laminar-flow biosafety cabinets that are open-fronted and ventilated. They are equipped with HEPA filters for air inflow and outflow. They provide personnel, environmental, and product protections. Depending upon the purpose, there are different types (A, A1, B1, B2, and A2) with increasing levels of protection.
    - **Class III** BSCs are totally enclosed, ventilated cabinets of gas-tight construction with exhaust air filtered by two HEPA filters. They provide maximum protection to workers and the environment.
- **Biosafety level (BSL)** is a set of laboratory precautions used to handle materials and microorganisms that are based on the individual and community risks from the materials and microorganisms being handled (ability to cause disease, mode of transmission, availability of treatment, and prevention measures). There are four biosafety levels (1 to 4) with clearly defined criteria based on these risks.
- **Biosafety level guidelines** were established to ensure the safety of those working in the laboratory or the surrounding environment. They have the fundamental objective of containing potentially harmful biological agents, including all pathogenic microorganisms (bacteria, viruses, and fungi that can lead to infection). The guidelines include safe laboratory practices and techniques, safety equipment (primary barriers and personal protective equipment [PPE]), and facility design and construction.

- **Biosecurity** is the protection, control, and accountability for valuable biological materials within laboratories in order to prevent their unauthorized access, loss, theft, misuse, diversion, or intentional release.
- **Bloodborne pathogens** are infectious microorganisms (bacteria, viruses, and other microorganisms) contained in blood and other potentially infectious materials, including urine, respiratory secretions, and other body fluids (e.g., cerebrospinal, peritoneal, pleural, pericardial, and synovial amniotic fluids, semen, vaginal secretions, breast milk, and saliva). The pathogens of primary concern are hepatitis B virus (HBV), hepatitis C virus (HCV), and HIV.
- **Microorganisms** are causative agents of infection, and include bacteria, viruses, fungi, and parasites. Some bacteria can exist in a vegetative state (during which the organism is active and infective) and as endospores (in which a rough, dormant, non-reproductive structure protects the cell). Endospores are more difficult to kill due to their protective coating.
- **Prions** are abnormal infectious protein particles that cause rare, progressive degenerative neurological disorders that affect both humans and animals. These disorders are known as transmissible spongiform encephalopathies, such as Creutzfeldt-Jakob disease, Gerstmann-Sträussler-Scheinker syndrome, fatal familial insomnia, and kuru in humans; scrapie in sheep and goats; bovine spongiform encephalopathy in cattle; and other transmissible encephalopathies of deer, elk, and mink. Prions are resistant to normal methods of disinfection and sterilization.

Background

The capacity of clinical laboratories differs according to the type and size of health care facility and the level of resources available. Some clinical laboratories do not perform microbiology while others conduct extensive microbiological tests. Laboratory workers who handle blood, other potentially infectious body fluids, or infectious microorganisms are at risk of accidental injury or exposure to pathogens.

It is difficult to determine the exact number of laboratory-acquired infections that occur as not all laboratories report. In an online survey of clinical laboratories in 88 health care facilities in the United States, one-third of the laboratories reported having experienced at least one laboratory-associated infection among their lab staff due to accidental exposure during handling and disposing of samples during the prior 3 years. (Baron and Miller 2008)

Infection prevention and control (IPC) practices for collecting, handling, and processing blood and body fluid specimens are relevant for all laboratories that receive and perform tests on blood and body fluids, even those that do not conduct any microbiological procedures. Tests such as hemoglobin levels, urinalysis, thick and thin smears, rapid tests, and microscopic stool analysis still require IPC precautions to protect staff from blood and body fluids.

For clinical and research laboratories with microbiological capacity, specific types of IPC practices and laboratory techniques are required, including appropriate containment equipment, facilities, and procedures used by the laboratory staff for specific microorganisms,[1] depending on the biosafety risk level. Biosafety guidelines are designed to prevent laboratory-acquired infections and contain biohazardous agents. An understanding of the levels of biosafety will help laboratory staff understand the occupational risks, safe work practices, laboratory design, the use of PPE, and appropriate waste management.

[1] Detailed information on recommendations for specific bacterial, fungal, parasitic, and viral agents can be found on the Centers for Disease Control and Prevention's website at http://www.cdc.gov/biosafety/publications/bmbl5/bmbl.pdf.

Laboratories processing samples for health care facilities are always considered biosafety Level 2 or above, which is the primary focus of this chapter. Table 1-1 describes biosafety levels and outlines the types of IPC practices required for laboratories of the various levels. The first priority in any setting is to ensure that the basic safe work practices and good microbiological techniques are always strictly followed. These measures can prevent many opportunities for exposure in the laboratory.

Table 1-1. Biosafety Level Description and Recommended IPC Practices

Biosafety Level	Risk Group	Description	Laboratory Type	Types of Organisms	Infection Prevention Practices	Safety Equipment
Basic (BSL-1)	No or low individual risk and no community risk. Unlikely to cause disease.	Lowest level of containment. Suitable for laboratories working with microorganisms that pose minimal potential hazards to staff and the environment and *not* known to cause infections in healthy adults.	Undergraduate and secondary training/ teaching laboratories and some physicians' offices	*Bacillus subtilis*, hay or grass bacteria	Standard infection control and good microbiological technique	None, open bench work
Basic (BSL-2)	Moderate individual and low community risk. A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock, or the environment.	Generally applied to laboratories working with any human blood, body fluids, or tissues. Initial processing of clinical specimens and identification of isolates except in extraordinary circumstances (e.g., suspected outbreak of hemorrhagic fever).	Primary health services, diagnostic services, research, and laboratories where work is done with human blood, body fluids, or tissues	*Salmonella* species, HBV, HCV, HIV, and others associated with human diseases of varying severity	Standard infection control and good microbiological technique Protective clothing Biohazard sign	Open bench with PPE BSC for potential aerosols
Containment (BSL-3)	High individual risk and low community risk. Causes serious disease but not easily spread from one individual to another.	Applicable to clinical, diagnostic, teaching, research, or production facilities working with agents that may cause serious or potentially lethal disease as a result of exposure by the inhalation route (aerosols or droplets).	Special diagnostic service, research	*Mycobacterium tuberculosis* [TB], yellow fever virus, severe acute respiratory syndrome (SARS) coronavirus, or varicella virus [chicken pox]	Standard infection control and good microbiological technique Protective clothing Biohazard sign Special clothing Controlled access Directional Airflow	BSC and/or other primary devices for all activities

Biosafety Level	Risk Group	Description	Laboratory Type	Types of Organisms	Infection Prevention Practices	Safety Equipment
Maximum Containment (BSL-4)	High individual and high community risk. Causes serious disease and easily spread from one individual to another.	Used where laboratory research is conducted on dangerous and easily transmittable agents causing life-threatening or untreatable disease with a high risk of aerosol transmission in the laboratory.	Dangerous pathogen units	Hemorrhagic fever viruses (e.g., Ebola, Marburg)	Standard infection control and good microbiological technique Protective clothing Biohazard sign Special clothing Controlled access Directional Airflow Airlock entry Shower exit Special waste disposal	Class III BSC or positive-pressure suits with Class II BSC, double-ended autoclave (through the wall), filtered air

BSC = Biosafety Cabinet

Adapted from: WHO 2004.

Routes of Exposure That Can Result in Laboratory-Acquired Infections

The clinical laboratory is a unique area of the health care facility in which the types of biological materials handled, along with the practices, procedures, and equipment used, can place the health care worker (HCW) at risk of occupational infection if recommended precautions are not taken. Error, accident, or carelessness in the handling of specimens and pathogens is the cause of most laboratory-acquired infections. Infections such as brucellosis, tuberculosis, typhoid, hepatitis, streptococcal infections, and others are known to have been acquired from the laboratory. Infections acquired from pathogenic organisms in the laboratory setting occur by several routes. The following are the most common routes of exposure:

- Injection (puncture of the skin)—Accidental injury to the skin (e.g., cuts, scrapes) from contaminated sharps (e.g., needles, blades, broken glassware). This may occur when using a needle and syringe to transfer liquid to/from a vial (not recommended), after accidental breakage of a glass pipette, or while cleaning up a spill from broken glassware. This is the leading cause of laboratory-acquired infections.
- Absorption—Splashes and sprays of contaminated fluids onto mucous membranes of the eyes, nose, and mouth. This can occur when working with contaminated body fluids or other liquids/solutions containing microorganisms. Touching contaminated hands to these areas can also be a source of infection. Rarely, absorption through intact skin may occur.
- Inhalation—Laboratory procedures can cause infectious particles to become aerosols, which can then be inhaled. Procedures and equipment used to process specimens may generate aerosols. These include mixing, grinding, blending, centrifuging, sonicating, flaming a transfer loop, and opening containers of infectious materials whose internal pressure may be different from the room pressure.
- Ingestion—Infectious agents can inadvertently be introduced into the mouth of laboratory workers and swallowed (e.g., from mouth pipetting, unconsciously putting fingers to the mouth, or eating in the lab).

To prevent infection, each person working in the laboratory must ensure that the standard safe work practices are always used, risk of each process is assessed, and additional safety methods are used when needed. Laboratory staff are also responsible for using and maintaining the administrative and engineering safety controls put in place by the facility to enhance safety.

Safe Work Practices and Recommended Infection Prevention and Control Practices

All Health Care Facility Laboratories

The first priority in any setting is to ensure that the basic safe work practices are always being strictly followed. The following are the recommended practices that apply to all health care facility laboratories that receive samples of blood or body fluid (classified as BSL 2), even those not performing any microbiology:

- Limit access:
  - Limit laboratory access to authorized persons.
  - Keep the laboratory door closed; post a biohazard sign.
- **Wear protective clothing:** All staff working in the laboratory should wear coveralls, gowns or uniforms, and closed-toe shoes.

- **Keep the laboratory and work surfaces clean:** The premises should be clean, tidy, and free of materials not required for the work.
- **Follow safe work practices:** Standard Precautions apply; treat all samples from all patients as potentially infectious. Wear gloves and perform hand hygiene, use PPE appropriate for the task, minimize dispersal of potentially infectious material by avoiding practices that increase risk of injection, absorption, inhalation, and ingestion.
- **Practice sharps safety:** Handle sharps safely, use safety devices, and limit the use of needles and syringes.
- **Clean carefully:** Properly decontaminate work surfaces and contain spills immediately.
- **Manage infectious waste appropriately:** Apply guidelines for special treatment of potentially infectious laboratory waste.
- **Use equipment safely:** Use and maintain as recommended.
- **Know the safe laboratory code of practice:** Understand and follow safety policies, practices, and procedures that reduce hazards.

Health Care Facility Laboratories Processing Clinical Microbiology Samples (BSL-2)

The first priority in any setting is to ensure that the basic safe work practices and IPC recommendations (known in laboratories as "good microbiological technique") described above are always strictly followed. These measures will prevent many opportunities for exposure in the laboratory. The following safe work practices apply to laboratories processing samples for health care facilities (these are always considered BSL-2 or above):

- **Limit access** (as above).
- Wear protective clothing:
  - Wear laboratory coveralls, gowns or uniforms, and closed-toe shoes at all times for work in the laboratory:
    - Avoid wearing these outside the lab.
    - Do not store these in the same locker with street clothes.
  - Routinely use eye protection (goggles, face shield or eye glasses with side panels).
- Keep the laboratory and work surfaces clean (as above).
- **Follow safe work practices:** Standard Precautions correlate with recommended safe work practices for laboratories and apply in this setting:
  - Collect, transport, and handle all specimens as potentially infectious.
  - Perform hand hygiene after touching potentially infectious material (specimens, cultures, equipment) and before leaving the laboratory.
  - Perform a risk assessment before proceeding with each task to decide what protective equipment is needed.
  - Wear recommended PPE for the task. Wear gloves when handling biohazardous materials. (See Module 3, Chapter 1, Personal Protective Equipment.)
- **Use biosafety equipment when available**. Table 1-2 outlines the protection that various items of equipment provide.

- **Perform all procedures in a manner that minimizes the dispersal** of blood and body fluids and other potentially infectious material and the creation of splashes and/or aerosols:
  - Use an enclosed electric micro-incinerator to sterilize transfer loops (there is a risk of spatter of infectious material in an open Bunsen burner flame).
  - Use disposable transfer loops.
  - Take care when drying sputum samples, to avoid creating aerosols.
  - Place discarded specimens and cultures for autoclaving and/or disposal in leak-proof containers (e.g., laboratory discard bags) and secure them (e.g., with autoclave tape) prior to disposal into waste containers.
  - Protect from contamination any written documents that are expected to be removed from the laboratory.
  - Ensure that specimens are stacked securely during storage (e.g., in the refrigerator/freezer) to avoid spills and breakage.
- Take precautions to avoid ingestion of infectious materials and contact with the skin and eyes:
  - Wear disposable gloves and shield face, eyes, and mouth during any operation that may result in splashing of potentially infectious materials.
  - Pull gloves up over the cuffs of gowns to protect the wrists.
  - Do not place any materials in the mouth, or touch the mouth, eyes, nose, or face. Avoid mouth pipetting, licking labels, eating, chewing gum, drinking, smoking, applying cosmetics, and handling contact lenses in the lab.
  - Do not store food in refrigerators that are used in the laboratory for storing specimens and other infectious agents.
- **Sharps safety** (see Module 4, Chapter 3, Sharps Injuries and Management of Exposure to Bloodborne Pathogens):
  - Practice safe handling of sharps.
  - Limit the use of needles and syringes; do not use them as substitutes for pipetting devices.
  - Use engineered sharps safety devices when syringes and needles are necessary.
  - Do not re-cap needles.
  - Use plastic rather than glass when possible. Do not use chipped or broken glassware.
  - Handle broken glass safely, wearing heavy-duty gloves. Sweep up broken glass using a broom and dust pan and dispose of in a sharps container as soon as possible.
  - Dispose of all sharps in puncture-proof/leak-proof containers. Do not fill above three-quarters full.
- **Cleaning:** (as above).
- Waste disposal:
  - Place infectious waste materials in appropriate waste containers.
  - Decontaminate all cultures, stocks, liquids, and other potentially infectious materials before disposal using an effective method.

- **Use equipment** as recommended by the manufacturer and follow cleaning and maintenance instructions, including those for BSCs.
- **Understand and follow the policies, procedures**, risk assessment, reporting requirements, and employee health guidance for laboratory work at the facility.

Table 1-2. Protection from Equipment Used in BSL-2 Laboratories

Equipment	Protection	Safety Feature
Pipetting aids	Hazards from mouth pipetting (e.g., ingestion of pathogens), inhalation of aerosols produced by mouth suction on pipette, blowing out of liquid or dripping from pipette, contamination of suction end of pipette	Ease of use Control contamination of suction end of pipette, protecting user and vacuum line Can be sterilized Control leakage from pipette tip
Micro transfer loops, completely closed with a diameter of 2–3 mm and shanks not more than 6 cm in length	Aerosol and spatter	Avoid the premature shedding of their loads Minimize vibration
Loop micro-incinerators, disposable loops	Spatter from transfer loops	Shielded in open-ended glass or ceramic tube Heated by gas or electricity Disposable loops, no heating necessary
Biological safety cabinets Class 1	Aerosol and spatter	Minimum inward airflow at work access opening Adequate filtration of exhaust air No product protection
Class 2	Aerosol and spatter	Minimum inward airflow at work access opening Adequate filtration of exhaust air Product protection
Vacuum line protection	Contamination of laboratory vacuum system with aerosols and overflow liquids	Filter prevents passage of aerosols Overflow flask contains disinfectant Rubber bulb may close off vacuum automatically when flask is full Entire unit is autoclavable
Screw capped bottles	Aerosols and spillage	Effective containment
Leak-proof vessels for collection and transport of infectious materials for sterilization within a facility	Aerosol, spillage, and leakage	Leak-proof construction with lip or cover Durable Autoclavable

Equipment	Protection	Safety Feature
Sharps disposal containers	Puncture wounds	Autoclavable Robust, puncture-proof
Transport containers between laboratories, institutions	Release of microorganisms	Robust Watertight primary and secondary containers to contain spills Absorbent material to contain spills
Autoclaves, manual or automatic	Infectious material made safe for disposal or reuse	Approved design Effective heat sterilization

Source: WHO 2004.

Laboratories without a Biosafety Cabinet

Health care facilities in low-resource settings may not have a dedicated BSC for routine diagnostic procedures conducted at the health care facility laboratory (health care facility laboratories receiving specimens are classified as BSL 2 or above). Performing certain procedures without a BSC presents a risk to laboratory workers. In the absence of a BSC, all other safe work practices and good microbiological techniques must be implemented meticulously. Follow aseptic techniques, use PPE appropriate to the task at hand, utilize autoclave or steam baths with a regular cleaning schedule to prevent contamination, and employ meticulous environmental cleaning.

Health Care Facility Laboratories Processing Samples That May Cause Serious and Potentially Lethal Disease (BSL-3 and 4)

The above practices are fundamental to laboratories of all biosafety levels. For staff working in laboratories or microbiologic research units operating under BSL-3 or 4, the guidelines are modifications and additions for the containment and safe handling of hazardous agents to protect the staff and the environment. BSL-3 and 4 entail enhanced laboratory design, use of BSCs, additional protective clothing, special PPE, additional training, medical surveillance of staff, and workflow requirements. Table 1-1 summarizes the additional practices required. These practices are out of the scope of most clinical laboratories at health care facilities in limited-resource settings. Details about these practices can be found in standard laboratory reference manuals such as that by the World Health Organization (2010) listed in the References for this chapter.

Administrative Support for Biosafety

Health care facility leaders can use the following strategies to support clinical laboratory staff in implementing good microbiological techniques and safe work practices to prevent infectious hazards in the laboratory:

- Actively and openly support and communicate the expectation that staff abide by safe work practices and good microbiological techniques to decrease infectious hazards in the clinical laboratory.
- Support the laboratory director in performing a laboratory risk assessment to ensure that appropriate equipment and facilities are available to support the work. In most facilities, and especially when resources are limited, expenditure on interventions to improve care must be prioritized. Providing work practices and environmental controls to prevent laboratory-associated infection should be a priority.

- Assign a laboratory-based staff member as a biosafety officer to champion IPC best practices, policies, and programs in the laboratory.

The following should be worked toward by the facility leadership to ensure high-quality laboratory practices:

- Develop written policies and procedures for safe work practices and good microbiological techniques to decrease infectious hazards in the clinical laboratory. Appointing a multidisciplinary biosafety committee may be helpful to develop policies and codes of practice.
- Ensure a continuous, on-the-job safety training program for laboratory and support staff.
- Provide a laboratory designed for the type of work assigned to it. Priority should be given, at minimum, to addressing conditions that are known to create safety problems, such as:
  - Formation of aerosols
  - Work with large volumes and/or high concentrations of microorganisms
  - Overcrowding and too much equipment
  - Infestation with rodents and insects
  - Unauthorized entrance
  - Workflow: use of specific samples and reagents
  - Lack of functioning hand hygiene facilities
- Ensure that resources for laboratory safety are provided:
  - Adequate and suitable PPE and other safety devices
  - Quality assurance in the laboratory processes
  - Routine and preventive maintenance of the BSC and other equipment following the manufacturers' instructions
  - Safety equipment
  - Maintenance and upgrades to laboratory facilities
- Provide adequate medical surveillance and vaccinations for laboratory staff suitable to the work performed (see Module 4, Chapter 2, Infection Prevention and Control Aspects of Occupational Health in Health Care Settings) including for BSL 2:
  - Pre-employment health check
  - Immunizations as recommended
  - Record of illnesses and absences
  - Education of women of childbearing age about the risks
  - Exclusion of highly susceptible individuals (such as pregnant or immunocompromised HCWs) from hazardous laboratory work
  - System for reporting sharps injuries and exposures with prompt assessment, counseling, and post-exposure prophylaxis when indicated
- The IPC department should work closely with the clinical microbiological laboratory to ensure good infection control in the laboratory, support exposure follow-up, and identify health care-associated infection, antibiotic resistance, and infectious disease outbreaks in the facility.

Infection Prevention and Control for Specific Laboratory Procedures

Phlebotomy/Blood Draw

Drawing blood from veins of patients (phlebotomy) is often performed by laboratory staff. Staff drawing blood should follow best-practice and local IPC policies and protocols to protect the HCWs from exposure to bloodborne pathogens (e.g., hepatitis B virus [HBV], hepatitis C virus [HCV], HIV, and hemorrhagic fever viruses) and the patients from the risk of health care-associated infections. HCWs performing phlebotomy should be trained and competent in performing the procedure.

In hospitalized patients, do not take blood from an existing peripheral IV site because this may give false results due to hemolysis, contamination, and presence of intravenous fluid and medication. Nursing staff and physicians may access central venous lines for specimens following protocols (see Module 10, Chapter 3, Preventing Intravascular Catheter-Associated Bloodstream Infections, for guidance on how to access intravascular devices). However, drawing specimens from central lines carries a risk of infection to the patient and false positives due to colonization of the central line. It is acceptable, but not ideal, to draw blood specimens when first introducing an in-dwelling venous device, before connecting the cannula to the intravenous fluids. Ultimately, blood draw from a new site is preferred.

Appropriate supplies for IPC during a blood draw include:

- Required supply of laboratory sample tubes for the tests requested:
  - Store dry and upright in a rack.
  - Ensure that the rack containing the sample tubes is close to the HCW, but away from the patient, to avoid its being accidentally tipped over.
  - Collect blood in vacuum-extraction blood tubes (preferred), sterile glass or plastic tubes with rubber caps, or glass tubes with screw caps (least preferred).
- A sterile glass or bleeding pack (collapsible) if large quantities of blood are to be collected.
- Well-fitting, non-sterile gloves; do not use the same pair of gloves on more than one patient.
- Blood-sampling devices of various sizes, preferably a vacuum-tube holder with needle that will allow filling of multiple sample tubes without withdrawing the needle or other safety-engineered devices or needles:
  - Use new, single-use, disposable equipment (syringes, needles, and lancets for every patient).
  - Do not use auto-disable syringes (a disposable syringe with a fixed needle that automatically is disabled after a single use) for phlebotomies.
- A new or cleaned tourniquet
- Alcohol-based handrub
- 70% alcohol swabs for skin disinfection:
  - Do not presoak and store swabs due to risk of contamination.
- Gauze or cotton-wool ball to be applied over the puncture site
- Laboratory specimen labels
- Writing equipment
- Laboratory forms
- Leak-proof transportation bags and containers

- A puncture-resistant sharps container:
  - Place the sharps container close by and in a location where no reaching will be necessary to place the sharp into the container.
  - Do not overfill containers; empty when three-quarters full.

Blood drawing

STEP 1: Perform hand hygiene.

STEP 2: Gather supplies and prepare the location where the blood will be drawn.

STEP 3: Prepare the patient and assess if a second person is needed to assist in case the patient may be uncooperative or difficult to handle (e.g., children, patients with mental impairment).

STEP 4: If the site is visibly soiled, wash it with soap and clean water, and then dry it with a clean cloth.

STEP 5: Perform hand hygiene.

STEP 6: Place the donor's arm on a clean surface or towel.

STEP 7: Apply a new or clean tourniquet and palpate the vein.

STEP 8: Unless drawing blood cultures, cleanse an area of about 2 cm (1 inch) with 70% alcohol swab for 30 seconds and allow the antiseptic solution to dry completely (30 seconds):

- When using alcohol, cleanse in a circular motion outward from the proposed needle insertion site.
- Do not touch the area after applying the antiseptic solution. It the site is touched, repeat the disinfection.

STEP 9: Put clean, non-sterile gloves on both hands.

STEP 10: Insert the needle into the vein without touching the cleansed skin with the hands:

- Palpation should be performed prior to skin cleansing.
- DO NOT place a finger over the vein to guide the shaft of the exposed needle.

STEP 11: If evacuated tubes with a needle and tube holder are available, insert, fill, and remove each tube required, one after the other. If this method is not available, fill a syringe with the amount of blood needed for the samples requested.

STEP 12: When completed, withdraw the needle and apply gentle pressure to the site with a clean gauze or dry cotton-wool ball. Ask the patient to hold the gauze or cotton-wool in place, with the arm extended and raised.

STEP 13: If not needed for filling laboratory sample tubes, discard the used blood-sampling device as a single unit, without recapping, directly into a puncture-resistant sharps container or go to the next step.

STEP 14: If manual filling of laboratory sample tubes is needed, use the safest method for the material available:

- When obtaining multiple tubes of blood, if evacuated tubes with a needle and tube holder are not available, use a syringe or winged needle set instead:
  - Place the tube into a rack before filling the tube.
  - Where possible, keep the tubes in a rack and move the rack toward you.
  - DO NOT remove the stopper of evacuated tubes because it will release the vacuum.

- Use one hand to fill the tube or use a needle shield between the needle and the hand holding the tube to prevent needle sticks:
  - > Pierce the stopper on the tube with the needle directly above the tube using slow, steady pressure.
  - > Do not press the syringe plunger for evacuated tubes because additional pressure increases the risk of hemolysis.
- If the sample tube does not have a rubber stopper, inject extremely slowly into the tube because minimizing the pressure and velocity used to transfer the specimen reduces the risk of hemolysis. (WHO 2010)

STEP 15: Pack samples in a leak-proof plastic bag with the laboratory request form in an outside compartment to avoid contamination. If there are multiple tubes, place them in a rack or padded holder to avoid breakage during transportation. Transport using standard precautions.

STEP 16: Discard remaining sharps as a single unit, without recapping, directly into a puncture-resistant sharps container and the other disposable items into the appropriate category of waste.

STEP 17: Clean reusable items to get them ready for the next patient and wipe down any visible soil in the work area. Clean up any blood spill following the recommendation in Module 5, Chapter 2, Environmental Cleaning.

STEP 18: Perform hand hygiene.

STEP 19: Follow the protocol for any exposure to body fluids; report exposures immediately and apply appropriate treatment along with follow-up testing and counseling (post-exposure prophylaxis, when indicated, should be started as soon as possible). (See Module 4, Chapter 3, Sharps Injuries and Management of Exposure to Bloodborne Pathogens.)

Safe Handling of Specimens

Improper collection, transport, and handling of specimens present a risk of infection to HCWs and laboratory staff.

Specimen containers and labels

- Use robust plastic (preferred) or glass containers that do not leak when the cap or stopper is correctly applied to collect specimens:
  - Use disposable specimen containers when possible.
- Clean material from the outside of the container prior to transporting the specimen.
- Label containers correctly and clearly so they can be easily identified.
- Place specimen requests or specification forms in separate, preferably waterproof, envelopes to protect from contamination.

Transporting specimens within the health care facility

- Collect all laboratory specimens using Standard Precautions including wearing gloves when touching the specimens and performing hand hygiene afterward.
- Use carrying containers such as boxes or baskets fitted with racks to transport specimens:
  - Specimen containers should remain upright to avoid accidental leakage or spillage.

  - Carrying containers should be made of material that is easily cleaned (metal or plastic) and autoclavable or resistant to the action of chemical disinfectants.
- Regularly decontaminate transport containers.

Receipt of specimens

- Designate a particular room or area for receiving specimens if the laboratory receives a large number:
  - Specimen bags should not be opened by reception staff.
  - Staff who receive and unpack specimens should be aware of the potential hazards involved, and should be trained to follow Standard Precautions.
- Have suitable disinfectants for spill cleanup available for use when needed.

Opening specimen tubes and sampling contents

- Primary specimen containers should be opened in a BSC, if available, or cover the end of blood collection tubes with a cap, cloth, or paper towel, and point them away from a person's face when opening.
- Wear gloves, eye and mucous membrane protection (goggles or face shield), and a plastic apron over protective clothing.
- Grasp the stopper through a piece of paper or gauze to prevent splashing.
- Handle fixed and stained blood, sputum, and fecal samples for microscopy as potentially infectious; use forceps, store them appropriately, and decontaminate and/or autoclave them before disposal. The fixing process does not necessarily kill all organisms or viruses on the smears.
- Always open ampoules of freeze-dried (lyophilized) infectious materials in a BSC as the contents may be under reduced pressure and the sudden inrush of air may aerosolize some of the contents:
  1. Decontaminate the outer surface of the ampoule.
  2. Make a file mark on the tube near to the middle of the cotton or cellulose plug, if present.
  3. Hold the ampoule in alcohol-soaked cotton to protect hands when breaking it at the file scratch.
  4. Remove the top gently and treat as contaminated material.
  5. If the plug is still above the contents of the ampoule, remove it with sterile forceps.
  6. Add liquid for resuspension slowly to the ampoule to avoid frothing.
- If freezing, store ampoules of infectious materials only in mechanical deep-freeze cabinets, on dry ice, or in the gaseous phase above the liquid nitrogen. Avoid immersing in liquid nitrogen because cracked or imperfectly sealed ampoules may break or explode on removal.

Safe Laboratory Bench Workspace

- Keep the area neat, clean, and free of materials that are not pertinent to the work.
- Fit open windows with insect-proof screens.
- Decontaminate work surfaces promptly after any spill of potentially infectious material and at the end of the working day.

- Decontaminate materials, specimens, and cultures before disposal or cleaning for reuse.
- Follow applicable national and/or international regulations for packing and transportation of samples.
- Decontaminate prior to sending contaminated equipment for servicing or repair.

Use of pipettes and pipetting aids

- Always use a pipetting aid. Pipetting by mouth is prohibited.
- Use mark-to-mark pipettes when possible as they do not require expulsion of the last drop.
- Use cotton plugs in all pipettes to reduce contamination of pipetting devices.
- Prevent hazards, dispersal, and aerosolization:
  - Avoid blowing air through a liquid containing infectious agents.
  - Avoid mixing infectious materials by alternating suction and expulsion through a pipette.
  - Avoid forcibly expelling liquids from pipettes.
  - Use an absorbent material on the working surface to absorb material dropped from a pipette; this material should be disposed of as infectious waste after use.
  - Use devices for opening septum-capped bottles that allow pipettes; syringes fitted with hypodermic needles must not be used for pipetting.
- Place the discard container for pipettes within the BSC when available (not outside of it).
- To decontaminate contaminated pipettes, completely submerge in a suitable disinfectant placed in an unbreakable container and leave the pipettes in the disinfectant for the recommended length of time before disposal or washing and sterilization for reuse (see Module 6, Processing of Surgical Instruments and Medical Devices).

Separation of serum

- Only properly trained staff should separate serum.
- Wear recommended PPE: gloves and eye and mucous membrane protection.
- Minimize splashes and aerosols by using practices outlined in the Safe Work Practices and Recommended Infection Prevention and Control Practices section:
  - Blood and serum should be pipetted carefully, not poured.
  - Refer to guidance on pipette use in the Use of Pipettes and Pipetting Aids section in this chapter.
- Place discarded single-use specimen tubes containing blood clots, etc. (with caps replaced) in suitable leak-proof containers for autoclaving and/or incineration.
- Ensure that suitable disinfectants for cleanup of splashes and spillages are available when needed.

Use of centrifuges

Satisfactory mechanical performance is a prerequisite of microbiological safety in the use of laboratory centrifuges.

- Operate centrifuges according to the manufacturers' instructions.

- Place centrifuges so that laboratory staff can see into the bowl to place trunnions and buckets correctly.
- Use centrifuge tubes and specimen containers made of plastic (preferred) or thick-walled glass for use in the centrifuge. Inspect for defects prior to each use.
- Securely cap (screw capped preferred) tubes and specimen containers for centrifugation.
- Use BSCs for loading, equilibrating, sealing, and opening centrifuge buckets.
- Paired by weight and, with tubes in place, correctly balance buckets and trunnions.
- Follow manufacturer's instructions for the amount of space that should be left between the level of the fluid and the rim of the centrifuge tube.
- Used distilled water or alcohol (propanol, 70%) for balancing empty buckets; Saline or hypochlorite solutions should not be used as they corrode metals.
- Only use sealable centrifuge buckets (safety cups) for microorganisms in Risk Groups 3 and 4.
- Take care to ensure that the tube is not overloaded when using angle-head centrifuge rotors, to prevent leaks.
- Inspect daily the interior of the centrifuge bowl for staining or soiling at the level of the rotor. If staining or soiling are evident then the centrifugation protocols should be re-evaluated.
- Inspect daily centrifuge rotors and buckets for signs of corrosion and for hair-line cracks.
- Decontaminate buckets, rotors, and centrifuge bowls after each use and store in an inverted position to drain the balancing fluid.

Infectious airborne particles may be ejected when centrifuges are used. These particles travel at speeds too high to be retained by BSC airflow if the centrifuge is placed in a traditional open-fronted Class I or Class II BSC. Enclosing centrifuges in Class III BSC prevents emitted aerosols from dispersing widely. However, good centrifuge technique and securely capped tubes offer adequate protection against these infectious aerosols and dispersed particles.

Use of homogenizers, shakers, blenders, sonicators, and tissue grinders

- Domestic-grade homogenizers may leak or release aerosols; laboratory blenders and stomachers are safer:
  - Keep caps and cups or bottles in good condition and free from flaws or distortion; caps should be well-fitting and gaskets should be in good condition.
- Be aware that pressure builds up in the vessel during the operation of homogenizers, shakers, and sonicators, and aerosols containing infectious materials may escape from between the cap and the vessel.
- Where possible, use plastic, in particular, polytetrafluoroethylene (PTFE) vessels to prevent breaking glass from causing injury and releasing infectious material.
- Cover homogenizers, shakers, and sonicators with a strong, transparent plastic casing.
- Disinfect the casing after use.
- Where possible, operate under plastic cover, in a BSC.
- Open the containers in a BSC at the end of the operation.

- Open and operate tissue grinders in a BSC.
- Hold glass grinders in absorbent material in a gloved hand. Plastic (PTFE) grinders are safer.

Care of Refrigerators and Freezers

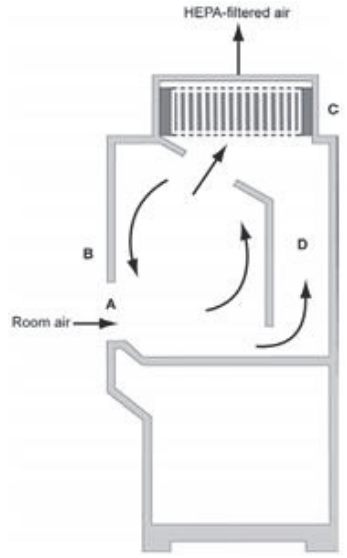
- Maintain an inventory of the contents of freezers.
- Label all containers stored in refrigerators and freezers with the scientific name of the contents, the date stored, and the name of the individual who stored them.
- Autoclave and discard unlabeled and obsolete materials.
- Periodically defrost and clean refrigerators, deep-freezers, and solid carbon dioxide (dry-ice) chests.
- Wear face protection and heavy-duty rubber gloves.
- Discard any ampoules, tubes, etc., that have broken.
- Disinfect the inner surfaces of the cabinet after cleaning.

Use of Biosafety Cabinets

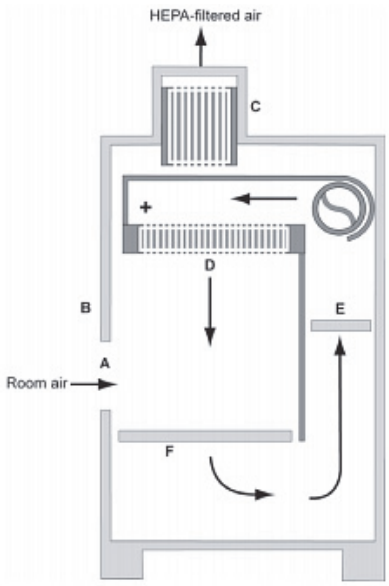
It is important for all users of BSCs (see Figure 1-1) to understand their use and limitations; the cabinet will not protect the operator from spillage, breakage, or poor technique:

- Only use the BSC if it is functioning properly.
- Do not open the glass viewing panel during use.
- Run the cabinet fan for at least 5 minutes before beginning work.
- Keep the equipment and material in the BSC to a minimum.
- Monitor that the air circulation at the rear plenum is not blocked.
- Be aware that heat produced in the BSC will distort the airflow and may damage the filters:
  - Do not use Bunsen burners.
  - Use sterile, disposable transfer loops or, if not available, an electric micro-incinerator.
- Carry out all work in the middle or rear part of the working surface where it is visible through the viewing panel. Adjust the height of the chair/seat so that the worker's face is above the opening to the BSC.
- Minimize traffic behind the operator.
- Ensure that all required materials are placed in the BSC prior to beginning work to minimize the entries and exits to the BSC. Avoid repeated removal and reintroduction of arms to minimize disruption of the airflow.
- Monitor that air grills are free from blockage with notes, pipettes, or other materials; disrupted airflow can result in contamination of the material and exposure of the operator.
- Do not put paperwork inside BSC.
- Run the cabinet fan for at least 5 minutes after completion of work in the cabinet.
- After use and at the end of the day, routinely disinfect the inside of the BSC with alcohol (70%) or a disinfectant consistent with the BSC manufacturer's instructions.

Figure 1-1. Biosafety Cabinet



BSC Class I
(A) front opening, (B) sash, (C) exhaust HEPA filter, (D) exhaust plenum.



BSC Class II, Type A2
(A) front opening, (B) sash, (C) exhaust HEPA filter, (D) supply HEPA filter, (E) positive-pressure common plenum, (F) negative-pressure plenum.

Sources: CDC 2009; US Department of Energy 2014.

Biosafety Cabinets Class III

BSC Class III provides the highest level of personnel protection and is used for BSL-4 agents. All penetrations in the cabinet are "gas tight." The access to the work space is by heavy-duty gloves attached to ports in the cabinet. (WHO 2004)

Disposal of Waste

The clinical laboratory is often one of the largest generators of infectious waste in the health care setting and specific procedures exist for laboratory infectious waste management. These may be governed by regional or national regulations that must be followed (see Module 5, Chapter 5, Waste Management in Health Care Facilities).

A Note about Prions

Conditions caused by prions in humans and animals are rare but have been identified in some parts of the world (such as Europe, the United States, Canada, and Papua New Guinea) but are difficult to confirm, even in sophisticated laboratories. Although Creutzfeldt-Jakob disease has been transmitted to humans, there have been no proven cases of laboratory-associated infections with diseases caused by prions. However, precautions should be taken when handling specific types of potentially infected or infected specimens. The highest concentrations of prions are found in central nervous system tissue. Consult national authorities or World Health Organization guidelines for laboratory biosafety for work with prions if regionally relevant. However, except for cerebrospinal fluid and nerve tissue, most other body fluids, secretions, and excretions including blood contain no infectivity, and need no special handling. See the References section for documents with further guidance.

Summary

The strict use of safe work practices and IPC recommendations in laboratories protects staff from laboratory-acquired infections. Biosafety guidelines are designed to guide the prevention of laboratory-acquired infections and contain biohazardous agents. Laboratory staff should understand occupational risks, safe work practices, laboratory design, use of appropriate PPE, and waste management. Laboratory staff also need appropriate supplies and equipment to work safely.

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Chapter 2. Infection Prevention and Control in Blood Bank and Transfusion Services

Key Topics

- Risks to donors, health care workers (HCWs), and blood transfusion recipients
- Protecting donors, HCWs, and blood transfusion recipients
- Components of safe blood bank services, from donation to transfusion
- Improving blood bank and transfusion services

Key Terms

- **Blood bank** is a facility or health care unit that performs the collection, processing, storage, and distribution of human blood or blood components.
- **Blood components** are therapeutic substances derived from human blood that include whole blood and its components; the most important are red cells (whole blood and packed red cells), platelets, and plasma (fresh frozen plasma and cryoprecipitate).
- **Blood donor** is a volunteer, family member, friend, or paid individual who gives blood or blood components for medical purposes.
- **Closed system for obtaining blood** is a system in which blood is not exposed to air or outside elements during collection and processing, including separation of components (e.g., platelets) prior to transfusion. The blood flows directly into the collection bag through a needle inserted into a vein. This is the safest way to collect, process, and store blood.
- **Lookback system** is a process of identifying recipients who have received blood transfusions from donors who are subsequently found to be infected with hepatitis B virus (HBV), hepatitis C virus (HCV), or HIV, and notifying the recipient, if appropriate.
- **Packed red blood cells** refers to donated blood that has had plasma removed.
- **Transfusion service** is a facility or health care unit that provides storage, pre-transfusion testing and cross-matching, and transfusion of blood/blood components.
- **Transfusion-transmitted infections** occur when a pathogen (e.g., bacterium, virus, or parasite) is transmitted to the transfusion recipient in donated blood.
- **Unit of blood** is a sterile, plastic bag with a fixed volume (generally 400–500 mL) of collected blood with a specified amount of anticoagulant (substance used to prevent the clotting of blood) added.
- **Urticarial reaction** is an allergic reaction consisting of itching, hives, skin rash, and/or similar allergic conditions occurring during or following a transfusion of blood/blood components.
- **Whole blood** is collected blood that has had no blood components removed; additives and anticoagulant solutions may be added.

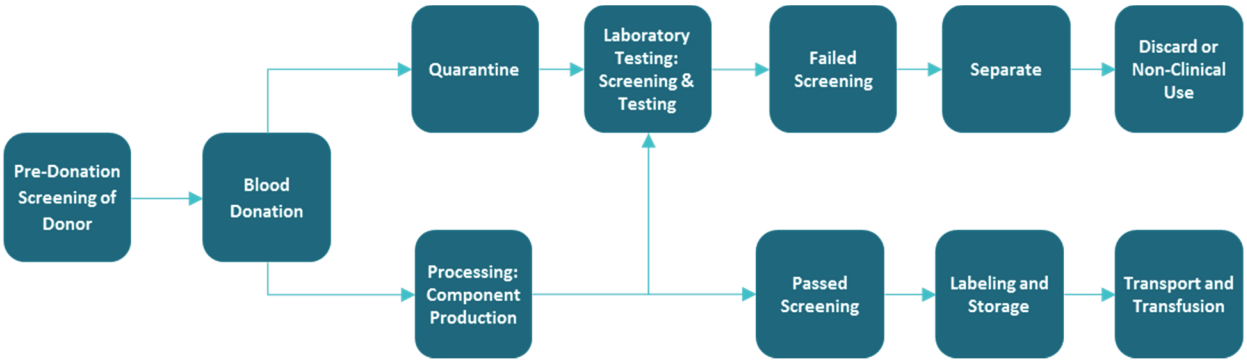
Background

Transfusing patients with blood and blood components has been used as a treatment for over 200 years. When blood transfusions occur safely, they can save lives and are an important medical treatment. However, overuse or inappropriate management can lead to acute or delayed complications and

transmission of infectious diseases. It is estimated that 108 million units of donated blood are collected globally each year. (WHO 2015)

Blood banks and transfusion services collect, process, store, and provide human blood and blood components intended for transfusion; perform pre-transfusion testing; and provide blood/blood component transfusions for patients (see Figure 2-1). The transfusion services are responsible for making safe blood/blood components available for transfusion and for protecting patients as well as staff working in the transfusion services area.

Figure 2-1. The Steps from Donation to Transfusion of Blood



In many respects, the transfusion of blood/blood components is similar to administering an intravenous infusion (e.g., antibiotic); however, there are additional, specific risks for patients who receive transfusions, such as the potential risk of infection with HBV, HCV, or HIV. To reduce these risks, guidelines for safely performing various screening and testing processes and procedures have been developed for blood transfusion services. These guidelines are very specific, and must be followed by HCWs providing transfusion services to ensure the safety of staff and the patients who receive transfusion.

Key components of providing safe blood include:

- Recruiting voluntary donors
- Screening the blood donors
- Using particular skin cleansing measures during blood collection
- Routinely screening donated blood for infection
- Safely processing blood into blood components
- Storing donated blood/blood components safely until transfusion
- Protecting the patient receiving the transfusion
- Ensuring the safety of laboratory staff and other HCWs
- Training blood transfusion service staff
- Conducting quality assurance throughout the process
- Documenting the transfusions meticulously
- Ensuring oversight by a national governing body

Adherence to these components reduces the risk of transfusion-related complications and health care-associated infections for patients and the risk of exposure and subsequent laboratory-acquired infections for HCWs.

Threats to the Safety of Transfusion Services

Factors that can threaten the safety of blood transfusion services include:

- Commercial and high-risk donors, such as commercial sex workers and intravenous drug users
- Minimal screening of donors for infectious diseases or other conditions (e.g., anemia) that normally should disqualify them as donors
- Inexperienced or undertrained staff and HCWs who are not aware of the risks to patients and themselves
- Pressure on transfusion staff to release blood before cross-matching and/or testing is completed
- Lack of lookback recordkeeping capabilities to track individuals who have received blood/blood components that are subsequently found to be seropositive for HBV, HCV, or HIV

Risks of Blood Transfusion to Donors, Health Care Workers, and Recipients

During the process of blood collection, storage, and transfusion there is a risk of infection for the donor, the recipient, and for HCWs who handle the blood and blood components:

- **Donor:** There is a small risk to the donor of an infection at the site from which the blood is drawn and from contaminated equipment or the hands of HCWs.
- **HCW:** There is also a risk to the HCW of exposure to bloodborne pathogens via splashes into mucous membranes of the eyes, nose, and mouth or from a sharps injury while collecting the donor specimen, during testing, and when infusing blood/blood components.
- **Recipient:** The greatest risk is to the recipient of the transfusion from an infection contained in the donated blood, known as transfusion transmitted infection (TTI). There is also a small risk of infection from the intravenous device used to deliver the blood transfusion or from contamination of the health care environment, equipment, or hands of HCWs.

Causes of TTI include contamination of the blood during collection (e.g., by microorganisms on the donor's skin, which multiply during storage) or bacterial, viral, or parasitic infections carried in the blood of the donor. These include HIV, HBV, HCV, syphilis, cytomegalovirus (CMV), and those endemic to the specific region (e.g., malaria, human T-cell lymphotropic virus [HTLV], and, theoretically, arboviruses and filariasis).

Ideally, there are systems in place to ensure that all donors are screened, donated blood undergoes screening tests for infectious diseases, there is quality assurance conducted throughout the process, and there is oversight by a national governing body. However, there are variations in the extent and effectiveness of blood screening processes globally. In some settings with low resources, the blood supply is either incompletely screened or not screened at all, putting the recipient at risk of acquiring preventable, life-threatening infections.

Protecting Donors, Health Care Workers, and Recipients

Protecting Donors

Risk to the donors can be reduced by following best practices for infection prevention and control (IPC) to prevent infection at the blood collection site and exposure to bloodborne pathogens (BBPs).

HCWs should follow Standard Precautions during each donor contact and procedure, including:

- Performing hand hygiene before and after each donor contact or procedure according to the World Health Organization's (WHO's) "5 Moments for Hand Hygiene" (See Module 2, Hand Hygiene.)
- Wearing a new pair of non-sterile gloves for each procedure or patient
- Wearing other PPE including face shield and gown as indicated
- Preparing the skin at the blood collection site using an appropriate antiseptic
- Using a sterile, single-use blood-collection device
- Using aseptic techniques
- Following safe injection and sharps safety practices
- Disinfecting work surfaces after every donor procedure
- Cleaning and disinfecting tourniquets and other equipment
- Appropriately disposing of waste materials

Protecting Health Care Workers

Staff working in blood banks and transfusion services are at risk of exposure to pathogens in blood in a number of ways, including while collecting the donor specimen, during testing, and when infusing blood/blood components.

As part of IPC best practices, laboratory staff and HCWs can reduce their risk of accidental exposure to BBPs by practicing the following measures while collecting donor blood and during testing, processing, transporting, and transfusing blood/blood components:

- Following Standard Precautions
- Performing hand hygiene before and after each patient contact or procedure
- Wearing a new pair of non-sterile gloves for each procedure or patient
- Conducting a risk assessment and wearing additional PPE accordingly
- Using safety devices when available (e.g., closed collection systems, safety needles, etc.)
- Practicing sharps safety
- Disinfecting work surfaces and cleaning up spills of blood and body fluids with 1% chlorine solution or other disinfectants (See Module 5, Chapter 2, Environmental Cleaning.)
- Following protocols for exposure to body fluids and reporting incidents
- Transporting blood in a safe manner in labeled, washable containers
- Disposing of waste as recommended

Protecting Transfusion Recipients

Risk to the transfusion recipient can be reduced by following best practices in IPC to prevent infection of the blood components and infection acquired from intravascular devices.

- At the time of donation:
  - Encourage use of voluntary, unpaid donors.
  - Screen donors for risk factors for infectious diseases.
  - Adhere strictly to the inclusion and exclusion criteria for donors.
  - Perform hand hygiene before and after each donor or procedure.
  - Wear a new pair of non-sterile gloves for each donor or procedure.
  - Perform appropriate skin cleansing of the donor site.
  - Use closed-system, sterile, single-use blood-collection devices and follow other injection safety guidelines.
  - Use aseptic techniques.
  - Disinfect work surfaces and patient care equipment.
- After the blood is collected:
  - Transport the blood in clean containers with the recommended cold chain.
  - Test the blood unit without entering the closed collection system.
  - Screen the blood for recommended infectious diseases.
  - Quarantine the blood until screening results have returned.
  - Exclude blood that is positive for infectious disease markers.
  - Document the progress of blood throughout the process.
  - Maintain appropriate temperature-controlled storage conditions.
  - Transfuse or discard the blood unit within the recommended period.
- When transfusing blood and blood products:
  - Follow Standard Precautions.
  - Wear a new pair of non-sterile gloves for each patient contact.
  - Perform hand hygiene before and after each patient contact.
  - Use aseptic techniques.
  - Insert and maintaining intravenous devices as recommended.
  - Use sterile, single-use equipment.
  - Practice sharps safety.
  - Perform recommended checks before, and monitor during, transfusion.
  - Start and complete the transfusion within the recommended time period.
  - Stop the transfusion immediately if an adverse reaction occurs.
  - Document and collect samples for transfusion reactions.

Safe Blood Bank Services

Blood bank and transfusion services involve:

1. Screening and informing blood donors and obtaining their consent
2. Collecting blood from screened donors
3. Quarantining blood and blood components
4. Performing screening tests for infectious diseases on blood components
5. Releasing blood and blood components from quarantine
6. Storing and transporting donated blood
7. Testing and cross-matching recipients' blood prior to transfusion
8. Transfusing blood and blood components

To attract volunteer donors and encourage their continual participation, the place where blood is collected should be kept clean and be as pleasant, safe, and convenient as possible.

1. Screening and Informing Blood Donors and Obtaining Their Consent

The donor screening process is one of the most important steps in protecting the safety of the blood supply. The process is intended to identify medical problems, high-risk donors (e.g., IV drug users, sex workers), or events that put a person at risk of being infected and transmitting a serious disease to the person receiving the transfusion. To accomplish this, donors should be questioned about their medical history and sexual practices (see Appendix 2-A, Abbreviated Donor History Questionnaire).

In general, potential donors should be at least 17 years old, unless there are special circumstances requiring a minor to give blood. There is no upper age limit if all other criteria are met. A limited physical examination is generally enough for screening potential donors. This examination should include pulse (60–100/minute); blood pressure (BP) (systolic 120–129 mmHg and diastolic 80–89 mmHg); examination of heart and lungs; blood tests for hemoglobin or hematocrit levels; and verbal screening for infectious diseases. Donors should be in good health, not severely anemic—a minimum hemoglobin level is 12.5 g% for women and 13.5 g% for men—and have no red-flags for infectious disease. (WHO 2012)

Informing donors and obtaining consent

Follow the blood bank protocol on counseling potential donors to ensure informed consent. This process should use simple language the donor understands and describe the procedure, risks (including fast pulse and occasionally fainting) (see Table 2-1), the amount of blood to be collected, that the donated blood will be screened for bloodborne pathogens (including HIV), and that the results of the tests will be shared with them.

Table 2-1. Potential Adverse Reactions to Blood Donation

Risk from	Potential Side Effects
Venipuncture (puncture of the vein to withdraw blood)	Phlebitis (inflammation of the veins) Localized infection at the site of the needle insertion Bacteremia (presence of bacteria in the blood) Septicemia (blood poisoning)
Removal of 400–500 mL of blood from the body	Tachycardia (rapid heart rate) Hyperventilation (rapid breathing) Feeling light-headed Fainting

2. Collecting Blood from Screened Donors

Staff collecting blood should be trained, certified and follow IPC guidelines during blood collection procedures to protect blood donors, themselves, and the transfusion recipients. Best practices for collecting blood from donors are similar to those for phlebotomy (see Chapter 1, Clinical Laboratory Biosafety, in this module).

Preparing the skin

Careful skin preparation using an aseptic (non-contamination) technique is a critical component of donor and recipient safety to minimize contamination of the donated blood by organisms from the donor's skin (which can multiply to dangerous levels during storage). Several studies suggest that fewer than two or three blood units per thousand will contain bacteria if aseptic technique is used and blood is collected in a closed system (Abrutyn et al. 1998). To minimize the risk of contamination, the following steps should be followed:

- Prepare skin. If 2% chlorhexidine gluconate in 70% isopropyl alcohol is not available for preparing the skin for a blood draw, use alcohol and tincture of iodine with a two-step procedure:
  - Step 1—use 70% isopropyl alcohol:
    - Cover the whole area and ensure that the skin area is in contact with the disinfectant for **at least** 30 seconds; and
    - Allow the area to dry **completely** (about 30 seconds).
  - Step 2—use tincture of iodine (more effective and dries quicker than povidine-iodine):
    - Cover the whole area and ensure that the skin area is in contact with the disinfectant for at least 30 seconds; and
    - Allow the area to dry completely (about 30 seconds).

  (WHO 2010)

Performing venipuncture

STEP 1: Make sure that venipuncture is completed by authorized, trained personnel according to country-specific policies. The donor should never be left alone at any time during the process. The following items should be made available for collecting blood in a closed system:

- A 16-gauge needle connected to a closed system blood collection bag (use retractable or safety needle with cover if available)
- A pair of new, non-sterile gloves
- A clean tourniquet or BP cuff
- Antiseptic solution (2% chlorhexidine gluconate in 70% alcohol) and clean gauze squares or cotton swabs (See the text above on preparing the skin with alcohol and tincture of iodine if 2% chlorhexidine gluconate in 70% alcohol is not available.)
- Surgical tape
- A towel to place under the donor's hand or forearm
- A basin of clean, warm water, soap, a face cloth, and a clean, dry towel to wash the donor's arm if it is visibly soiled
- Labels and a pen
- Sterile scissors
- A leak-proof waste container suitable for disposal of infectious waste (See Module 5, Chapter 5, Waste Management in Health Care Facilities.)
- A puncture-resistant, leak-proof sharps container (placed within arm's reach of the HCW) (See Module 4, Chapter 3, Sharps Injuries and Management of Exposure to Bloodborne Pathogens.)
- Equipment for blood sample collection (See the Phlebotomy/Blood Draw section in Chapter 1, Clinical Laboratory Biosafety, in this module.)

STEP 2: Prepare the materials using aseptic technique to set up the blood collection kit.

STEP 3: Explain the entire process to the donor.

STEP 4: If the venipuncture site is visibly soiled, wash it with soap and clean water, and then dry it with a clean cloth.

STEP 5: Perform hand hygiene.

STEP 6: Place the donor's arm on a clean surface or towel.

STEP 7: Identify the best veins for inserting the IV needle. (Blood should be drawn from a large, firm vein—usually the antecubital space in front of the elbow—that is free of skin lesions or rashes. Both arms should be checked.) Apply the tourniquet or BP cuff on the upper arm about 9 cm (3–4 inches) above the antecubital space (in front of the elbow) to confirm that the vein is visible and then release the tourniquet or BP cuff.

Note: Allow antiseptic solution to dry completely (for about 2 minutes) to ensure that the antiseptic action is complete.

STEP 8: Cleanse an area about 3 cm (1.5 inches) wide with 2% chlorhexidine gluconate in 70% isopropyl alcohol solution for 30 seconds, followed by 30 seconds of drying time. (See the text above on preparing the skin with alcohol and tincture of iodine if 2% chlorhexidine gluconate in 70% alcohol is not available.)

- When using chlorhexidine, scrub the insertion site in a back-and-forth motion for 30 seconds.
- Do not touch the area after applying the antiseptic solution.

STEP 9: Put clean, non-sterile gloves on both hands. Do not touch the area after applying the antiseptic solution.

STEP 10: Insert the hypodermic needle into the vein without touching the skin, if possible, release the tourniquet or BP cuff, and then secure the needle by placing a short piece of tape across the blood collection tubing below the area cleansed with antiseptic.

STEP 11: Monitor the patient during the collection and use hand hygiene before and after handling the blood collection kit.

Note: If a BP cuff is used, collect the blood under 40–60 mmHg pressure. If a tourniquet is used, it should be applied just tightly enough to keep the vein full and firm, but not so tightly as to cause discomfort to the donor.

When the required amount of blood has been obtained:

STEP 1: Perform hand hygiene.

STEP 2: Remove the needle without touching the barrel or tip of the needle and place the needle in a puncture-resistant sharps container.

STEP 3: Cover the insertion site with a 5 x 5 cm (2 x 2 inch) gauze square and apply pressure until the bleeding stops. The donor can be shown how to continue to apply pressure as it may take several minutes before all bleeding stops.

STEP 4: Check the arm. If the bleeding has stopped, secure the gauze square using one or two short pieces of surgical tape.

STEP 5: Cut the needle off the collection kit directly into the sharps container using a sterile pair of scissors.

STEP 6: Collect blood samples for laboratory testing (see the Phlebotomy/Blood Draw section in Chapter 1, Clinical Laboratory Biosafety, in this module).

STEP 7: Prior to removing gloves, place waste items in the appropriate waste containers.

STEP 8: Remove gloves and place them in a contaminated-waste container (see Module 3, Chapter 1, Personal Protective Equipment, for details on proper removal of gloves).

STEP 9: Perform hand hygiene.

STEP 10: Have the donor rest on a bed or in the donor chair for several minutes after the collection procedure is completed.

STEP 11: Provide the donor with something to drink and a piece of bread, cracker, cookie, or biscuit to help the body recover from the loss of blood.

STEP 12: Advise the donor:

- To drink more fluids than usual during the next 4 hours and avoid vigorous exercise, alcohol, or smoking until more food has been eaten.
- To apply pressure and raise that arm over the head if there is bleeding where the needle was inserted.
- For dizziness or nausea, sit down, bend forward, and rest the head between the knees until the dizziness or nausea passes.

STEP 13: Ensure that collected **blood unit** is labeled correctly and promptly stored at the recommended temperature.

STEP 14: Ensure that collected **blood samples** are labeled correctly, stored, and delivered to the laboratory with completed documentation, at the recommended temperature, and in a leak-proof, closed container:

- Correct labeling is critical to ensure correct identification throughout the screening process and linkage of screening test results from the test samples to the blood and the individual donor.

If any exposure to body fluids occur, follow the protocol (See Module 4, Chapter 1, Injection Safety, and Chapter 3, Sharps Injuries and Management of Exposure to Bloodborne Pathogens.)

3. Quarantining Blood and Blood Components

Blood components should be held in quarantine until screening test results are available and not be released for transfusion unless the results of all screening tests are negative (see Figure 2-1).

Managing quarantine

- Store unscreened blood in a storage refrigerator separate from that for screened blood.
- Document the location of each unit of blood and its eventual fate as it moves though the system:
    1. Before placing unscreened blood in quarantine, cross-check labeling of the blood unit and the samples taken for screening tests so blood components from that unit can later be matched with the screening test results.
- Designate a person(s) with authority to accept and release blood production from quarantine.
- Keep the quarantine storage refrigerator locked to prevent accidental release.
- For each access to the quarantine storage, log the person, date, and time of access and what was added or taken.

4. Performing Screening Tests for Blood Components, Antibodies, and Infectious Diseases

Tests generally required on all donated blood/blood components for transfusion to patients include the following:

- Tests not related to infection disease:
    - Donor's blood group as A, B, O, or AB, using anti-A and anti-B reagents.
    - Donor's blood's Rh factor following standard operating procedures for and using anti-D reagent. Generally, blood is either Rh-positive or Rh-negative. If the test results indicate Rh-negative, a further test should be conducted to identify if weak positivity is present.
    - Unexpected red cell antibodies, especially from donors with a history of transfusions or pregnancies.
- Screening for infectious disease:
    - Screening donated blood for infectious diseases that are transmittable by transfusion and can cause illness and/or death is a mandatory component of providing blood for transfusion. Infections transmissible by blood transfusion are those that survive in blood for long periods when stored at or lower than 4°C (39.2°F), have a long incubation period, or have an asymptomatic phase in the blood donor making it difficult to identify during donor selection.

Note: When either Rh type test is positive, the blood unit will be labeled as Rh-positive. If both tests are negative, then it is labeled as Rh-negative.

Note: After handling blood and blood components, remove surgical gloves and wash hands or use a waterless, antiseptic handrub.

- Laboratory staff should always adhere to the national screening strategy when conducting screening tests on blood. WHO (2010) recommends that all blood be tested for at least the following:
  - **HIV-1 and HIV-2**—screening for a combination of HIV antigen-antibody or HIV antibodies
  - **Hepatitis B**—screening for hepatitis B surface antigen (HBsAg)
  - **Hepatitis C**—screening should be performed using an HCV antibody immunoassay or a combination HCV antigen-antibody immunoassay
  - **Syphilis** (*Treponema pallidum*)—screening using specific assays such as *T. pallidum* hemagglutination assays (TPHA) and enzyme immunoassay (EIA) for treponema antibodies

- Other screening:
  - **Cytomegalovirus (CMV)** – screening with a highly sensitive CMV total antibody enzyme immunoassay may be needed for vulnerable populations receiving blood (premature neonates, pregnant women, and immunosuppressed patients). CMV-screened whole blood and blood components are not required for immunocompetent individuals. In the absence of screening, selective leucodepletion may be considered.
  - **Other regionally specific infectious diseases** (e.g., malaria, or HTLV in Africa and Chagas disease in South and Central America) should be done based on the burden of disease in the region (refer to the local guidelines):
    - **Malaria**—Screening is done with direct detection of parasite by thick film or antigen assays, which detect a lower level of parasites.
      Note*:* Strategies for screening for malaria in endemic countries are generally complex, combining specific criteria for donor selection and deferral, based on the season, geography, and availability of anti-malarial prophylaxis, with laboratory-based screening.
    - **HTLV**—When implemented in endemic countries, screening for specific anti-HTLV-I/II should be performed using a highly sensitive HTLV-I/II antibody enzyme immunoassay.
    - **Emerging and re-emerging infections** (e.g., Creutzfeldt-Jakob disease, West Nile virus, babesiosis, dengue, and chikungunya). A cautious and measured response is needed when considering if any new or re-emerging disease has the potential to be transmitted via blood transfusions. WHO (2010) guidance suggests blood transfusion services develop contingency plans that ensure: surveillance for emerging infections, assessment of their transmissibility by transfusion and the actual likelihood of transmission, information about the diseases that may be associated with transmission, and action to be taken in the event of increasing incidence of infection, including to pandemic level.

Note: Screening for additional TTIs should not be implemented until systems are already in place to ensure that all donations are screened for the four major bloodborne pathogens in a quality-assured manner. Screen for additional diseases only when there is clear evidence that the blood supply safety would be significantly compromised without including the additional disease. When evaluating the inclusion of additional diseases, include only if:

- There is a proven risk of transmission of infection to recipients.
- The transmission carries a significant disease risk.
- An appropriate screening assay is available.

When there is a **proven** risk of TTI but no appropriate screening tests are available, develop donor selection criteria to identify and defer potentially infected donors for an appropriate period of time. If there is a **theoretical** risk of transfusion-associated transmission and no appropriate screening assays are available, donor selection criteria *may* be considered.

Performing screening tests and analyzing results

Laboratory staff should always adhere to IPC recommendations, the national or local standard procedures, and results algorithm when conducting and analyzing the results of screening tests on donor blood.

Highly sensitive and specific assays that are specifically for blood screening should be used as screening tests to test donor blood. The details of the test protocols will vary based on the specific test used. Follow the steps below to screen blood and arrive at the decisions regarding use of blood for transfusion (see Figure 2-2).

1. Conduct a single assay (A) validated for a specific TTI and test a blood sample singly in accordance with standard operating procedure.

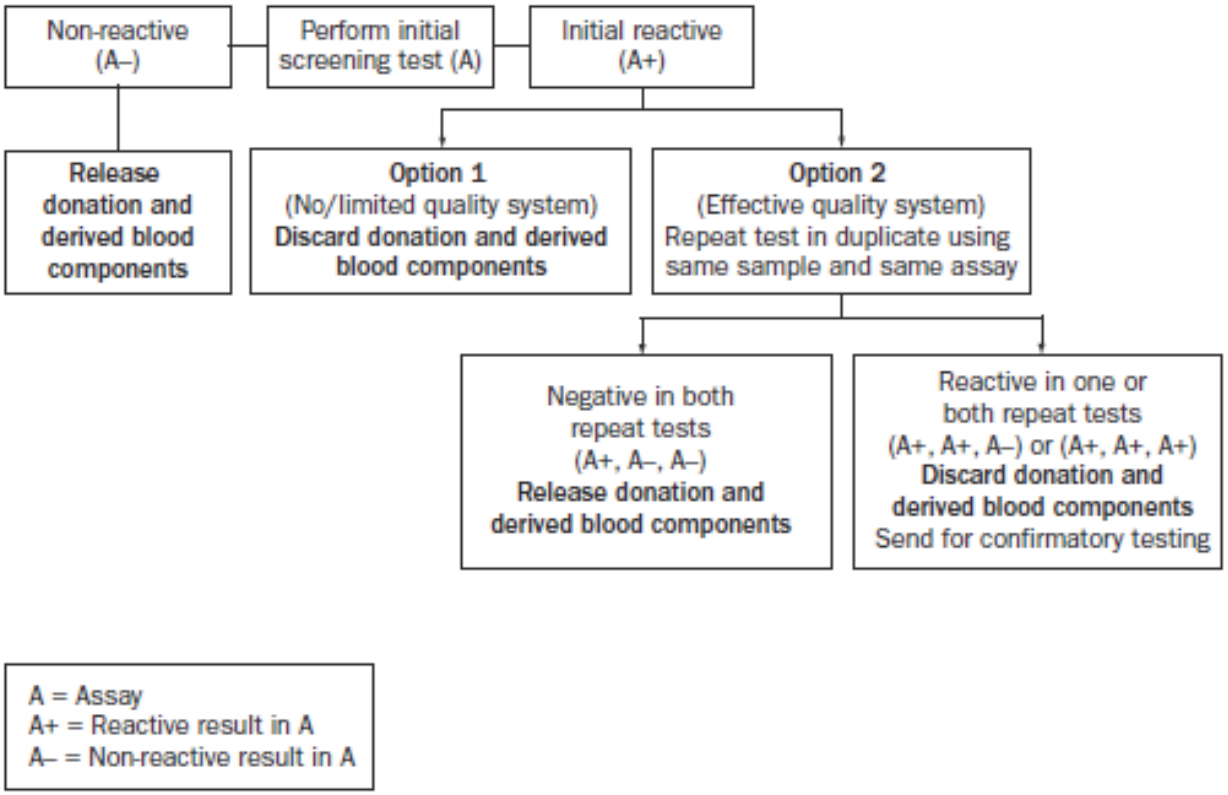
7. If the result is non-reactive (A-), the blood unit can be released for transfusion.

8. If the result is reactive (A+):

    - **Option 1**: (Any laboratory with limited or no quality control systems should choose this option): Immediately segregate the blood donation and all blood components derived from that unit.
    - **Option 2** (available to laboratories with well-established quality systems): Repeat the test twice using the same sample and the same assay:
        - If the result of both repeat tests are non-reactive (A+, A-, A-), release the blood for transfusion.
        - If the results of one or both of the repeat tests are reactive ([A+, A+, A-] or [A+, A+, A+]), immediately segregate the blood donation and all blood components derived from that unit.

9. Any blood unit that tests reactive should be immediately labeled as “NOT FOR TRANSFUSION” and should be immediately disposed of or stored securely and safely until it is disposed of.

Figure 2-2. Algorithm for Testing Donated Blood Using Screening Tests



Source: WHO 2005.

5. Releasing Blood and Blood Components from Quarantine

When blood is determined to be negative for all screening tests, it can be released from quarantine for clinical use (see Figure 2-2):

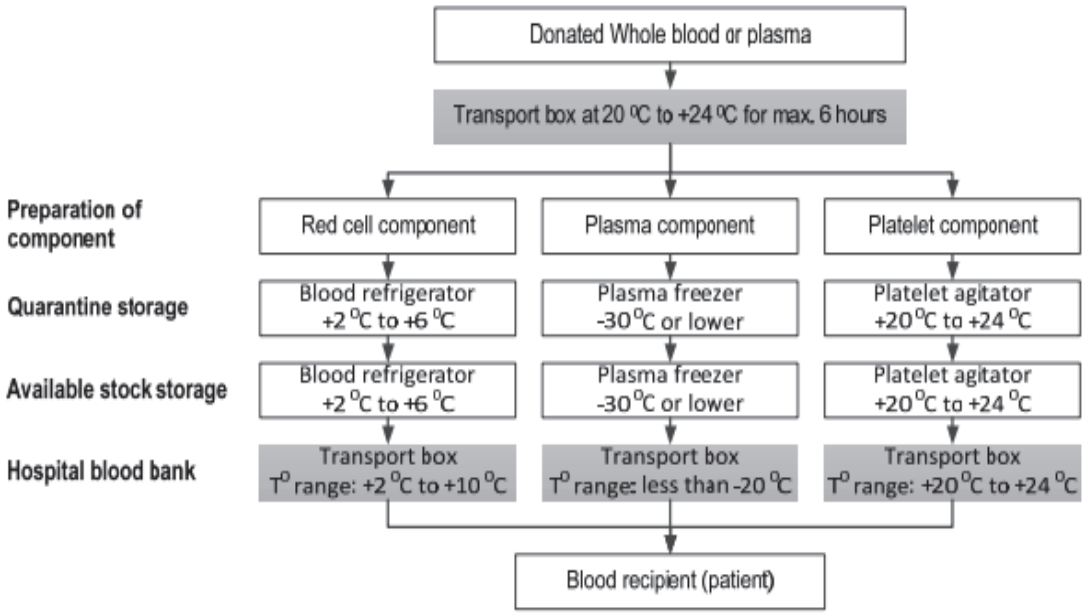
- Perform cross-checks to identify the unit against the test results.
- Inspect the blood component before release for signs of contamination and infection:
  - Hemolysis
  - Change of color (e.g., darker or purple/black)
  - Clots
  - Leak/air
- Label released blood component as “ready for clinical use” according to the facility procedures.
  - Once the blood is released from quarantine, the label should contain relevant details such as:
    - Temperature of storage
    - Date blood was collected
    - Expiry date of the component prepared
    - Blood group (ABO + Rh(D)) of the blood component
    - Donation or pack number
    - Name and volume of the anticoagulant solution

- Name of the blood bank producing the component
- Batch number

6. Storing and Transporting Donated Blood

Successful transportation and storage of blood and blood components is dependent upon a "cold chain," which is temperature controlled supply chain that is made up of critical equipment, personnel, and processes from blood collection to transfusion. Any break in the cold chain can have potentially fatal consequences for the blood recipient, thus it is important for each step in the chain to be carefully maintained. Figure 2-3 summarizes the blood cold chain from collection to transfusion.

Figure 2-3. The Blood Cold Chain from Collection to Transfusion



Source: WHO 2005.

Storing donated blood

General storage principles include:

- Temperature:
  - Storage temperatures and conditions must be strictly maintained, monitored, and recorded for all donations, blood components, blood samples, test kits, and reagents.
  - Never store blood components and plasma derivatives in a location without appropriate temperature monitoring (see Figure 2-3).
- Organization:
  - Store blood in an orderly way.
  - Store blood at different parts of the process in separate storage refrigerators if possible (or at least on separate shelves). The following should be stored separately and clearly labelled:
    - Unscreened blood

    - Blood with positive screening results
    - Blood with unresolved or indeterminate results
    - Blood that has been screened and released for use
  - Store blood components in date order, according to the date of expiry, in the quarantine section as well as in the available stock section.
  - Ensure that there is a record, updated daily, of all the blood components in quarantine or available stock.
- Equipment:
- Blood component storage equipment should have appropriate alarm systems, a back-up energy source, and temperature monitoring devices. The following are ideal design features for blood component storage equipment:
  - Audiovisual alarms: temperature out of range, door ajar, and power failure (warning) with battery back-up
  - Temperature display unit with 0.1°C graduation
  - Continuous temperature recorder: 7-day chart with battery back-up
  - Roll-out type of drawers or trays
  - Interface for remote temperature monitoring
  - Casters for easy movement of the equipment
  - Stainless steel construction

Storing samples, test kits, and reagents

- Use manufacturers' recommended methods for safe storage and transportation to avoid deterioration or poor performance of the reagents.
- Test blood samples as soon as possible after collection; delays can decrease the reliability of the results.
- Check the method of collection, storage, and transportation of blood samples according to the type(s) of laboratory test to be carried out.

Storing donated blood after collection

- Cool collected blood to between +2–10°C (35.6–50°F) unless blood is to be used for the preparation of platelet concentrates (in which case, do not cool to below +20°C [68°F]). (See Figure 2-3.)
- Do not store for longer than 6 hours before transport from the collection site to the component preparation laboratory.

Storing in the blood bank

- Store blood in an orderly way; it may be most convenient to store blood components according to ABO blood group and Rh type.
- Store blood components in date order according to the date of expiry.
- Ensure that the inventory record is updated daily.

- Figure 2-3 summarizes the temperatures at which blood components must be stored:
  - Whole blood and packed red cells must always be stored at +2–6°C (35.6–42.8°F).
  - Red cells, platelets, or whole blood must never be allowed to freeze.
  - Platelet concentrates should be stored at a temperature of +20–24°C (68–75.2°F) with continuous agitation. (See the section directly below about storage at facilities without certain equipment.)
  - The optimal storage temperature for fresh frozen plasma and cryoprecipitate is –30°C (–22°F), and they must always be frozen solid.

For facilities without certain equipment

- If there is no automated temperature monitoring system on blood component storage:
  - Use a thermometer placed inside the refrigerator. A thermometer that records minimum and maximum temperatures is ideal (if not used, there is no guarantee that cold chain has been maintained).
    - > Check and document at regular intervals to monitor and record temperatures.
    - > Ensure that there is a clear procedure in place if the temperature is outside of the recommended range.
    - > The supervisor should monitor the temperature log daily for quality control.
  - For frozen blood components, place an elastic band around the component prior to freezing and then remove the band. If the component thaws, the crinkles caused by the band will no longer be present, indicating it has thawed and should be discarded.

- If no platelet agitator or rotator is available:
  - It is not possible to store platelets without an agitator. Once prepared, they must be transfused immediately unless the blood bank is equipped with:
    - > An air-conditioned facility with a temperature monitoring system that will maintain an ambient temperature of between +20–24°C (68–75.2°F), or
    - > A platelet incubator that will keep the platelet concentrates at a temperature of between +20–24°C (68–75.2°F).

Storing on the ward/intensive care unit/operating theater

- In some areas of the hospital, such as the operating theater or the intensive care unit (ICU), there may be a blood bank refrigerator that stores blood components for immediate use.
- Maintain and monitor the ward/ICU/operating theater blood refrigerator at a temperature of between +2–6°C (35.6–42.8°F).
- Ensure that it is fitted with an appropriate temperature alarm.
- Post a sign that no other items are to be stored in the blood refrigerator to reduce door openings.
- Unless the alarm notifies the blood bank automatically, ensure that the staff in the ward or theater are trained to respond if the alarm on a blood refrigerator is activated; it is their responsibility to

notify the blood bank (or other entity in charge of blood products) so the contents of the refrigerator are safeguarded.

- If an approved blood refrigerator is available, and the transfusion cannot be commenced within 30 minutes, store the blood component in the approved and monitored blood storage refrigerator in the hospital ward/ICU/theater until required for transfusion.
- If no approved blood refrigerator is available and the transfusion cannot be administered within 30 minutes, return the blood component to the blood bank for storage until it is needed.

Handling blood components returned to the blood bank

If a blood component is returned to the blood bank, the following checklist should be used to decide whether it should be put back into stock or discarded:

- Check that the blood component has been returned to the blood bank within 30 minutes of issue: Discard if more than 30 minutes.
- If the "tagging" system was used for transport (see the section below on transportation of blood components from the blood bank to clinical areas), check the seal: Discard if the seal is broken.
- Verify that the blood component has not been opened, by squeezing it gently and looking for blood at the entry port: Discard if opened.
- Check the temperature by hand or by folding the blood component around a thermometer: Discard if over 10°C (50°F).
- Mix the blood component gently, keep it in the upright position while it "settles out" in the refrigerator and look for signs of hemolysis or other signs of deterioration in the plasma and red cells: Discard if there is any sign of hemolysis or discoloration.

Disposing of blood components

Although precious, blood products may need to be discarded if they do not meet the requirements for clinical use.

- Store blood components awaiting disposal in a separate, locked refrigerator to avoid accidental use and excessive growth of bacteria that would occur at room temperature.
- Discard blood components marked for disposal using the following procedures:
    - Disposal by autoclave:
        1. Perform a two-person check to identify the blood component that requires disposal and cross-check with records.
        10. Confirm authorization by the quality assurance officer or person in a similar role at the facility.
        11. Sign the blood component out of inventory.
        12. Wear non-sterile or utility gloves.
        13. Decontaminate the blood component in an autoclave at 121°C (249.8°F) for 20 minutes. (See the text directly below for facilities without access to an autoclave.)
        14. After the autoclave cycle, dispose of it in a covered container for non-infectious wastes according to hospital or facility waste management guidelines.

- Disposal by incineration when there is no autoclave:

  1. Perform a two-person check to identify the blood component that requires disposal and cross-check.
  15. Confirm authorization by the quality assurance officer or person in a similar role at the facility.
  16. Sign the blood component out of inventory.
  17. Wear non-sterile or utility gloves.
  18. Dispose of the blood components in a covered container for contaminated wastes.
  19. Transport to a high temperature incinerator (> 1,200°C [2,192°F]). Blood transfusion bags contain high levels of polyvinyl chlorine (PVC), which is converted to poisonous dioxins and furans at low temperatures and released into the environment. (See Module 5, Chapter 5, Waste Management in Health Care Facilities, for information on incineration.)

- Disposal into sewer or drain with soak away pit: Disposal of discarded blood into sinks or drains is strongly discouraged without prior disinfection with a chlorine-based solution and neutralization of potentially infected effluents into a buffer tank. In any case, the drainage system should be connected to the sewerage or to a soak-away pit more than 30 meters from existing water sources. (WHO 2005)

Transporting donated blood

In order to maintain the cold chain, the recommended temperature requirement must be maintained when blood components are moved from one place to another:

- Maintain temperatures for the specific component being transported.
- Monitor the temperature during transport with a thermometer that registers highest and lowest temperatures reached.
- Do not exceed 24-hour transit time for blood and blood components.
- If transportation takes longer than 24 hours, consider collecting blood locally.
- During packing of the box, place a maximum/minimum thermometer sandwiched between two packs that have been rubber-banded together.
- Place ice above the blood because cold air moves downward:
  - Cubed ice melts more slowly than chipped ice.
  - Ice packs at < -5°C (23°F) may be used.
  - Use at least as much ice as the volume of blood or plasma.
- Place a “this way up” label on the box.
- Upon arrival, record the maximum and minimum temperature achieved during transport for each batch. The maximum or minimum temperature readings attained during transportation are noted when the box is opened in the blood bank.

Equipment

Boxes for the transportation of blood components must meet WHO-defined specifications to ensure that the blood is safe. Transport boxes must be designed to maintain internal temperatures between +2–10°C (35.6–50°F) for at least 24 hours. The type of coolants needed depends on the type of blood products being transported. The following are ideal design features for blood component storage equipment:

- Lightweight
- Robust
- Secure and lockable
- Maintains required temperatures for at least 30 hours at 43°C (109.4°F) ambient temperature

Transporting whole blood from the collection site to the laboratory

- Blood and blood components collected at donor sessions should be transported to the blood center as soon as possible (within 6 hours).
- Red blood cell components must be kept at a temperature of +2–10°C (35.6–50°F) during transportation unless blood is to be used for the preparation of platelet concentrates (then do not cool to below +20°C [68°F]).
- If the distance and the ambient temperature will cause the blood to reach more or less than +20–24°C (68–75.2°F), special gel pouches can be used to maintain these temperatures during transportation. If these are not available, the blood packs should be transported as quickly as possible at a temperature of +2–10°C (35.6–50°F), but cannot then be used for the preparation of platelet concentrates.

Transporting blood components from one blood bank to another

- Whole blood and packed red cells:
  - Keep the temperature of whole blood and red cell components at +2–10°C (35.6–50°F) during transport.
  - Use specially designed blood transport boxes, wherever possible. If these are not available, use sturdy, well-insulated containers only after evaluation and validation to ensure that they can reliably maintain temperatures at +2–10°C (35.6–50°F) for the planned journey, using appropriate coolants or ice packs.
  - Use wet ice in leak-proof containers, such as plastic bags. Wet ice from commercial ice-making machines is satisfactory.
  - Avoid freezing:
    - > Avoid super-cooled cubed ice, canned ice, or dry ice for shipping or storing whole blood or red cells.
    - > Blood shipped by air may freeze if transported in an unpressurized storage compartment.
    - > Never let the red blood cell component come into contact with the ice.
- Frozen plasma and cryoprecipitate:
  - During transport, frozen components must remain frozen.

  - Use dry or wet ice in well-insulated containers or standard shipping cartons lined with insulating material such as plastic air bubble packaging or dry packaging fragments.
- Platelet concentrates:
  - Maintain platelets at temperatures between +20–24°C (68–75.2°F) during shipment. In most climates, a well-insulated container without added ice is often sufficient. If the distance and the ambient temperature will cause the blood to reach more or less than +20–24°C (68–75.2°F), see the Transportation of Whole Blood from the Collection Site to the Laboratory section above on gel pouches for platelet transportation.

Transporting blood components from the blood bank to clinical areas for transfusion

- Unless the rapid transfusion of large quantities of blood is required, to avoid wastage, remove only one unit of red cells from the blood bank refrigerator at a time.
- Record the time of issue when blood is issued from the blood bank.
- Issue red blood cell components in a cold box or insulated carrier that will keep components at the recommended temperature (see above).
  - Use a tagged or sealed box, if available. A tag that has to be broken by the ward staff before the blood can be taken from the box for use assists the blood bank in deciding whether blood that has been returned by ward staff can be placed in available stock (see the Handling Blood Components Returned to the Blood Bank section above).
- Issue platelet concentrates from the blood bank in a carrier that will keep the temperature at +20–24°C (68–75.2°F) (see above).
- Transfuse platelets as soon as possible. Never place unused platelets in a refrigerator, but return them immediately to the blood bank.
- Thaw fresh, frozen plasma and cryoprecipitate at +30–37°C (86–98.6°F) in the blood bank before issue:
  - Transport it to the ward at ambient temperature.
  - Use immediately, never refreeze.

Blood transported short distances (e.g., from the blood bank or transfusion service within a health care facility) require no special handling. However, blood should **not** be allowed to reach temperatures outside the acceptable range.

For facilities where electricity is inconsistent or inadequate

- Ice-lined compression-type refrigerators:
  - Ice-lined refrigerators are usually of the “chest type” and are especially designed to have a long hold-over time so they hold the temperature below +10°C (50°F) for up to 17 hours following a power cut.
  - The ice lining consists of plastic tubes or other containers filled with water that is frozen during operation. During periods of no electricity, the ice packs act as cold storage to protect the units of blood in the refrigerator.
  - There may also be a freezer section for the storage of ice packs. The freezer section is approved for the freezing of ice packs, but not for the storage of plasma products.

- Solar or photovoltaic-powered compression refrigerators (they convert solar energy into Direct Current (DC), as an alternative source of electricity):
  - The insulation of the cabinet is higher than that of standard refrigerators so the hold-over time is at least 24 hours.
  - Batteries store the electrical energy during daylight.
  - In the event of disconnection from solar panels or poor sunlight, the batteries continue to provide electricity, thus adding to the hold-over time.
  - There may also be a freezer section for storing ice packs, but not for the storage of plasma products.

(WHO 2005)

7. Testing and Cross-Matching Recipients' Blood Prior to Transfusion

The purpose of pre-transfusion testing is to select blood/blood components that will not cause harm to the recipient and to ensure that the red cells will survive (not be destroyed too rapidly) when transfused. When performed properly, pre-transfusion tests will confirm the ABO group of the red cells, Rh blood type, the presence of clinically significant red cell antibodies in the recipient's blood, and compatibility between selected samples of donor blood with the recipient's blood (cross-matching). Following are the steps for pre-transfusion testing:

STEP 1: Test a sample of the recipient's blood following recommended IPC practices described earlier for testing donor blood. Recipient blood should be tested for ABO group and Rh typing using anti-D reagent. Rh-positive blood should not be transfused to a patient who is Rh-negative. In case of emergency when ABO compatible Rh-negative blood is not available for a patient who is Rh-negative, consult with a transfusion medicine specialist for alternative approaches to manage the transfusion.

STEP 2: Repeat testing of the donor blood to confirm the ABO group and Rh blood type.

STEP 3: Cross-match the red blood cells of the selected donor against the serum or plasma of the recipient to be sure that there are no ABO and/or clinically significant antibody problems. Do not transfuse if there are significant antibodies in the recipient's blood. Choose another donor's blood and perform the cross-match until appropriate blood is found.

STEP 4: Label pre-transfusion blood bags to avoid the possibility of mismatching donated blood (see Box 2-1).

If no clinically significant antibodies were detected in the recipient's blood and there is no prior record of antibodies, serologic cross-matching, which is quicker and less difficult to perform, is acceptable.

Box 2-1. Proper Labeling of Pre-Transfusion Blood Bags

1. Name of facility where the blood/blood components were collected
2. Name of blood components
3. Volume of blood/blood component
4. Donation number
5. ABO group
6. Rh blood type
7. Date of collection of the blood/blood components
8. Temperature of storage
9. Date of issue to the health care facility

8. Transfusing Blood and Blood Components

Like any other medical treatment, the decision to complete a blood/blood component transfusion for a patient should be based on the need (indications) for transfusion and weighed against the risks, potential benefits, and alternative treatments available. In addition, before receiving a transfusion, the patient should clearly understand the reasons a transfusion is needed, accept the risks, and have questions answered before starting the procedure. (If the patient is unconscious or incapable of giving consent, a spouse, relative, or adult friend should give the consent, when possible.)

In situations of acute bleeding, the transfusion threshold is 30–40% blood loss for otherwise healthy adults, provided blood volume is maintained. If the blood volume is maintained, healthy, resting adults are able to tolerate an acute decrease in red cells to hemoglobin of 5 g/dL without evidence of lack of tissue oxygenation. (ASATF 1996; Weiskopf et al. 1998)

Indications for different types of transfusions

The main reason for transfusion of whole blood or packed red blood cells (plasma removed) is to increase the oxygen-carrying capacity to meet the demands for oxygen of the recipient's tissues (see Table 2-2). For whole blood, the objectives of initial treatment are to stop the bleeding and to restore intravascular volume in order to prevent hypovolemic shock (shock due to decreased fluid in the circulation). Thus, the immediate need is to give IV fluids that will help restore the circulation and then restore oxygen-carrying capacity.

For chronic anemia, the objective should be to prevent patients from being symptomatic—weakness, dizziness, breathlessness, heart palpitations, or rapid heart rate (Hebert et al. 1999). Generally, this means keeping the hemoglobin levels from 7–9 g/dL.

Table 2-2. Indications for Different Types of Transfusions

Type of Transfusion	Indication(s)
Whole blood	Acute hemorrhage or trauma Obstetrical hemorrhage Gastrointestinal hemorrhage
Packed red blood cells	Anemia
Platelets (4–6 units of blood)	Thrombocytopenia Bone marrow failure
Plasma (3–6 FFP)*	Disseminated intravascular coagulation Dilution coagulopathy Liver diseases
Albumin	Severe burns Extensive surgery Severe sepsis Acute respiratory distress syndrome Initial management of acute cirrhosis and nephrosis

*FFP = Fresh, frozen plasma (plasma collected from donated blood and frozen for later use).

Providing the transfusion

Countries are moving away from transfusing whole blood due to the increased number of reactions to whole blood. Using packed red cells and IV fluids in combination is becoming routine in many large facilities in some resource-limited settings. In a typical adult, one unit of whole blood or packed red cells will raise the hemoglobin about 1 g/dL or increase the hematocrit levels by 3%.

Note: With the exception of sterile isotonic (0.9%) saline, no drugs or medications should be added to whole blood units or blood components.

Reactions to the transfusion of blood include allergic or urticarial (allergic) reactions (from mild itching and hives to serious breathing problems), hemolysis (destruction of red cells), infectious (contaminated blood components) reactions, fever, chills, rapid heart rate (tachycardia), hyperventilation, fainting, and, rarely, cardiac arrest. Delayed reactions can occur several days or weeks after the transfusion and may be due to serum sickness (antigen-antibody reaction).

STEP 1: Explain the procedure to the patient, determine if the person has ever had a transfusion, and record adverse reactions, if any.

STEP 2: With another HCW, correctly identify the blood component to be used and the correct transfusion patient:

- Confirm the patient's name, date of birth, and armband, if available.
- Check the compatibility tag and blood/blood component expiration date attached to the blood bag.
- For whole blood, check ABO group and Rh type and verify if it is a correct match with the transfusion patient's blood type, which should be designated on the patient's chart.
- Double-check the blood or type of blood component with the physician's order.
- Check the blood for clots in the blood unit bag.
- Record the transfusion patient's baseline pulse and BP.
- Have another HCW read back the information on the blood/blood component to be used and on the transfusion patient's chart to double-check that it is accurate and compatible before beginning the infusion process.

STEP 3: Ask the patient to immediately report any chills, headaches, itching, or rash (an urticarial reaction) while the person is receiving the transfusion.

STEP 4: Begin a peripheral IV line. (The detailed steps for starting a peripheral IV line with a large-gauge needle or plastic catheter [No. 18 or 19] and setting up an IV administration set are described in Module 10, Chapter 3, Preventing Intravascular Catheter-Associated Bloodstream Infections.)

STEP 5: Once the transfusion has begun, monitor the patient according to the facility's protocol and document vital signs and any adverse reactions:

- Do not leave the patient alone at any time during the transfusion process or while the patient is in recovery.
- Monitor the patient according to the facility's protocol and document vital signs. In many facilities, the HCW takes the patient's pulse and BP every 5 minutes for the first 15 minutes of transfusion, and hourly thereafter until the transfusion is over (transfusions can take 1 to 4 hours).
- Monitor for adverse reactions: Observe the patient for flushing (red face or cheeks), itching, difficulty breathing, and hives or other rashes (urticarial reaction) when checking vital signs.

- Stop the transfusion immediately if an adverse reaction occurs:
  - Collect the samples required for transfusion reactions.
  - Document the reaction in the patient's chart.

STEP 6: When the transfusion is completed, record the administration of the blood/blood component in the patient's chart.

STEP 7: Dispose of waste. The steps for removing and disposing of the administration set, IV tubing and needle, and blood-contaminated waste items are described in Module 10, Chapter 3, Preventing Intravascular Catheter-Associated Bloodstream Infections.

Improving Blood Bank and Transfusion Services

In countries where resources are limited, blood bank and transfusion services can be inadequately supervised and poorly monitored; screening of prospective donors can be limited; and testing for infectious diseases, even for syphilis, may not be available. Under these circumstances, complications (transfusion reactions) and transmission of life-threatening infections to unsuspecting patients can frequently occur. The full commitment and support of Ministry of Health officials, health care facility administrators, and IPC committees or working groups are needed to implement basic blood bank and transfusion service policies and guidelines to improve the quality and safety of blood transfusions.

As outlined above, many of the processes and procedures that can improve the quality of blood bank and transfusion services and make them safer for patients and blood transfusion services staff are inexpensive and doable. Improving performance and compliance with recommended policies and guidelines can be significantly enhanced with:

- Consistent support from health care facility administrators to improve the quality of services (e.g., identified deficiencies are corrected, dangerous practices are eliminated, and staff are actively encouraged to seek inexpensive local solutions)
- Regular supportive supervision to ensure compliance with standard operating procedures, such as screening of donors and aseptic techniques
- Role models, especially physicians and other senior staff, who actively support recommended policies and guidelines

Summary

The collection, processing, storage, and transfusion of blood/blood components are an essential service that all health care facilities providing emergency care must be prepared to deliver using high standards of quality. In addition, the safety of the blood donors, transfusion patients, HCWs, and fellow personnel requires that blood bank and transfusion service staff be qualified to perform the required tasks and follow recommended IPC practices consistently.

Appendix 2-A. Abbreviated Donor History Questionnaire

	Yes	No
Are you feeling healthy and well today?		
Have you read the educational materials today?		
In the past **48 hours,**		
Have you taken aspirin or anything that has aspirin in it?		
In the past **8 weeks,** have you		
Donated blood, platelets or plasma?		
Had any vaccinations or other shots?		
In the past **16 weeks,**		
Have you donated a double unit of red cells using an apheresis machine?		
Since your **last donation,** have you		
Female donors: Been pregnant or are you pregnant now?		
Had any new medical problems or diagnoses?		
Had any new medical treatments?		
Been advised not to donate blood because of a medications you are taking?		
Come into contact with someone else's blood?		
Had an accidental needle-stick?		
Had sexual contact with anyone who has HIV/AIDS or has had a positive test for the HIV/AIDS virus?		
Had sexual contact with a prostitute or anyone else who takes money or drugs or other payment for sex?		
Had sexual contact with anyone who has ever used needles to take drugs or steroids, or anything not prescribed by their doctor?		
Female donors: Had sexual contact with a male who had sexual contact with another male in the past 12 months?		
Lived with a person who has hepatitis?		
Received money, drugs, or other payment for sex?		
Male donors: had sexual contact with another male?		
Had a tattoo?		
Had ear or body piercing?		
Been in juvenile detention, lockup, jail, or prison for more than 72 consecutive hours?		
Used needles to take drugs, steroids, or anything not prescribed by your doctor?		

Source: AABB 2016.

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