

WHO guidelines on drawing blood:

best practices in phlebotomy



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Acronyms

CDC	Centers for Disease Control and Prevention, Atlanta, USA
EHT	Department of Essential Health Technologies (WHO)
HBV	hepatitis B virus
HCV	hepatitis C virus
HIV	human immunodeficiency virus
HSS	Health Systems and Services (WHO)
PEP	post-exposure prophylaxis
SIGN	Safe Injection Global Network
WHO	World Health Organization



Executive summary

Phlebotomy – the drawing of blood – has been practised for centuries and is still one of the most common invasive procedures in health care. Each step in the process of phlebotomy affects the quality of the specimen and is thus important for preventing laboratory error, patient injury and even death. For example, the touch of a finger to verify the location of a vein before insertion of the needle increases the chance that a specimen will be contaminated. This can cause false blood culture results, prolong hospitalization, delay diagnosis and cause unnecessary use of antibiotics. Jostling and jarring of test tubes in transit can lyse or break open red blood cells, causing false laboratory results. Clerical errors in completing forms and identifying patients are common, costly and preventable. Other adverse effects for patients are common; they include bruising at the site of puncture, fainting, nerve damage and haematomas. These guidelines outline the simple but important steps that can make phlebotomy safer for patients.

Phlebotomy also poses risks for health workers. It is still common to see a phlebotomist carry out dangerous practices known to increase the risk of needle-stick injury and transmission of disease. Dangerous practices include:

- recapping used needles using two hands;
- recapping and disassembling vacuum-containing tubes and holders;
- reusing tourniquets and vacuum-tube holders that may be contaminated with bacteria and sometimes blood;
- working alone with confused or disoriented patients who may move unexpectedly, contributing to needle-sticks.

Phlebotomy involves the use of large, hollow needles that have been in a blood vessel. The needles can carry a large volume of blood that, in the event of an accidental puncture, may be more likely to transmit disease than other sharps. Bloodborne organisms that have been transmitted after needle-sticks include viruses such as hepatitis B and human immunodeficiency virus (HIV), bacteria such as syphilis and parasites such as malaria.

Producing the guidelines

These guidelines were produced to improve the quality of blood specimens and the safety of phlebotomy for health workers and patients, by promoting best practices in phlebotomy.

In April 2008, the WHO Injection Safety programme – part of the Department of Essential Health Technologies (EHT) at WHO Headquarters in Geneva – convened a consultation on best practices for phlebotomy and blood collection. The consultation included special categories, such as arterial blood sampling, capillary blood sampling and paediatric blood collection. A working group of international experts and colleagues from WHO departments identified the need for phlebotomy guidelines, and this document was produced in response.

This document provides guidance on the steps recommended for safe phlebotomy, and reiterates the accepted principles for drawing and collecting blood. The guidelines are based on a literature review that focused on identifying systematic literature reviews and evidence relating specifically to phlebotomy practices in developing countries. Draft guidelines and evidence were reviewed by an expert panel, who reached consensus on the recommendations.



Protecting patients

To reduce the risk of adverse effects for patients, health workers undertaking phlebotomy need to be trained in procedures specific to the types of specimen they collect. Such procedures may include arterial sampling, capillary sampling, blood culture collection and venous blood draws. Health workers who collect specimens from children and infants will need special training and practice for these procedures. Phlebotomists working in settings with more technology may be trained in techniques for plasma and red cell exchange, photopheresis, stem cell collection and cord blood collection. Health workers may need to collect specimens from in-dwelling central lines or arterial lines. Training should include techniques that ensure that the specimen collected will be adequate, and measures that reduce the risk of contamination, clerical error, infection and injury.

When taking blood, health workers should wear well-fitting, non-sterile gloves, and should also carry out hand hygiene before and after each patient procedure, before putting on gloves and after removing them. The blood should be taken in a dedicated location that ensures patient comfort and privacy. To remove the risk of environmental contamination with pathogens, counter and work surfaces, and chair arms should be cleaned with disinfectant at the start of each shift and when visibly dirty. To prevent infections and other adverse events, health workers should follow the guidelines on patient identification, hand hygiene, use of gloves, skin disinfection, use of appropriate blood-sampling devices and safe transportation of laboratory samples.

Patient consent and cooperation are important components of respecting patient rights. A patient information leaflet or poster that explains the procedure in simple terms is helpful.

Protecting health workers

Best practices in phlebotomy protect health workers as well as patients. One way to reduce accidental injury and blood exposure among health workers is to use safety (i.e. engineered) devices such as retractable lancets, syringes with needle covers or retractable needles and, when appropriate, plastic laboratory tubes. Another approach is to eliminate two-handed needle recapping and manual device disassembly, and instead dispose of the sharps into a puncture-resistant sharps container (i.e. a safety container) immediately after use. The best practice is to discard the needle and syringe, or needle and tube holder, as a single unit, into a sharps container that is clearly visible and within arm's reach. The size of the container should permit disposal of the entire device rather than just the needle.

Institutions should conduct surveillance on sharps injuries and accidental exposure to blood, so that preventable factors can be identified. Support services should also be available for health workers accidentally exposed to blood. These should include immunization with hepatitis B before assuming duties that include potential exposure to blood and body fluids, and post-exposure prophylaxis for HIV and hepatitis B. All health-care facilities should display clear instructions for procedures to follow in case of accidental exposure to blood and body fluids.

These guidelines also outline the responsibilities of managerial staff, including provision of:

- gloves in multiple sizes, single-use disposable needles, and syringes or lancing devices in sufficient numbers to ensure that each patient has a sterile needle and collection device or equivalent for each blood sampling;
- sufficient laboratory sample tubes to prevent reuse and manual washing.



Best practice in disinfection

After reviewing the evidence on best practice in phlebotomy, the expert panel found that further evidence was needed on the best method for skin preparation before blood collection for the purpose of blood transfusion. The panel commissioned a systematic review from the Cochrane group to investigate the literature on whether “alcohol alone” or “any skin disinfectant followed by alcohol for skin preparation” is more effective in reducing the risk of blood contamination or bacteraemia.

The Cochrane group found that no research had been conducted to compare these two methods, and commented that, until better evidences emerges, decisions would probably need to be based on convenience and cost.

In line with WHO guidelines for the development of recommendations, additional infection control experts were consulted. Based on expert opinion, including considerations of convenience and cost, these guidelines recommend a one-step procedure for skin preparation. Health workers should clean the skin with a combination of 2% chlorhexidine gluconate in 70% isopropyl alcohol, covering the whole area and ensuring that the skin area is in contact with the disinfectant for at least 30 seconds; they should then should allow the area to dry completely (about 30 seconds).

Implementing and revising the guidelines

In some countries, these guidelines will be adapted to meet local needs, although key steps and recommendations will be maintained. The WHO Injection Safety programme can also provide technical support for adapting and implementing the guidelines at regional and country levels, if requested. The feasibility of recommended practices and the impact of the guideline on phlebotomy practices will be evaluated by the WHO Injection Safety programme, in collaboration with WHO Regional Offices. The recommendations in this document are expected to remain valid until 2014, when they will be reviewed.



PART I BACKGROUND

1 Introduction

1.1 Overview

Phlebotomy – the drawing of blood – has been practiced for centuries and is still one of the most common invasive procedures in health care (1). However, practice varies considerably between countries, and between institutions and individuals within the same country (2). These differences include variations in blood-sampling technique, training (both formal and “on-the-job”), use of safety devices, disposal methods, reuse of devices and availability of hepatitis B vaccine.

The methods and the evidence base used to develop this document are given in Annex A.

1.1.1 Issues in phlebotomy

By its nature, phlebotomy has the potential to expose health workers and patients to blood from other people, putting them at risk from bloodborne pathogens. These pathogens include human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), and those causing viral haemorrhagic fevers (Crimean Congo haemorrhagic fever, Ebola, Lassa and Marburg) and dengue (3). For example, outbreaks of hepatitis B have been reported with the use of glucometers (devices used to determine blood glucose concentration) (4, 5). Diseases such as malaria and syphilis may also be transmitted via contaminated blood (6, 7), and poor infection-control practices may lead to bacterial infection where the needle is inserted and contamination of specimens.

If a blood sample is poorly collected, the results may be inaccurate and misleading to the clinician, and the patient may have to undergo the inconvenience of repeat testing. The three major issues resulting from errors in collection are haemolysis, contamination and inaccurate labelling.

Factors that increase the risk of haemolysis include:

- use of a needle of too small a gauge (23 or under), or too large a gauge for the vessel;
- pressing the syringe plunger to force the blood into a tube, thus increasing the shear force on the red blood cells;
- drawing blood specimens from an intravenous or central line;
- underfilling a tube so that the ratio of anticoagulant to blood is greater than 1:9;
- reusing tubes that have been refilled by hand with inappropriate amounts of anticoagulants;
- mixing a tube too vigorously;
- failing to let alcohol or disinfectant dry;
- using too great a vacuum; for example, using too large a tube for a paediatric patient, or using too large a syringe (10–20 ml).

Serious adverse events linked with phlebotomy are rare, but may include loss of consciousness with tonic clonic seizures. Less severe events include pain at the site of venepuncture, anxiety and fainting. The best documented adverse events are in blood transfusion services, where poor venepuncture practice or anatomical abnormality has resulted in bruising, haematoma and injury to anatomical structures in the vicinity of the needle entry. For example, one study reported bruising and haematoma at the venepuncture site in 12.3% of blood donors (8). Nerve injury and damage to adjacent anatomical structures occurred infrequently, and syncope occurred in less than 1% of individuals (8). Vasovagal attacks occurred occasionally, varying from mild to severe; fainting was reported in 5.3% of cases and usually occurred in first-time female blood donors (8-11).



Injuries from sharps (i.e. items such as needles that have corners, edges or projections capable of cutting or piercing the skin) commonly occur between the use and disposal of a needle or similar device (12, 13). One way to reduce accidental injury and blood exposure among health workers is to replace devices with safety (i.e. engineered) devices (14–16). Safety devices can avoid up to 75% of percutaneous injuries (17); however, if they are disassembled or manually recapped, or if the needle safety feature is not activated, exposure to blood becomes more likely. Eliminating needle recapping and instead immediately disposing of the sharp into a puncture-resistant sharps container (i.e. a safety container) markedly reduces needle-stick injuries (18, 19).

Reporting of accidental exposure to blood and body fluids is more frequent from well-established health-care systems; however, it is thought that the incidence of such exposures is actually higher in systems that are not so well equipped (20, 21).

Home-based care is a growing component of health delivery, and current global trends suggest that home-based phlebotomy will become increasingly common. In this situation, stronger protection of community-based health workers and the community will be needed. This can be achieved by improving sharps disposal, and by using safety needles with needle covers or retractable needles to minimize the risk of exposure to needles (22) and lancets.

1.1.2 The need for guidelines

Phlebotomy services are available worldwide in a range of health-care facilities (e.g. hospitals, outpatient facilities and clinics), and are usually performed by both medical and nonmedical personnel. Laboratory staff or members of phlebotomy teams appear to achieve lower rates of contamination than staff who have broader responsibilities, even if both have the same training (23). For example, for obtaining a blood sample for routine genetic screening of babies, the use of capillary heel-pricks by a trained phlebotomist was found to be the most successful and pain-free blood-sampling procedure (capillary sampling is undertaken for rapid tests that require small quantities of blood) (24).

Phlebotomy practice varies among health-care personnel, even though perceptions of risk are similar and there are guidelines for such practice (20, 25). To help standardize practice, several countries have established formal training that phlebotomists must undertake before they can practice clinically, but physicians can often practice phlebotomy without formal training (26).

During phlebotomy procedures, the greatest concern is the safety of health workers and patients; therefore, guidance for staff on best practice is critical (27, 28). Training on, and adherence to, the guidance presented here should substantially reduce the risks to both patients and staff, and will improve blood collection for laboratory tests and from blood donors.

1.1.3 Definitions

For the purposes of this document, the term “phlebotomy” covers the terms:

- *blood sampling* for purposes of laboratory tests;
- *blood collection* for donation.



1.2 Purpose and scope

The aim of these guidelines is to summarize best practices in phlebotomy, to improve outcomes for health workers and patients.

These guidelines recommend best practices for all levels of health care where phlebotomy is practised. They extend the scope of the existing guidelines from the World Health Organization (WHO) and the Safe Injection Global Network (SIGN), which is a WHO-hosted network. These existing guidelines are:

- *WHO Aide-memoire for a national strategy for the safe and appropriate use of injection (29)*;
- *Best infection control practices for intradermal, subcutaneous, and intramuscular needle injections (30)*.

This document also discusses best practices for venous and arterial blood sampling, and blood collection for transfusion for adult and paediatric populations. The document does not discuss collection from in-dwelling central lines, arterial lines or cord blood; also, it does not cover stem cell collection.

1.3 Objectives

The objectives of these guidelines are to:

- improve knowledge and awareness of the risks associated with phlebotomy among all health workers involved in the practice;
- increase safe practices and reduce bloodborne virus exposure and transmission;
- improve patient confidence and comfort;
- improve the quality of laboratory tests.

1.4 Target audience

This document is aimed at:

- people who perform or supervise phlebotomy in the private and public sectors, in hospitals, community clinics and other health-care facilities, including those involved in home-based care;
- health trainers and educators;
- procurement officials (who need to be aware of which equipment and supplies are safe and cost effective).

1.5 Indications for blood sampling and blood collection

The most common use of blood sampling is for laboratory tests for clinical management and health assessment. Categories that require specialist training include:

- arterial blood gases for patients on mechanical ventilation, to monitor blood oxygenation;
- neonatal and paediatric blood sampling
 - heel-prick (i.e. capillary sampling);
 - scalp veins in paediatrics;



- capillary sampling (i.e. finger or heel-pricks or, rarely, an ear lobe puncture) for analysis of capillary blood specimens for all ages; examples include testing of iron levels before blood donation, blood glucose monitoring, and rapid tests for HIV, malaria and syphilis.

Blood collection is used to obtain blood from donors for various therapeutic purposes.

1.6 Structure of document

This document is divided into five parts:

- Part I introduces the topic and the document.
- Part II covers different aspects of phlebotomy. Each chapter in this part is divided into sections that give background information, practical guidance and illustrations (where applicable). Part 2 includes
 - the steps recommended for safe phlebotomy, including accepted principles for drawing and collecting blood (Chapter 2);
 - the various open and closed systems available for phlebotomy (Chapter 3);
 - collection of blood for transfusion (Chapter 4);
 - collection of arterial blood, for determination of blood gases (Chapter 5);
 - aspects of blood sampling specific to paediatric and neonatal patients (Chapter 6);
 - capillary sampling (Chapter 7)
- Part III deals with implementation, monitoring and evaluation; it covers
 - ways to implement best practices in phlebotomy (Chapter 8);
 - use of a monitoring and evaluation system to document improvements in phlebotomy practice (Chapter 9).
- Part IV lists the references.
- Part V contains a set of annexes that provide additional information on specific topics; it also includes a glossary.



**PART II ASPECTS
OF PHLEBOTOMY**

2 Best practices in phlebotomy

This chapter covers all the steps recommended for safe phlebotomy and reiterates the accepted principles for blood drawing and blood collection (31). The chapter includes background information (Section 2.1), practical guidance (Section 2.2) and illustrations (Section 2.3) relevant to best practices in phlebotomy.

The information given in this section underpins that given in the remainder of Part II for specific situations. Chapter 4 also provides information relevant to the procedure for drawing blood given below in Section 2.2, but focuses on blood collection from donors.

Institutions can use these guidelines to establish standard operating procedures. Such procedures should clearly state the risks to patients and health workers, as well as the means to reduce those risks – discussed below in Sections 2.1.4 and 2.2.

2.1 Background information on best practices in phlebotomy

Best practices in phlebotomy involve the following factors:

- planning ahead;
- using an appropriate location;
- quality control;
- standards for quality care for patients and health workers, including
 - availability of appropriate supplies and protective equipment;
 - availability of post-exposure prophylaxis (PEP);
 - avoidance of contaminated phlebotomy equipment;
 - appropriate training in phlebotomy;
 - cooperation on the part of patients;
- quality of laboratory sampling.

2.1.1 Planning ahead

This is the most important part of carrying out any procedure, and is usually done at the start of a phlebotomy session.

2.1.2 Using an appropriate location

The phlebotomist should work in a quiet, clean, well-lit area, whether working with outpatients or inpatients.

2.1.3 Quality control

Quality assurance is an essential part of best practice in infection prevention and control (1). In phlebotomy, it helps to minimize the chance of a mishap. Table 2.1 lists the main components of quality assurance, and explains why they are important.



Table 2.1 Elements of quality assurance in phlebotomy

Element	Notes
Education and training	Education and training is necessary for all staff carrying out phlebotomy. It should include an understanding of anatomy, awareness of the risks from blood exposure, and the consequences of poor infection prevention and control.
Standard operating procedures (SOPs)	SOPs are required for each step or procedure. They should be written and be readily available to health workers.
Correct identification of the patient	Identification should be through matching to the laboratory request form. <ul style="list-style-type: none"> • For blood donation, the identity of the donor should be accurately matched to the results of screening tests. • For blood sampling, after samples have been taken from a patient or donor, a system of identification and tracking is essential to ensure that the sample is correctly matched with the result and with the patient or donor.
The condition of the sample	The condition of the sample should be such that the quality of the results is satisfactory.
Safe transportation	Making safe transportation of blood or blood products part of best practices will improve the quality of results from laboratory testing (32).
An incident reporting system	A system is required for reporting all adverse events. A log book or register should be established with accurate details of the incident, possible causes and management of adverse events (27).

2.1.4 Quality care for patients and health workers

Several factors can improve safety standards and quality of care for both patients and health workers, and laboratory tests. These factors, discussed below, include:

Availability of appropriate supplies and protective equipment

Procurement of supplies is the direct responsibility of the administrative (management) structures responsible for setting up phlebotomy services. Management should:

- provide hand-hygiene materials (soap and water or alcohol rub), well-fitting non-sterile gloves, single-use disposable needles, and syringes or lancing devices in sufficient numbers to ensure that each patient has a sterile needle and syringe or equivalent for each blood sampling;
- make available sufficient laboratory sample tubes to prevent dangerous practices (e.g. decanting blood to recycle laboratory tubes).

Several safety-engineered devices are available on the market; such devices reduce exposure to blood and injuries. However, the use of such devices should be accompanied by other infection prevention and control practices, and training in their use. Not all safety devices are applicable to phlebotomy. Before selecting a safety-engineered device, users should thoroughly investigate available devices to determine their appropriate use, compatibility with existing phlebotomy practices, and efficacy in protecting staff and patients (12, 33). Annex B provides further information on infection prevention and control, safety equipment and best practice; Annex C provides a comprehensive guide to devices available for drawing blood, including safety-engineered equipment.

For settings with low resources, cost is a driving factor in procurement of safety-engineered devices.

Where safety-engineered devices are not available, skilled use of a needle and syringe is acceptable.



Availability of post-exposure prophylaxis

Accidental exposure and specific information about an incident should be recorded in a register.

Support services should be promoted for those who undergo accidental exposure. PEP can help to avert HIV and hepatitis B infections (13, 27). Hepatitis B immunization should be provided to all health workers (including cleaners and waste handlers), either upon entry into health-care services or as part of PEP (34). Annex D has details of PEP for hepatitis B and HIV.

Avoidance of contaminated phlebotomy equipment

Tourniquets are a potential source of methicillin-resistant *Staphylococcus aureus* (MRSA), with up to 25% of tourniquets contaminated through lack of hand hygiene on the part of the phlebotomist or reuse of contaminated tourniquets (35). In addition, reusable finger-prick devices and related point-of-care testing devices (e.g. glucometers) contaminated with blood have been implicated in outbreaks of hepatitis B (4, 5, 36).

To avoid contamination, any common-use items, such as glucometers, should be visibly clean before use on a patient, and single-use items should not be reused.

Training in phlebotomy

All staff should be trained in phlebotomy, to prevent unnecessary risk of exposure to blood and to reduce adverse events for patients.

- Groups of health workers who historically are not formally trained in phlebotomy should be encouraged to take up such training; lax infection prevention and control practices result in poor safety for staff and risk to patients (20, 37).
- The length and depth of training will depend on local conditions; however, the training should at least cover the essentials (see Annex E) (38).
- Supervision by experienced staff and structured training is necessary for all health workers, including physicians, who undertake blood sampling.

Patient cooperation

One of the essential markers of quality of care in phlebotomy is the involvement and cooperation of the patient; this is mutually beneficial to both the health worker and the patient.

Clear information – either written or verbal – should be available to each patient who undergoes phlebotomy. Annex F provides sample text for explaining the blood-sampling procedure to a patient.

2.1.5 Quality of laboratory sampling

Factors that influence the outcome of laboratory results during collection and transportation include:

- knowledge of staff involved in blood collection;
- use of the correct gauge of hypodermic needle (see Table 3.1 in Chapter 3) to prevent haemolysis or abnormal results;
- the anatomical insertion site for venepuncture;
- the use of recommended laboratory collection tubes;
- patient–sample matching (i.e. labelling);
- transportation conditions;
- interpretation of results for clinical management.



2.2 Practical guidance on best practices in phlebotomy

2.2.1 Provision of an appropriate location

- In an outpatient department or clinic, provide a dedicated phlebotomy cubicle containing:
 - a clean surface with two chairs (one for the phlebotomist and the other for the patient);
 - a hand wash basin with soap, running water and paper towels;
 - alcohol hand rub.
- In the blood-sampling room for an outpatient department or clinic, provide a comfortable reclining couch with an arm rest.
- In inpatient areas and wards:
 - at the patient’s bedside, close the bed curtain to offer privacy
 - ensure that blood sampling is done in a private and clean manner.

2.2.2 Provision of clear instructions

Ensure that the indications for blood sampling are clearly defined, either in a written protocol or in documented instructions (e.g. in a laboratory form).

2.2.3 Procedure for drawing blood

At all times, follow the strategies for infection prevention and control listed in Table 2.2.

Table 2.2 Infection prevention and control practices

Do	Do not
DO carry out hand hygiene (use soap and water or alcohol rub), and wash carefully, including wrists and spaces between the fingers for at least 30 seconds (follow WHO’s ‘My 5 moments for hand hygiene’ ^a)	DO NOT forget to clean your hands
DO use one pair of non-sterile gloves per procedure or patient	DO NOT use the same pair of gloves for more than one patient DO NOT wash gloves for reuse
DO use a single-use device for blood sampling and drawing	DO NOT use a syringe, needle or lancet for more than one patient
DO disinfect the skin at the venepuncture site	DO NOT touch the puncture site after disinfecting it
DO discard the used device (a needle and syringe is a single unit) immediately into a robust sharps container	DO NOT leave an unprotected needle lying outside the sharps container
Where recapping of a needle is unavoidable, DO use the one-hand scoop technique (see Annex G)	DO NOT recap a needle using both hands
DO seal the sharps container with a tamper-proof lid	DO NOT overfill or decant a sharps container
DO place laboratory sample tubes in a sturdy rack before injecting into the rubber stopper	DO NOT inject into a laboratory tube while holding it with the other hand
DO immediately report any incident or accident linked to a needle or sharp injury, and seek assistance; start PEP as soon as possible, following protocols	DO NOT delay PEP after exposure to potentially contaminated material; beyond 72 hours, PEP is NOT effective

PEP, post-exposure prophylaxis; WHO, World Health Organization.

^a <http://www.who.int/gpsc/5may/background/5moments/en/index.html>



Step 1 – Assemble equipment

Collect all the equipment needed for the procedure and place it within safe and easy reach on a tray or trolley, ensuring that all the items are clearly visible. The equipment required includes:

- a supply of laboratory sample tubes, which should be stored dry and upright in a rack; blood can be collected in
 - sterile glass or plastic tubes with rubber caps (the choice of tube will depend on what is agreed with the laboratory);
 - vacuum-extraction blood tubes; or
 - glass tubes with screw caps;
- a sterile glass or bleeding pack (collapsible) if large quantities of blood are to be collected;
- well-fitting, non-sterile gloves;
- an assortment of blood-sampling devices (safety-engineered devices or needles and syringes, see below), of different sizes;
- a tourniquet;
- alcohol hand rub;
- 70% alcohol swabs for skin disinfection;
- gauze or cotton-wool ball to be applied over puncture site;
- laboratory specimen labels;
- writing equipment;
- laboratory forms;
- leak-proof transportation bags and containers;
- a puncture-resistant sharps container.

Ensure that the rack containing the sample tubes is close to you, the health worker, but away from the patient, to avoid it being accidentally tipped over.

Step 2 – Identify and prepare the patient

Where the patient is adult and conscious, follow the steps outlined below.

- Introduce yourself to the patient, and ask the patient to state their full name.
- Check that the laboratory form matches the patient's identity (i.e. match the patient's details with the laboratory form, to ensure accurate identification).
- Ask whether the patient has allergies, phobias or has ever fainted during previous injections or blood draws.
- If the patient is anxious or afraid, reassure the person and ask what would make them more comfortable.
- Make the patient comfortable in a supine position (if possible).
- Place a clean paper or towel under the patient's arm.
- Discuss the test to be performed (see Annex F) and obtain verbal consent. The patient has a right to refuse a test at any time before the blood sampling, so it is important to ensure that the patient has understood the procedure.

For paediatric or neonatal patients, see Chapter 6.



Step 3 – Select the site

General

- Extend the patient's arm and inspect the antecubital fossa or forearm.
- Locate a vein of a good size that is visible, straight and clear. The diagram in Section 2.3, shows common positions of the vessels, but many variations are possible. The median cubital vein lies between muscles and is usually the most easy to puncture. Under the basilic vein runs an artery and a nerve, so puncturing here runs the risk of damaging the nerve or artery and is usually more painful. **DO NOT** insert the needle where veins are diverting, because this increases the chance of a haematoma.
- The vein should be visible without applying the tourniquet. Locating the vein will help in determining the correct size of needle.
- Apply the tourniquet about 4–5 finger widths above the venepuncture site and re-examine the vein.

Hospitalized patients

In hospitalized patients, do not take blood from an existing peripheral venous access site because this may give false results. Haemolysis, contamination and presence of intravenous fluid and medication can all alter the results (39). Nursing staff and physicians may access central venous lines for specimens following protocols. However, specimens from central lines carry a risk of contamination or erroneous laboratory test results.

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.

Step 4 – Perform hand hygiene and put on gloves

- Perform hand hygiene; that is
 - wash hands with soap and water, and dry with single-use towels; or
 - if hands are not visibly contaminated, clean with alcohol rub – use 3 ml of alcohol rub on the palm of the hand, and rub it into fingertips, back of hands and all over the hands until dry.
- After performing hand hygiene, put on well-fitting, non-sterile gloves.

Step 5 – Disinfect the entry site

- Unless drawing blood cultures, or prepping for a blood collection, clean the site with a 70% alcohol swab for 30 seconds and allow to dry completely (30 seconds) (40–42).

Note: alcohol is preferable to povidone iodine, because blood contaminated with povidone iodine may falsely increase levels of potassium, phosphorus or uric acid in laboratory test results (6, 7).

- Apply firm but gentle pressure. Start from the centre of the venepuncture site and work downward and outwards to cover an area of 2 cm or more.
- Allow the area to dry. Failure to allow enough contact time increases the risk of contamination.
- **DO NOT** touch the cleaned site; in particular, **DO NOT** place a finger over the vein to guide the shaft of the exposed needle. If the site is touched, repeat the disinfection.



Step 6 – Take blood

Venepuncture

Perform venepuncture as follows.

- Anchor the vein by holding the patient's arm and placing a thumb **BELOW** the venepuncture site.
- Ask the patient to form a fist so the veins are more prominent.
- Enter the vein swiftly at a 30 degree angle or less, and continue to introduce the needle along the vein at the easiest angle of entry.
- Once sufficient blood has been collected, release the tourniquet **BEFORE** withdrawing the needle. Some guidelines suggest removing the tourniquet as soon as blood flow is established, and always before it has been in place for two minutes or more.
- Withdraw the needle gently 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. Ask the patient **NOT** to bend the arm, because doing so causes a haematoma.

Step 7 – Fill the laboratory sample tubes

- When obtaining multiple tubes of blood, use evacuated tubes with a needle and tube holder. This system allows the tubes to be filled directly. If this system is not available, use a syringe or winged needle set instead.
- If a syringe or winged needle set is used, best practice is to place the tube into a rack before filling the tube. To prevent needle-sticks, use one hand to fill the tube or use a needle shield between the needle and the hand holding the tube.
- Pierce the stopper on the tube with the needle directly above the tube using slow, steady pressure. Do not press the syringe plunger because additional pressure increases the risk of haemolysis.
- Where possible, keep the tubes in a rack and move the rack towards you. Inject downwards into the appropriate coloured stopper. **DO NOT** remove the stopper because it will release the vacuum.
- If the sample tube does not have a rubber stopper, inject extremely slowly into the tube as minimizing the pressure and velocity used to transfer the specimen reduces the risk of haemolysis. **DO NOT** recap and remove the needle.
- Before dispatch, invert the tubes containing additives for the required number of times (as specified by the local laboratory).

Step 8 – Draw samples in the correct order

Draw blood collection tubes in the correct order, to avoid cross-contamination of additives between tubes. As colour coding and tube additives may vary, verify recommendations with local laboratories. For illustration purposes, Table 2.3 shows the revised, simplified recommended order of draw for vacuum tubes or syringe and needle, based on United States National Committee Clinical Laboratory Standards consensus in 2003 (43).



Table 2.3 Recommended order of draw for plastic vacuum tubes

Order of use ^a	Type of tube/usual colour ^b	Additive ^c	Mode of action	Uses
1	Blood culture bottle (yellow-black striped tubes)	Broth mixture	Preserves viability of microorganisms	Microbiology – aerobes, anaerobes, fungi
2	Non-additive tube			
3	Coagulation tube ^d (light blue top)	Sodium citrate	Forms calcium salts to remove calcium	Coagulation tests (protime and prothrombin time), requires full draw
4	Clot activator (red top)	Clot activator	Blood clots, and the serum is separated by centrifugation	Chemistries, immunology and serology, blood bank (cross-match)
5	Serum separator tube (red-grey tiger top or gold)	None	Contains a gel at the bottom to separate blood from serum on centrifugation	Chemistries, immunology and serology
6	Sodium heparin (dark green top)	Sodium heparin or lithium heparin	Inactivates thrombin and thromboplastin	For lithium level use sodium heparin, for ammonia level use either
7	PST (light green top)	Lithium heparin anticoagulant and a gel separator	Anticoagulants with lithium, separates plasma with PST gel at bottom of tube	Chemistries
8	EDTA (purple top)	EDTA	Forms calcium salts to remove calcium	Haematology, Blood Bank (cross-match) requires full draw
9	Blood tube (pale yellow top)	Acid-citrate-dextrose (ACD, ACDA or ACDB)	Complement inactivation	HLA tissue typing, paternity testing, DNA studies
10	Oxalate/fluoride (light grey top)	Sodium fluoride and potassium oxalate	Antiglycolytic agent preserves glucose up to five days	Glucoses, requires full draw (may cause haemolysis if short draw)

ACD, acid-citrate-dextrose; DNA, deoxyribonucleic acid; EDTA, ethylenediaminetetraacetic acid; HLA, human leucocyte antigen; PST, plasma separating tube.

^a "1" indicates draw first, and "10" draw last (if used).

^b Verify with local laboratory in case local colour codes differ.

^c Gently invert tubes with additives to mix thoroughly; erroneous test results may be obtained when the blood is not thoroughly mixed with the additive.

^d If a routine coagulation assay is the only test ordered, then a single light blue top tube may be drawn. If there is a concern about contamination by tissue fluids or thromboplastins, then a non-additive tube can be drawn before the additive tube. The PST tube contains lithium heparin anticoagulant and a gel separator; if used, draw in the order shown.

Source: Table adapted with permission from WebPath, Mercer University, United States (<http://library.med.utah.edu/WebPath/webpath.html>). Order is based on United States National Committee for Clinical Laboratory Standards consensus (43).



Step 9 – Clean contaminated surfaces and complete patient procedure

- Discard the used needle and syringe or blood sampling device into a puncture-resistant sharps container.
- Check the label and forms for accuracy. The label should be clearly written with the information required by the laboratory, which is typically the patient's first and last names, file number, date of birth, and the date and time when the blood was taken.
- Discard used items into the appropriate category of waste. Items used for phlebotomy that would not release a drop of blood if squeezed (e.g. gloves) may be discarded in the general waste, unless local regulations state otherwise.
- Perform hand hygiene again, as described above.
- Recheck the labels on the tubes and the forms before dispatch.
- Inform the patient when the procedure is over.
- Ask the patient or donor how they are feeling. Check the insertion site to verify that it is not bleeding, then thank the patient and say something reassuring and encouraging before the person leaves.

Step 10 – Prepare samples for transportation

- Pack laboratory samples safely in a plastic leak-proof bag with an outside compartment for the laboratory request form. Placing the requisition on the outside helps avoid contamination.
- If there are multiple tubes, place them in a rack or padded holder to avoid breakage during transportation.

Step 11 – Clean up spills of blood or body fluids

If blood spillage has occurred (e.g. because of a laboratory sample breaking in the phlebotomy area or during transportation, or excessive bleeding during the procedure), clean it up. An example of a safe procedure is given below.

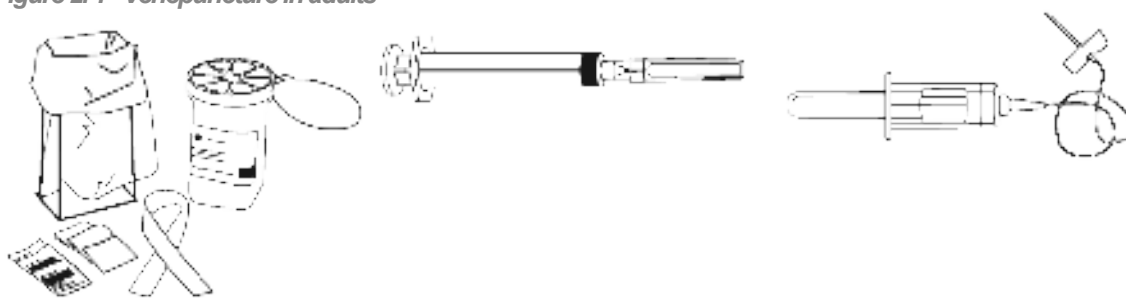
- Put on gloves and a gown or apron if contamination or bleaching of a uniform is likely in a large spill.
- Mop up liquid from large spills using paper towels, and place them into the infectious waste.
- Remove as much blood as possible with wet cloths before disinfecting.
- Assess the surface to see whether it will be damaged by a bleach and water solution.
- For cement, metal and other surfaces that can tolerate a stronger bleach solution, flood the area with an approximately 5000 parts per million (ppm) solution of sodium hypochlorite (1:10 dilution of a 5.25% chlorine bleach to water). This is the preferred concentration for large spills (44). Leave the area wet for 10 minutes.
- For surfaces that may be corroded or discoloured by a strong bleach, clean carefully to remove all visible stains. Make a weaker solution and leave it in contact for a longer period of time. For example, an approximately 525 ppm solution (1:100 dilution of 5.25% bleach) is effective.
- Prepare bleach solution fresh daily and keep it in a closed container because it degrades over time and in contact with the sun.

If a person was exposed to blood through nonintact skin, mucous membranes or a puncture wound, complete an incident report, as described in *WHO best practices for injections and related procedures toolkit*. For transportation of blood samples outside a hospital, equip the transportation vehicle with a blood spillage kit. Annex H has further information on dealing with a blood spillage.

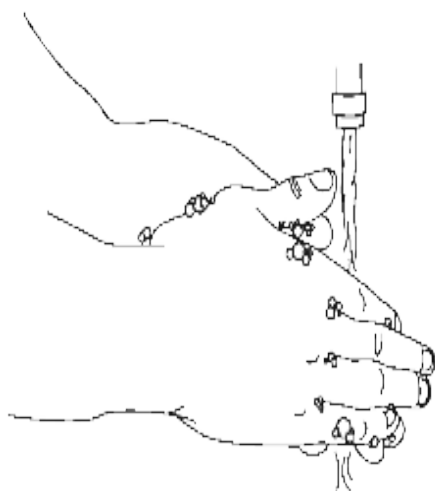


2.3 Illustrations for best practices in phlebotomy

Figure 2.1 Venepuncture in adults



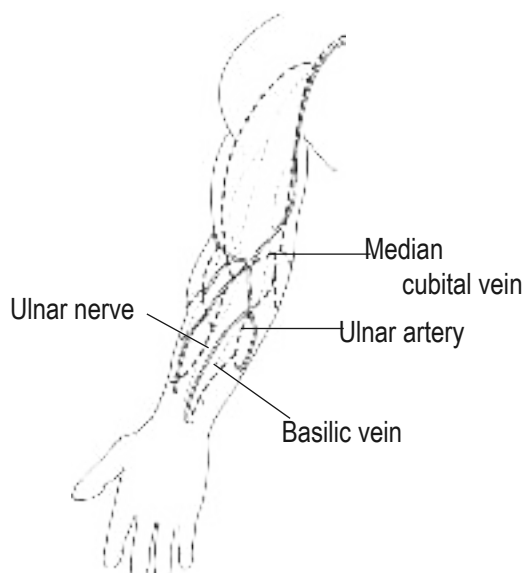
1. Assemble equipment and include needle and syringe or vacuum tube, depending on which is to be used.



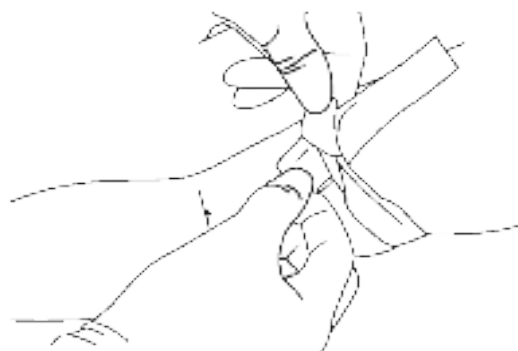
2. Perform hand hygiene (if using soap and water, dry hands with single-use towels).



3. Identify and prepare the patient.

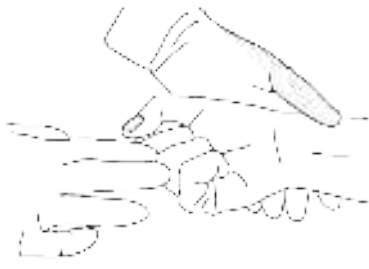


4. Select the site, preferably at the antecubital area (i.e. the bend of the elbow). Warming the arm with a hot pack, or hanging the hand down may make it easier to see the veins. Palpate the area to locate the anatomic landmarks. DO NOT touch the site once alcohol or other antiseptic has been applied.



5. Apply a tourniquet, about 4–5 finger widths above the selected venepuncture site.





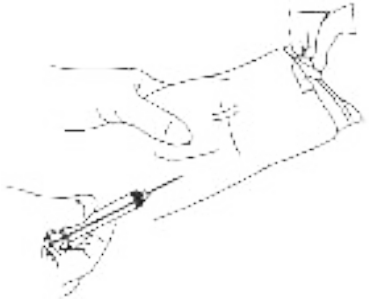
6. Ask the patient to form a fist so that the veins are more prominent.



7. Put on well-fitting, non-sterile gloves.



8. Disinfect the site using 70% isopropyl alcohol for 30 seconds and allow to dry completely (30 seconds).



9. Anchor the vein by holding the patient's arm and placing a thumb BELOW the venepuncture site.



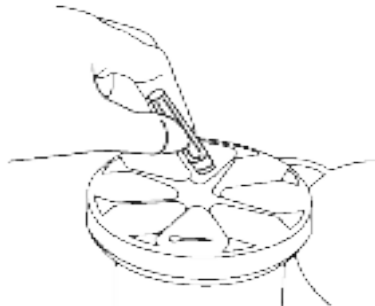
10. Enter the vein swiftly at a 30 degree angle.



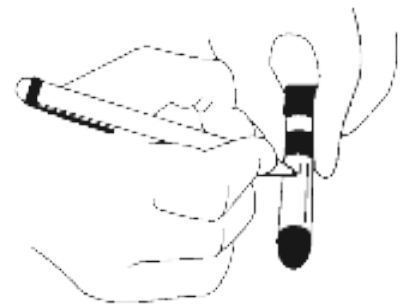
11. Once sufficient blood has been collected, release the tourniquet BEFORE withdrawing the needle.



12. Withdraw the needle gently and then give the patient a clean gauze or dry cotton-wool ball to apply to the site with gentle pressure.



13. Discard the used needle and syringe or blood-sampling device into a puncture-resistant container.



14. Check the label and forms for accuracy.



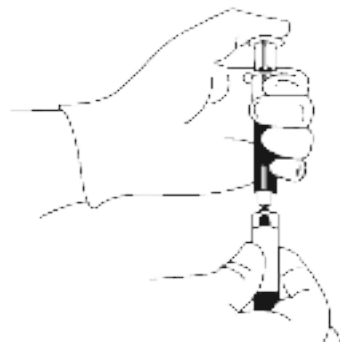
15. Discard sharps and broken glass into the sharps container. Place items that can drip blood or body fluids into the infectious waste.



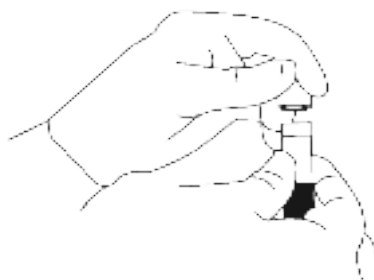
16. Remove gloves and place them in the general waste. Perform hand hygiene. If using soap and water, dry hands with single-use towels.



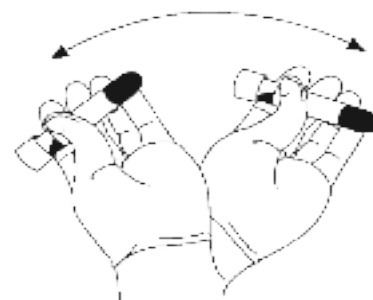
Figure 2.2 Filling tubes



1. If the tube does not have a rubber stopper, press the plunger in slowly to reduce haemolysis (this is safer than removing the needle).



2. Place the stopper in the tube.



3. Following laboratory instructions, invert the sample gently to mix the additives with the blood before dispatch.



3 Blood-sampling systems

Users of these guidelines should read Chapter 2 before reading the information given below. This chapter covers background information (Section 3.1), practical guidance (Section 3.2) and illustrations (Section 3.3) relevant to closed and open blood-sampling systems.

Several blood-sampling systems are available for phlebotomy. The system most appropriate for the procedure should be chosen. Annex C provides detailed information on all the systems available for drawing blood, and outlines the advantages and disadvantages of each device.

3.1 Background information on blood-sampling systems

3.1.1 Closed systems

Closed systems for blood sampling are preferable because they have proven to be safer than open systems (23).

Needle and syringe

The use of a hypodermic needle and syringe is the most common means of blood sampling.

Choice of gauge

If the needle is too large for the vein for which it is intended, it will tear the vein and cause bleeding (haematoma); if the needle is too small, it will damage the blood cells during sampling, and laboratory tests that require whole blood cells, or haemoglobin and free plasma, will be invalid.

Blood collection for transfusion requires a larger gauge than is used for blood drawing.

Vacuum extraction systems

The use of vacuum extraction tube systems as closed systems for blood collecting reduces the risk of direct exposure to blood and has made it easier to take multiple samples from a single venepuncture.

Vacuum extraction systems are widely available in most well-resourced countries. These are recommended, but users should check their own country's recommendations. Although vacuum extraction systems are safe, training and skill is required for their use.

Double-ended needles are available in several recommended gauge sizes. The end covered by a rubber cuff is screwed into the barrel (also known as the tube holder, evacuated tube needle holder or bulldog). A thread separates the two ends, and this is where the barrel is screwed into place. The barrel holds the sample collection tube in place and protects the phlebotomist from direct contact with blood. The sample tube is under vacuum. Once the needle is in the vein, the tube is pressed on to the needle and the blood is drawn automatically into the sample tube by vacuum until the required amount is collected. This system comes complete with needle, barrel and the laboratory sample tubes with appropriately coloured tops for different types of samples. Tubes for adult and paediatric specimens are available.

Discard the barrel and syringe as a single entity where possible. If there is a need to reuse the barrel, use a one-hand scoop technique (Annex G) to cover the sharp end of the needle and thus to safely remove the needle from the barrel. Alternately, use a sharps container with a needle removal hold, again employing a one-handed technique.



Some systems have a mechanism that can be activated once the needle has been used; the mechanism retracts the used needle into the barrel and snaps it shut. Others have a quick-release mechanism to dislodge the used needle into the sharps container.

Vacuum systems may also be used with a winged butterfly needle and luer-lock connectors. Winged butterfly needles are also available with safety-engineered devices.

The sharps container must be within arm's reach and clearly visible, to ensure safe disposal of sharps.

3.1.2 Open systems

Open systems include hypodermic needle and syringes, as well as winged steel needles attached to a syringe.

3.2 Practical guidance on blood-sampling systems

3.2.1 Needle and syringe

To use a needle and syringe system:

- open the packaging of the hypodermic needle from the hub end (back of the needle), keeping it capped;
- open the sterile packaging of the syringe from the plunger end (back of the syringe), keeping the nozzle protected in the packaging;
- carefully remove the syringe from the packaging and insert the nozzle of the syringe firmly into the exposed hub of the capped hypodermic needle;
- leave the needle and syringe in place until ready for use.

3.2.2 Choice of gauge

Choose the gauge of hypodermic needle that fits comfortably into the most prominent vein with little discomfort (Table 3.1).

Table 3.1 Recommended needle gauge, length and device for routine injection and phlebotomy procedures for different age groups

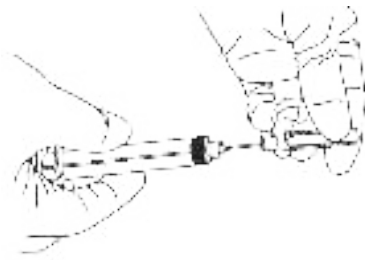
Needle gauge	Patient population			Procedure
	Adult	Paediatric, elderly, small veins	Neonatal	
16–18	√			√ Blood donation
19–20	NA	NA	NA	
21	√ (1–1.5 inch or 2.54 cm)	NA	NA	
22	√ (1 inch or 2.54 cm)	√ (1 inch or 2.54 cm)	NA	
23	√ (1–1.5 inch or 2.54 cm)	√ (Winged set [butterfly]; 0.5 inch or 0.75 cm)	√ (Winged set [butterfly]; 0.5 inch or 0.75 cm)	

NA, not applicable.



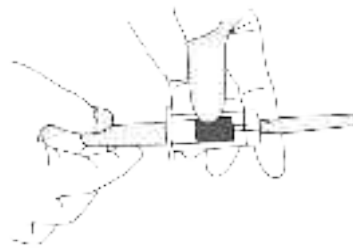
3.3 Illustrations for blood-sampling systems

Figure 3.1 Blood-sampling systems



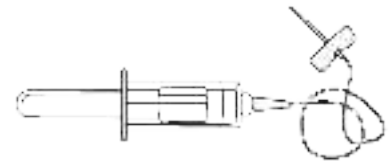
Needle and syringe system

Remove the syringe from the packaging and insert the nozzle of the syringe firmly into the exposed hub of the capped hypodermic needle.



Vacuum extraction system

The barrel holds the sample collection tube in place and protects the phlebotomist from direct contact with blood. Do not push the laboratory tube onto the needle inside the barrel until the needle is in the blood vessel, or the vacuum will be lost.



Winged butterfly system (vacuum extraction)

A vacuum system combined with a winged butterfly needle. Do not push the laboratory tube onto the needle inside the barrel until the winged needle is inside the blood vessel or the vacuum will be lost.



Winged butterfly system (syringe)

A syringe combined with a winged butterfly needle.



4 Venepuncture for blood donation

The information given here supplements that given in Chapters 2 and 3. Users of these guidelines should read Chapters 2 and 3 before reading the information given below. This chapter covers background information (Section 4.1) and practical guidance (Section 4.2) relevant to venepuncture for blood donation.

4.1 Background information on venepuncture for blood donation

Blood banks use various processes to try to prevent infections that can be transmitted by infected blood donation. One important measure to prevent infection is to recruit donors from populations that are known to have low rates of infection for bloodborne diseases, such as voluntary, unpaid donors and people with no history of intravenous drug use. A second measure is to ask donors a series of additional screening questions (these will vary by region) to help identify those who may be at higher risk of infection. Phlebotomists must adhere strictly to the rules for including and excluding blood donors. A third measure is to test donated blood for infections common in the area before processing it for use for various therapeutic purposes.

The process for collecting blood from donors is similar to that used for blood sampling; however, a few additional measures are required for collection of donated blood. These measures are primarily to ensure patient safety, but also to minimize exogenous contamination of a donated blood unit or its derived components, particularly contamination from the skin flora of the donor's arm. Because of the volume of blood collected and the length of storage, pathogens can multiply during storage. Safe collection ensures that the blood products are safe for therapeutic use throughout their shelf life.

Skin flora is a common source of contaminants; it is therefore important to use an effective antiseptic on the donor's arm before blood donation. Transfusion with blood components that are contaminated with exogenous bacteria or other agents can cause fatal complications (30, 45). Studies on the topic have been inconclusive (46); however, based on available literature and expert opinion, the recommended option for skin antisepsis for blood donation is the one-step application of a combination of 2% chlorhexidine gluconate and 70% isopropyl alcohol for 30 seconds, followed by 30 seconds drying time (47–49).

Blood donations should be collected only by trained and qualified blood transfusion services personnel.

4.1.1 Minimum requirements for venepuncture for blood donation

The relevant guidance given in Chapter 2 on planning, location and infection prevention and control practices should be followed, as should the guidance in Chapter 3 on closed systems. Additional requirements for a collection system for blood donation are listed below.

- Equipment:
 - All equipment used for collection of blood donations should be regularly calibrated, maintained and serviced, as required. Such equipment includes blood pressure monitors, scales, donor couches or chairs, blood collection monitors or mixers, blood bag tube sealers, blood transportation boxes and blood bank refrigerators.
 - Furniture and equipment in the area of blood donation and processing should be made of cleanable surfaces (e.g. vinyl rather than fabric). Containers used to transport supplies and specimens should also be cleanable by disinfectants such as sodium hypochlorite bleach solutions. Fabric or textile carriers should be machine washable.



- A closed collection system with a sterile blood collection bag containing anticoagulant, and with an integrally attached tube and needle should be used. Some bags include diversion pouches to sequester the first 20 ml of blood collected, to minimize contamination from skin flora and the skin core (50). If blood for haemoglobin testing is gathered with a capillary stick, a single-use sterile lancet should be used and then placed immediately in a safety box.
- Location:
 - Premises should be of sufficient size for efficient operations, with separate areas for clean and dirty processes, clean running water, and surfaces cleanable by disinfectants.
 - Floors should not be carpeted.
 - Waiting areas should be outside the collection area, to minimize the risk of respiratory pathogens for workers.
 - All fixed and mobile blood donation sites should be safe, clean, hygienic and tidy, and should meet defined standards of environmental safety.
 - The donation sites should be organized in a way that ensures the safety of blood donors, staff and donated blood units, and avoids errors in the blood donation process.

4.1.2 Before a blood donation

WHO has developed a set of basic requirements for blood transfusion services, which cover the steps to take before donation (51). Blood donation should be voluntary; it should not involve duress, coercion or remuneration. Also, potential blood donors should be selected carefully, according to the national criteria for donor selection.

Before a person donates blood (52):

- the potential donor should be given pre-donation information, advice and counselling about the process of blood donation;
- a relevant history of the donor should be taken, covering health and high-risk behaviour, and including
 - history of mastectomy (blood should be taken from the arm opposite the site of surgery) (48, 53);
 - current and recent medications or chronic infections;
 - history of prolonged bleeding or a past diagnosis of bleeding disorders;
 - history of previous donations, to ensure the waiting period is respected;
- a preliminary physical check-up of the donor should be done, including weight, blood pressure, signs of infection or scarring at potential sites;
- the donor should be offered fluids, to help reduce the risk of fainting after blood donation (54);
- the person should provide informed written consent, based on the national requirements.



4.2 Practical guidance on venepuncture for blood donation

4.2.1 Collecting blood

For collection of blood for donation, use the procedure detailed in Chapter 2 for blood sampling (e.g. for hand hygiene and glove use), as far as it is relevant, and follow the six steps given below.

Step 1 – Identify donor and label blood collection bag and test tubes

- Ask the donor to state their full name.
- Ensure that:
 - the blood collection bag is of the correct type;
 - the labels on the blood collection bag and all its satellite bags, sample tubes and donor records have the correct patient name and number;
 - the information on the labels matches with the donor's information.

Step 2 – Select the vein

- Select a large, firm vein, preferably in the antecubital fossa, from an area free from skin lesions or scars.
- Apply a tourniquet or blood pressure cuff inflated to 40–60 mm Hg, to make the vein more prominent.
- Ask the donor to open and close the hand a few times.
- Once the vein is selected, release the pressure device or tourniquet before the skin site is prepared.

Step 3 – Disinfect the skin

- If the site selected for venepuncture is visibly dirty, wash the area with soap and water, and then wipe it dry with single-use towels.
- *One-step procedure* (recommended – takes about one minute):
 - use a product combining 2% chlorhexidine gluconate in 70% isopropyl alcohol;
 - cover the whole area and ensure that the skin area is in contact with the disinfectant for **at least** 30 seconds;
 - allow the area to dry **completely**, or for a minimum of 30 seconds by the clock.
- *Two-step procedure* (if chlorhexidine gluconate in 70% isopropyl alcohol is not available, use the following procedure – takes about two minutes):
 - *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;
 - allow the area to dry **completely** (about 30 seconds);
 - *step 2* – use tincture of iodine (more effective than povidine iodine) or chlorhexidine (2%);
 - cover the whole area and ensure that the skin area is in contact with the disinfectant for **at least** 30 seconds;
 - allow the area to dry **completely** (about 30 seconds).
- Whichever procedure is used, DO NOT touch the venepuncture site once the skin has been disinfected.



Step 4 – Perform the venepuncture

Perform venepuncture using a smooth, clean entry with the needle, as described in step 6 of Section 2.2.3. Take into account the points given below, which are specific to blood donation.

- In general, use a 16-gauge needle (see Table 3.1 in Chapter 3), which is usually attached to the blood collection bag. Use of a retractable needle or safety needle with a needle cover is preferred if available, but all should be cut off at the end of the procedure (as described in step 6, below) rather than recapped.
- Ask the donor to open and close the fist slowly every 10–12 seconds during collection.
- Remove the tourniquet when the blood flow is established or after 2 minutes, whichever comes first.

Step 5 – Monitor the donor and the donated unit

- Closely monitor the donor and the injection site throughout the donation process – look for:
 - sweating, palor or complaints of feeling faint that may precede fainting;
 - development of a haematoma at the injection site;
 - changes in blood flow that may indicate the needle has moved in the vein, and needs to be repositioned.
- About every 30 seconds during the donation, mix the collected blood gently with the anticoagulant, either manually or by continuous mechanical mixing.

Step 6 – Remove the needle and collect samples

- Cut off the needle using a sterile pair of scissors.
- Collect blood samples for laboratory testing.

4.2.2 After a blood donation

Donor care

After the blood has been collected:

- ask the donor to remain in the chair and relax for a few minutes;
- inspect the venepuncture site; if it is not bleeding, apply a bandage to the site; if it is bleeding, apply further pressure;
- ask the donor to sit up slowly and ask how the person is feeling;
- before the donor leaves the donation room, ensure that the person can stand up without dizziness and without a drop in blood pressure;
- offer the donor some refreshments.

Blood unit and samples

- Transfer the blood unit to a proper storage container according to the blood centre requirements and the product (55–58).
- Ensure that collected blood samples are stored and delivered to the laboratory with completed documentation, at the recommended temperature, and in a leak-proof, closed container (55, 57, 58).



4.2.3 Adverse events in blood donation

Be aware of possible adverse events, and the actions to take if these occur (Table 4.1).

Table 4.1 Adverse events in blood donation

Adverse event	Incidence	Cause	Management	Remarks
Haematoma	2–3%	<ul style="list-style-type: none"> • Poor or failed venepuncture • Skin pierced at too great an angle – and exiting vein • Needle puncturing the vein twice during the donation • Inadequate pressure after the donation 	<ul style="list-style-type: none"> • Apply pressure and a firm bandage • Advise donor to move arm freely but to avoid heavy lifting • Apologize, and reassure the donor 	Give relevant contact information to donor in case the donor has any further inquiries
Vasovagal reaction or faint, due to a hypothalamic response resulting in bradycardia, vomiting, sweating, arterial dilatation and a low blood pressure	1% of all donations (but more frequent in first-time donors – 1.7% versus 0.19%)	<ul style="list-style-type: none"> • Anxiety • Lowered blood volume and other associated causes: <ul style="list-style-type: none"> – hypoglycaemia – lack of fluids – poor sleep • Atmosphere in donation room (hot or humid) <p><i>Signs and symptoms</i></p> <ul style="list-style-type: none"> • Staring • Sighing • Pallor or sweating • Slow pulse • Drop in blood pressure • Vomiting • Loss of consciousness (occasionally) • Convulsions (rare) 	<p><i>Mild vasovagal reaction</i></p> <ul style="list-style-type: none"> • Discontinue donation • Recline chair • Loosen clothes • Monitor blood pressure and pulse • Reassure donor • Give fluids to the donor to drink (recovery is usually rapid) <p><i>Severe vasovagal reaction</i></p> <ul style="list-style-type: none"> • Call physician • If the donor becomes unconscious, put the person in recovery position (i.e. head to the side and chin up) and ensure that airways are clear • Occasionally, severe faint with delayed recovery, or epileptiform episode with or without incontinence, might occur; this is usually an anoxic fit rather than epilepsy • In the case of an epileptiform fit, generally, do not report to donor because it may cause unnecessary anxiety • If incontinence occurs, then inform the donor and deal with privately <p><i>Faints</i></p> <ul style="list-style-type: none"> • These are usually self limiting and do not require investigation because they have no underlying pathology 	<p><i>Care of the donor</i></p> <p>The physician will:</p> <ul style="list-style-type: none"> • explain to the donor the nature of what has happened • reassure the person that this is only related to the donation process <p><i>Future donations</i></p> <ul style="list-style-type: none"> • Severe faints – person should not donate again • Mild faints – person may donate, but defer if develops another fainting attack



Table 4.1 *continued*

Adverse event	Incidence	Cause	Management	Remarks
Delayed faint (syncope)	1 in 10,000 donors	<ul style="list-style-type: none"> Physical stress Inadequate fluid intake Cause unknown <p>Occurs 1–4 hours after donation, usually outside the blood bank</p>	Hot drinks or water before donating blood; sitting in a supine position, audio or visual distraction; and minimal pain and stress during blood donation	<p>Try to find cause</p> <p><i>Future donations</i></p> <p>May donate, but if develops a second time, then defer</p>
Arterial puncture	1 in 30,000–50,000	<ul style="list-style-type: none"> Brachial artery sometimes lies anatomically very close to the vein Detected by observing that the blood collected is bright red and has a rapid flow May result in late complications such as arteriovenous fistulae 	<ul style="list-style-type: none"> Discontinue donation or continue if identified towards the completion of the donation Call the donor care physician Apply firm pressure (by the nurse or medical staff), for at least 15 minutes Apply pressure bandage and check the radial pulse Inform and reassure donor, and explain that the puncture is unlikely to have serious consequences, but that bad bruising may occur, and healing takes about 10–14 days 	Give relevant contact information to donor in case the person has any further inquiries
Nerve damage		<ul style="list-style-type: none"> Nerve endings brushed during venepuncture Pressure from haematoma <p><i>Symptoms and signs</i></p> <ul style="list-style-type: none"> Pain or parasthesia Motor or sensory loss 	<ul style="list-style-type: none"> Recovery is usually spontaneous and rapid within 24 hours (in rare cases, up to 6 months) Refer the donor to the physician to explain and reassure the donor, and refer the donor to a neurologist if the damage is severe 	Give relevant contact information to donor in case the donor has any further inquiries

Sources: (8–10, 54).



5 Arterial blood sampling

The information given here supplements that given in Chapters 2 and 3. Users of these guidelines should read Chapters 2 and 3 before reading the information given below. This chapter covers background information (Section 5.1), practical guidance (Section 5.2) and illustrations (Section 5.3) relevant to arterial blood sampling.

5.1 Background information on arterial blood sampling

An arterial blood sample is collected from an artery, primarily to determine arterial blood gases. Arterial blood sampling should only be performed by health workers for whom the procedure is in the legal scope of practice for their position in their country and who have demonstrated proficiency after formal training.

The sample can be obtained either through a catheter placed in an artery, or by using a needle and syringe to puncture an artery. These syringes are pre-heparinized and handled to minimize air exposure that will alter the blood gas values. This chapter describes only the procedure for a radial artery blood draw.

5.1.1 Choice of site

Several different arteries can be used for blood collection. The first choice is the radial artery, which is located on the thumb side of the wrist; because of its small size, use of this artery requires extensive skill in arterial blood sampling. Alternative sites for access are brachial or femoral arteries, but these have several disadvantages in that they:

- may be harder to locate, because they are less superficial than the radial artery;
- have poor collateral circulation;
- are surrounded by structures that could be damaged by faulty technique.

5.1.2 Complications related to arterial blood sampling

There are several potential complications related to arterial blood sampling. The points below list some of the complications related to the procedure, and how they can be prevented (59).

- *Arteriospasm* or involuntary contraction of the artery may be prevented simply by helping the patient relax; this can be achieved, for example, by explaining the procedure and positioning the person comfortably.
- *Haematoma* or excessive bleeding can be prevented by inserting the needle without puncturing the far side of the vessel and by applying pressure immediately after blood is drawn. Due to the higher pressure present in arteries, pressure should be applied for a longer time than when sampling from a vein, and should be supervised more closely, to check for cessation of bleeding.
- *Nerve damage* can be prevented by choosing an appropriate sampling site and avoiding redirection of the needle.
- *Fainting* or a *vasovagal response* can be prevented by ensuring that the patient is supine (lying down on their back) with feet elevated before beginning the blood draw. Patients requiring arterial blood sampling are usually inpatients or in the emergency ward, so will generally already be lying in a hospital bed. Children may feel a loss of control and fight more if placed in a supine position; in such cases, it may be preferable to have the child sitting on the parent's lap, so that the parent can gently restrain the child.
- *Other problems* can include a drop in blood pressure, complaints of feeling faint, sweating or pallor that may precede a loss of consciousness.



5.1.3 Sampling errors

Inappropriate collection and handling of arterial blood specimens can produce incorrect results. Reasons for an inaccurate blood result include:

- presence of air in the sample;
- collection of venous rather than arterial blood;
- an improper quantity of heparin in the syringe, or improper mixing after blood is drawn;
- a delay in specimen transportation.

5.2 Practical guidance on arterial blood sampling

5.2.1 Equipment and supplies

Assemble the relevant items described in Section 2.2.3, plus the following specimen collection equipment and supplies:

- pre-heparinized syringe;
- needles (20, 23 and 25 gauge, of different lengths) – choose a size that is appropriate for the site (smaller gauges are more likely to lyse the specimen);
- a safety syringe with a needle cover that allows the syringe to be capped before transport, without manually recapping (this is best practice for radial blood sampling);
- a bandage to cover the puncture site after collection;
- a container with crushed ice for transportation of the sample to the laboratory (if the analysis is not done at the point of care);
- where applicable, local anesthetic and an additional single-use sterile syringe and needle.

5.2.2 Procedure for arterial blood sampling using radial artery

For sampling from the radial artery using a needle and syringe, follow the steps outlined below.

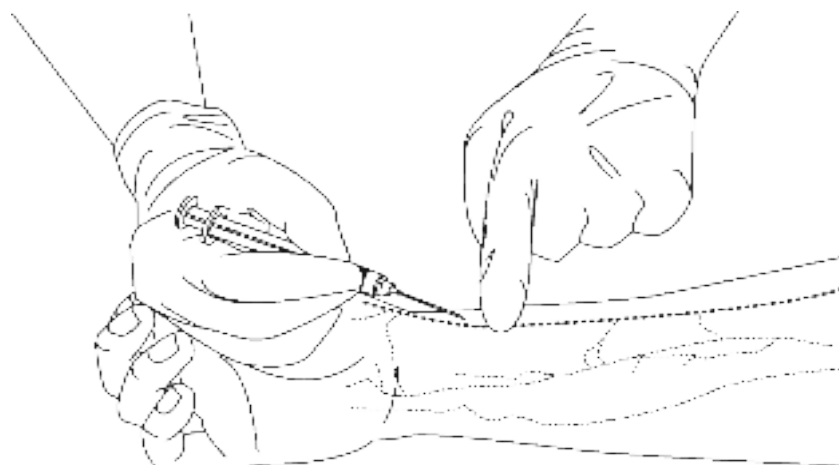
1. Approach the patient, introduce yourself and ask the patient to state their full name.
2. Place the patient on their back, lying flat. Ask the nurse for assistance if the patient's position needs to be altered to make them more comfortable. If the patient is clenching their fist, holding their breath or crying, this can change breathing and thus alter the test result.
3. Locate the radial artery by performing an Allen test (see Annex I) for collateral circulation. If the initial test fails to locate the radial artery, repeat the test on the other hand. Once a site is identified, note anatomic landmarks to be able to find the site again. If it will be necessary to palpate the site again, put on sterile gloves.
4. Perform hand hygiene, clear off a bedside work area and prepare supplies. Put on an impervious gown or apron, and face protection, if exposure to blood is anticipated.
5. Disinfect the sampling site on the patient with 70% alcohol and allow it to dry.
6. If the needle and syringe are not preassembled, assemble the needle and heparinized syringe and pull the syringe plunger to the required fill level recommended by the local laboratory.
7. Holding the syringe and needle like a dart, use the index finger to locate the pulse again, inform the patient that the skin is about to be pierced then insert the needle at a 45 degree angle, approximately 1 cm distal to (i.e. away from) the index finger, to avoid contaminating the area where the needle enters the skin.



8. Advance the needle into the radial artery until a blood flashback appears, then allow the syringe to fill to the appropriate level. **DO NOT** pull back the syringe plunger.
9. Withdraw the needle and syringe; place a clean, dry piece of gauze or cotton wool over the site and have the patient or an assistant apply firm pressure for sufficient time to stop the bleeding. Check whether bleeding has stopped after 2–3 minutes. Five minutes or more may be needed for patients who have high blood pressure or a bleeding disorder, or are taking anticoagulants.
10. Activate the mechanisms of a safety needle to cover the needle before placing it in the ice cup. In the absence of a safety-engineered device, use a one-hand scoop technique (as explained in Annex G) to recap the needle after removal.
11. Expel air bubbles, cap the syringe and roll the specimen between the hands to gently mix it. Cap the syringe to prevent contact between the arterial blood sample and the air, and to prevent leaking during transport to the laboratory.
12. Label the sample syringe.
13. Dispose appropriately of all used material and personal protective equipment.
14. Remove gloves and wash hands thoroughly with soap and water, then dry using single-use towels; alternatively, use alcohol rub solution.
15. Check the patient site for bleeding (if necessary, apply additional pressure) and thank the patient.
16. Transport the sample immediately to the laboratory, following laboratory handling procedures.

5.3 Illustrations for arterial blood sampling

Figure 5.1 Arterial blood sampling



Locate artery and take a sample



6 Paediatric and neonatal blood sampling

The information given here supplements that given in Chapters 2 and 3. Users of these guidelines should read Chapters 2 and 3 before reading the information given below. This chapter covers background information (Section 6.1), practical guidance (Section 6.2) and illustrations (Section 6.3) relevant to paediatric and neonatal blood sampling.

6.1 Background information on paediatric and neonatal blood sampling

This chapter discusses aspects specific to paediatric and neonatal blood sampling (60, 61). Anyone taking blood from children and neonates must be well trained and practiced in venepuncture techniques. A uniform sampling technique is important to reduce pain and psychological trauma.

6.1.1 Choice of procedure and site

The choice of site and procedure (venous site, finger-prick or heel-prick – also referred to as “capillary sampling” or “skin puncture”) will depend on the volume of blood needed for the procedure and the type of laboratory test to be done. Venepuncture is the method of choice for blood sampling in term neonates (62, 63); however, it requires an experienced and trained phlebotomist. If a trained phlebotomist is not available, the physician may need to draw the specimen. Section 7.1 provides information on when a capillary blood specimen from a finger-prick or a heel-prick is appropriate. The blood from a capillary specimen is similar to an arterial specimen in oxygen content, and is suitable for only a limited number of tests because of its higher likelihood of contamination with skin flora and smaller total volume.

Finger and heel-prick

Whether to select a finger-prick or a heel-prick will depend on the age and weight of the child. Section 7.1 explains which procedure to select, based on these two elements.

Patient immobilization is crucial to the safety of the paediatric and neonatal patient undergoing phlebotomy, and to the success of the procedure. A helper is essential for properly immobilizing the patient for venepuncture or finger-prick, as described in Section 6.2.

6.2 Practical guidance on paediatric and neonatal blood sampling

6.2.1 Patient identification

For paediatric and neonatal patients, use the methods described below to ensure that patients are correctly identified before taking blood.

- Use a wrist or foot band only if it is attached to the patient; DO NOT use the bed number or a wrist band that is attached to the bed or cot.
- If a parent or legal guardian is present, ask that person for the child’s first and last names.
- Check that the name, date of birth and hospital or file number are written on the laboratory form, and match them to the identity of the patient.



6.2.2 Venepuncture

Venepuncture is the preferred method of blood sampling for term neonates, and causes less pain than heel-pricks (64).

Equipment and supplies for paediatric patients.

- Use a winged steel needle, preferably 23 or 23 gauge, with an extension tube (a butterfly):
 - avoid gauges of 25 or more because these may be associated with an increased risk of haemolysis;
 - use a butterfly with either a syringe or an evacuated tube with an adaptor; a butterfly can provide easier access and movement, but movement of the attached syringe may make it difficult to draw blood.
- Use a syringe with a barrel volume of 1–5 ml, depending on collection needs; the vacuum produced by drawing using a larger syringe will often collapse the vein.
- When using an evacuated tube, choose one that collects a small volume (1 ml or 5 ml) and has a low vacuum; this helps to avoid collapse of the vein and may decrease haemolysis.
- Where possible, use safety equipment with needle covers or features that minimize blood exposure. Auto-disable (AD) syringes are designed for injection, and are not appropriate for phlebotomy.

Preparation

Ask whether the parent would like to help by holding the child. If the parent wishes to help, provide full instructions on how and where to hold the child; if the parent prefers not to help, ask for assistance from another phlebotomist.

Immobilize the child as described below.

- Designate one phlebotomist as the technician, and another phlebotomist or a parent to immobilize the child.
- Ask the two adults to stand on opposite sides of an examination table.
- Ask the immobilizer to:
 - stretch an arm across the table and place the child on its back, with its head on top of the outstretched arm;
 - pull the child close, as if the person were cradling the child;
 - grasp the child's elbow in the outstretched hand;
 - use their other arm to reach across the child and grasp its wrist in a palm-up position (reaching across the child anchors the child's shoulder, and thus prevents twisting or rocking movements; also, a firm grasp on the wrist effectively provides the phlebotomist with a "tourniquet").

If necessary, take the following steps to improve the ease of venepuncture.

- Ask the parent to rhythmically tighten and release the child's wrist, to ensure that there is an adequate flow of blood.
- Keep the child warm, which may increase the rate of blood flow by as much as sevenfold (65), by removing as few of the child's clothes as possible and, in the case of an infant, by:
 - swaddling in a blanket; and
 - having the parent or caregiver hold the infant, leaving only the extremity of the site of venepuncture exposed.
- Warm the area of puncture with warm cloths to help dilate the blood vessels.
- Use a transilluminator or pocket pen light to display the dorsal hand veins and the veins of the antecubital fossa.



Drawing blood

- Follow the procedures given in Section 2.2.3 for:
 - hand hygiene;
 - advance preparation;
 - patient identification and positioning;
 - skin antiseptics (but DO NOT use chlorhexidine on children under 2 months of age).
- Once the infant or child is immobilized, puncture the skin 3–5 mm distal to (i.e. away from) the vein (66); this allows good access without pushing the vein away.
- If the needle enters alongside the vein rather than into it, withdraw the needle slightly without removing it completely, and angle it into the vessel.
- Draw blood slowly and steadily.

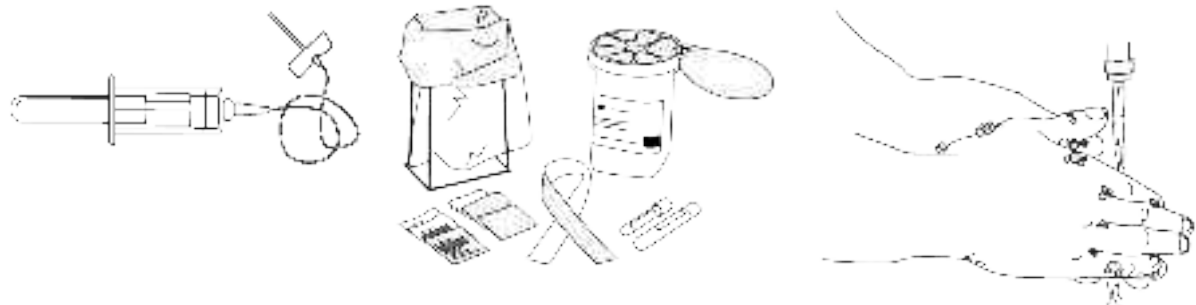
6.2.3 Finger and heel-prick

See Section 7.2, which describes the steps for both finger and heel-pricks, for paediatric and neonatal patients, and for adults.

Select the proper lancet length for the area of puncture, as described in Section 7.2.

6.3 Illustrations for paediatric and neonatal blood sampling

Figure 6.1 Paediatric and neonatal venepuncture



1. Use a winged steel needle, usually 23 or 25 gauge, with an extension tube (butterfly). Keep the tube and needle separate until the needle is in the vein.
2. Collect supplies and equipment.
3. Perform hand hygiene (if using soap and water, dry hands with single-use towels).





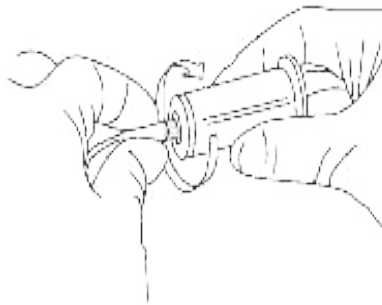
4. Immobilize the baby or child.



5. Put the tourniquet on the patient about two finger widths above the venepuncture site.



6. Put on well-fitting, non-sterile gloves.



7. Attach the end of the winged infusion set to the end of the vacuum tube and insert the collection tube into the holder until the tube reaches the needle.



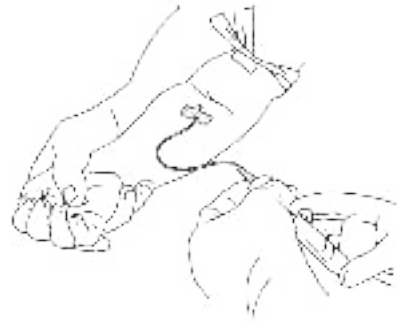
8. Remove the plastic sleeve from the end of the butterfly.



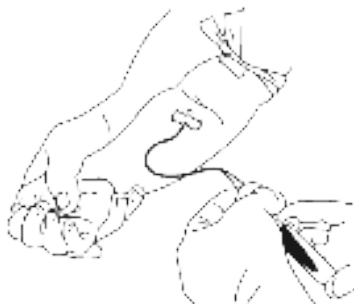
9. Disinfect the collection site and allow to dry.



10. Use a thumb to draw the skin tight, about two finger widths below the venepuncture site.



11. Push the vacuum tube completely onto the needle.



12. Blood should begin to flow into the tube.

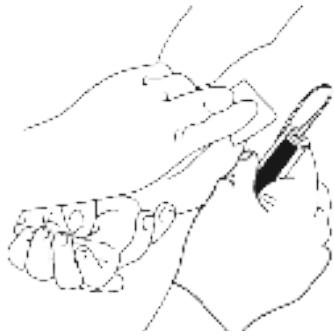


13. Fill the tube until it is full or until the vacuum is exhausted; if filling multiple tubes, carefully remove the full tube and replace with another tube, taking care not to move the needle in the vein.



14. After the required amount of blood has been collected, release the tourniquet.

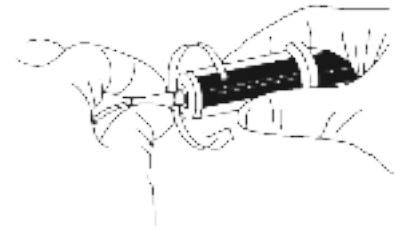




15. Place dry gauze over the venepuncture site and slowly withdraw the needle.



16. Ask the parent to continue applying mild pressure.



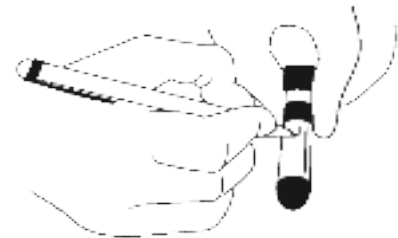
17. Remove the butterfly from the vacuum tube holder.



18. Dispose of the butterfly in a sharps container.



19. Properly dispose of all contaminated supplies.



20. Label the tube with the patient identification number and date.



21. Put an adhesive bandage on the patient if necessary.



22. Remove gloves, dispose of them appropriately and perform hand hygiene (if using soap and water, dry hands with single-use towels).



7 Capillary sampling

The information given here supplements that given in Chapter 2. Users of these guidelines should read Chapter 2 before reading the information given below. This chapter covers background information (Section 7.1), practical guidance (Section 7.2) and illustrations (Section 7.3) relevant to capillary sampling.

Capillary sampling from a finger, heel or (rarely) an ear lobe may be performed on patients of any age, for specific tests that require small quantities of blood. However, because the procedure is commonly used in paediatric patients, Sections 7.1.1 and 7.1.2 focus particularly on paediatric capillary sampling.

7.1 Background information on capillary sampling

7.1.1 Choice of site

Adult patients

The finger is usually the preferred site for capillary testing in an adult patient. The sides of the heel are only used in paediatric and neonatal patients. Ear lobes are sometimes used in mass screening or research studies.

Paediatric and neonatal patients

Selection of a site for capillary sampling in a paediatric patient is usually based on the age and weight of the patient. If the child is walking, the child's feet may have calluses that hinder adequate blood flow. Table 7.1 shows the conditions influencing the choice of heel or finger-prick.

Table 7.1 Conditions influencing the choice of heel or finger-prick

Condition	Heel-prick	Finger-prick
Age	Birth to about 6 months	Over 6 months
Weight	From 3–10 kg, approximately	Greater than 10 kg
Placement of lancet	On the medial or lateral plantar surface	On the side of the ball of the finger perpendicular to the lines of the fingerprint
Recommended finger	Not applicable	Second and third finger (i.e. middle and ring finger); avoid the thumb and index finger because of calluses, and avoid the little finger because the tissue is thin

Specimens requiring a skin puncture are best obtained after ensuring that a baby is warm, as discussed in Section 6.2.2.



7.1.2 Selecting the length of lancet

Adult patients

A lancet slightly shorter than the estimated depth needed should be used because the pressure compresses the skin; thus, the puncture depth will be slightly deeper than the lancet length. In one study of 52 subjects, pain increased with penetration depth, and thicker lancets were slightly more painful than thin ones (67). However, blood volumes increased with the lancet penetration and depth.

Lengths vary by manufacturer (from 0.85 mm for neonates up to 2.2 mm). In a finger-prick, the depth should not go beyond 2.4 mm, so a 2.2 mm lancet is the longest length typically used.

Paediatric and neonatal patients

In heel-pricks, the depth should not go beyond 2.4 mm. For premature neonates, a 0.85 mm lancet is available.

The distance for a 7 pound (3 kg) baby from outer skin surface to bone is:

- medial and lateral heel – 3.32 mm;
- posterior heel – 2.33 mm (this site should be avoided, to reduce the risk of hitting bone);
- toe – 2.19 mm.

The recommended depth for a finger-prick is:

- for a child over 6 months and below 8 years – 1.5 mm;
- for a child over 8 years – 2.4 mm.

Too much compression should be avoided, because this may cause a deeper puncture than is needed to get good flow.

7.1.3 Order of draw

With skin punctures, the haematology specimen is collected first, followed by the chemistry and blood bank specimens. This order of drawing is essential to minimize the effects of platelet clumping. The order used for skin punctures is the reverse of that used for venepuncture collection. If more than two specimens are needed, venepuncture may provide more accurate laboratory results.

7.1.4 Complications

Complications that can arise in capillary sampling include:

- collapse of veins if the tibial artery is lacerated from puncturing the medial aspect of the heel;
- osteomyelitis of the heel bone (calcaneus) (68);
- nerve damage if the fingers of neonates are punctured (69);
- haematoma and loss of access to the venous branch used;
- scarring;
- localized or generalized necrosis (a long-term effect);
- skin breakdown from repeated use of adhesive strips (particularly in very young or very elderly patients) – this can be avoided if sufficient pressure is applied and the puncture site is observed after the procedure.



7.2 Practical guidance on capillary sampling

7.2.1 Selection of site and lancet

- Using the guidance given in Section 7.1, decide whether to use a finger or heel-prick, and decide on an appropriate size of lancet.
- DO NOT use a surgical blade to perform a skin puncture.
- DO NOT puncture the skin more than once with the same lancet, or use a single puncture site more than once, because this can lead to bacterial contamination and infection.

7.2.2 Procedure for capillary sampling

Adult patients

Prepare the skin

- Apply alcohol to the entry site and allow to air dry (see Section 2.2.3).
- Puncture the skin with one quick, continuous and deliberate stroke, to achieve a good flow of blood and to prevent the need to repeat the puncture.
- Wipe away the first drop of blood because it may be contaminated with tissue fluid or debris (sloughing skin).
- Avoid squeezing the finger or heel too tightly because this dilutes the specimen with tissue fluid (plasma) and increases the probability of haemolysis (60).
- When the blood collection procedure is complete, apply firm pressure to the site to stop the bleeding.

Take laboratory samples in the correct order to minimize erroneous test results

- With skin punctures, collect the specimens in the order below, starting with haematology specimens:
 - haematology specimens;
 - chemistry specimens;
 - blood bank specimens.

Paediatric and neonatal patients

Immobilize the child

- First immobilize the child by asking the parent to:
 - sit on the phlebotomy chair with the child on the parent's lap;
 - immobilize the child's lower extremities by positioning their legs around the child's in a cross-leg pattern;
 - extend an arm across the child's chest, and secure the child's free arm by firmly tucking it under their own;
 - grasp the child's elbow (i.e. the skin puncture arm), and hold it securely;
 - use his or her other arm to firmly grasp the child's wrist, holding it palm down.

Prepare the skin

- Prepare the skin as described above for adult patients.
- DO NOT use povidone iodine for a capillary skin puncture in paediatric and neonatal patients; instead, use alcohol, as stated in the instructions for adults.



Puncture the skin

- Puncture the skin as described above for adult patients.
- If necessary, take the following steps to improve the ease of obtaining blood by finger-prick in paediatric and neonatal patients:
 - ask the parent to rhythmically tighten and release the child's wrist, to ensure that there is sufficient flow of blood;
 - keep the child warm by removing as few clothes as possible, swaddling an infant in a blanket, and having a mother or caregiver hold an infant, leaving only the extremity of the site of capillary sampling exposed.
- Avoid excessive massaging or squeezing of fingers because this will cause haemolysis and impede blood flow (60).

Take laboratory samples in the order that prevent cross-contamination of sample tube additives

- As described above for adult patients, collect the capillary haematology specimen first, followed by the chemistry and blood bank specimens.
- Clean up blood spills.
- Collect all equipment used in the procedure, being careful to remove all items from the patient's bed or cot; to avoid accidents, DO NOT leave anything behind.

Give follow-up care

There are two separate steps to patient follow-up care – data entry (i.e. completion of requisitions), and provision of comfort and reassurance.

Data entry or completion of requisitions

- Record relevant information about the blood collection on the requisition and specimen label; such information may include:
 - date of collection;
 - patient name;
 - patient identity number;
 - unit location (nursery or hospital room number);
 - test or tests requested;
 - amount of blood collected (number of tubes);
 - method of collection (venepuncture or skin puncture);
 - phlebotomist's initials.

Comfort and reassurance

Show the child that you care either verbally or physically. A simple gesture is all it takes to leave the child on a positive note; for example, give verbal praise, a handshake, a fun sticker or a simple pat on the back.

A small amount of sucrose (0.012–0.12 g) is safe and effective as an analgesic for newborns undergoing venepuncture or capillary heel-pricks (70).

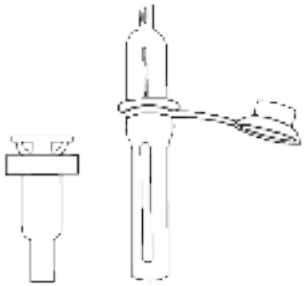
Unsuccessful attempts in paediatric patients

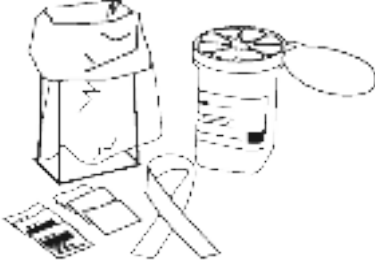
Adhere strictly to a limit on the number of times a paediatric patient may be stuck. If no satisfactory sample has been collected after two attempts, seek a second opinion to decide whether to make a further attempt, or cancel the tests.




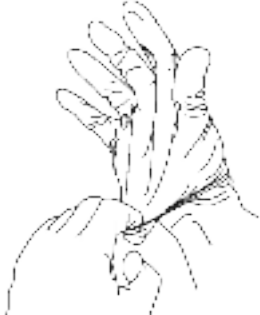
7.3 Illustrations for capillary sampling


Figure 7.1 Capillary sampling

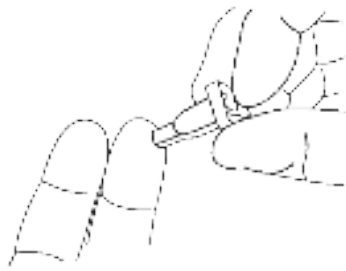
- 


1. Lancet and collection tube.
- 

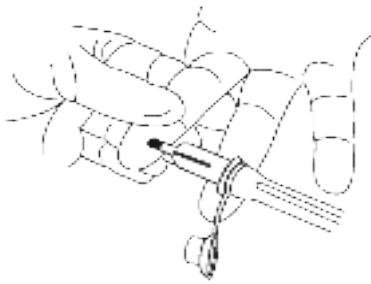
2. Assemble equipment and supplies.
- 

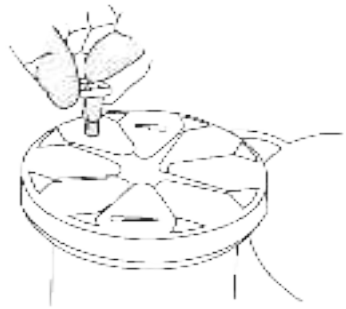
3. Perform hand hygiene (if using soap and water, dry hands with single-use towels).
- 


4. Put on well-fitting, non-sterile gloves.
- 


5. Select the site. Apply 70% isopropyl alcohol and allow to air dry.
- 

6. Puncture the skin.
- 

7. Wipe away the first drop of blood.
- 

8. Avoid squeezing the finger too tightly.
- 

9. Dispose of all sharps appropriately.
- 

10. Dispose of waste materials appropriately.
- 

11. Remove gloves and place in general waste. Perform hand hygiene (if using soap and water, dry hands with single-use towels).



**PART III IMPLEMENTATION,
EVALUATION AND
MONITORING**

8 Implementing best phlebotomy practices

8.1 Setting policies and standard operating procedures

As explained in Chapter 1, these best practice guidelines for phlebotomy extend the scope of the two WHO/SIGN documents on related topics that are currently available (29, 30). At the heart of the document are three principles.

- Standards of safe practice globally should be governed by evidence-based principles.
- Each phlebotomy service should, within its capacity, ultimately strive to achieve best practices.
- Health workers should be protected and allowed to work in a safe environment, armed with knowledge that reduces harm to themselves, patients and the community.

This chapter provides recommendations (in boxes) and gives further information for each recommendation (text below the boxes).

8.2 Procurement

Recommendation on procurement (in conjunction with the WHO guiding principle for injection device security (71))

Procurement agencies must ensure that all health-care facilities have sufficient supplies of phlebotomy and personal protective equipment. Such equipment must meet at least the minimum standards of sterility, quality and safety to prevent complications related to unsafe practices.

To prevent the complications related to unsafe practices discussed in Parts I and II of this document, equipment (including materials for hand hygiene) and personal protective clothing must be routinely available in sufficient quantities. Items needed include:

- personal protective equipment;
- safe blood-sampling equipment of high quality, based on a cost–effectiveness analysis of the country’s needs and finances;
- antiseptics.

All items to be used on more than one patient should be designed so that they can be cleaned and disinfected. Such items include laboratory transport boxes or trays, tourniquets, evacuated tube holders, scissors and so on. Also, it is best to buy high-quality items even if they are more expensive. Trying to save money by purchasing cheap items that are of poor quality can be more costly in the long run; for example, if items have to be replaced more frequently.

Governments and procurement agencies should work to ensure that appropriate products are available in the country, by:

- providing detailed technical specifications to companies wishing to enter the market – such specifications should include detailed minimum standards acceptable for safety, quality and usability;
- working with manufactures to communicate defined needs to improve products;
- working with national or international regulatory authorities to test products before importation, to ensure they meet their stated claims and are more effective than cheaper products available on the market;



- working together to ensure fair, transparent competition and input of end users during product selection;
- conducting post-marketing surveillance to track defects and adverse events associated with products.

Facilities that cannot afford the supplies needed to minimize risk to staff and patients, or supplies of the quality necessary for valid and reliable laboratory test results, should reassess whether they should offer phlebotomy or the related laboratory services.

8.2.1 Blood-sampling equipment

Recommendation on blood-sampling equipment (Annex C)

Safety-engineered evacuated tube systems or winged needle sets are safer than a hypodermic needle and syringe, but all are effective for blood sampling. Safety features (e.g. needle covers, needleless transfer systems or adaptors, and retractable lancets) can further reduce the risks associated with manual recapping, needle removal, disassembly and transfer of blood from syringes to tubes.

- A needle and syringe is the most common tool for withdrawing large quantities of blood.
- A sterile single-use needle and syringe should be used for each patient, and should be placed, as a single unit, into a sharps container immediately after use.
- Safety-engineered equipment offers better protection to the health worker, but should be appropriate for the specific task. Some devices designed to prevent reuse (e.g. auto-disable syringes) are not appropriate for phlebotomy. Safety devices are more expensive, so if resources are limited, their use may need to be restricted to procedures associated with the greatest rates or risk of sharps injury.
- Capillary punctures should be performed using a sterile device – preferably with safety features that automatically retract the lancet – to help prevent both reuse and sharps injuries.

8.2.2 Protection

Recommendation on personal protection

Health workers should wear well-fitting, non-sterile gloves when taking blood; they should also carry out hand hygiene before and after each patient procedure, before putting on and after removing gloves.

Clean, non-sterile examination gloves in multiple sizes should be available for personnel who carry out phlebotomy. It is recommended that:

- well-fitting gloves are worn for each procedure, irrespective of the site of blood sampling or the status of the patient; these gloves can be latex or latex-free, and should be non-sterile (i.e. examination gloves);
- the gloves are changed between patients;
- masks, visors and eye protection may also be needed if additional blood exposure is anticipated; for example, during arterial blood sampling.



8.3 Phlebotomy training

Recommendation on phlebotomy training (Annex E)

All health workers undertaking phlebotomy must be trained in infection prevention and control procedures. Staff should receive training and demonstrate proficiency on the specific methods that they will use on the job; for example, adult and paediatric sampling; and venous, arterial and capillary blood sampling.

- Regular in-service training and supportive supervision should be provided.
- The training programme should provide theoretical and practical knowledge in blood sampling and blood drawing (31).
- A certificate of competence should be issued upon successful demonstration of phlebotomy after completion of the training programme.

8.4 Safe waste and sharps disposal

Recommendation on safe disposal of sharps (72)

The blood-sampling device – a needle and syringe, evacuated needle and tube holder, or winged butterfly – should be disposed of immediately after use as a single unit. It should be placed in a puncture-proof, leak-proof, closable sharps container that is clearly visible and is placed within arm's reach of the health worker.

- The safe disposal of sharps is one of the major challenges, particularly in poorly resourced countries.
- Shortage of sharps containers can result in increases in needle-stick injuries due to:
 - needle recapping;
 - decanting of used sharps containers;
 - recycling of containers;
 - overfilling of sharps containers.
- Another issue is that staff may separate a needle and syringe as a cost-saving exercise and discard the two parts in different waste systems.
- The immediate discard of used sharps into a puncture-resistant sharps container that can be closed is an essential part of managing waste without needle-stick injuries (73).



8.5 Prevention and management of incidents and adverse events

Recommendation on infection control (Annex B)

Infection control procedures that help to prevent health-care associated infections include:

- hand hygiene;
- glove use;
- skin antiseptics;
- sterile, single-use blood-sampling devices;
- sharps containers;
- disinfection of surfaces and chairs;
- cleaning and disinfection of tourniquets;
- transportation of laboratory samples in labelled, washable containers.

Annex B summarizes the recommendations for best infection control practices in phlebotomy. The points listed below contribute to infection control.

- The workplace should be clean, tidy and uncluttered. There should be no sign of blood contamination on the chairs, counters or walls. The working surface should be visibly clean.
- Hand hygiene (hand washing or use of an alcohol rub) should be carried out before well-fitting, non-sterile gloves are put on and after they are removed (45).
- Only sterile, single-use blood-sampling devices should be used to take blood.
- Skin at the venepuncture site should be disinfected, taking into consideration the type of specimen, the age and the allergy history of the patient (40–42).
- Once the procedure has been completed and the blood sample or samples have been put into the laboratory sampling tubes, the used devices should be discarded immediately into a sharps container.
- Specimens should be transported in containers that help to prevent breakage or spillage of blood.

8.5.1 Patient related

Recommendation on increasing patient confidence (Annex F)

Health-care facilities should provide a patient information leaflet or poster explaining the procedure in simple terms, to increase patient confidence.

- Patient information (leaflets or posters) is recommended. In a busy clinic, there may not be time to explain the procedure to the patient, or the reason for the blood sample being taken.
- Information should be provided to a fully conscious patient in such a way that the person can make an informed decision. Being well informed also helps the patient to relax and may reduce discomfort during the procedure.
- If the patient is mentally incapacitated (e.g. through mental illness, organic impairment, or traumatic or drug-associated loss of consciousness), essential blood sampling may be carried out without permission, in accordance with the institutional or national policy. However, the status of the patient should be clearly documented in the patient's clinical notes.



- If the patient is unconscious or unable to give informed consent, the next of kin or legal guardian (which can be a court of law) can give permission for a blood sample to be taken.
- When carrying out blood sampling on a minor, verbal or written permission from the parent or legal guardian, or a court of law may be necessary for medicolegal reasons.

8.5.2 Health-worker related

Recommendation on health worker and patient safety policies

A post-exposure prophylaxis protocol must be available in all health-care facilities and phlebotomy areas, providing clear instructions to follow in case of accidental exposure to blood or body fluids.

- Should an exposure occur, health workers should be aware of the policy on PEP. Ideally, this policy should offer support for exposure to HIV, HBV and HCV (27).
- Worksites should have clear notices giving the point of contact (both during the day and at night) where staff may receive assistance, support and care, including PEP and the benefits of prompt reporting for preventing infection. This applies to potentially exposed patients as well.
- Occupational injuries should be reported in a system that allows medical management and tracking of exposed individuals, but also allows anonymous analysis of incidents, to identify factors that can be modified to prevent accidents. Some facilities supplement requests for medical management with periodic anonymous surveys to improve reporting of exposures and near misses.
- The benefits of PEP for HIV may be greatest if it is started as soon as possible; certainly, it should be started no later than 72 hours after exposure (27). Both the source patient and the exposed individual should undergo rapid testing to avoid unnecessary treatment. Based on the test result or if the risk assessment requires it, antiretroviral therapy prophylaxis should be proposed as soon as possible; ideally within the first hours, and certainly no later than 72 hours after the exposure.
- Hepatitis B immunization should be offered to all those working in health-care facilities, and especially to phlebotomists. One to two months after completing the three-dose series, the health worker should be tested to verify seroprotection (i.e. a concentration of antibodies to hepatitis B surface antigen of at least 10 milli-international units per millilitre [10 mIU/ml]). This is important because follow-up – including repeat serology testing after exposure to a patient positive for hepatitis B surface antigen – is unnecessary if the exposed person was known to have responded to the vaccine. Titres will decrease over time, even in those who are seroprotected, but the vaccinated person remains protected. In case of exposure, national guidelines on PEP for HBV exposure should be consulted. If none are available, detailed instructions on the use of hepatitis B immune serum globulin (HBIG) and immunization against HBV are available from WHO (27).
- A fourth dose of hepatitis B vaccine should be offered to those who have completed their immunization but were tested 1–2 months after completing the vaccination and had a hepatitis B surface antibody titre below 10 mIU/ml. If fewer than three doses of hepatitis B immunization have been given, a course of hepatitis B immunization should be provided or completed.
- There is no recommended PEP for exposure to HCV. If feasible, testing of the source patient and health worker may be helpful to ensure workers compensation in the case that occupationally acquired infection is demonstrated. Research on PEP for HCV is ongoing to determine whether a regimen involving peginterferon alfa-2b is effective. However, at least one recent trial failed because none of the 213 workers exposed to HCV developed infection, whether they received PEP or not (74).



8.5.3 Risk assessment and risk reduction strategies

There is a risk to both patients (or blood donors) and health workers if the phlebotomist is not well informed of the patient's risks. A short clinical history from the patient is essential.

Risk can be reduced by following best practices in infection prevention and control, after obtaining informed consent from the patient and blood donors (Table 8.1).

Table 8.1 Summary of risks and risk-reduction strategies

Risk	Type of risk	Risk reduction strategy
Patient/ blood donors	Exposure to bloodborne viruses through reuse of needles, syringes and lancets, contaminated work surfaces	<ul style="list-style-type: none"> • Hepatitis B vaccine for workers • Sterile single-use devices only • Safety-engineered devices • Clean work surfaces with disinfectant
	Infection at blood sampling site	<ul style="list-style-type: none"> • Perform hand hygiene • Clean patient's skin with 70% isopropyl alcohol and allow to dry • Use sterile needle and syringe removed from the packaging just before use
	Pain at blood sampling site	<ul style="list-style-type: none"> • Well-trained person should take the blood sample • Venepuncture is less painful than heel-pricks in neonates • Use needle of smaller gauge than the selected vein
	Haematoma or thrombus	<ul style="list-style-type: none"> • Enter vessel at an angle of 30 degrees or less • Use gauge of needle smaller than the vein • Apply pressure to a straight arm for 3–5 minutes after drawing blood
	Extensive bleeding	<ul style="list-style-type: none"> • Take a history to identify patients on anticoagulants and with a history of bleeding • Use a gauge of needle smaller than the vein
	Nerve damage (8, 10)	<ul style="list-style-type: none"> • Avoid finger-pricks for children • Use antecubital vessels when possible • Avoid probing
	Vasovagal reaction Syncope, fainting (8, 10)	<ul style="list-style-type: none"> • Hydrate patient, take postural blood pressure if dehydrated • Reduce anxiety • Have patient lie down if the person expresses concern • Provide audio-visual distraction
	Allergies	<ul style="list-style-type: none"> • Ask about allergies to latex, iodine and alcohol before starting the procedure
Health worker	Needle or sharps injury during or after the procedure Breakage of blood containers Splashes (rare)	<ul style="list-style-type: none"> • Use safety devices such as needle covers, tube holders that release needles with one hand and safety lancets • Avoid two-handed recapping and disassembly • Place sharps container in sight and within arm's reach • Dispose of used sharps immediately
	Exposure to blood	<ul style="list-style-type: none"> • Hepatitis B vaccination • Wear gloves • Use evacuated tubes and transfer devices when drawing multiple tubes • Follow protocol for exposure to body fluids and report incident, even if post-exposure prophylaxis is not desired • Cover broken skin area with a waterproof dressing



9 Monitoring and evaluation

A monitoring and evaluation system should be in place to offer surveillance of management of phlebotomy services and adverse events, and to document improvements. The indicators to use include:

- number and rate per 100 full-time workers of sharps exposures and other occupational injuries occurring among health workers in the past 12 months;
- number and rate of patients with adverse events in response to phlebotomy such as haematoma, syncope, infection or nerve damage;
- number of reported cases of bloodborne pathogens transmitted during phlebotomy (disease surveillance for hepatitis B and C, and HIV) as part of a public health surveillance system that is capable of receiving and responding to reports of cases and clusters of infections;
- number (and percentage) of phlebotomy sessions where essential equipment was not available and phlebotomy sessions were cancelled;
- number (and percentage) of laboratory test results lost due to errors or poor quality; for example
 - blood culture contamination rate;
 - blood transfusion adverse events;
 - haemolysis;
 - number of specimens with illegible or missing paperwork or labels;
 - number of specimens that could not be processed due to inadequate sample volumes;
- number (and percentage) of trained staff in the health-care facility working in phlebotomy;
- number (and proportion) of juniors who are supervised by trained staff.



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PART V ANNEXES

Annex A: Methods and evidence base

A1 Consultation with experts and scope of recommendations

In April 2008, the WHO Injection Safety programme – which is part of the Department of Essential Health Technologies (EHT) at WHO Headquarters in Geneva – convened a consultation on best practices for phlebotomy and blood collection. The consultation included special categories such as arterial blood sampling, capillary blood sampling and paediatric blood collection.

A working group was convened, comprising international experts and colleagues from WHO departments involved in infection control and safety of health-care practices.

The specific objectives of the consultation were to:

- review the first draft of this document, which had been developed in response to clinical questions and a suggested scope developed by SIGN in consultation with other WHO experts and the Centres for Disease Control and Prevention;
- identify critical steps in phlebotomy procedure as a basis for making recommendations.

The focus of the consultation was primarily on the needs of developing and transitional countries, in which injection safety programmes are not yet well developed or in which quality systems are lacking. The consultation identified the need for guidelines on best phlebotomy practices in policy and organizational issues, and in technical and scientific aspects of blood collection.

Recommendations of the working group

Content of guidelines

Guidelines should include information on the importance of:

- safe practices in phlebotomy;
- an uninterrupted supply of single-use devices in situations where safety-engineered devices are unaffordable;
- training in phlebotomy, to avoid adverse effects to the patient and the health worker, and blood samples of poor quality.

Evidence base

Recommendations should be evidence based.

Consistency and flexibility

Recommendations should be designed to:

- promote a consistent approach to ensuring phlebotomy safety and quality of blood drawn;
- be sufficiently flexible to allow for variations in device selection and training curricula.



A2 Evidence base

An initial literature search was conducted by the guideline writer – Professor Mehtar (chair of the working group) – using PubMed, MedLine, the WHO library database and regional databases. Particular efforts were made to identify systematic literature reviews and evidence that related specifically to phlebotomy practices in developing countries.

The panel reviewed the draft guidelines and the evidence retrieved, and reached consensus on all but one of the recommendations. It found that further evidence was needed to determine the effect of “alcohol alone” versus “any skin disinfectant followed by alcohol for skin preparation” before blood collection for the purpose of blood transfusion. The panel commissioned a systematic review with evidence tables based on GRADE¹ from the Cochrane group. The overall finding from the review, which is given in Annex J (1), was as follows:

In conclusion there is currently no evidence of a difference in either blood contamination or bacteraemia when donor skin is cleansed pre-venepuncture with a one-step alcohol based process or a two-step alcohol plus antiseptic process. This lack of evidence for a difference however results from a complete absence of research and therefore a real difference cannot be discounted. Until better evidence emerges, decisions about which mode of pre-blood donation skin cleansing to use are likely to be driven by convenience and cost.

This conclusion was circulated to the guideline development group, with a request for advice on the best recommendation to incorporate into the guideline. Additional infection control experts (see list of additional reviewers) were consulted by e-mail, in line with the WHO guideline development procedure which notes that, when evidence is lacking, a recommendation should be based on expert opinion as well as on convenience and cost. Consensus was reached by asking the experts to vote on the final recommendation.

The group was able to make a recommendation on best practice for skin disinfection in blood transfusion (see Section 4.2.1). Due to lack of evidence, the recommendation was based on expert opinion.

A3 Peer review and technical editing

Following the internal and external review and revision, an advanced draft of the document was sent to Dr Mary Catlin and Dr Michael Borg for a thorough peer review. The guideline was then submitted to the guideline development group and to additional experts who contributed to the development of the recommendation on skin disinfection before blood donation. The expert group amended the guidelines in light of the comments received and agreed.

The technical editing of this document was undertaken by Dr Hilary Cadman, under the technical guidance of Dr Selma Khamassi.

A4 Implementation and evaluation plans

The final phlebotomy guidelines will be translated into all United Nations languages, and printed for distribution in all six WHO Regional Offices and in many different countries. It will also be made available through the WHO Injection Safety Website. A CD-ROM containing the phlebotomy document, posters illustrating each of the practices described and a training package will be produced and translated. The document will also be adapted to local needs in some countries, although key steps and recommendations will be maintained.

1 The Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group is an informal collaboration that has developed a common, sensible and transparent approach to grading quality of evidence and strength of recommendations (<http://www.gradeworkinggroup.org>).



Upon request, the WHO Injection Safety programme will provide technical support for adapting and implementing the guideline at regional and country levels.

The feasibility of recommended practices and the impact of the guideline on phlebotomy practices will be evaluated by the WHO Injection Safety programme, in collaboration with WHO Regional Offices. Feasibility and impact will be evaluated using the revised injection safety assessment tool C, developed by the WHO Injection Safety programme (2).

A5 Review and updating of the recommendations

The recommendations in this document are expected to remain valid for five years; that is, until 2014. The WHO Injection Safety programme will initiate a review of these recommendations at that time.

A6 Monitoring and evaluation of the implementation

The indicators listed in Chapter 9 should be used to monitor and evaluate the implementation of these guidelines.



Annex B: Infection prevention and control, safety equipment and best practice

Table B.1 Recommendations for infection prevention and control, safety equipment and best practice

Item	Best practice	Rationale
Personal protection and hygiene		
Hand hygiene ^a	Before and after each patient contact, as well as between procedures on the same patient	Reduces risk of cross-contamination between patients
Gloves ^a	A pair of well-fitting, clean, disposable latex or latex-free gloves per patient or per procedure	Reduces the health-care worker's potential exposure to blood and reduces the patient's risk of cross-contamination between patients
Masks, visors or goggles	Not indicated	
Apron/gown or cover	Not indicated	
Safe blood-sampling equipment		
Tourniquet	Clean elastic tourniquet reprocessed between patients	Contamination with nosocomial bacteria has been documented on tourniquets
	DO NOT use latex gloves as a tourniquet if patients have an history of latex allergy	Some patients may have latex allergy
Sharps containers	Puncture and leak-proof containers, that are sealed after use Keep container visible and within arms' reach	Prevents needle-stick injury to patients, health workers and the community at large
Skin preparation	Inspect skin, clean if visibly dirty Apply 70% alcohol with single-use swab or clean cotton-wool ball	Prevents insertion-site infection and contamination of the blood collected Cotton wool that is pre-torn with bare hands is contaminated and bacteria can multiply over time Do not leave containers of cotton saturated alcohol and cotton; dampen cotton immediately before use without contaminating the primary container
	For blood donation, a one-step combination of 2% chlorhexidine gluconate in 70% isopropyl alcohol is recommended; allow to air dry	Reduces contamination of the blood collected
Blood sampling		
Drawing venous blood	Closed vacuum extraction tubes with single-use needle and needle holder	Reduces exposure to blood and likelihood of contamination If needleholders must be reused due to cost, they should be removed with one hand; some safety boxes have slots for this purpose
	Winged needles with needle cover Safety syringes with retractable needles	Safer for health workers and patients – reduces exposure to blood and sharps injuries



Table B.1 *continued*

Item	Best practice	Rationale
Blood sampling		
Small quantities of capillary blood	Single-use lancet Retractable lancet Lancet platform or glucometer is dedicated to one patient during hospital stay, or platform or device is cleaned of all visible dirt and disinfected with alcohol between uses	Hypodermic needles should be used with care as they may enter deeper than is desirable; they should never be used for heel-pricks Hepatitis infections have been transmitted to patients when lancet platforms or glucometers were used on several patients without reprocessing (i.e. without cleaning and disinfection)
Blood-sampling system	Blood-sampling tubes or containers (single use)	Vacuum-extraction sampling reduces exposure to blood
Blood-drawing system	Sterile blood collection bag (single or multiple bag systems) with integrated needle and needle protection Blood collected in these systems should be stored and transported according to blood-bank procedures and the product (i.e. warm or cold stored) 150–500 ml sterile bag or bags for blood (medical or blood donation)	Reduces bacterial contamination Protects the health worker and patient Platelets may be stored at room temperature Some sterile blood bags may have a diversion pouch to separate the first 10 ml or so of blood to reduce contamination
Transportation of laboratory samples	Closed system that keeps samples upright and snugly fitted in stackable trays or racks Clearly labelled blood sample containers (Some samples – such as cold agglutinins – may need to be transported in a warm transportation system)	Closed system keeps blood samples contained in case of breakage or spillage Clearly labelled sample containers with tracking system allows samples to be traced
Request forms	A legible completed form must accompany blood sample to laboratory Form is stored with samples but in a separate compartment of the laboratory transport system	Provides accurate information on tests required and patient identification Some facilities use a plastic bag with an outer pouch that keeps the paper with the specimen but protects it from contamination
Specimen storage and blood sampling area	Storage in a cool, separate area; temperature regulated to around 25° C	Keeps samples secure and away from the general public
Patient information	Verbal explanation and consent (information leaflet)	Helps to ensure patient cooperation and respect of patient rights

^a Source for information on hand hygiene and gloves: (3, 4).



Annex C: Devices available for drawing blood

The information given in this appendix is based on advice from the Centers for Disease Control and Prevention (5).

Table C.1 Devices for drawing blood

Type of device	Advantages	Disadvantages
Conventional devices		
Hypodermic single-use needle and syringe	<ul style="list-style-type: none"> Widely available Least expensive Comes in wide range of needle lengths and gauges Does not require special training Can be used for blood drawing in paediatric population For patient with small or difficult veins, blood drawing can be easier than an evacuated tube system If heparinized, can be used for arterial blood drawing 	<ul style="list-style-type: none"> Requires blood transfer, creating additional risk for needle-stick injuries or blood splashing Difficult to draw large or multiple blood samples A smaller syringe and paediatric laboratory tube should be used for paediatric patients
Vacuum-tube systems	<ul style="list-style-type: none"> Safer than using hypodermic needle and syringe Eliminates blood transfer Allows numerous blood samples to be collected through single venepuncture 	<ul style="list-style-type: none"> Requires user to be skilled in its use Reuse of needle holder (tube holder) creates risk for needle-stick injuries during disassembly Mixing components from different manufactures can create a problem during use A smaller tube with a reduced vacuum should be used for paediatric patients Higher cost
Winged steel needles (butterfly)	<ul style="list-style-type: none"> Good for blood drawing from paediatric population or patient with small or difficult veins Allows better precision than hypodermic needle or evacuated tube needle 	<ul style="list-style-type: none"> Because of the air in the tubing, first tube must be collected without additive or discarded Difference in winged steel needles for evacuated system tubes and winged infusion set can create confusion Higher cost
Safety-engineered devices		
<i>Passive</i>		
Auto-disable (AD) syringes NOT recommended for blood drawing	<ul style="list-style-type: none"> Not recommended for phlebotomy Designed to prevent reuse, does not reduce the risks of needle-sticks 	<ul style="list-style-type: none"> During probing, safety mechanism can be activated, requiring new venepuncture Requires blood transfer, creating risk of needle-stick injuries Difficult to draw large or multiple blood samples Does NOT offer needle-stick prevention Air in the syringe can affect test results Requires additional training
Lancets	Retractable; prevent needle-stick injuries	



Table C.1 *continued*

Type of device	Advantages	Disadvantages
Safety-engineered devices		
<i>Active</i>		
Manually retractable syringes	Safety mechanism retracts the needle into the syringe, reducing the hazard of needle-stick exposure and the possibility of reuse	Safety mechanism cannot be activated when syringe is full of blood and during blood transfer Requires health worker to use it as recommended Requires blood transfer, creating risk of needle-stick injuries Difficult to draw large or multiple blood samples High cost
Self re-sheathing needles and syringes	Sleeve forwarded over the needle provides guard around the used needle, reducing the risk of needle-stick injury; also prevents reuse	Needle cannot be covered when syringe is full of blood or during blood transfer Requires user's compliance Additional training High cost
Winged steel needles with passive or active safety mechanism	Needle-locking mechanism helps to reduce the risk of needle-stick injury and prevents reuse If syringe is used for blood drawing, allows for safer transfer of blood	If used in connection with vacuum tubes, because of the air in tubing, the first tube is either without additive or discarded Requires additional training High cost
Manually retractable evacuated tube systems	Safer than using hypodermic needle and syringe because does not require blood transfer Allows numerous blood samples to be collected through single venepuncture Safety mechanism prevents reuse and helps to reduce the risk of needle-stick injuries	Requires skill in its use Reuse of needle (or tube) holders creates risk of needle-stick injuries during disassembly Components from different manufacturers may be incompatible Smaller volume (1–5 ml) tube with lower vacuum should be used for paediatric patients to reduce haemolysis Requires additional training High cost



Annex D: Managing occupational exposure to hepatitis B, hepatitis C and HIV

Health workers may occasionally be accidentally exposed to blood and other body fluids that are potentially infected with HIV, hepatitis virus or other bloodborne pathogens. Occupational exposure may occur through direct contact from splashes into the eyes or mouth, or through injury with a used needle or sharp instrument. Post-exposure prophylaxis (PEP) can help to prevent the transmission of pathogens after a potential exposure (6).

This annex describes the steps in managing exposure to blood or other fluids that are potentially infected with hepatitis B virus (HBV); hepatitis C virus (HCV) or HIV.

Step 1 – Provide immediate first-aid care to the exposure site

Provide immediate first-aid care as follows.

- Wash wounds and skin with soap and water. Do not use alcohol or strong disinfectants.
- Let the wound bleed freely.
- Do not put on a dressing.
- Flush eyes, the nose, the mouth and mucous membranes with water for at least 10 minutes.

Step 2 – Determine the risk associated with the exposure

Determine the risk associated with the exposure by considering:

- the type of fluid; for example, blood, visibly bloody fluid, other potentially infectious fluid, or tissue and concentration of virus;
- the type of exposure; for example, there is a higher risk associated with percutaneous injury with a large, hollow-bore needle, a deep puncture, visible blood on the device, a needle used in an artery or vein, and exposure to a large volume of blood or semen, and less risk associated with exposure of mucous membranes or nonintact skin, or exposure to a small volume of blood, semen or a less infectious fluid (e.g. cerebrospinal fluid).

Step 3 – Evaluate the source of the potential exposure

To evaluate the source of the potential exposure:

- assess the risk of infection, using available information;
- test the source person whenever possible, and only with his or her informed consent; but
- do not test discarded needles or syringes for virus contamination.



Step 4 – Manage individuals exposed to HBV and HIV

There is no PEP regimen recommended for HCV; however, there are specific steps that can be taken to reduce the risk of infection for those exposed to HBV and HIV, as described below.

Post-exposure prophylaxis for HBV

A person's response to exposure to HBV depends on his or her immune status, as determined by the history of hepatitis B vaccination and vaccine response if tested 1–2 months after vaccination (see Table D.1), and whether the exposure poses a risk of infection. HBV PEP is safe for women who are pregnant or breastfeeding.

Table D.1 Recommendations for HBV post-exposure prophylaxis, according to immune status

HBV immune status	Post-exposure prophylaxis
Unvaccinated	HBV vaccination and HBIG
Previously vaccinated, known responder (anti-hepatitis B surface antigen positive)	None
Previously vaccinated, known nonresponder	HBV vaccination and HBIG
Antibody response unknown	Test; if antibody response is < 10 IU/ml, give HBV vaccination and HBIG

HBIG, hepatitis B immunoglobulin; HBV, hepatitis B virus.
Source: CDC (7).

Post-exposure prophylaxis for HIV

Check the current national guidelines. This section is based on the *WHO/ILO Guidelines on post exposure prophylaxis prophylaxis (PEP) to prevent human immunodeficiency virus (HIV) infection* (6). In addition to first-aid care and evaluation of exposure and risk, PEP for HIV includes counselling, HIV testing based on informed consent, and – depending on the risk assessment – the provision of a short course (28 days) of antiretroviral (ARV) drugs, with follow-up and support.

The recommendation for HIV PEP is based on an evaluation of the risk of infection described in step 2.

If the source person is identified, it is important to obtain information on that person's serostatus and, if positive, an evaluation of the clinical status and treatment history.

Testing and counselling

If testing is available, the exposed person should be offered the chance to be tested for HIV and receive appropriate counselling. The person should always have the choice to refuse testing. Perform HIV-antibody testing at baseline, and at 6–12 weeks and 6 months after exposure. If the person develops HIV antibodies, he or she should be referred for treatment, care and support.

Whenever possible, the source patient should also be tested, with his or her informed consent.

Antiretroviral drugs for post-exposure prophylaxis

ARV drugs should be started as soon as possible, and certainly within 72 hours of exposure. The drugs should be taken continuously for 28 days. Health workers should not wait for tests results before taking or administering PEP. If the test results show that the source person is negative, the prophylaxis can be stopped. Counselling should include provision of information on the importance of adhering to treatment, and information on HIV prevention in general and in the workplace. The person should be advised to use condoms, and not to donate blood



or organs for up to 6 months after exposure. Women of childbearing age should be advised to use contraception, and alternatives to breastfeeding should be discussed with women currently feeding their infants, because there is a high risk of transmitting HIV to the infant if the mother becomes infected during breastfeeding.

Based on WHO recommendations, a two-drug PEP regimen should be used (see Table D.2), unless there is suspicion or evidence of drug resistance. The standard regimen consists of two nucleotide reverse transcriptase inhibitors (NRTIs). When there is suspicion that the virus could be resistant to one or more of the drugs included in the standard PEP regimen, a third drug – a protease inhibitor – should be added to the two chosen NRTIs (see Table D.2). In this situation, it is best to consult an HIV expert.

Table D.2 Recommended two and three-drug post-exposure prophylaxis regimens

Two-drug regimens	
Preferred regimens	1. ZDV + 3TC 2. d4T + 3TC
Alternative regimen	3. TDF + 3TC
Three-drug regimens	
Preferred regimen	1. ZDV + 3TC + LPV/r
Alternative regimens	2. ZDV + 3TC plus SQV/r or ATV/r or FPV/r 3. TDF + 3TC plus SQV/r or ATV/r or FPV/r 4. TDF + FTC plus SQV/r or ATV/r or FPV/r 5. (d4T) + 3TC plus SQV/r or ATV/r or FPV/r

3TC, lamivudine; ATV/r, atazanavir/ritonavir; d4T, stavudine; FPV/r, Fosamprenavir/ritonavir; FTC, emtricitabine; LPV/r, lopinavir/ritonavir; SQV/r, siquinavir/ritonavir; TDF, tenofovir; ZDV, zidovudine.

Women of childbearing age should not be prescribed medications such as the combination didanosine plus stavudine. They should be offered a pregnancy test before starting the PEP regimen. Lactating women should be aware that ARVs are excreted in breast milk, and that the virus itself can be transmitted through breastfeeding. When and where feasible, alternatives options to breastfeeding should be discussed with the mother.

Follow-up

Follow-up visits should aim to support the person's adherence to PEP, prevent or treat adverse effects of the medicines, and detect seroconversion, if it occurs.

Advise those who have been exposed to take precautions to prevent secondary transmission during the follow-up period. Such precautions include:

- avoiding pregnancy and seeking safe alternatives to breastfeeding;
- avoiding donating blood, tissue or sperm;
- using condoms during sexual intercourse, until the test at 6 months confirms that the exposed person remains seronegative.

PEP for HIV and hepatitis B is not indicated:

- if the exposed person is already HIV-positive from a previous exposure;
- in the context of chronic exposure (e.g. repeated exposure to HIV from unprotected sexual intercourse with a known HIV-positive partner); or
- if the exposure poses no risk of transmission; for example, in the case of
 - exposure of intact skin to potentially infectious body fluids;
 - exposure to body fluids that are not known to transmit HIV or HBV (faeces, saliva, urine or sweat); or



- exposure to body fluids from a person known to be HIV-negative, unless the source person is identified as being at high risk of having been recently infected and is currently within the window period for seroconversion.

Step 5 – Report the incident

After the incident, refer the exposed person to a trained service provider who can give counselling, evaluate the risk of transmission of bloodborne pathogens having occurred, and decide on the need to prescribe ARV drugs or hepatitis B vaccine to prevent infection with HIV or HBV, respectively.

Both the incident report and the evaluation of the risk of exposure should lead to quality control and evaluation of the safety of working conditions.

Take correctional measures to prevent exposure to HIV and other bloodborne pathogens.



Annex E: Training course content for phlebotomists

Before undertaking phlebotomy, health workers should be trained in, and demonstrate proficiency for, the blood collection procedures on the patient population that will be within their scope of practice.

Training should cover paediatric, neonatal and intensive care, and blood transfusion, as appropriate.

Competence in phlebotomy practices should be an essential part of the final evaluation of those training as health workers.

The outcome of the course should be safety of patients, adequacy of the laboratory specimens, and safety of health workers and the community.

Course contents

- Anatomy of the phlebotomy sites from which the worker is authorized to access blood.
- Infection prevention and control:
 - elements of standard precautions relevant to venepuncture (hand hygiene, wearing non-sterile gloves);
 - use of antiseptics – skin disinfection;
 - cleaning and disinfection of materials used on more than one patient, including tourniquets, scissors and specimen carriers;
 - disposal of used equipment, especially sharps.
- Protection of the patient:
 - patient identification, including children and confused patients;
 - awareness of the institution's rule to halt and seek help after a defined number of unsuccessful draws;
 - informed consent and patient rights;
 - managing supplies for patients in isolation;
 - awareness of contraindications to blood draws including drawing on the same side as a mastectomy, through infected or scarred tissues, and through in-dwelling vascular devices (per institutional policy).
- Protection of the health worker:
 - immunization with hepatitis B;
 - awareness of high risk devices and practices;
 - ability to state who and when to contact for support in the event of exposure to blood and body fluids;
 - awareness of the benefits of PEP and the need to have source patients tested and HIV PEP started, preferably within hours;
 - avoidance of two-handed needle recapping, disassembly of devices, removal of needles prior to injecting blood into tube;
 - placement and use of sharps container within arm's reach;
 - appropriate use of personal protective equipment, including gloves.



- Types of equipment available for blood sampling, and procurement and use of equipment.
- Practice taking blood samples, including blood sampling and simulated blood sampling (capillary blood, arterial blood, venous blood from adults and children according to responsibilities).
- Practice on artificial arms and clinical skills development.
- Special techniques:
 - capillary puncture
 - heel and finger-pricks
 - lancets
 - capillary tubes (filter paper, capillary blood tubes, rapid test strips, etc.)
 - venous blood
 - large volume (blood letting – aware that this must be done under direct physician order and management)
 - winged needles
 - evacuated tubes
 - blood cultures.
- Adverse events and management.
- Occupational exposure and management:
 - the country’s relevant occupational health regulations, including PEP for prevention of HIV and hepatitis B;
 - the procedure for, and benefits of, reporting occupational exposure to blood;
 - first aid after exposure (see management);
 - PEP (importance of timely response);
 - surveillance and use of data for prevention of occupational exposure.
- Waste management, including disposal of waste and sharps, and procedures for spillage and breakage.
- Laboratory practices, including type of samples, forms, labelling and transportation.
- Standards of practice.
- Sustainability of training programme.
- Career path.
- Skill-based incentives.



Annex F: Explaining the procedure to a patient

Introduction:

Hello, I am _____ I work at this health-care facility.

What is your name? (Health-care worker checks first and last name against order for tests and the patient's name band if present).

I am trained to take blood for laboratory tests (or medical reasons) and I have experience in taking blood.

I will introduce a small needle into your vein and gently draw some blood for _____ tests. (Tell the patient the specific tests to be drawn).

Then I will label them with your name and contact details and send them off for tests to the laboratory. The results will be returned to Dr _____ (mention the name of the clinician who ordered the tests).

Do you have any questions? Did you understand what I explained to you? Are you willing to be tested?

Please sit down and make yourself comfortable.

Now, I will ask you a few questions so that both of us feel comfortable about the procedure.

- Have you ever had blood taken before?
- (If yes) How did it feel? How long ago was that?
- Are you scared of needles?
- Are you allergic to anything? (Ask specifically about latex, povidone iodine, tape.)
- Have you ever fainted when your blood was drawn?
- Have you eaten or drunk anything in the past two hours?
- How are you feeling at the moment?

Shall we start? If you feel unwell or uncomfortable, please let me know at once.



Annex G: Disassembly of needle from syringe or other devices

Safe methods of removing the needle from the syringe or other devices are necessary to protect health workers from injury.

This procedure must be carried out close to a sharps container, and the needle must be discarded immediately.

NEVER disassemble an exposed, used needle with your bare hands.

If the needle has to be disassembled from the barrel or syringe, re-sheath using a one-hand scoop technique, then remove the needle using a removal device. Both of these procedures are explained below.

One-hand scoop technique

1. Leave the needle cap on the surface and guide the tip of the used needle tip into it using only one hand. Clean the surface with disinfectant afterward to avoid leaving blood.
2. Place the needle cap against a firm upright surface with its opening towards the phlebotomist, and place the used needle tip into it.
3. Lift the needle and syringe vertically and, once the tip is covered, use the other hand to fix the cap into place.

Use of a removal device

- Needle pliers – Hold the needle with pliers or artery forceps. Dislodge the needle by unscrewing or pulling it off. Discard immediately into a sharps container.
- Needle guard (mushroom) – Place the cap in the device. Using one hand, insert the needle tip into the cap vertically and turn firmly to fix the needle in the cap. Lift the syringe or barrel and removed the covered needle. Discard immediately.



Annex H: Blood spillage

Blood spillage may occur because a laboratory sample breaks in the phlebotomy area or during transportation, or because there is excessive bleeding during the procedure. In this situation, clean up the spillage and record the incident, using the following procedure.

1. Wear a pair of non-sterile gloves.
2. Use tongs or a pan and brush to sweep up as much of the broken glass (or container) as possible. Do not pick up pieces with your hands.
3. Discard the broken glass in a sharps container. If this is not possible due to the size of the broken glass, wrap the glass or container in several layers of paper and discard it carefully in a separate container. Do not place it in the regular waste container.
4. Use disposable paper towels to absorb as much of the body fluids as possible.
5. Wipe the area with water and detergent until it is visibly clean.
6. Saturate the area again with sodium hypochlorite 0.5% (10 000 ppm available chlorine). This is a 1:10 dilution of 5.25% sodium hypochlorite bleach, which should be prepared daily.
7. Rinse off the tongs, brush and pan, under running water and place to dry.
8. Remove gloves and discard them.
9. Wash hands carefully with soap and water, and dry thoroughly with single-use towels.
10. Record the incident in the incident book if a specimen was lost, or persons were exposed to blood and body fluids.



Annex I: Modified Allen test

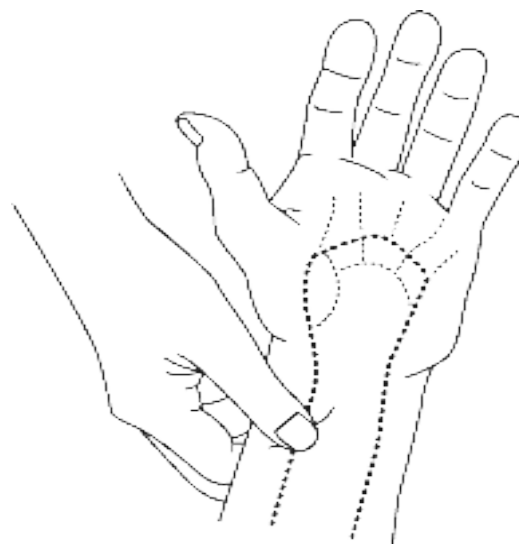
A modified Allen test measures arterial competency, and should be performed before taking an arterial sample. The procedure for performing the test is as follows (see Figure I.1, below).

1. Instruct the patient to clench his or her fist; if the patient is unable to do this, close the person's hand tightly.
2. Using your fingers, apply occlusive pressure to both the ulnar and radial arteries, to obstruct blood flow to the hand.
3. While applying occlusive pressure to both arteries, have the patient relax his or her hand, and check whether the palm and fingers have blanched. If this is not the case, you have not completely occluded the arteries with your fingers.

Figure I.1 Allen test



Thumbs occlude radial and ulnar arteries. Pallor is produced by clenched fist.



Thumb occludes radial artery while ulnar artery is released and patent. Unclenched hand returns to baseline colour because of ulnar artery and connecting arches.

Source: http://fitsweb.uchc.edu/student/selectives/TimurGraham/Modified_Allen%27s_Test.html

Release the occlusive pressure on the ulnar artery only to determine whether the modified Allen test is positive or negative.

- *Positive modified Allen test* – If the hand flushes within 5–15 seconds it indicates that the ulnar artery has good blood flow; this normal flushing of the hand is considered to be a positive test.
- *Negative modified Allen test* – If the hand does not flush within 5–15 seconds, it indicates that ulnar circulation is inadequate or nonexistent; in this situation, the radial artery supplying arterial blood to that hand should not be punctured.



Annex J: Cochrane review

Skin preparation with alcohol versus alcohol followed by any antiseptic for preventing bacteraemia or contamination of blood for transfusion.

Review information

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What's new

Date	Event	Description
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History

Date	Event	Description
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Abstract

Background

Blood for transfusion may become contaminated at any point between collection and transfusion and may result in bacteraemia (the presence of bacteria in the blood), severe illness or even death for the blood recipient. Donor arm skin is one potential source of blood contamination, so it is usual to cleanse the skin with an antiseptic before blood donation. One-step and two-step alcohol based antiseptic regimens are both commonly advocated but there is uncertainty as to which is most effective.

Objectives

To assess the effects of cleansing the skin of blood donors with alcohol in a one-step compared with alcohol in a two-step procedure to prevent contamination of collected blood or bacteraemia in the recipient.

Search strategy

We searched the Cochrane Wounds Group Specialised Register (March 10 2009); The Cochrane Central Register of Controlled Trials (CENTRAL) *The Cochrane Library* 2009, Issue 1; Ovid MEDLINE – (1950 to February Week 4 2009); Ovid EMBASE – (1980 to 2009 Week 9); and EBSCO CINAHL – (1982 to February Week 4 2009). We also searched the reference lists of key papers.

Selection criteria

All randomised trials (RCTs) comparing alcohol based donor skin cleansing in a one-step versus a two-step



Skin preparation with alcohol versus alcohol followed by any antiseptic for preventing bacteraemia or contamination of ... process that includes alcohol and any other antiseptic for pre-venepuncture skin cleansing were considered. Quasi randomised trials were to have been considered in the absence of RCTs.

Data collection and analysis

Two review authors independently assessed studies for inclusion.

Main results

No studies (RCTs or quasi RCTs) met the inclusion criteria.

Authors' conclusions

We did not identify any eligible studies for inclusion in this review. It is therefore unclear whether a two-step, alcohol followed by antiseptic skin cleansing process prior to blood donation confers any reduction in the risk of blood contamination or bacteraemia in blood recipients, or conversely whether a one-step process increases risk above that associated with a two-step process.

Plain language summary

Alcohol, with or without an antiseptic, for preparing the skin before blood collection, to prevent bacteraemia or contamination of blood for transfusion.

When blood is collected from blood donors for transfusion it may become contaminated during collection, storage or transfusion. Blood contamination can cause bacteraemia (the presence of bacteria in the blood), severe illness or even death in the blood recipient. When blood is being taken from donors, the skin on the arm of the donor is one potential source of contamination, so it is usual to cleanse the arm with an antiseptic first, and both one-step and two-step alcohol based regimens are commonly used, however there is uncertainty about which regimen is the most effective for reducing the microbial load (the number of microscopic bacterial organisms) on the donor arm. We looked for studies that compared the use of alcohol alone versus the use of alcohol followed by another antiseptic to clean the arm before the needle is inserted to draw blood, but we did not find any relevant studies. It is currently unclear whether donor skin cleansing with a one-step alcohol based regimen reduces the risk of blood contamination compared with a two-step alcohol based regimen during blood donation.

Background

Complications associated with the infusion of blood and blood-related products have reduced in recent years, due to considerable advances in detecting transfusion-related viral pathogens, such as human immunodeficiency virus (HIV) and hepatitis C and B virus (HCV and HBV). In contrast, bacteraemia, resulting from bacterial contamination of blood products continues to be an ongoing problem (Sandler 2003; Wagner 2004). Exogenous contamination of donor blood may occur at any point during collection, storage and transfusion (McDonald 2001). One of the sources of contamination is thought to be the donor's skin, as a result of inadequate skin cleansing (de Korte 2006; McDonald 2006).

Description of the condition

Bacteraemia, or the presence of bacteria in the blood, is a potentially fatal condition. It is associated with high rates of morbidity (Hakim 2007; Sligl 2006). Microorganisms may enter the blood stream through almost any organ (for example the lungs following pneumonia), through a surgical site, or via an implanted device such as an intravenous catheter. Prognosis is related to the virulence of the infective organism, severity of the sepsis at diagnosis and the underlying health of the patient (Herchline 1997). Although the aetiology of bacteraemia is often difficult to identify, transfusion-transmitted infection is a rare cause. The incidence of bacterial transmission through donated blood is estimated at between 1 per 100,000 and 1 per 1,000,000 units for packed red blood cells, and between 1 per 900 and 1 per 100,000 units for platelets (Walther-Wenke 2008). Fatalities are associated with 1 in 8,000,000 red cell units and 1 in 50,000 to 500,000 white cell units (Wagner 2004). The reason for higher rates in platelet transfusion is thought to be because frozen platelets are thawed and stored at room temperature before infusion and if they are not used immediately there is an opportunity for any organisms that may be present to multiply before the product is transfused. Further reduction of infection rates depends on ensuring that blood for transfusion is free of contaminants. One way of achieving this is through careful preparation and cleansing of the donor's skin at the collection site.

Description of the intervention

There is no standard method for cleansing the site on the blood donor's skin from which the blood will be taken (generally the cubital fossa, or the inner aspect of the elbow). However, alcohol, followed by an application of povidone iodine has been traditionally used (Shahar 1990; Kiyoyama 2009). Consequently, the interventions of interest for this review are skin cleansing with alcohol (usually 70% isopropyl alcohol) for skin preparation in a one-step process, compared with a two-step process involving alcohol followed by povidone iodine or other antiseptic solution. Antiseptics are antimicrobial substances that are applied to living tissue or skin to reduce the possibility of infection, sepsis or putrefaction. They should generally be distinguished from antibiotics that destroy bacteria within the body, and from disinfectants, which destroy microorganisms found on non-living objects. Alcohol is widely used prior to venepuncture and is available from a number of manufacturers as easy-to-use disinfection wipes. Isopropyl alcohol is a flammable, colourless liquid; also known as 2-propanol (MSDS



Skin preparation with alcohol versus alcohol followed by any antiseptic for preventing bacteraemia or contamination of ...
2006).

How the intervention might work

Alcohol kills most bacteria and fungi by acting on lipid and protein components of the cell. It is less effective against viruses (Adams 2007). Isopropyl alcohol has some advantages over other products because it requires a shorter contact time to achieve antiseptics. For example some two-step procedures take up to two minutes to perform, which is considered too long for some blood bank services (McDonald 2006). Antiseptics are toxic to living tissues as well as bacterial cells, some antiseptics are true germicides, capable of destroying microbes (bacteriocidal), whilst others are bacteriostatic and only prevent or inhibit their growth (Morgan 1993).

Why it is important to do this review

Although a range of antiseptics has been used to cleanse the skin of the donor arm, a two-step process, including alcohol and iodine is widely used (Shahar 1990; Kiyoyama 2009). The effectiveness of this regimen, and other forms of cleansing has been evaluated in a number of studies by measuring the microbial load on the donor arm (Cid 2003; Follea 1997; Goldman 1997; McDonald 2001; Wong 2004) and any contamination of platelet concentrates (de Korte 2006; Lee 2002) however it remains unclear whether isopropyl alcohol alone is as effective as alcohol plus povidone iodine (or any other antiseptic) in preventing the clinical consequences of contaminated blood. This review question was brought to us by the World Health Organisation (WHO) and a scoping search did not identify any existing systematic review which had previously addressed this question.

Objectives

To assess the effects of cleansing the donor arm with alcohol in a one-step regimen compared with a two-step regimen including alcohol followed by any other antiseptic to prevent donor blood contamination or recipient bacteraemia.

Methods

Criteria for considering studies for this review

Types of studies

All randomised controlled trials (RCTs) comparing a one-step alcohol regimen with any two-step regimen that includes alcohol followed by another antiseptic for pre-venepuncture skin cleansing were considered. Cluster randomised trials and crossover trials were also eligible for inclusion. Quasi randomised trials were to have been considered in the absence of RCTs.

Types of participants

Studies enrolling people of any age and in any setting, having venepuncture and blood collection were eligible, irrespective of whether the venepuncture was for the purpose of blood donation. Studies should also include follow up from the recipients of the donated blood in order to measure outcomes occurring in the recipient.

Types of interventions

Studies which compared one-step donor skin cleansing with alcohol (any concentration or application method) with a two-step method which involved alcohol (any strength or application method) followed by any other antiseptic (any concentration or application method) were eligible.

Types of outcome measures

At least one of the primary outcomes was to have been reported for the study to be considered for inclusion in the review.

Primary outcomes

- Bacteraemia in the blood recipient (the presence of bacteria in the blood stream) as measured by blood culture.
- Blood product contamination (blood products include whole blood, platelets, red blood cells or any other product derived from the blood collection) at any time between collection and transfusion as detected most commonly by blood culture.

Proxy outcome measures, such as skin contamination or skin colonisation, were not considered for several reasons. Namely, any antiseptic will reduce levels of microflora on the skin and swabbing skin for bacteria is really a 'sampling procedure' which is subject to inconsistencies in sampling. In addition, a positive skin culture does not automatically mean that the blood collected for transfusion will be positive for bacteria (in the same way that a positive skin culture before surgery does not mean the person will develop a surgical site infection).

Secondary outcomes

- Death of the blood recipient, attributed to the transfusion.
- Any adverse effects in the blood recipient associated with the transfusion. This may include sepsis (a grouping of signs such as fever, chills, or hypotension), septic shock (severe disturbances of temperature, respiration, heart rate or white blood cell count) or multiple organ dysfunction syndrome (altered organ function in a severely ill patient that requires medical intervention to prevent death).



Skin preparation with alcohol versus alcohol followed by any antiseptic for preventing bacteraemia or contamination of ...

Search methods for identification of studies

Electronic searches

We searched the following databases:

Cochrane Wounds Group Specialised Register (Searched March 10 2009);
The Cochrane Central Register of Controlled Trials (CENTRAL) – *The Cochrane Library* 2009, Issue 1;
Ovid MEDLINE – 1950 to February Week 4 2009;
Ovid EMBASE – 1980 to 2009 Week 9;
EBSCO CINAHL – 1982 to February Week 4 2009.

The Cochrane Central Register of Controlled Trials (CENTRAL) was searched using the following strategy:

```
#1 MeSH descriptor Blood Specimen Collection explode all trees
#2 MeSH descriptor Blood Transfusion explode all trees
#3 MeSH descriptor Blood Donors explode all trees
#4 (blood NEXT collection*) or (blood NEXT donor*) or (blood NEXT donation*):ti,ab,kw
#5 (collection NEAR/1 blood) or (donation NEAR/1 blood):ti,ab,kw
#6 ven*puncture NEXT site*:ti,ab,kw
#7 (#1 OR #2 OR #3 OR #4 OR #5 OR #6)
#8 MeSH descriptor Antisepsis explode all trees
#9 MeSH descriptor Anti-Infective Agents, Local explode all trees
#10 MeSH descriptor Iodine Compounds explode all trees
#11 MeSH descriptor Povidone-Iodine explode all trees
#12 MeSH descriptor Alcohols explode all trees
#13 MeSH descriptor Disinfectants explode all trees
#14 MeSH descriptor Disinfection explode all trees
#15 skin NEXT preparation:ti,ab,kw
#16 disinfect*:ti,ab,kw
#17 ("alcohol" or "alcohols" or iodine or povidone-iodine or chlorhexidine):ti,ab,kw
#18 (#8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17)
#19 (#7 AND #18)
```

The search strategies for Ovid MEDLINE, Ovid EMBASE and EBSCO CINAHL can be found in [Appendix 2](#), [Appendix 3](#) and [Appendix 4](#) respectively. The Ovid MEDLINE search was combined with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximizing version (2008 revision) ([Lefebvre 2008](#)). The Ovid EMBASE and EBSCO CINAHL searches were combined with the trial filters developed by the Scottish Intercollegiate Guidelines Network ([SIGN 2008](#)). There was no restriction on the basis of date or language of publication.

Searching other resources

Reference lists of articles retrieved in full were searched.

Data collection and analysis

Selection of studies

Titles and abstracts identified through the search process were independently reviewed by two review authors. Full reports of all potentially relevant studies were retrieved for further assessment of eligibility based on the inclusion criteria. Differences of opinion were settled by consensus or referral to a third review author. There was no blinding to study authorship when we did these assessments.

Data extraction and management

We had planned to extract the following data, where available (to be extracted by one review author and checked by a second review author):

- details of the trial/study (first author, year of publication, journal, publication status, period);
- setting and country of study;
- source of funding;
- inclusion and exclusion criteria;
- baseline characteristics of participants (age, sex);
- aspects of morbidity of the blood recipients, e.g. predictors of susceptibility to bacteraemia;
- number of participants in each arm of the trial;
- description of intervention (type, duration);
- description of control intervention (type, duration);
- details and duration of follow up;
- primary and secondary outcomes (by group);
- design / methodological quality data as per risk of bias criteria;
- unit of randomisation (where relevant);
- unit of analysis;
- results and primary statistical analysis.



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Assessment of risk of bias in included studies

Two review authors were to independently assess study risk of bias using the Cochrane Collaboration tool (Higgins 2008a). This tool addresses six specific domains, namely sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting and other issues (e.g. co-interventions) (see Appendix 1 for details of criteria on which the judgements were to have been based). Blinding and completeness of outcome data would have been assessed for each outcome separately and we had planned to complete a risk of bias table for each eligible study.

We planned to contact investigators of included studies to resolve any ambiguities. We also planned to include data from duplicate publications only once, but to retrieve all publications pertaining to a single study to enable full data extraction and risk of bias quality assessment.

For any eligible study, we planned to present assessment of risk of bias using a 'risk of bias summary figure', which presents the judgments in a cross-tabulation of study by entry. This display of internal validity indicates the weight the reader may give the results of each study.

Measures of treatment effect

For individual trials, effect measures for categorical outcomes (e.g. rates of bacteraemia) would have included relative risk (RR) with its 95% confidence interval (CI). For continuous outcomes, we planned to use the mean difference (MD) or, if the scale of measurement differed across trials, standardized mean difference (SMD), each with its 95% CI. For any meta-analyses (see below), for categorical outcomes the typical estimates of RR with their 95% CI would have been calculated; and for continuous outcomes the weighted mean difference (WMD) or a summary estimate for SMD, each with its 95% CI, would have been calculated.

We planned to analyse data using The Cochrane Collaboration's Review Manager 5 software.

Dealing with missing data

If outcome data had remained missing despite our attempts to obtain complete outcome data from authors, we would have performed an available-case analysis, based on the numbers of patients for whom outcome data were known. If standard deviations were missing, we would have imputed them from other studies or, where possible, computed them from standard errors using the formula $SD = SE \times \sqrt{N}$, where these were available (Higgins 2008b).

Assessment of heterogeneity

Heterogeneity would have been assessed visually and by using the chi-squared statistic with significance being set at $p < 0.10$. In addition, the degree of heterogeneity would have been investigated by calculating the I^2 statistic (Deeks 2008). If evidence of significant heterogeneity had been identified ($I^2 > 50\%$), we would have explored potential causes and a random-effects approach to the analysis would have been used if a meta-analysis had been appropriate.

Assessment of reporting biases

Reporting bias would have been assessed using guidelines in the Cochrane Handbook for Systematic Reviews of Interventions (Sterne 2008).

Data synthesis

Where appropriate, results of comparable trials would have been pooled and the pooled estimate together with its 95% CI would have been reported. We planned to conduct a narrative review of eligible studies if statistical synthesis of data from more than one study was not possible or considered not appropriate.

Subgroup analysis and investigation of heterogeneity

We planned to analyse potential sources of heterogeneity using the following subgroup analysis: concealment of allocation (adequate versus not reported).

Sensitivity analysis

We planned to undertake a sensitivity analysis to explore the effect of excluding studies where concealment of allocation was unclear

Results

Description of studies

We did not find any randomised or quasi-randomised controlled trials that met the inclusion criteria.

Results of the search

Our initial search identified 457 citations of which 19 were considered potentially relevant. Full copies of these papers were obtained and reviewed independently by two review authors, however, none met the inclusion criteria.

Included studies



Skin preparation with alcohol versus alcohol followed by any antiseptic for preventing bacteraemia or contamination of ...

No studies were included.

Excluded studies

The Table: [Characteristics of excluded studies](#) contains reasons for excluding 19 potentially eligible studies. In summary, two citations were for unsystematic literature reviews ([Blajchman 2004](#); [Wendel 2002](#)) eight trials did not compare the eligible interventions ([Calfee 2002](#); [Choudhuri 1990](#); [Little 1999](#); [Mimoz 1999](#); [Schifman 1993](#); [Sutton 1999](#); [Suwanpimolkul 2008](#); [Trautner 2002](#)). Eight studies were not randomised or quasi randomised controlled trials ([Kiyoyama 2009](#); [de Korte 2006](#); [Goldman 1997](#); [Lee 2002](#); [McDonald 2006](#); [Pleasant 1994](#); [Shahar 1990](#); [Wong 2004](#)). One study examined techniques for quantifying bacterial reduction ([Follea 1997](#)).

Risk of bias in included studies

No studies were included.

Effects of interventions

We did not identify any eligible randomised or quasi randomised controlled trials, nor were we able to identify any ongoing trials.

Discussion

We have been unable to identify any trials addressing the effectiveness of alcohol alone compared with alcohol followed by any other antiseptic to prevent bacteraemia from transfused blood or blood products. This may be because infusion related bacteraemia is a relatively rare event and very large trials would be needed to investigate the effect of donor-arm cleansing. Sepsis rates for platelet transfusions are around 1:50,000 and for red cell transfusions around 1:500,000 ([Sandler 2003](#)). Therefore mounting a trial large enough to detect differences in clinical outcomes, based on products used for arm cleansing, would be prohibitively expensive and lengthy.

Because of this, surrogate measures, such as contamination of stored blood have been used to evaluate antiseptics efficacy. However, again, we found no trials that compared alcohol alone with alcohol followed by any other antiseptic for cleansing the donor skin. A number of studies used the surrogate outcome of post-cleansing skin microbial load at the venepuncture site however we excluded such studies *a priori* on the grounds that this is a surrogate outcome of unproven validity; it is not known how skin contamination relates to blood recipient outcomes. Moreover none of these trials compared a one-step with a two-step cleansing process ([de Korte 2006](#); [Follea 1997](#); [Goldman 1997](#)).

Whilst we did identify two studies that compared the effects of the eligible interventions they were otherwise ineligible for important methodological reasons and did not meet our pre-specified study design eligibility criteria. The first compared blood culture contamination following pre-venepuncture cleansing with 70% alcohol for one minute followed by povidone iodine solution for an additional minute with brief swabbing of the skin three to five times with 70% alcohol. Patients who were suspected of having bacteraemia had two blood samples taken; once using the two-step method and once with the standard method. Unfortunately it appeared from the report that the order in which the methods were used was not randomised and samples may have been taken from the same or a closely adjacent site with an unreported time lapse between sampling. Of the 181 cultures tested in each group, eight (4.4%) were positive in the two-step group compared with six (3.3%) in the one-step preparation group (no statistically significant difference) ([Shahar 1990](#)). The second study potentially suffers from important selection bias in that the treatment groups were in different settings as well as receiving different modes of skin cleansing and compared blood culture contamination rates between patients in whom blood had been drawn in the emergency department and who received a one-step 70% alcohol cleansing with inpatients who received a two-step 70% alcohol followed by povidone iodine procedure. Although there was a statistically significant difference in positive culture rates in favour of the one step process (189 (6.6%) positive cultures in the one-step group versus 248 (8.9%) in the two step, alcohol plus iodine group ($p = 0.0015$) ([Kiyoyama 2009](#)) this study was not eligible for inclusion in the review due to the inherent risk of selection bias (inpatients and emergency department patients may well be at different levels of risk of positive blood culture). Thus whilst the authors presented additional data to suggest that baseline positive blood culture rates were similar between inpatients and emergency department patients the risk of selection bias remains and this study was excluded ([Kiyoyama 2009](#)).

In conclusion there is currently no evidence of a difference in either blood contamination or bacteraemia when donor skin is cleansed pre-venepuncture with a one-step alcohol based process or a two-step alcohol plus antiseptic process. This lack of evidence for a difference however results from a complete absence of research and therefore a real difference cannot be discounted. Until better evidence emerges, decisions about which mode of pre-blood donation skin cleansing to use are likely to be driven by convenience and cost. It is also important to note that arm cleansing is only one of the points at which blood contamination may occur. Careful collection and storage of blood and blood products, and systematic surveillance to detect bacterial contamination can all contribute to the safety of patients requiring blood transfusions. Eliminating all bacteria from stored blood may not be possible. So, following relevant clinical guidelines (for example [UK BTS Guidelines 2005](#)) for collection and for detecting bacterial contamination in stored blood, both at the time of collection and at the time of issue, may be the most effective way of reducing infusion related bacteraemia ([Yomtovian 2006](#)).

Summary of main results



Skin preparation with alcohol versus alcohol followed by any antiseptic for preventing bacteraemia or contamination of ...

We did not identify any eligible studies for inclusion in this review. It is therefore unclear whether a two-step, alcohol followed by antiseptic skin cleansing process prior to blood donation confers any reduction in the risk of blood contamination or bacteraemia in blood recipients (or conversely whether a one-step process increases risk above that associated with a two-step process).

Potential biases in the review process

Biases in the review process were minimised as far as possible by adhering to the guidance provided by the Cochrane Handbook (Higgins 2008). We believe that publication bias is unlikely in this case; whilst no trials met the inclusion criteria, this is probably due to the difficulty and expense associated with mounting a trial large enough to answer the question.

Authors' conclusions

Implications for practice

We did not find any eligible randomised or quasi randomised controlled trials. Until further research emerges, decisions about which mode of pre-blood donation skin cleansing to use are likely to be driven by convenience and cost. It is also important to note that arm cleansing is only one of the points at which blood contamination may occur.

Implications for research

Cleansing the donor skin before taking blood for transfusion is important, but conducting a trial to compare the effects of using specific antiseptics on bacteraemia rates would be logistically difficult given the relatively rare event rate. It may be possible to estimate the effects of disinfecting with alcohol alone versus alcohol plus other antiseptics on blood contamination rates but this would still require very large sample sizes to detect clinically important differences. Alternatively, high quality observational studies may provide additional information to guide practice. A future comprehensive evidence synthesis that summarised the evidence for all competing alternative approaches to pre-blood donation skin cleansing would be worthwhile.

Acknowledgements

The authors would like to acknowledge the peer referees: Martin Bland, Julie Bruce, Mike Clarke, Jo Dumville, Carmel Hughes, Susan O'Meara, Ian Roberts and David Tovey. Nicky Cullum provided editorial input throughout the review process and checked the search results.

Contributions of authors

Joan Webster: designed the review, checked the search results and all papers retrieved in full, wrote the review draft, responded to the peer referee feedback, made an intellectual contribution to the review and approved the final review prior to submission. Guarantor of the review

Sally Bell-Syer: coordinated the review, edited the review draft, responded to the peer referee feedback, made an intellectual contribution to the review and approved the final review prior to submission.

Ruth Foxlee: designed the search strategy, conducted the literature searches and retrieved papers. Edited the search methods section and responded to the peer referee feedback and approved the final review prior to submission.

Declarations of interest

none known

Differences between protocol and review

Nil

Published notes

This rapid review was undertaken at the request of the World Health Organisation (WHO). This organisation framed the review question but they did not provide funding or influence its publication.

Characteristics of studies

Characteristics of included studies

Footnotes

Characteristics of excluded studies

Blajchman 2004

Reason for exclusion	Narrative, non-systematic literature review
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Calfee 2002



Skin preparation with alcohol versus alcohol followed by any antiseptic for preventing bacteraemia or contamination of ...

Reason for exclusion	None of the four study arms involved a two-step skin preparation process.
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Choudhuri 1990

Reason for exclusion	Comparison of two one-step processes; alcohol swab compared with iodine swab.
----------------------	---

de Korte 2006

Reason for exclusion	Single arm study evaluating a double-swab isopropyl alcohol disinfection process.
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Follea 1997

Reason for exclusion	Examined techniques for quantifying bacterial reduction by comparing a three-step process with no skin disinfection.
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Goldman 1997

Reason for exclusion	Abstract only available and it was unclear how patients were allocated to groups. Though this was not likely to have been randomised or quasi-randomised because one group was treated in a particular way on the basis that they were allergic to iodine. Also there was no one-step, alcohol-only skin preparation group.
----------------------	---

Kiyoyama 2009

Reason for exclusion	Not a randomised or quasi-randomised controlled trial. Two independent groups were considered; one group from an inpatient ward was treated with isopropyl alcohol + povidone-iodine and the other from an emergency department was treated with isopropyl alcohol alone.
----------------------	---

Lee 2002

Reason for exclusion	Not a randomised or quasi-randomised controlled trial. Comparison of two two-step processes in consecutive time periods. Cetrimide/ chlorhexidine solution + isopropyl alcohol compared with povidone-iodine + isopropyl alcohol.
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Little 1999

Reason for exclusion	Povidone-iodine was compared with iodine tincture, i.e. not a comparison of a one-step with a two-step skin preparation.
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McDonald 2006

Reason for exclusion	An uncontrolled before and after evaluation of a two-step process involving isopropyl alcohol + tincture of iodine.
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Mimoz 1999

Reason for exclusion	Povidone-iodine compared with chlorhexidine, i.e. not a comparison of a one-step with a two-step skin preparation.
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Pleasant 1994

Reason for exclusion	Only available in abstract form; no information to suggest this was a randomised controlled trial; attempts to contact the authors were unsuccessful.
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Skin preparation with alcohol versus alcohol followed by any antiseptic for preventing bacteraemia or contamination of ...

Schifman 1993

Reason for exclusion	Comparison of two two-step processes, namely, isopropyl alcohol pads + povidone-iodine swabs compared with isopropyl alcohol/acetone scrub + povidone-iodine dispenser.
----------------------	---

Shahar 1990

Reason for exclusion	Not a randomised or quasi-randomised controlled trial; the venepuncture site was cleansed with a two-step process after which a culture was taken, at a later time point the venepuncture site was cleansed with a one-step process after which a culture was taken. The two samples were collected from the same person but it is not clear from the report if the two venepuncture sites were different, if there was a possibility of cross contamination between sites and what time period separated the sampling process..
----------------------	--

Sutton 1999

Reason for exclusion	Isopropyl alcohol (IPA) compared with no IPA skin preparation, i.e. not a comparison of a one-step with a two-step skin preparation.
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Suwanpimolkul 2008

Reason for exclusion	Chlorhexidine in alcohol compared with povidone-iodine, i.e. not a comparison of a one-step with a two-step skin preparation.
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Trautner 2002

Reason for exclusion	Chlorhexidine gluconate compared with iodine tincture, i.e. not a comparison of a one-step with a two-step skin preparation .
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Wendel 2002

Reason for exclusion	Narrative, non-systematic literature review.
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Wong 2004

Reason for exclusion	An uncontrolled before and after study of a one-step process involving chlorhexidine gluconate.
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Footnotes

Characteristics of studies awaiting classification

Footnotes

Characteristics of ongoing studies

Footnotes

Summary of findings tables

Additional tables

References to studies

Included studies

Excluded studies

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Classification pending references

Data and analyses

Figures

Sources of support

Internal sources

- Department of Health Sciences, University of York, UK

External sources

- No sources of support provided

Feedback

Appendices

1 Criteria for a judgment of 'yes' for the sources of bias

1. Was the allocation sequence randomly generated?

Yes, low risk of bias

A random (unpredictable) assignment sequence.

Examples of adequate methods of sequence generation are computer-generated random sequence, coin toss (for studies with two groups), rolling a dice (for studies with two or more groups), drawing of balls of different colours, dealing previously shuffled cards.

No, high risk of bias

– Quasi-randomised approach: Examples of inadequate methods are: alternation, birth date, social insurance/security number, date in which they are invited to participate in the study, and hospital registration number

– Non-random approaches: Allocation by judgement of the clinician; by preference of the participant; based on



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the results of a laboratory test or a series of tests; by availability of the intervention.

Unclear

Insufficient information about the sequence generation process to permit judgement

2. Was the treatment allocation adequately concealed?

Yes, low risk of bias

Assignment must be generated independently by a person not responsible for determining the eligibility of the participants. This person has no information about the persons included in the trial and has no influence on the assignment sequence or on the decision about whether the person is eligible to enter the trial. Examples of adequate methods of allocation concealment are: Central allocation, including telephone, web-based, and pharmacy controlled, randomisation; sequentially numbered drug containers of identical appearance; sequentially numbered, opaque, sealed envelopes.

No, high risk of bias

Examples of inadequate methods of allocation concealment are: alternate medical record numbers, unsealed envelopes; date of birth; case record number; alternation or rotation; an open list of random numbers any information in the study that indicated that investigators or participants could influence the intervention group.

Unclear

Randomisation stated but no information on method of allocation used is available.

3. Blinding was knowledge of the allocated interventions adequately prevented during the study?

Was the participant blinded to the intervention?

Yes, low risk of bias

The treatment and control groups are indistinguishable for the participants or if the participant was described as blinded and the method of blinding was described.

No, high risk of bias

– Blinding of study participants attempted, but likely that the blinding could have been broken; participants were not blinded, and the nonblinding of others likely to introduce bias.

Unclear

Was the care provider blinded to the intervention?

Yes, low risk of bias

The treatment and control groups are indistinguishable for the care/treatment providers or if the care provider was described as blinded and the method of blinding was described.

No, high risk of bias

Blinding of care/treatment providers attempted, but likely that the blinding could have been broken; care/treatment providers were not blinded, and the nonblinding of others likely to introduce bias.

Unclear

Was the outcome assessor blinded to the intervention?

Yes, low risk of bias

Adequacy of blinding should be assessed for the primary outcomes. The outcome assessor was described as blinded and the method of blinding was described.

No, high risk of bias

No blinding or incomplete blinding, and the outcome or outcome measurement is likely to be influenced by lack of blinding

Unclear

4. Were incomplete outcome data adequately addressed?

Was the drop-out rate described and acceptable?

The number of participants who were included in the study but did not complete the observation period or were not included in the analysis must be described and reasons given.

Yes, low risk of bias

If the percentage of withdrawals and drop-outs does not exceed 20% for short-term follow-up and 30% for long-term follow-up and does not lead to substantial bias. (N.B. these percentages are arbitrary, not supported by literature);

No missing outcome data;

Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias);

Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups;

Missing data have been imputed using appropriate methods.

No, high risk of bias



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Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups;

Unclear

Were all randomised participants analysed in the group to which they were allocated? (ITT analysis)

Yes, low risk of bias

Specifically reported by authors that ITT was undertaken and this was confirmed on study assessment, or not stated but evident from study assessment that all randomised participants are reported/analysed in the group they were allocated to for the most important time point of outcome measurement (minus missing values) irrespective of non-compliance and co-interventions.

No, high risk of bias

Lack of ITT confirmed on study assessment (patients who were randomised were not included in the analysis because they did not receive the study intervention, they withdrew from the study or were not included because of protocol violation) regardless of whether ITT reported or not

'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomisation; potentially inappropriate application of simple imputation.

Unclear

Described as ITT analysis, but unable to confirm on study assessment, or not reported and unable to confirm by study assessment.

5. Are reports of the study free of suggestion of selective outcome reporting?

Yes, low risk of bias

If all the results from all pre-specified outcomes have been adequately reported in the published report of the trial. This information is either obtained by comparing the protocol and the final trial report, or in the absence of the protocol, assessing that the published report includes enough information to make this judgment.

Alternatively a judgement could be made if the trial report lists the outcomes of interest in the methods of the trial and then reports all these outcomes in the results section of the trial report.

No, high risk of bias

Not all of the study's pre-specified primary outcomes have been reported;

One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. sub scales) that were not prespecified;

One or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect);

One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis;

The study report fails to include results for a key outcome that would be expected to have been reported for such a study.

Unclear

6. Other sources of potential bias:

Were co-interventions avoided or similar?

There were no co-interventions or there were co-interventions but they were similar between the treatment and control groups.

Was the compliance acceptable in all groups?

The review author determines if the compliance with the interventions is acceptable, based on the reported intensity, duration, number and frequency of sessions for both the treatment intervention and control intervention(s). For example, ultrasound treatment is usually administered over several sessions; therefore it is necessary to assess how many sessions each participant attended or if participants completed the course of an oral drug therapy. For single-session interventions (for example: surgery), this item is irrelevant.

2 Ovid MEDLINE search strategy

1 exp Blood Specimen Collection/

2 exp Blood Transfusion/

3 exp Blood Donors/

4 (blood collection\$ or blood donor\$ or blood donation\$).ti,ab.

5 ((collect\$ adj1 blood) or (donat\$ adj1 blood)).ti,ab.

6 ven?puncture site\$.ti,ab.

7 or/1-6

8 exp Antisepsis/

9 exp Anti-Infective Agents, Local/

10 exp Iodine Compounds/

11 exp Povidone-Iodine/

12 exp Alcohols/



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- 13 exp Disinfectants/
- 14 exp Disinfection/
- 15 skin preparation.ti,ab.
- 16 disinfect\$.ti,ab.
- 17 (alcohol\$1 or iodine or povidone-iodine or chlorhexidine).ti,ab.
- 18 or/8-17
- 19 7 and 18

3 Ovid EMBASE search strategy

- 1 exp Blood Sampling/
- 2 exp Blood Transfusion/
- 3 exp Blood Donor/
- 4 (blood collection\$ or blood donor\$ or blood donation\$.ti,ab.
- 5 ((collect\$ adj1 blood) or (donat\$ adj1 blood)).ti,ab.
- 6 exp Vein Puncture/
- 7 ven?puncture site\$.ti,ab.
- 8 or/1-7
- 9 exp Antisepsis/
- 10 exp Topical Antiinfective Agent/
- 11 exp Iodine/
- 12 exp Povidone Iodine/
- 13 exp Chlorhexidine/
- 14 exp Alcohol/
- 15 exp Disinfectant Agent/
- 16 exp Disinfection/
- 17 skin preparation.ti,ab.
- 18 disinfect\$.ti,ab.
- 19 (alcohol\$1 or iodine or povidone-iodine or chlorhexidine).ti,ab.
- 20 or/9-19
- 21 8 and 20

4 EBSCO CINAHL search strategy

- S19 S9 and S18
- S18 S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17
- S17 TI (alcohol or alcohols or iodine or povidone-iodine or chlorhexidine) or AB (alcohol or alcohols or iodine or povidone-iodine or chlorhexidine)
- S16 TI disinfect* or AB disinfect*
- S15 TI skin preparation or AB skin preparation
- S14 (MH "Disinfectants")
- S13 (MH "Alcohols+")
- S12 (MH "Povidone-Iodine")
- S11 (MH "Iodine")
- S10 (MH "Antiinfective Agents, Local+")
- S9 S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8
- S8 TI venepuncture site* or AB venepuncture site*
- S7 (MH "Venipuncture+")
- S6 TI blood donation* or AB blood donation*
- S5 TI blood donor* or AB blood donor*
- S4 TI blood collection* or AB blood collection*
- S3 (MH "Blood Donors")
- S2 (MH "Blood Transfusion+")
- S1 (MH "Blood Specimen Collection+")



Annex references

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Glossary

Acquired immunodeficiency syndrome (AIDS)

Morbidity resulting from infection with the human immunodeficiency virus.

Administrative controls to reduce exposure

A method of minimizing patient or employee exposures through enforcement of policies and procedures, modification of work assignment, training in specific work practices, and other administrative measures designed to reduce the exposure.

Alcohol-based hand rub

An alcohol-containing preparation (liquid, gel or foam) designed for application to the hands to reduce the growth of microorganisms. Such preparations may contain one or more types of alcohol with excipient (a relatively inert substance used as a carrier for the active ingredients of a medication), or other active ingredients and humectants.

Antiseptic handwashing

Washing hands with water and soap or other detergents containing an antiseptic agent. Recommended when carrying out an aseptic technique.

Antiseptics

Antimicrobial substances applied to living tissue or skin to prevent infection. They differ from antibiotics, which destroy bacteria within the body, and from disinfectants, which are used on nonliving objects. Some antiseptics are true germicides, capable of destroying microbes whereas others are bacteriostatic and only prevent or inhibit their growth.

Aseptic technique

The manner of conducting procedures to prevent microbial contamination. An aseptic technique alters the method of hand hygiene, PPE worn, the location and physical characteristics where a procedure is conducted, the use of skin antiseptics and disinfectants in the environment, the manner of opening of packages and the use of sterile supplies.

Auto-disable (AD) syringe

A syringe designed to prevent reuse by locking or disabling after giving a single injection. Several types of AD syringes are commercially available.

Biohazard (biological hazard)

A risk to the health of humans caused by exposure to harmful bacteria, viruses or other dangerous biological agents, or by a material produced by such an organism.

Bloodborne pathogens

Pathogenic microorganisms in human blood that are transmitted through exposure to blood or blood products, and cause disease in humans. Common pathogens of occupational concern include hepatitis B virus, hepatitis C virus and human immunodeficiency virus.

Capillary blood collection

Blood collected from capillaries, the smallest of a body's blood vessels, measuring 5–10 μm in diameter, which connect arterioles and venules. Blood collected by this method is usually by heel or finger-prick.

Cross-contamination

The act of spreading microbes (bacteria and viruses) from one surface to another. Since bloodborne viruses can live on objects and surfaces for up to a week, and other pathogens for months or more, microbes could be spread when surfaces are not disinfected correctly or equipment is not cleaned and sterilized between patients.



Disinfection

Killing of infectious agents outside the body by direct exposure to chemical or physical agents. Disinfection is necessary only for diseases spread by indirect contact.

Disposal

Intentional burial, deposit, discharge, dumping, placing or release of any waste material into or on any air, land or water. In the context of this document, disposal refers to the storage and subsequent destruction of injection or blood sampling equipment to avoid reuse or injury.

Engineering controls

Methods of isolating or removing hazards from the workplace. Examples include sharps disposal containers and safer medical devices (e.g. sharps with engineered sharps-injury protections and needleless systems), laser scalpels and ventilation, including the use of ventilated biological cabinets (laboratory fume hoods). In the context of sharps injury prevention, engineering controls means control that isolates or removes the bloodborne pathogens from the workplace.

Finger-prick

A method of capillary sampling. In medicine, some blood tests are conducted on venous blood obtained by finger-prick. There are ways of opening a small wound that produces no more than a few drops of blood. The procedure can be painful, but can also be quicker and less distressing than venepuncture.

Hand hygiene

Any type of hand cleansing.

Handwashing

Washing hands with soap and water, and drying thoroughly afterwards with single-use towels.

Hepatitis B infection

Hepatitis caused by hepatitis B virus (HBV) and transmitted by exposure to blood or blood products, or during sexual intercourse. It causes acute and chronic hepatitis. Chronic hepatitis B can cause liver disease, cirrhosis and liver cancer.

Hepatitis C infection

Hepatitis caused by a hepatitis C virus (HCV) and transmitted by exposure to blood or blood products. Hepatitis C is usually chronic and can cause cirrhosis and primary liver cancer.

Hierarchy of controls

A concept developed in occupational health industrial hygiene to emphasize prevention. The hierarchy, in order of priority for their efficacy in controlling exposure to hazards and preventing injury or illness resulting from exposure hazards, is as follows:

- elimination of the hazard;
- engineering controls;
- administrative controls;
- work practice controls; and
- use of personal protective equipment.

See also Annex 4 of *Joint ILO/WHO guidelines on health services and HIV/AIDS* (Annex reference 8) for the application of the hierarchy of controls to the hazard of bloodborne pathogen exposure and needle-stick injuries.



Human immunodeficiency virus (HIV)

A virus mainly transmitted during sexual intercourse or through exposure to blood or blood products. HIV causes acquired immunodeficiency syndrome (AIDS).

Infection control

A health-care organization's program, including policies and procedures, for the surveillance, prevention and control of health-care associated infections. Such a program includes all patient care and patient care support departments and services. Examples of infection control measures include immunization, hand hygiene, antimicrobial stewardship, review of facility constructions, supervision of disinfection and sterilization, surveillance, use of protective clothing and isolation.

Injection

Percutaneous introduction of a medicinal substance, fluid or nutrient into the body. This may be accomplished most commonly by a needle and syringe, but also by jet injectors, transdermal patches, micro-needles and other newer devices. The injections are commonly classified by the target tissue (e.g. intradermal, subcutaneous, intramuscular, intravenous, intraosseous, intra-arterial, peritoneal).

Intradermal injection

A shallow injection given between the layers of the skin, creating a "weal" on the skin.

Intramuscular injection

An injection given into the body of a muscle.

Intravenous injection

An injection given into a vein.

Intravascular

Within a blood vessel.

Jet injector

A needle-free device that allows the injection of a substance through the skin under high pressure.

Lancet

A blood-sampling device to obtain a capillary sample of blood for testing. It is most commonly used by people with diabetes during blood glucose monitoring. The depth of skin penetration can be adjusted by selecting lancets of different lengths.

Needle-stick

Penetrating stab wound caused by a needle.

Occupational exposure

Exposure to materials that results from the performance of an employee's duties.



Other potentially infectious materials

Body fluids that are potentially infectious for HIV, HBV and HCV including:

- semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;
- any unfixated tissue or organ (other than intact skin) from a human (living or dead);
- cell or tissue cultures, or organ cultures containing HIV;
- culture medium or other solutions containing HIV, HBV or HCV;
- blood, organs or other tissues from experimental animals infected with HIV, HBV or HCV.

Parenteral

Piercing mucous membranes or the skin barrier through subcutaneous, intramuscular, intravenous or arterial routes; for example, through injections, needle-stick, cuts or abrasions.

Pathogen

A microorganism capable of causing disease.

Personal protective equipment

Specialized equipment worn by an employee to protect against a defined hazard. Such equipment includes gloves, lab coats, gowns, aprons, shoe covers, goggles, glasses with side shields, masks, respirators and resuscitation bags. The purpose of personal protective equipment is to prevent hazardous materials from reaching the workers' skin, mucous membranes or personal clothing. The equipment must create an effective barrier between the exposed worker and the hazard.

Phlebotomy

The act of drawing or removing blood from the circulatory system through an incision or puncture to obtain a sample for analysis and diagnosis.

Post-exposure care and prophylaxis for HIV

Preventive interventions offered to manage the specific aspects of exposure to HIV, and prevent HIV infection in exposed individuals. The services include counselling, risk assessment, HIV testing (based on informed consent), first care and, when needed, the provision of short-term (28 days) antiretroviral drugs, with follow-up and support.

Post-exposure prophylaxis (PEP)

A medical response given to prevent the transmission of bloodborne pathogens after potential exposure. It is available for HIV and hepatitis B.

Quality control

A management function whereby control of the quality of raw materials, assemblies, produced materials and components; services related to production; and management, production and inspection processes is exercised for the purpose of preventing undetected production of defective material or the rendering of faulty services.

Recapping

The act of replacing a protective sheath on a needle. Recapping needles using two-handed methods increases the risk of needle-stick injuries and is not recommended. However, where such action is unavoidable, the one-hand scoop technique reduces the risk of needle-sticks.



Safe injection

An injection that does no harm to the recipient, does not expose the health worker to any risk and does not result in waste that puts the community at risk.

Sharp

Any object that can penetrate the skin; sharps include needles, scalpels, broken glass, broken capillary tubes and exposed ends of dental wires.

Sharps container

A puncture-resistant, rigid, leak-resistant container designed to hold used sharps safely during collection, disposal and destruction. Sometimes referred to as a “sharps box” or “safety box”.

Sharps injury

An exposure event occurring when any sharp penetrates the skin.

Sharps protection device

A sharp or needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids. The device has a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.

Single-use syringe

A sterile syringe intended for the aspiration of fluids or for the injection of fluids immediately after filling (ISO 7886-1).

Solid sharp

A sharp that does not have a lumen through which material can flow; for example, a suture needle, scalpel or lancet.

Standard precautions

A set of practices designed to prevent the spread of infection between health workers and patients from contact with infectious agents in recognized and unrecognized sources of infection. Such precautions are recommended for use with all patients, regardless of patient diagnoses or presumed infectious status. Key elements include hand hygiene, cleaning of the environment, reprocessing of equipment between patients, use of personal protective equipment, placement of patients with known infection or colonization into isolation, laundry management, injection safety, preventing exposure to bloodborne pathogens, waste management and respiratory hygiene.

Sterile

Free from living microorganisms.

Subcutaneous injection

An injection delivered under the skin.

Syringe with reuse prevention feature

A sterile single-use hypodermic syringe of a design such that it can be rendered unusable after use (ISO 7886-4).

Work practice controls

Techniques that reduce the likelihood of exposure by changing the way a task is performed.

