

**OFFICE INSPECTION
(Office-Based Surgery)**

Kansas State Board of Healing Arts
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OFFICE REQUIREMENTS
K.A.R. ARTICLE 25

ARTICLE 25.--OFFICE REQUIREMENTS

- 100-25-1. Definitions.
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100-25-1. Definitions.

As used in this article, the following terms shall have the meanings specified in this regulation.

- a. "General anesthesia" means a drug that, when administered to a patient, results in the patient's controlled state of unconsciousness accompanied by a loss of protective reflexes, including the loss of the independent and continuous ability to maintain the airway and a regular breathing pattern, and the loss of the ability to respond purposefully to verbal commands or tactile stimulation.
- b. "Local anesthesia" means a drug that, when administered to a localized part of the human body by topical application or by local infiltration in close proximity to a nerve, produces a transient and reversible loss of sensation. This term shall include lidocaine injections not exceeding seven milligrams per kilogram of body weight and also tumescent local anesthesia.
- c. "Medical care facility" has the meaning specified in K.S.A. 65-425 and amendments thereto.
- d. "Minimal sedation" means an oral sedative or oral analgesic administered in doses appropriate for the unsupervised treatment of insomnia, anxiety, or pain.
- e. "Minor surgery" means surgery that meets both of the following conditions:
 1. Any complication from the surgery requiring hospitalization is not reasonably foreseeable.
 2. The surgery can safely and comfortably be performed either on a patient who has received no anesthesia or on a patient who has received local anesthesia or topical anesthesia.
- f. "Office" means any place intended for the practice of the healing arts in the state of Kansas. This term shall not include a medical care facility, as defined by K.S.A. 65-425 and amendments thereto, that is licensed by the Kansas department of health and environment.
- g. "Office-based surgery" means any surgery that requires any anesthesia, parenteral analgesia, or sedation and that is performed by or upon the order of a physician in an office. Office-based surgery shall not include minor surgery.
- h. "Physician" means a person licensed to practice medicine and surgery or osteopathic medicine and surgery in the state of Kansas.
- i. "Reportable incident" means any act by a licensee or a person performing professional services under the licensee's supervision, order, or direction that meets either of the following criteria:
 1. Could be below the applicable standard of care and has a reasonable probability of causing injury to a patient; or
 2. could be grounds for disciplinary action by the board.

- j. "Sedation" means a depressed level of consciousness in which the patient retains the independent and continuous ability to perform the following:
1. Maintain adequate cardiorespiratory functioning;
 2. maintain an open airway;
 3. maintain a regular breathing pattern;
 4. maintain the protective reflexes; and
 5. respond purposefully and rationally to tactile stimulation and verbal commands.
- k. "Special procedure" means any patient care service that involves any potentially painful contact with the human body, with or without instruments, for the purpose of diagnosis or therapy and for which the applicable standard of care necessitates any anesthesia to prevent or reduce pain. This term shall include a diagnostic or therapeutic endoscopy, invasive radiology, manipulation under anesthesia, and an endoscopic examination. This term shall include the conduct of pain management when performed using anesthesia levels exceeding local anesthesia.
- l. "Surgery" means a manual or operative method that involves the partial or complete excision or resection, destruction, incision, or other structural alteration of human tissue by any means, including the use of lasers, performed upon the human body for the purpose of preserving health, diagnosing or treating disease, repairing injury, correcting deformity or defects, prolonging life, terminating pregnancy, or relieving suffering, or for aesthetic, reconstructive, or cosmetic purposes.
- m. "Topical anesthesia" means a drug applied to the skin or mucous membranes for the purpose of producing a transient and reversible loss of sensation to a circumscribed area.
- n. "Tumescent local anesthesia" means local anesthesia administered in large volumes of highly diluted lidocaine not exceeding 55 milligrams per kilogram of body weight, epinephrine not exceeding 1.5 milligrams per liter of solution, and sodium bicarbonate not exceeding 15 milliequivalents per liter of solution in a sterile saline solution by slow infiltration into subcutaneous fat. Tumescent local anesthesia shall not include the concomitant administration of any sedatives, analgesics, or hypnotic drugs, or any combination of these, at any dosage that poses a significant risk of impairing the patient's independent and continuous ability to maintain adequate cardiorespiratory functioning, an open airway, a regular breathing pattern, and protective reflexes and to respond purposefully to tactile stimulation and verbal commands.

(Authorized by K.S.A. 65-2865; implementing K.S.A. 65-2837; effective, T-100-8-22-05, Aug. 22, 2005; effective, T-100-12-20-05, Dec. 20, 2005; effective March 17, 2006.)

100-25-2. General requirements.

- a. Except in an emergency, a person licensed to practice a branch of the healing arts shall not perform direct patient care in an office unless all of the following conditions are met:
1. The office at which the direct patient care is performed is sanitary and safe.
 2. Smoking is prohibited in all patient care areas and all areas where any hazardous material is present.
 3. Medical services waste is segregated, stored, collected, processed, and disposed of in accordance with K.A.R. 28-29-27.
- b. On and after July 1, 2006, each person licensed to practice a branch of the healing arts who maintains an office within this state shall adopt and follow a written procedure for sanitation and safety that includes at least the following:

1. Standards for maintaining the cleanliness of the office. The standards shall specify the following:
 - A. The methods for and the frequency of cleaning and decontaminating the walls, ceilings, floors, working surfaces, furniture, and fixtures. The written procedure shall identify the types of disinfectants and cleaning materials to be used; and
 - B. the methods to prevent the infestation of insects and rodents and, if necessary, to remove insects and rodents;
2. standards for infection control and the disposal of biological waste. The standards shall be at least as stringent as the standards in all applicable laws pertaining to the disposal of medical and hazardous waste and shall specify the following:
 - A. The procedures to limit the spread of infection among patients and personnel through universal precautions, hand hygiene, and the proper handling and disposal of sharp objects;
 - B. the methods to decontaminate infected items with germicidal, virucidal, bactericidal, tuberculocidal, and fungicidal products; and
 - C. the procedures to sterilize reusable medical instruments and devices;
3. standards for maintaining drugs, supplies, and medical equipment. The standards shall be at least as stringent as the standards in all applicable laws pertaining to the supply, storage, security, and administration of controlled drugs and shall specify the following:
 - A. The manner of storing drugs and supplies to guard against tampering and theft;
 - B. the procedures for disposal of expired drugs and supplies; and
 - C. the procedures for maintaining, testing, and inspecting medical equipment;
4. standards for maintaining the safety of physical facilities. The standards shall require that all of the following conditions are met:
 - A. The office is properly equipped and maintained in good repair as necessary to prevent reasonably foreseeable harm to patients, personnel, and the public;
 - B. the lighting, ventilation, filtration, and temperature control are adequate for the direct patient care to be performed;
 - C. the floors, walls, and ceilings have surfaces that can be cleaned, disinfected, sterilized, or replaced as appropriate for the direct patient care to be performed;
 - D. adequate measures are in place to deter any unauthorized individuals from entering the treatment rooms; and
 - E. all passageways are free of clutter; and
5. a plan for reporting each reportable incident pursuant to K.S.A. 65-28,122 and K.S.A. 65-4923 and amendments thereto.

(Authorized by K.S.A. 65-2865; implementing K.S.A. 65-2837; effective, T-100-8-22-05, Aug. 22, 2005; effective, T-100-12-20-05, Dec. 20, 2005; effective March 17, 2006.)

100-25-3. Requirements for office-based surgery and special procedures.

A physician shall not perform any office-based surgery or special procedure unless the office meets the requirements of K.A.R. 100-25-2. Except in an emergency, a physician shall not perform any office-based surgery or special procedure on and after January 1, 2006 unless all of the following requirements are met:

a. Personnel.

1. All health care personnel shall be qualified by training, experience, and licensure as required by law.
2. At least one person shall have training in advanced resuscitative techniques and shall be in the patient's immediate presence at all times until the patient is discharged from anesthesia care.

b. Office-based surgery and special procedures.

1. Each office-based surgery and special procedure shall be within the scope of practice of the physician.
2. Each office-based surgery and special procedure shall be of a duration and complexity that can be undertaken safely and that can reasonably be expected to be completed, with the patient discharged, during normal operational hours.
3. Before the office-based surgery or special procedure, the physician shall evaluate and record the condition of the patient, any specific morbidities that complicate operative and anesthesia management, the intrinsic risks involved, and the invasiveness of the planned office-based surgery or special procedure or any combination of these.
4. The physician or a registered nurse anesthetist administering anesthesia shall be physically present during the intraoperative period and shall be available until the patient has been discharged from anesthesia care.
5. Each patient shall be discharged only after meeting clinically appropriate criteria. These criteria shall include, at a minimum, the patient's vital signs, the patient's responsiveness and orientation, the patient's ability to move voluntarily, and the ability to reasonably control the patient's pain, nausea, or vomiting, or any combination of these.

c. Equipment.

1. All operating equipment and materials shall be sterile, to the extent necessary to meet the applicable standard of care.
2. Each office at which office-based surgery or special procedures are performed shall have a defibrillator, a positive-pressure ventilation device, a reliable source of oxygen, a suction device, resuscitation equipment, appropriate emergency drugs, appropriate anesthesia devices and equipment for proper monitoring, and emergency airway equipment including appropriately sized oral airways, endotracheal tubes, laryngoscopes, and masks.
3. Each office shall have sufficient space to accommodate all necessary equipment and personnel and to allow for expeditious access to the patient, anesthesia machine, and all monitoring equipment.
4. All equipment shall be maintained and functional to ensure patient safety.
5. A backup energy source shall be in place to ensure patient protection if an emergency occurs.

d. Administration of anesthesia. In an emergency, appropriate life-support measures shall take precedence over the requirements of this subsection. If the execution of life-support measures requires the temporary suspension of monitoring otherwise required by this subsection, monitoring shall resume as soon as possible and practical. The physician shall identify the emergency in the patient's medical record and state the time when monitoring resumed. All of the following requirements shall apply:

1. A preoperative anesthetic risk evaluation shall be performed and documented in the patient's record in each case. In an emergency during which an evaluation cannot be documented

preoperatively without endangering the safety of the patient, the anesthetic risk evaluation shall be documented as soon as feasible.

2. Each patient receiving intravenous anesthesia shall have the blood pressure and heart rate measured and recorded at least every five minutes.

3. Continuous electrocardiography monitoring shall be used for each patient receiving intravenous anesthesia.

4. During any anesthesia other than local anesthesia and minimal sedation, patient oxygenation shall be continuously monitored with a pulse oximeter. Whenever an endotracheal tube or laryngeal mask airway is inserted, the correct functioning and positioning in the trachea shall be monitored throughout the duration of placement.

5. Additional monitoring for ventilation shall include palpation or observation of the reservoir breathing bag and auscultation of breath sounds.

6. Additional monitoring of blood circulation shall include at least one of the following:

- A. Palpation of the pulse;
- B. auscultation of heart sounds;
- C. monitoring of a tracing of intra-arterial pressure;
- D. pulse plethysmography; or
- E. ultrasound peripheral pulse monitoring.

7. When ventilation is controlled by an automatic mechanical ventilator, the functioning of the ventilator shall be monitored continuously with a device having an audible alarm to warn of disconnection of any component of the breathing system.

8. During any anesthesia using an anesthesia machine, the concentration of oxygen in the patient's breathing system shall be measured by an oxygen analyzer with an audible alarm to warn of low oxygen concentration.

e. Administrative policies and procedures.

1. Each office shall have written protocols in place for the timely and safe transfer of the patients to a prespecified medical care facility within a reasonable proximity if extended or emergency services are needed. The protocols shall include one of the following:

- A. A plan for patient transfer to the specified medical care facility;
- B. a transfer agreement with the specified medical care facility; or
- C. a requirement that all physicians performing any office-based surgery or special procedure at the office have admitting privileges at the specified medical care facility.

2. Each physician who performs any office-based surgery or special procedure that results in any of the following quality indicators shall notify the board in writing within 15 calendar days following discovery of the event:

- A. The death of a patient during any office-based surgery or special procedure, or within 72 hours thereafter;
- B. the transport of a patient to a hospital emergency department;
- C. the unscheduled admission of a patient to a hospital within 72 hours of discharge, if the admission is related to the office-based surgery or special procedure;
- D. the unplanned extension of the office-based surgery or special procedure more than four hours beyond the planned duration of the surgery or procedure being performed;
- E. the discovery of a foreign object erroneously remaining in a patient from an office-based surgery or special procedure at that office; or
- F. the performance of the wrong surgical procedure, surgery on the wrong site, or surgery on the wrong patient.

(Authorized by K.S.A. 65-2865; implementing K.S.A. 65-2837; effective, T-100-8-22-05, Aug. 22, 2005; effective, T-100-12-20-05, Dec. 20, 2005; effective March 17, 2006.)

100-25-4. Office-based surgery and special procedures using general anesthesia or a spinal or epidural block.

- a. In addition to meeting the requirements stated in K.A.R. 100-25-2 and 100-25-3, a physician shall not perform any office-based surgery or special procedure using general anesthesia or a spinal or epidural block unless the office is equipped with the following:
 1. Medications and equipment available to treat malignant hyperthermia when triggering agents are used. At a minimum, the office shall have a supply of dantrolene sodium adequate to treat each patient until the patient is transferred to an emergency facility;
 2. tracheotomy and chest tube kits;
 3. an electrocardiogram that is continuously displayed from the induction and during the maintenance of general anesthesia or the spinal or epidural block;
 4. a means readily available to measure the patient's temperature; and
 5. qualified, trained personnel available and dedicated solely to patient monitoring.
- b. On and after July 1, 2006, each physician who performs any office-based surgery or special procedure using general anesthesia or a spinal or epidural block shall perform the office-based surgery or special procedure only in an office that meets at least one of the following sets of standards, all of which are hereby adopted by reference except as specified:
 1. Sections 110-010 through 1031-02 in the "standards and checklist for accreditation of ambulatory surgery facilities" by the American association for accreditation of ambulatory surgery facilities, inc., revised in 2005;
 2. "section two: accreditation" and the glossary, except the definition of "physician," in "accreditation requirements for ambulatory care/surgery facilities" by the healthcare facilities accreditation program of the American osteopathic association, 2001-2002 edition;
 3. section 1 and section 2 in "accreditation manual for office-based surgery practices" by the joint commission on accreditation of healthcare organizations, second edition, dated 2005;
 4. "accreditation standards for ambulatory facilities" by the institute for medical quality, 2003 edition. The appendices are not adopted; or
 5. chapters 1 through 6, 8 through 10, 15, 16, 19, 22, and 24 and appendices A and I in the "accreditation handbook for ambulatory health care" by the accreditation association for ambulatory health care, inc., 2005 edition.
- c. A physician who maintains an office shall not permit any office-based surgery or special procedure involving general anesthesia or a spinal or epidural block to be performed in that office unless the office meets at least one of the five sets of standards adopted in subsection (b).
- d. Accreditation of an office by an organization whose standards are adopted in subsection (b) shall be prima facie evidence that those standards are currently being met.
- e. This regulation shall not apply to any professional service performed in an emergency.

(Authorized by K.S.A. 65-2865; implementing K.S.A. 65-2837; effective, T-100-8-22-05, Aug. 22, 2005; effective, T-100-12-20-05, Dec. 20, 2005; effective March 17, 2006.)

100-25-5. Standard of care.

Each person licensed to practice a branch of the healing arts who performs direct patient care in an office or who performs any office-based surgery or special procedures in an office shall meet the standard of care established by the regulations in this article.

(Authorized by K.S.A. 65-2865; implementing K.S.A. 65-2837; effective, T-100-8-22-05, Aug. 22, 2005; effective, T-100-12-20-05, Dec. 20, 2005; effective March 17, 2006.)

MEDICAL SERVICES WASTE
K.A.R. 28-29-27

28-29-27. Medical services waste.

(a) "Medical services waste" means those solid waste materials which are potentially capable of causing disease or injury and which are generated in connection with human or animal care through inpatient and outpatient services. Medical services waste shall not include any solid waste which has been classified by the secretary as a hazardous waste under K.S.A. 1982 Supp. 65-3431 and any amendments thereto, or that is radioactive treatment material licensed under K.S.A. 1982 Supp. 48-1607 and regulations adopted under that statute.

(b) Segregation. All medical services waste shall be segregated from other solid wastes at the point of origin.

(c) Storage. All medical services waste shall be stored in a manner and in a container that will prevent the transmission of disease or the causing of injury. Hypodermic needles and syringes, scalpel blades, suture needles, or other sharp objects shall be stored only in a rigid, puncture-resistant container that has been closed to prevent the escape of any material, including liquids or aerosols. All reusable containers used to store infectious waste shall be cleaned and disinfected before each use.

(d) Collection. Medical services wastes shall be collected at least daily from the point of origin for transport to a storage or disposal area or a processing facility. Personnel shall take precautions to prevent accidental contact with the waste during transfer.

(e) Transportation. All medical services wastes transported off-site shall be transported in a manner which will prevent the spread of disease or the causing of injury to persons.

(1) The waste transporter or disposal firm shall be notified of the types of waste.

(2) Containers of medical services waste transported off-site shall be labeled or color coded in accordance with 29 CFR 1910.1030(g)(1)(i), as in effect on July 1, 1996.

(f) Processing. In all processing of medical services waste, dispersal of aerosols and liquids shall be prevented through the use of proper coverings, seals, and ventilation. Personnel shall be protected against contact with the waste through the use of protective clothing and equipment. Medical services waste that has been processed may be combined with other solid waste. Where feasible, all medical services wastes shall be processed before transportation off-site by using either of the following methods:

(1) Sterilizing infectious wastes by autoclaving or chemical treatment, to destroy the disease-transmission potential; or

(2) grinding, melting, or pulverizing sharp objects to destroy their injury producing potential.

(g) Disposal. Medical services waste shall be disposed of in a manner which minimizes the risk to health, safety, or the environment. The following shall be considered acceptable disposal methods:

(1) Discharge of liquids to a sanitary sewer which is connected to a secondary sewage treatment plant;

(2) incineration of combustible solids, followed by disposal of the ash in a sanitary landfill;

(3) disposal in a hazardous waste disposal facility which has a permit issued under ~~K.A.R. 28-31-9~~ K.A.R. 28-31-270; [modified by 28-29-1a] or

(4) disposal in a sanitary landfill in accordance with the provisions of K.A.R. 28-29-109. (Authorized by and implementing K.S.A. 1996 Supp. 65-3406, as amended by L. 1997, Ch. 139, Sec. 1; effective May 1, 1982; amended, T-84-41, Dec. 21, 1983; effective May 1, 1984; amended July 10, 1998.)

KDHE MEDICAL WASTE MANAGEMENT



Medical Services Waste Technical Guidance Document SW 00-01

This guidance document will outline the acceptable practices for handling, storage, and disposal of medical services waste so that Health or Medical Facility managers can make informed decisions about medical waste management.

Background

The primary reason for reviewing medical services waste management is the proposed Hospital/Medical/Infectious Waste Incinerator (HMIWI) regulations which the Kansas Department of Health and Environment (KDHE) plans to adopt in 2000. EPA will enforce federal regulations if KDHE does not adopt state regulations.

Affected facilities will have one year to comply with these regulations which will require expensive stack testing for emissions. This will probably result in the closure of many small medical waste incinerators. Many Health Facility managers must explore other management options for the processing or disposal of medical waste.

Medical waste issues are complicated by the lack of uniformity between regulatory agencies. EPA, USDOT, OSHA, and KDHE each have their own definitions and regulations. Terminology includes regulated medical waste, infectious waste, biohazard waste, and (in Kansas) medical services waste. OSHA specifically regulates under the Bloodborne Pathogen Rule.

In Kansas, medical services waste means those solid waste materials which are potentially capable of causing disease or injury and which are generated in connection with human or animal care through inpatient and outpatient services (K.A.R. 28-29-27).

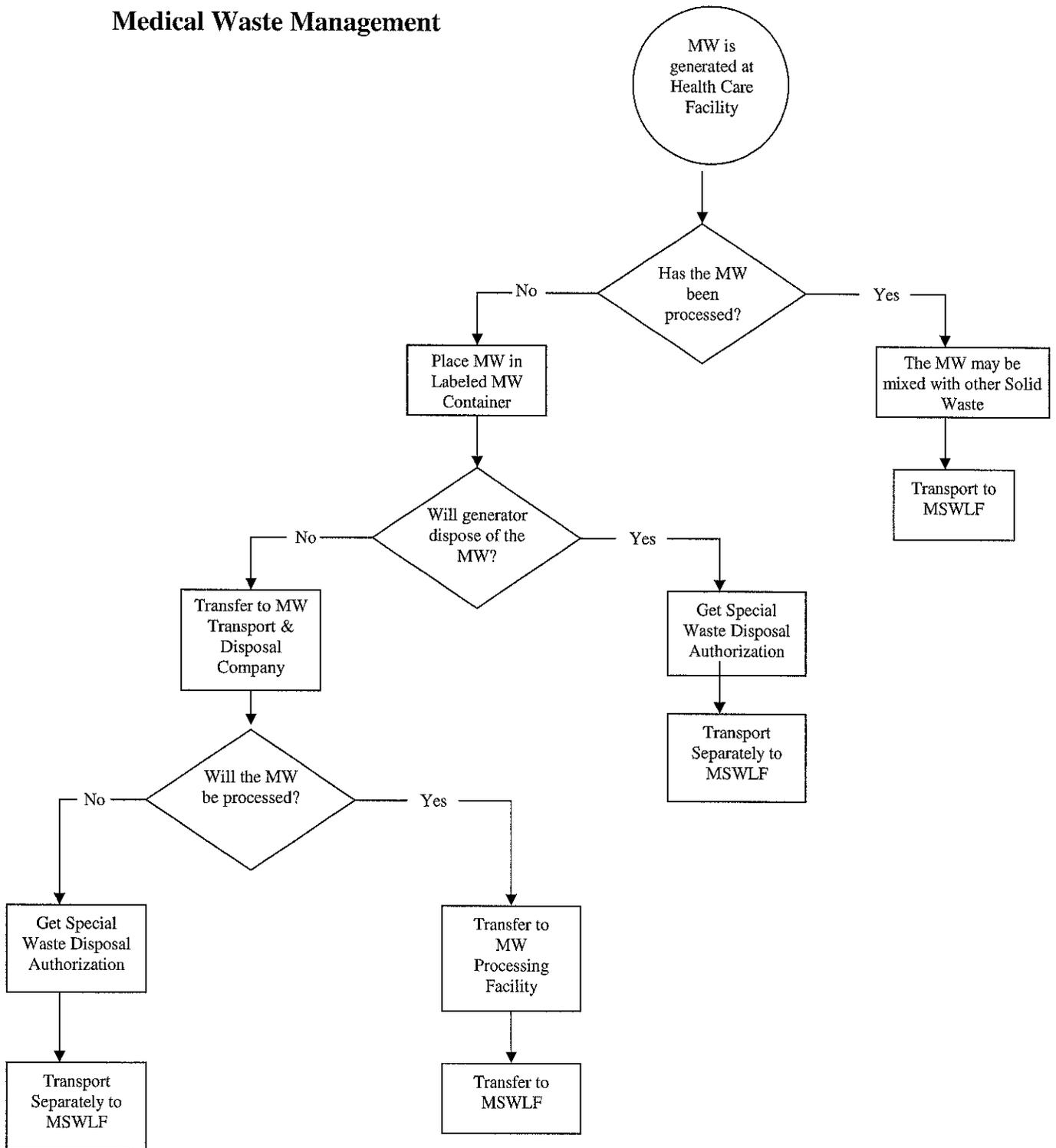
For additional information regarding proper management of solid waste, you may contact the Bureau of Waste Management at (785)296-1600 or the address at the top of this document.

Management of Medical Services Waste

Medical services waste should be managed according to the following standards:

- ◆ The medical waste must be placed in containers which are: closable, constructed to contain all contents and prevent leakage of fluids, and closed prior to removal. The containers must be labeled or color-coded as specified by 29 CFR 1910.130. The labels must have the **BIOHAZARD** legend. Red bags or red containers may be substituted for labels.
- ◆ The facility may process the medical waste by incineration or by sterilization using autoclaving, microwaving, chemical treatment, or other approved methods. If the potential to cause disease or injury is removed, then the waste can be mixed with general solid waste and transported to a Municipal Solid Waste Landfill (MSWLF).
- ◆ If the medical waste is not processed:
 - 1) the facility may obtain a Special Waste Disposal Authorization per K.A.R. 28-29-109 and transport the medical waste separately to a MSWLF; or
 - 2) the facility may contract with a medical waste company for transportation and disposal of the medical waste to a MSWLF (with SWDA) or to a permitted medical waste processing facility.

Medical Waste Management



REPORTING REQUIREMENTS
K.S.A. 65-28, 122 & 65-4923

65-28,122. Person licensed to practice healing arts required to report knowledge of violation of 65-2836 to state board of healing arts.

a. Subject to the provisions of subsection (c) of K.S.A. 65-4923, any person licensed to practice the healing arts who possesses knowledge not subject to the physician-patient privilege that another person so licensed has committed any act enumerated under K.S.A. 65-2836 and amendments thereto which may be a ground for disciplinary action pursuant to K.S.A. 65-2836 and amendments thereto shall immediately report such knowledge, under oath, to the state board of healing arts. A person licensed to practice the healing arts who possesses such knowledge shall reveal fully such knowledge upon official request of the state board of healing arts.

b. This section shall be part of and supplemental to the Kansas healing arts act.

History: L. 1983, ch. 213, § 4; L. 1986, ch. 229, § 47; July 1.

Chapter 65: Public Health

Article 49: Health Care Providers

65-4923. Reporting requirements. (a) If a health care provider, or a medical care facility agent or employee who is directly involved in the delivery of health care services, has knowledge that a health care provider has committed a reportable incident, such health care provider, agent or employee shall report such knowledge as follows:

(1) If the reportable incident did not occur in a medical care facility, the report shall be made to the appropriate state or county professional society or organization, which shall refer the matter to a professional practices review committee duly constituted pursuant to the society's or organization's bylaws. The committee shall investigate all such reports and take appropriate action. The committee shall have the duty to report to the appropriate state licensing agency any finding by the committee that a health care provider acted below the applicable standard of care which action had a reasonable probability of causing injury to a patient, or in a manner which may be grounds for disciplinary action by the appropriate licensing agency, so that the agency may take appropriate disciplinary measures.

(2) If the reportable incident occurred within a medical care facility, the report shall be made to the chief of the medical staff, chief administrative officer or risk manager of the facility. The chief of the medical staff, chief administrative officer or risk manager shall refer the report to the appropriate executive committee or professional practices peer review committee which is duly constituted pursuant to the bylaws of the facility. The committee shall investigate all such reports and take appropriate action, including recommendation of a restriction of privileges at the appropriate medical care facility. In making its investigation, the committee may also consider treatment rendered by the health care provider outside the facility. The committee shall have the duty to report to the appropriate state licensing agency any finding by the committee that a health care provider acted below the applicable standard of care which action had a reasonable probability of causing injury to a patient, or in a manner which may be grounds for disciplinary action by the appropriate licensing agency, so that the agency may take appropriate disciplinary measures.

(3) If the health care provider involved in the reportable incident is a medical care facility, the report shall be made to the chief of the medical staff, chief administrative officer or risk manager of the facility. The chief of the medical staff, chief administrative officer or risk

manager shall refer the report to the appropriate executive committee which is duly constituted pursuant to the bylaws of the facility. The executive committee shall investigate all such reports and take appropriate action. The committee shall have the duty to report to the department of health and environment any finding that the facility acted in a manner which is below the applicable standard of care and which has a reasonable probability of causing injury to a patient, so that appropriate disciplinary measures may be taken.

(4) As used in this subsection (a), "knowledge" means familiarity because of direct involvement or observation of the incident.

(5) This subsection (a) shall not be construed to modify or negate the physician-patient privilege, the psychologist-client privilege or the social worker-client privilege as codified by Kansas statutes.

(b) If a reportable incident is reported to a state agency which licenses health care providers, the agency may investigate the report or may refer the report to a review or executive committee to which the report could have been made under subsection (a) for investigation by such committee.

(c) When a report is made under this section, the person making the report shall not be required to report the reportable incident pursuant to K.S.A. 65-28,122 or 65-4216, and amendments to such sections. When a report made under this section is investigated pursuant to the procedure set forth under this section, the person or entity to which the report is made shall not be required to report the reportable incident pursuant to K.S.A. 65-28,121, 65-28,122 or 65-4216, and amendments to such sections.

(d) Each review and executive committee referred to in subsection (a) shall submit to the secretary of health and environment, on a form promulgated by such agency, at least once every three months, a report summarizing the reports received pursuant to subsections (a)(2) and (a)(3) of this section. The report shall include the number of reportable incidents reported, whether an investigation was conducted and any action taken.

(e) If a state agency that licenses health care providers determines that a review or executive committee referred to in subsection (a) is not fulfilling its duties under this section, the agency, upon notice and an opportunity to be heard, may require all reports pursuant to this section to be made directly to the agency.

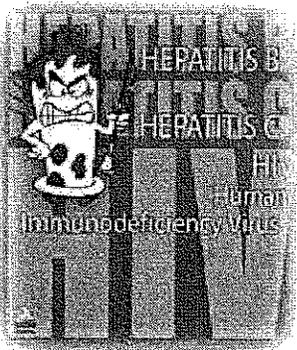
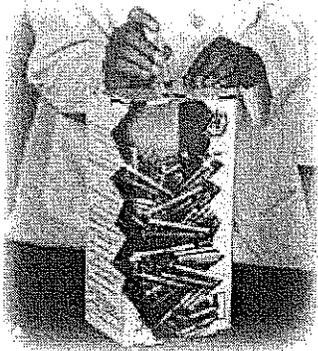
(f) The provisions of this section shall not apply to a health care provider acting solely as a consultant or providing review at the request of any person or party.

History: L. 1986, ch. 229, § 4; L. 1987, ch. 176, § 10; L. 1988, ch. 236, § 3; July 1.

WHO UNIVERSAL PRECAUTIONS



World Health
Organization



WHO best practices for injections and related procedures toolkit



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Preface

A safe injection is one that does not harm the recipient, does not expose the provider to any avoidable risks and does not result in waste that is dangerous for the community. Unsafe injection practices can lead to transmission of bloodborne pathogens, with their associated burden of disease.

To ensure rational and safe use of injections globally, better injection safety practices are needed. The responsibility for ensuring injection safety rests with national governments, prescribers, administrators, receivers of injections and the wider community. The World Health Organization (WHO) acknowledges this responsibility of its member states and the challenges they face. Through the WHO Injection Safety programme and the Safe Injection Global Network (SIGN – whose secretariat is hosted by WHO), the organization demonstrates its commitment to preventing injection-related disease transmission for patients, health workers and the community at large, through the rational and safe use of injections. WHO and SIGN recognize the importance of infection prevention and control in injection safety.

The WHO strategy for the safe and appropriate use of injections worldwide has four objectives:

- formulating national policies and plans for the safe and appropriate use of injections;
- ensuring quality and safety of injection equipment;
- facilitating equitable access to safe injection practices and equipment;
- achieving appropriate, rational and cost-effective use of injections.

In keeping with these objectives, SIGN has developed this toolkit for injection safety and related procedures.

The toolkit covers elements of standard precautions relevant to the transmission of bloodborne pathogens through unsafe injection practices in health-care settings. The document will help to increase health workers' awareness of the importance of standard precautions relevant to injection safety. Its main target is health workers actively engaged in the administration of the various types of injections in all health and related care services, particularly at the peripheral level. However, other people administering injections may find the toolkit useful.

The main areas covered by the toolkit are:

- bloodborne pathogens transmitted through unsafe injection practices;
- relevant elements of standard precautions and associated barrier protection;
- best injection and related infection prevention and control practices;
- occupational risk factors and their management.

The toolkit is illustrated with practical designs that make it an easy source of reference for the user, and can be used to produce posters, flash cards and spreadsheets. WHO has also produced an aide-memoire, to introduce the reader to the subject.

Compliance with the toolkit is recommended, as it is expected to improve the safety of injections for both patients and health workers.

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Acronyms

| | |
|------|--|
| AIDS | acquired immunodeficiency syndrome |
| CDC | Centers for Disease Control and Prevention, Atlanta, GA, USA |
| HBV | hepatitis B virus |
| HCV | hepatitis C virus |
| HIV | human immunodeficiency virus |
| PEP | post-exposure prophylaxis |
| SIGN | Safe Injection Global Network |
| SOP | standard operating procedure |
| WHO | World Health Organization |



1 Background

Medical treatment is intended to save life and improve health, and all health workers have a responsibility to prevent transmission of health-care associated infections. Adherence to safe injection practices and related infection control is part of that responsibility – it protects patients and health workers.

What is a safe injection (1)

A safe injection, phlebotomy (drawing blood), lancet procedure or intravenous device insertion is one that:

- does not harm the recipient;
- does not expose the provider to any avoidable risk;
- does not result in any waste that is dangerous for other people.

1.1 Unsafe injection

Unsafe injections can result in transmission of a wide variety of pathogens, including viruses, bacteria, fungi and parasites (2). They can also cause non-infectious adverse events such as abscesses and toxic reactions. Reuse of syringes or needles is common in many settings. It exposes patients to pathogens either directly (via contaminated equipment) or indirectly (via contaminated medication vials) (3, 4). The risks of unsafe injection practices have been well documented for the three primary bloodborne pathogens – human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV). The estimated global burden of disease for the year 2000 from unsafe injection practices for these pathogens included (3):

- 21 million HBV infections (32% of new HBV infections);
- 2 million HCV infections (40% of new HCV infections);
- 260 000 HIV infections (5% of new HIV infections).

These bloodborne pathogens also contribute to illness among health workers – an estimated 4.4% of HIV infections and 39% of HBV and HCV infections are attributed to occupational injury (5). Among susceptible health workers who do not receive post-exposure prophylaxis (PEP), the risk of infection after needle-stick injury is 23–62% for HBV and 0–7% for HCV (6). Infections may also be transmitted (to other health workers and to patients) from cross-contamination of health workers' hands, medications, medical equipment and devices or environmental surfaces. Thus, proper injection techniques and procedures contribute to the safety of both patients and health workers (1).

1.2 Purpose and scope

The purpose of this toolkit is to promote implementation of safe practices associated with the following medical procedures:

- intradermal, subcutaneous and intramuscular needle injections;
- intravenous infusions and injections;
- dental injections;
- phlebotomy;
- lancet procedures.



The document complements and expands existing World Health Organization (WHO) guidelines and related materials (1, 7, 8). The toolkit describes:

- best injection practices (Chapter 2);
- best practices for phlebotomy and blood collection (Chapter 3);
- assessment and management of occupational risks and injuries (Chapter 4).

Important terms related to injection safety are included in the glossary. Key reference documents are included in the CD-ROM and the reference list. All of these documents may be copied for training purposes, provided that the source is acknowledged.

1.3 Target audience

This toolkit is intended to be used to guide training and daily practice of all health workers in public and private health services. It is primarily aimed at workers who give injections or draw blood, and at those who handle medical waste. However, it will also be useful for health facility administrators, those responsible for infection-control policy and practice, and those responsible for procurement of injection equipment and other health-care supplies.

1.4 Bloodborne virus transmission

Risk of transmission of bloodborne infections depends on the particular pathogen and on the volume and type of blood exposure (9–11). Pathogens such as HBV, HCV and HIV (discussed below) may be transmitted in the absence of visible blood contamination.

Vector-borne diseases such as malaria can also be transmitted through blood, but require large volumes, such as are found in a blood transfusion. Infections transmissible by blood transfusion are covered in other documents on blood safety.

1.4.1 Hepatitis B virus

Newly acquired HBV infection is often asymptomatic – only 30–50% of children over 5 years of age and adults have initial clinical signs or symptoms (12, 13). The fatality rate among people with reported cases of acute symptomatic hepatitis B is 0.5–1.0 (13).

Chronic HBV infection develops in about 90% of those infected as infants, 30% of infected children under 5 years of age, and less than 5% of infected individuals over 5 years of age (12, 13). Overall, about 25% of those who become chronically infected during childhood, and 15% of those who become chronically infected after childhood, die prematurely from cirrhosis or liver cancer (12, 13).

There is no specific treatment for acute hepatitis B; treatment for chronic infection with HBV is costly and often not available.

HBV is transmitted by percutaneous or mucosal exposure to infectious blood or body fluids. Infections can also result from unnoticed exposures, such as inoculation into cutaneous scratches, lesions or mucosal surfaces (14). Hepatitis B surface antigen (which indicates chronic infection) has been detected in multiple body fluids; however, only serum, semen and saliva have been shown to be infectious (12).



HBV is most highly concentrated in serum, with lower concentrations in semen and saliva. The virus is comparatively stable in the environment and remains viable for 7 days or longer on environmental surfaces at room temperature (12). Among susceptible health workers, the risk of HBV infection after a needle-stick injury involving an HBV-positive source is 23–62% (5, 6, 14). Prompt and appropriate interventions with PEP measures can lessen this risk. However, the recommendation is to vaccinate health workers, including waste handlers, with hepatitis B vaccine. The vaccination should be given during pre-service training for those who did not receive it in childhood (see Chapter 4) (15).

1.4.2 Hepatitis C virus

Individuals with acute HCV infection are typically either asymptomatic or have a mild clinical illness. Antibody to HCV (anti-HCV) can be detected in 80% of patients within 15 weeks after exposure, and in 97% by 6 months after exposure (16). Chronic HCV infection develops in 75–85% of infected individuals (16).

Most people remain asymptomatic until onset of cirrhosis or end-stage liver disease, which develops in approximately 10–20% of infected individuals within 20–30 years (16). There is no specific treatment for acute hepatitis C; treatment for chronic HCV infection is costly and is often not available (17).

HCV is transmitted primarily through percutaneous exposures to blood, but transmission is less efficient than for HBV. HCV is viable in the environment for at least 16–23 hours (18, 19). The risk for transmission from exposure to fluids or tissues other than HCV-infected blood has not been quantified, but is expected to be low. Transmission rarely occurs from exposure to blood through mucous membranes or nonintact skin (16, 17, 20). The average incidence of anti-HCV seroconversion after accidental percutaneous exposure from an HCV-positive source is 1.8% (range: 0–7%) (16). Currently, there is no vaccine or effective PEP for HCV (see Chapter 4).

1.4.3 Human immunodeficiency virus

Transmission of HIV occurs through sexual contact, vertical transmission or blood exposure caused by unsafe blood transfusions, unsafe medical injection practices and the sharing of needles and syringes by injecting drug users (21).

HIV is less stable in the environment and less transmissible than either HBV or HCV. Potentially infectious materials include blood and body fluids, semen and vaginal secretions that are visibly contaminated with blood; other body fluids are considered less infectious. HIV causes a brief primary infection several weeks after exposure, and quickly becomes detectable by antibody tests. There is no cure for HIV infection, but antiretroviral treatment is increasingly available for acquired immunodeficiency syndrome (AIDS).

Exposures that pose a risk of transmission in occupational settings include percutaneous injuries, contact of mucous membranes, or contact of nonintact skin with potentially infected fluids (2, 6, 14, 22). The average risk for HIV transmission after a percutaneous exposure to HIV-infected blood has been estimated to be about 0.3% (95% confidence interval [CI]: 0.2–0.5%) and after mucous membrane exposure, approximately 0.09% (95% CI: 0.006–0.5%). Risk from nonintact skin exposure has not been quantified, but is estimated to be less than that for mucous membrane exposure. Guidelines for the use of antiretroviral PEP are discussed in Chapter 4.



1.5 Prevention strategies

Eliminating unnecessary injections is the best way to prevent injection-associated infections. Up to 70% of injections in some countries are medically unnecessary (23). When effective treatment can be given by other routes (oral or rectal), this is preferred, because it reduces potential exposure to blood and infectious agents, and thus reduces infection risks.

Vaccination of health workers with hepatitis B vaccine is important in protecting both health workers and patients.

Methods for reducing exposure and preventing infection transmission include hand hygiene, barrier protection (gloves), minimal manipulation of sharp instruments (including injection equipment), and appropriate segregation and disposal of sharps waste (note: sharps are items such as needles that have corners, edges or projections capable of cutting or piercing the skin) (Table 1.1).

Injections are unsafe when given with unsterile or improper equipment or technique. It is important to avoid contamination of injectable medications. Physically separating clean and contaminated equipment and supplies helps to prevent cross-contamination. For example, immediate disposal of a used syringe and needle in a safety box placed within arm's reach is the first step in safe waste management (1, 24).

Table 1.1 Examples of conditions causing risks in giving injections or collecting blood

| Patients or clients | Health workers who give injections or collect blood | Community or other health workers |
|---|---|--|
| Unnecessary injections | Unnecessary injections | Increased waste from unnecessary injections |
| Reuse of injection equipment | Two-handed recapping of needles | Unsafe disposal of sharps waste: |
| Non-sterile or reprocessed syringes and needles | Manipulation of used sharps | • outside safety boxes |
| Poor hand hygiene | Lack of sharps box within arm's reach | • mixed with hospital linen |
| Cross-contamination through: | Poor positioning of patient | • in nonsecure disposal sites |
| • poor hand hygiene | Poor phlebotomy technique | Lack of protective clothing (boots, gloves, etc.) for waste handlers |
| • medication vials | Two-handed transfer of blood | Reuse of needles or syringes |
| Improper injection technique or site | Unsafe transport of blood | |
| Sharps in hospital linen or other unexpected places | Poor hand hygiene | |
| | Nonsegregated sharps waste | |

Protection of health workers also requires a prompt response to and reporting of occupational exposures. Post-exposure management and prophylaxis is discussed in Chapter 3.

Injection safety is an important component of basic infection control. The concept of "standard precautions", with mandatory safe practices, must be routinely applied in all health-care settings, and every person in such settings should be considered a potential source of infection. Best practices for injection, the collection and handling of blood samples, and waste management are discussed in the following chapter.



2 Best practices for injection

This chapter assimilates the best practices for delivering injections in health-care and related facilities. It is based on a range of evidence and expands the scope of the WHO publication *Best infection control practices for intradermal, subcutaneous, and intramuscular needle injection* (7). The chapter outlines recommended practices, skin preparation, preparation and administration of injections, and related health procedures.

Best injection practices described are aimed at protecting patients, health workers and the community.

2.1 General safety practices

This section describes the following practices that are recommended to ensure the safety of injections and related practices:

- hand hygiene;
- gloves where appropriate;
- other single-use personal protective equipment;
- skin preparation and disinfection.

2.1.1 Hand hygiene

Hand hygiene is a general term that applies to either handwashing, antiseptic handwash, antiseptic hand rub or surgical hand antisepsis (25). It is the best and easiest way to prevent the spread of microorganisms. Hand hygiene should be carried out as indicated below, either with soap and running water (if hands are visibly soiled) or with alcohol rub (if hands appear clean).

Practical guidance on hand hygiene

Perform hand hygiene BEFORE:

- starting an injection session (i.e. preparing injection material and giving injections);
- coming into direct contact with patients for health-care related procedures;
- putting on gloves (first make sure hands are dry).

Perform hand hygiene AFTER:

- an injection session;
- any direct contact with patients;
- removing gloves.

You may need to perform hand hygiene between injections, depending on the setting and whether there was contact with soil, blood or body fluids.

Avoid giving injections if your skin integrity is compromised by local infection or other skin conditions (e.g. weeping dermatitis, skin lesions or cuts), and cover any small cuts.

Indications and precautions for hand hygiene are shown in Table 2.1.



Table 2.1 Indications and precautions for hand hygiene

| Key elements | Indications | Precautions |
|---|--|---|
| Hand hygiene (handwashing or alcohol-based handrub)  | Hand hygiene before and after contact with every patient is the single most important means of preventing the spread of infection <ul style="list-style-type: none"> When hands are visibly dirty or contaminated with proteinaceous material, wash them with antibacterial or plain soap and running water, then dry them using single-use paper towels When hands appear clean (i.e. are not visibly soiled), clean them with an alcohol-based hand product for routine decontamination, then dry them using single-use paper towels | <ul style="list-style-type: none"> Ensure hands are dry before starting any activity DO NOT use alcohol-based hand products when hands are visibly soiled DO NOT use alcohol-based hand products after exposure of nonintact skin to blood or body fluids; in such cases, wash hands with antibacterial or plain soap and running water, then dry them using single-use paper towels |

2.1.2 Gloves

Health workers should wear non-sterile, well-fitting latex or latex-free gloves when coming into contact with blood or blood products (26). Indications for glove use in injection practice are shown in Table 2.2.

Practical guidance on gloves

Table 2.2 Indications for glove use in injection practice

| Key elements | Indications | Precautions |
|---|--|---|
| Glove use  | Wear non-sterile, well-fitting, single-use gloves: <ul style="list-style-type: none"> when there is a likelihood of coming into direct contact with a patient's blood or other potentially infectious materials (e.g. body fluids, moist body substances and saliva [in dental procedures]), mucous membranes and nonintact skin when performing venepuncture or venous access injections, because of the potential for blood exposure at the puncture site if the health worker's skin is NOT intact (e.g. through eczema, or cracked or dry skin) if the patient's skin is NOT intact (e.g. through eczema, burns or skin infections). | When undertaking injections, DO NOT use gloves: <ul style="list-style-type: none"> for routine intradermal, subcutaneous and intramuscular injections if the health worker's skin is intact if the patient's skin is intact. Gloves DO NOT provide protection against needle-stick or other puncture wounds caused by sharp objects. Needles, scalpels and other sharps should be handled with extreme caution. |

Note: This table provides information on glove use in relation to any type of injection. A table on glove use in general health-care settings is given in Annex A.

2.1.3 Other single-use personal protective equipment

Masks, eye protection and other protective clothing ARE NOT indicated for the injection procedures covered by this document unless exposure to blood splashes is expected.

Practical guidance on single-use personal protective equipment

When using single-use personal protective equipment, dispose of the equipment immediately after use.



2.1.4 Skin preparation and disinfection

Table 2.3 shows the skin preparation protocols for different types of injection.

Table 2.3 Skin preparation for different types of injection

| Type of injection | Skin preparation and disinfection | |
|-------------------|-----------------------------------|--|
| | Soap and water | 60–70% alcohol (isopropyl alcohol or ethanol) |
| Intradermal | Yes | No |
| Subcutaneous | Yes | No |
| Intramuscular | | |
| • immunization | Yes | No |
| • therapeutic | Yes ^a | Yes ^a |
| Venous access | No | Yes |

^a Unresolved issue because there is insufficient evidence on the need to disinfect the skin with alcohol before an intramuscular injection to change the 2003 WHO recommendation (7); further studies are warranted.

Practical guidance on skin preparation and disinfection

To disinfect skin, use the following steps (27–29):

1. Apply a 60–70% alcohol-based solution (isopropyl alcohol or ethanol) on a single-use swab or cotton-wool ball. **DO NOT** use methanol or methyl-alcohol as these are not safe for human use.
2. Wipe the area from the centre of the injection site working outwards, without going over the same area.
3. Apply the solution for 30 seconds then allow it to dry completely.

DO NOT pre-soak cotton wool in a container – these become highly contaminated with hand and environmental bacteria.

DO NOT use alcohol skin disinfection for administration of vaccinations.



2.1.5 Summary of best practice

The steps outlined above are summarized in Table 2.4, below.

Table 2.4 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 B) | 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 World Health Organization (30).

2.2 Injection devices and medications

2.2.1 Injection devices

Health-care settings should ensure that an adequate supply of single-use devices is available, to allow providers to use a new device for each procedure.

Practical guidance on use of injection devices

When using a sterile single-use device (i.e. a syringe and hypodermic needle that is not separated or manipulated unless necessary (7):

- use a new device for each procedure, including for the reconstitution of a unit of medication or vaccine;
- inspect the packaging of the device to ensure that the protective barrier has not been breached;
- discard the device if the package has been punctured, torn or damaged by exposure to moisture, or if the expiry date has passed.



2.2.2 Medication

Types of medication containers and recommendations on their use are given in Table 2.5.

Table 2.5 Recommendations on medication containers

| Type of container | Recommendations | Reason |
|---|---------------------------------------|---|
| Single-dose vial | Preferred | Low likelihood of contamination |
| Multiple-dose vial | Only if unavoidable | High likelihood of contamination if aseptic technique is poor |
| Ampoules | Pop-open preferred | Breaking a glass ampoule may result in particulate matter escaping from the vial, it may also injure the person opening the ampoule |
| Fluid or solution bags (100–1000 ml) for reconstitution | Not recommended for routine injection | High likelihood of contamination |

Practical guidance on giving medications

- When giving medication:
 - DO NOT use a single loaded syringe to administer medication to several patients (i.e. ensure one needle, one syringe, one patient!);
 - DO NOT change the needle in order to reuse the syringe;
 - DO NOT use the same mixing syringe to reconstitute several vials;
 - DO NOT combine leftover medications for later use.
- *Single-dose vials* – Whenever possible, use a single-dose vial for each patient, to reduce cross-contamination between patients.
- *Multidose vials* – Only use multidose vials if there is no alternative.
 - Open only one vial of a particular medication at a time in each patient-care area.
 - If possible, keep one multidose vial for each patient, and store it with the patient's name on the vial in a separate treatment or medication room.
 - DO NOT store multidose vials in the open ward, where they could be inadvertently contaminated with spray or spatter.
- *Discard a multidose vial:*
 - if sterility or content is compromised;
 - if the expiry date or time has passed (even if the vial contains antimicrobial preservatives);
 - if it has not been properly stored after opening;
 - within 24 hours of opening, or after the time recommended by the manufacturer, if the vial does not contain antimicrobial preservatives;
 - if found to be undated, improperly stored, inadvertently contaminated or perceived to be contaminated, regardless of expiration date.
- *Pop-open ampoules* – Whenever possible, use pop-open ampoules rather than ampoules that require use of a metal file to open. If using an ampoule that requires a metal file to open, protect your fingers with a clean barrier (e.g. a small gauze pad) when opening the ampoule (7).



2.2.3 Preparing injections

Injections should be prepared in a designated clean area where contamination by blood and body fluids is unlikely (1, 7).

Practical guidance on preparing injections

Three steps must be followed when preparing injections.

1. Keep the injection preparation area free of clutter so all surfaces can be easily cleaned.
2. Before starting the injection session, and whenever there is contamination with blood or body fluids, clean the preparation surfaces with 70% alcohol (isopropyl alcohol or ethanol) and allow to dry.
3. Assemble all equipment needed for the injection:
 - sterile single-use needles and syringes;
 - reconstitution solution such as sterile water or specific diluent;
 - alcohol swab or cotton wool;
 - sharps container.

Procedure for septum vials

Wipe the access diaphragm (septum) with 70% alcohol (isopropyl alcohol or ethanol) on a swab or cotton-wool ball before piercing the vial, and allow to air dry before inserting a device into the bottle.

- Use a sterile syringe and needle for each insertion into a multidose vial.
- Never leave a needle in a multidose vial.
- Once the loaded syringe and needle has been withdrawn from a multidose vial, administer the injection as soon as possible.

Labelling

- After reconstitution of a multidose vial, label the final medication container with:
 - date and time of preparation;
 - type and volume of diluent (if applicable);
 - final concentration;
 - expiry date and time after reconstitution;
 - name and signature of the person reconstituting the drug.
- For multidose medications that DO NOT require reconstitution, add a label with:
 - date and time of first piercing the vial;
 - name and signature of the person first piercing the vial.



2.2.4 Administering injections

An aseptic technique should be followed for all injections.

Practical guidance on administering injections

General

- When administering an injection:
 - check the drug chart or prescription for the medication and the corresponding patient's name and dosage;
 - perform hand hygiene;
 - wipe the top of the vial with 60–70% alcohol (isopropyl alcohol or ethanol) using a swab or cotton-wool ball;
 - open the package in front of the patient to reassure them that the syringe and needle have not been used previously;
 - using a sterile syringe and needle, withdraw the medication from the ampoule or vial.

Reconstitution

- If reconstitution using a sterile syringe and needle is necessary, withdraw the reconstitution solution from the ampoule or vial, insert the needle into the rubber septum in the single or multidose vial and inject the necessary amount of reconstitution fluid.
- Mix the contents of the vial thoroughly until all visible particles have dissolved.
- After reconstituting the contents of a multidose vial, remove the needle and syringe and discard them immediately as a single unit into a sharps container.

Needleless system

- If a needleless system is available:
 - wipe the rubber septum of the multidose vial with an alcohol swab;
 - insert the spike into the multidose vial;
 - wipe the port of the needleless system with an alcohol swab;
 - remove a sterile syringe from its packaging;
 - insert the nozzle of the syringe into the port;
 - withdraw the reconstituted drug.

Delay in administration

- If the dose cannot be administered immediately for any reason, cover the needle with the cap using a one-hand scoop technique.
- Store the device safely in a dry kidney dish or similar container.

Important points

- DO NOT allow the needle to touch any contaminated surface.
- DO NOT reuse a syringe, even if the needle is changed.
- DO NOT touch the diaphragm after disinfection with the 60–70% alcohol (isopropyl alcohol or ethanol).
- DO NOT enter several multidose vials with the same needle and syringe.
- DO NOT re-enter a vial with a needle or syringe used on a patient if that vial will be used to withdraw medication again (whether it is for the same patient or for another patient).
- DO NOT use bags or bottles of intravenous solution as a common source of supply for multiple patients (except in pharmacies using laminar flow cabinets).



2.3 Prevention of sharps injuries to health workers

Use of best practices can help to prevent sharps injuries to health workers (31–33). Further information on this topic can be found in Chapter 4.

Practical guidance on prevention of sharps injuries

To avoid sharps injuries:

- ensure that the patient is adequately prepared for the procedure;
- do not bend, break, manipulate or manually remove needles before disposal;
- avoid recapping needles, but if a needle must be recapped, use a single-handed scoop technique;
- discard used sharps and glass ampoules immediately after use in the location where they were used, disposing of them into a robust sharps container that is leak and puncture resistant;
- place the sharps container within arm's reach (preferably in a secured area) to allow for easy disposal of sharps;
- seal and replace sharps container when the container is three quarters full.

2.4 Waste management

Use of sealed, puncture and leak-proof sharps containers helps to prevent access to used devices (24, 34).

Practical guidance on waste management

To ensure that waste is dealt with safely:

- transport and store sharps containers in a secure area before final disposal;
- close, seal and dispose of sharps containers when the containers are three quarters full; assign responsibility in written policy for monitoring the fill level of sharps containers and replacing them when three quarters full;
- discard waste that is not categorised as sharp or infectious in appropriate colour-coded bags;
- ensure that infectious waste bags and sharps containers are closed before they are transported for treatment or disposal.



3 Best practice in phlebotomy and blood collection

Phlebotomy is one of the most common invasive procedures in health care. This chapter outlines the risks associated with unsafe phlebotomy, and summarizes best practice in phlebotomy, with the aim of improving outcomes for health workers and patients. Institutions can use the principles given here to establish standing operating procedures (SOPs).

3.1 Potential effects of unsafe phlebotomy

Unsafe phlebotomy can cause adverse effects for patients; such effects are rare, but range from pain or bruising at the site of puncture, to fainting, nerve damage and haematoma. The adverse events that have been best documented are in blood transfusion services, where poor venepuncture practice or anatomical abnormality has resulted in haematoma and injury to anatomical structures in the vicinity of the needle entry (35).

Another issue for patients is that if a blood sample is poorly collected or destroyed during transportation, the results may be inaccurate and misleading to the clinician, or the patient may have to undergo the inconvenience of repeat testing (36).

Poor infection-control practices can lead to bacterial infection at the site where the needle was inserted into the skin (37).

Both patients and health workers can be exposed through phlebotomy to blood from other people, putting them at risk from bloodborne pathogens. These pathogens include (2, 5, 12, 14, 17, 23, 31):

- viruses, such as HBV, HCV and HIV;
- bacteria, such as syphilis;
- parasites, such as malaria.

An example of the spread of bloodborne pathogens through phlebotomy is the reporting of outbreaks of hepatitis B associated with the use of glucometers (devices used to determine blood glucose concentration) (38, 39).

Another issue for health workers is sharps injuries; these commonly occur between the use and disposal of a needle or similar device.

3.2 Background information on best practices in phlebotomy

Using best practices in phlebotomy reduces the risks to both patients and health workers. For example, the use of sharps protection devices and immediate disposal of the used syringe and needle as a single unit into a puncture-resistant sharps container (i.e. a safety container), markedly reduce needle-stick injuries and blood exposure among health workers (40).

In home-based care, phlebotomy can be made safer by improving sharps disposal, to minimize the risk of exposure to hollow-bore and venepuncture needles (41).

This section provides background information on phlebotomy, Sections 3.2.1–3.2.3 cover blood sampling, and Section 3.2.4 covers blood collection for transfusions.



Best practices in phlebotomy involve the following factors:

- *planning ahead* – this is the most important part of carrying out any procedure, and is usually done at the start of a phlebotomy session;
- *using an appropriate location* – the phlebotomist should work in a quiet, clean, well-lit area, whether working with outpatients or inpatients (see Section 3.3.1);
- *quality control* – this is an essential part of best practice in infection prevention and control; in phlebotomy, it helps to minimize the chance of a mishap;
- *standards for quality care for patients and health workers* – discussed in detail in Section 3.2.1.

Table 3.1 lists the main components of quality assurance and explains why they are important.

Table 3.1 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 awareness of 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 (42). |
| 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 the adverse events (43). |

3.2.1 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 include:

- availability of appropriate supplies and protective equipment;
- availability of PEP;
- avoidance of contaminated phlebotomy equipment;
- appropriate training in phlebotomy;
- cooperation on the part of patients.



3.2.2 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 to prevent haemolysis or abnormal results;
- the appropriate 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.

Each of these issues is discussed in detail in *WHO guidelines on drawing blood: best practices in phlebotomy* (44).

3.2.3 Blood-sampling systems

Several choices of blood-sampling system are available for phlebotomy.

- *Closed systems* – A hypodermic needle and syringe or a vacuum-extraction tube system are the closed systems most commonly used in blood sampling.
- *Open systems* – Open systems include a hypodermic needle and syringe, and a winged steel needle attached to a syringe.

Choice of system

The system most appropriate for the procedure should be chosen. Closed systems are safer than open systems (45, 46). Table 3.2 gives details of existing systems, and outlines the advantages and disadvantages of each device.

Table 3.2 Systems used for blood sampling

| Type of device | Advantages | Disadvantages |
|--|---|--|
| <i>Conventional devices</i> | | |
| Hypodermic single-use needle and syringe | <ul style="list-style-type: none"> • Widely available • Inexpensive • Comes in wide range of needle lengths and gauges • Use does not require special training • Can be safer for blood drawing in paediatric population • For patient with small or difficult veins, blood drawing can be easier • Can be used for arterial blood drawing | <ul style="list-style-type: none"> • Requires blood transfer, which creates additional risk of needle-stick injuries or blood splashing • Difficult to draw large or multiple blood samples • Can be reused • A smaller syringe and paediatric tube should be used for paediatric patients |
| Vacuum-tube systems | <ul style="list-style-type: none"> • Safer than using hypodermic needle and syringe because does not require 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 • Needle holders designed for reuse create additional risk of needle-stick injuries • Mixing components from different manufactures can create a problem • Paediatrics requires a reduced vacuum • Relatively high cost |



Table 3.2 *continued*

| Type of device | Advantages | Disadvantages |
|---|--|--|
| 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 and syringe | <p>Because of the air in the tubing, a tube without additive or a discard tube needs to be collected first</p> <p>The difference between winged steel needles for evacuated-tube systems and winged infusion sets can create confusion</p> <p>Relatively high cost</p> |
| Safety-engineered devices | | |
| <i>Passive</i> | | |
| Auto-disable syringes ^a NOT recommended for blood drawing | <ul style="list-style-type: none"> • NOT recommended for phlebotomy • If properly used, safety mechanism prevents reuse • Do not require activation of the safety mechanism | <ul style="list-style-type: none"> • During probing, safety mechanism can be activated, requiring new venepuncture • Requires blood transfer, which creates 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 • Additional training is necessary |
| Lancets | <ul style="list-style-type: none"> • Retractable | |
| <i>Active</i> | | |
| Manually retractable syringes | <ul style="list-style-type: none"> • Safety mechanism retracts the needle into the syringe reducing the hazard of needle-stick exposure and reuse | <ul style="list-style-type: none"> • Safety mechanism cannot be activated when syringe is full of blood or during the blood transfer • Requires user's compliance • Requires blood transfer, which creates risk of needle-stick injuries • Difficult to draw large or multiple blood samples • Relatively high cost |
| Self re-sheathing needles and syringes | <ul style="list-style-type: none"> • Sleeve moved over the needle provides guard around the used needle; this reduces the risk of needle-stick injury and prevents reuse | <ul style="list-style-type: none"> • Needle cannot be covered when syringe is full of blood or during blood transfer • Requires user's compliance • Additional training is necessary • Relatively high cost |
| Winged steel needles with active safety mechanism | <ul style="list-style-type: none"> • Needle locking mechanism helps to reduce the risk of needle-stick injury and prevents reuse • If syringe is used for blood drawing, blood can be transferred in a safer way | <ul style="list-style-type: none"> • If used in connection with vacuum tubes, because of the air in the tubing, a tube without additive or a discard tube needs to be collected first • Additional training is necessary • Relatively high cost |
| Manually retractable evacuated tube systems | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • Requires skill in its use • Needle holders designed for reuse create risk of needle-stick injuries • Mixing components from different manufactures can create a problem • Vacuum may be too strong for paediatric patients • Additional training is necessary • Relatively high cost |

^a Auto-disable syringes DO NOT prevent needle-stick injuries, and put both patient and worker at risk if used for phlebotomy. Therefore, they are NOT recommended for blood drawing.



Choice of gauge

It is best to choose the gauge of hypodermic needle that fits comfortably into the most prominent vein with little discomfort. Table 3.3 summarizes advice on appropriate gauge, length and device.

Table 3.3 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.

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.

3.2.4 Blood collection for blood transfusion purposes

Collection of large volumes of blood is an everyday practice in blood transfusion services. The donated blood is tested, and processed to ensure that it is free from major infections that are transmissible by transfusion, therefore ensuring that it will not harm the recipient of the blood.

Before a blood donation

WHO has developed a set of basic requirements for blood transfusion services, which cover the steps to be undertaken before donation (47). 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 (48):

- 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) (49, 50);
 - 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 undertaken, 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 (51);
- the person should provide informed written consent, based on the national requirements.

Collection systems – minimum requirements

The relevant guidance given on planning, location and infection prevention and control practices should be followed, as should the guidance on closed systems. Additional requirements for a collection system for blood donation are given 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 integral 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 (52). 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 sharps container (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.



3.3 Practical guidance on best practices in phlebotomy

This section provides practical guidance – Sections 3.3.1–3.3.3 cover blood sampling, and Sections 3.3.4–3.3.6 cover blood donation.

3.3.1 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 handwash 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:
 - close the bed curtain to offer privacy;
 - ensure that blood sampling is done in a private and clean manner.

3.3.2 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) (36, 53).

3.3.3 Procedure for drawing blood

At all times, follow the strategies for infection prevention and control listed in Table 2.4, in Section 2.1.5.

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;
 - 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 the 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, 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 and obtain verbal consent, as shown in Annex F of *WHO guidelines on drawing blood: best practices in phlebotomy* (44). 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.

Step 3 – Select the site

Illustrations to accompany these guidelines are given in Figure 3.1 in Section 3.4, at the end of this chapter.

General

- Extend the patient's arm and inspect the antecubital fossa or forearm.
- Locate a vein of good size that is visible, straight and clear. The diagram in Section 3.4 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 (54). 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:
 - 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 blood collection, clean the site with a 70% alcohol swab and allow to dry (27–29, 36).

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 (55, 56).
- 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 for 30 seconds.
- Allow the area to dry for at least 30 seconds. 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 lab 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, to reduce the risk of haemolysis (to reduce the risk of haemolysis when transferring blood through a needle on a syringe, minimize the pressure and velocity used to transfer the specimen). 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).

See Figure 3.2 in Section 3.4.

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. Details of the recommended order are given in *WHO guidelines on drawing blood: best practices in phlebotomy (44)*.

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 name, 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 in step 4.
- 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. Place the requisition on the outside to help 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. Leave the area wet for 10 minutes.
- For surfaces that may be corroded or discoloured by a strong bleach solution, clean carefully to remove all visible stains. Make a weaker solution and leave it in contact for more than 10 minutes. 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 (see Section 4.3 for details of how to manage exposures to infectious materials). For transportation of blood samples outside a hospital, equip the transportation vehicle with a blood spillage kit (for details, see *WHO guidelines on drawing blood: best practices in phlebotomy* (44)).

3.3.4 Collecting blood for blood donation

For collection of blood for donation, use the procedure detailed above 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):
 - cover the whole area with 2% chlorhexidine gluconate in 70% isopropyl alcohol 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 disinfectant is not available, use the following procedure – takes about two minutes):
 - *step 1* – cover the whole area with 70% isopropyl alcohol 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* – cover the whole area with tincture of iodine (more effective than povidine iodine) or 2% chlorhexidine) and ensure that the skin area is in contact with the disinfectant for **at least 30 seconds**;
 - allow the area to dry **completely** for 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 3.3.3. Take into account the points given below, which are specific to blood donation.

- In general, use a 16-gauge needle (see Table 3.3), 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).
- 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, pallor 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.

3.3.5 After a blood donation

Donor care

Once 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

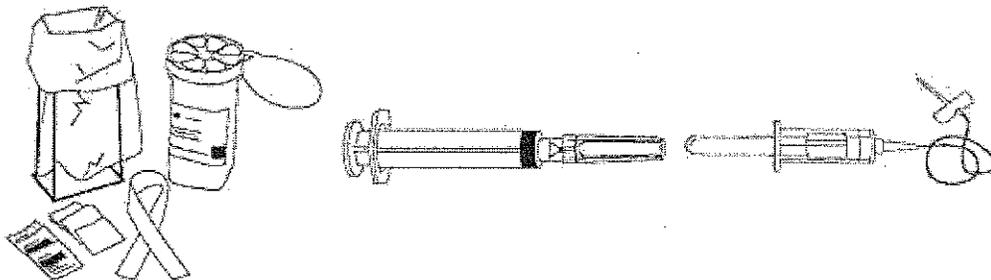
- Transfer the blood unit to a proper storage container according to the blood centre requirements and the product (57–59).
- Ensure that collected blood samples are stored and delivered to the laboratory with completed documentation, at the recommended temperature and in a leak-proof, closed container (57, 59, 60).

3.3.6 Adverse events in blood donation

Be aware of possible adverse events, and the actions to take if these occur. The document *WHO guidelines on drawing blood: best practices in phlebotomy* (44) provides details of possible adverse reactions and their prevention. The most frequent adverse events include haematoma, a vasovagal reaction or faint, and a delayed faint.

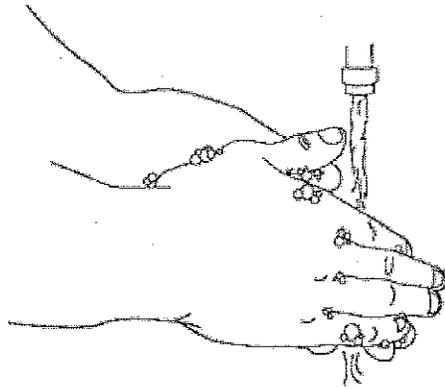
3.4 Illustrations for best practices in phlebotomy

Figure 3.1 Venepuncture in adults

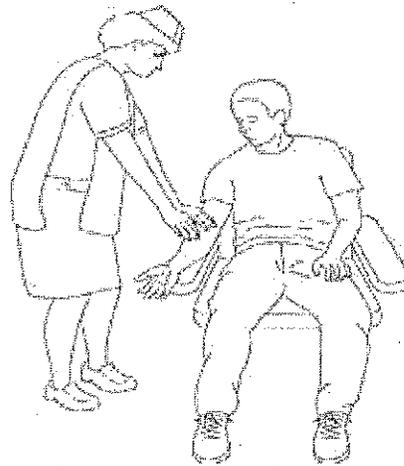


1. Assemble equipment, and include needle and syringe or vacuum tube, depending on which is to be used.

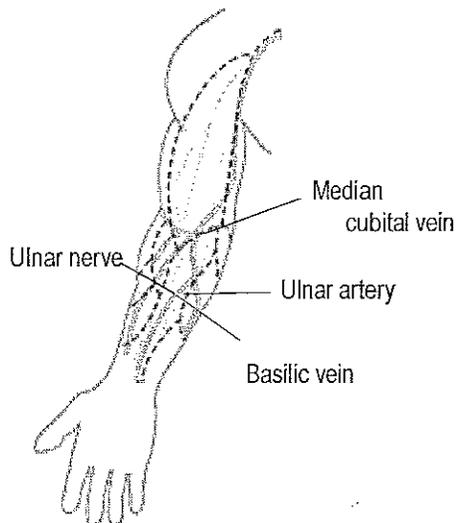




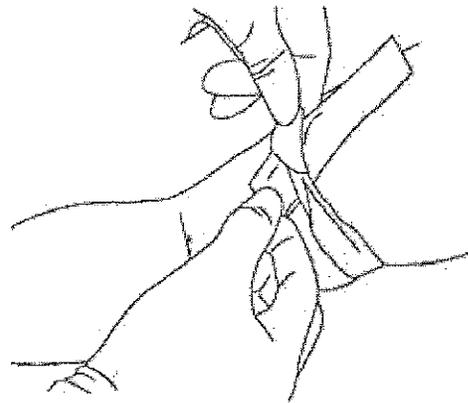
2. Perform hand hygiene (if using soap and water, dry hands with single-use towels).



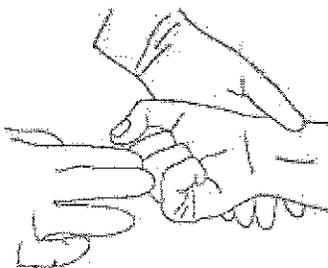
3. Identify and prepare the patient.



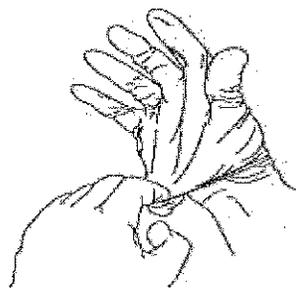
4. Select the site, preferably at the antecubital area (i.e. the bend of the elbow). Warming the arm with a hot pack, or hanging the hand down may make it easier to see the veins. Palpate the area to locate the anatomic landmarks. **DO NOT** touch the site once alcohol or other antiseptic has been applied.



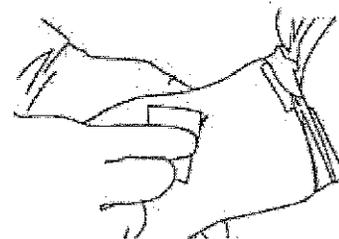
5. Apply a tourniquet, about 4–5 finger widths above the selected venepuncture site.



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

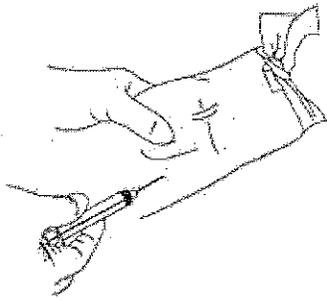


7. Put on well-fitting, non-sterile gloves.

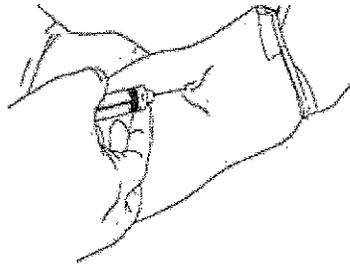


8. Disinfect the site using 70% isopropyl alcohol for 30 seconds and allow to dry completely (30 seconds).

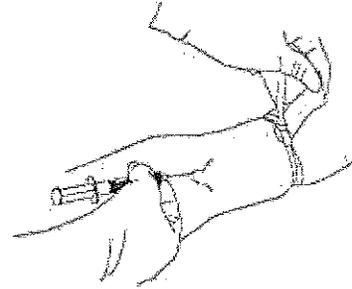




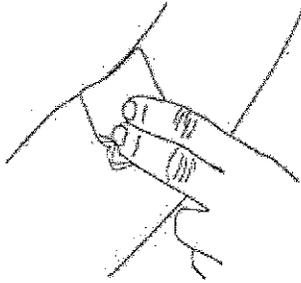
9. Anchor the vein by holding the patient's arm and placing a thumb **BELOW** the venepuncture site.



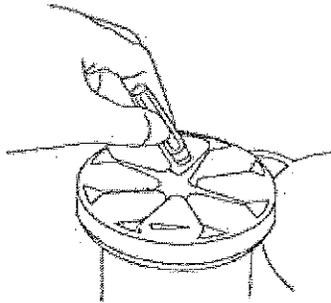
10. Enter the vein swiftly at a 30 degree angle.



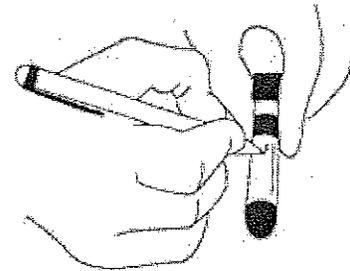
11. Once sufficient blood has been collected, release the tourniquet **BEFORE** withdrawing the needle.



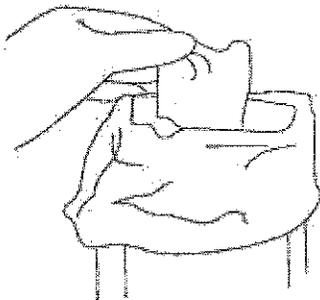
12. Withdraw the needle gently and then give the patient a clean gauze or dry cotton-wool ball to apply to the site with gentle pressure.



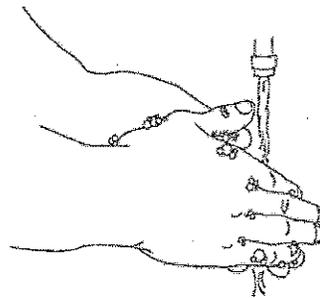
13. Discard the used needle and syringe or blood-sampling device into a puncture-resistant container.



14. Check the label and forms for accuracy.



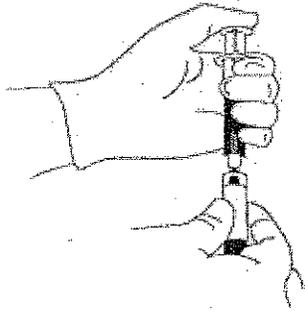
15. Discard sharps and broken glass into the sharps container. Place items that can drip blood or body fluids into the infectious waste.



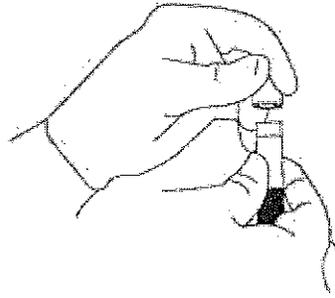
16. Remove gloves and place them in the general waste. Perform hand hygiene. If using soap and water, dry hands with single-use towels.



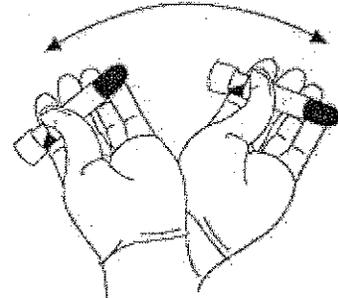
Figure 3.2 Filling tubes



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.



4 Occupational risks and management of bloodborne pathogens

Preventing occupational exposure to and infection from bloodborne pathogens is a key element of infection safety. Thus, such prevention is an important part of any comprehensive programme for protecting health workers and patients.

The main interventions that are needed to prevent exposure and infection are:

- basic occupational health care, including immunization and awareness of current health status;
- prevention of needle-stick injuries and other blood exposures;
- management of exposures to blood; this includes PEP.

Each of these interventions is discussed below.

4.1 Basic occupational health care

4.1.1 Immunization against hepatitis B

WHO considers universal immunization to be the most effective preventive measure against diseases induced by infection with hepatitis B. Strategies include:

- integration of hepatitis B vaccine (HepB) into routine infant immunization programmes (13, 61);
- provision of a HepB dose at birth to prevent perinatal transmission (13, 61);
- vaccination of those at risk, including health workers (with a catch-up vaccination).

All health workers – including waste disposal workers, and emergency and safety workers exposed to the risk of bloodborne pathogens – are at risk of exposure. They should be immunized either before training or as soon as possible when at work, unless they are already immunized (15).

The World Health Assembly has resolved that all health workers should be protected from infection with HBV by receiving immunization for hepatitis B early in their careers (15).

Vaccines are widely available that are safe, cost effective and meet the current WHO quality requirements (13).

Routine immunization of health workers against infection with HBV is recommended.

- Pre-vaccination serological testing is unnecessary.
- Many different schedules are available. A schedule including three doses at 0, 1 and 6 months is highly effective; it provides long-term protection in most individuals. The usual adult dose is 1.0 ml (twice the monovalent paediatric dose of 0.5 ml) and the vaccine is administered intramuscularly.
- Serological testing at 2–6 months after the third dose of HBV vaccine can demonstrate whether an antibody response has developed against hepatitis B surface antigen (62).



4.1.2 Testing for HBV, HCV and HIV

All health workers should have access to the tests available for HBV, HCV and HIV infection. If they know their own status for these infections, health workers can access treatment and care if necessary. Also, in cases of exposure to HBV, HCV or HIV, test results provide baseline information on immune status; this is critical for the safe and efficient management of the post-exposure procedures available for hepatitis B and HIV.

Any testing should be undertaken in conditions that respect the worker's rights and is based on informed consent. These conditions are described in guidelines developed by the International Labour Organization and WHO, on health services and HIV/AIDS (63).

4.2 Prevention of needle-stick injuries and other blood exposures using a hierarchy of controls

Methods used to control occupational hazards have traditionally been discussed in terms of a hierarchy and presented in order of priority. A hierarchy of controls to prevent needle-stick injuries and other blood exposures is given below by order of effectiveness (most effective first) (64, 65).

- *Elimination of hazard* – Complete removal of a hazard from the work area is the most effective way to control hazards; this approach should be used whenever possible. Examples include (24, 66):
 - removing sharps and needles when possible (e.g. by substituting jet injectors for needles and syringes, or using needleless intravenous systems);
 - eliminating all unnecessary injections;
 - eliminating unnecessary sharps such as towel clips.
- *Engineering controls* – These are used to isolate or remove a hazard from a workplace. Examples include (33, 67–69):
 - sharps disposal containers;
 - when possible, use of sharps protection devices for all procedures (devices with needles that retract, sheathe or blunt immediately after use).
- *Administrative controls* – These are policies, such as SOPs, which aim to limit exposure to the hazard. Examples include (1, 62):
 - allocation of resources demonstrating a commitment to health-worker safety;
 - a needle-stick injury prevention committee;
 - an exposure control plan;
 - removal of all unsafe devices;
 - consistent training on the use of safe devices.
- *Work practice controls* – These are controls to change the behaviour of workers, to reduce exposure to occupational hazards. Examples include (1, 62):
 - no needle recapping;
 - placing sharps containers at eye level and within arms' reach;
 - sealing and discarding sharps containers when they are three quarters full;
 - establishing means for the safe handling and disposal of sharps devices before beginning a procedure.



- *Personal protective equipment* – These provide barriers and filters between the worker and the hazard. They will prevent exposures to blood splashes but will not prevent needle-stick injuries (34, 70, 71). Examples include eye goggles, gloves, masks and gowns.

4.3 Overview of management of exposure to blood

This section discusses management of occupational exposure to blood and other potentially infectious material. The exposure can occur through needle-stick and sharp injuries, and from splashes contaminated with blood or body fluids. Management includes first aid, risk assessment, notification and reporting for HBV, HCV and HIV, and provision of PEP. The prophylaxis should be administered as soon after exposure as possible; it entails medical evaluation, follow-up care and prevention, and is specific to the etiologic agent involved (43).

The risks of transmission of infection from an infected patient to the health worker following a needle-stick injury are estimated to be (6):

- hepatitis B – 3–10% (up to 30%);
- hepatitis C – 0.8–3%;
- HIV – 0.3% (mucous membrane exposure risk is 0.1%).

Factors that can increase the risk of transmission of HIV include a deep wound, visible blood on the device, a hollow-bore blood-filled needle, use of the device to access an artery or vein, and high-viral-load status of the patient (6, 63). Together, these factors can increase the risk of transmission of HIV from a contaminated sharp to 5%.

The box below summarizes the steps to take in case of occupational exposure to blood. The management of exposure to specific agents (HBV, HCV and HIV) is discussed in detail below. In all cases, the person who has been exposed to potentially infectious material should be counseled; where PEP is available, the counselling should include the decision on whether or not to take PEP.

Box 4.1 Steps to take in cases of occupational exposure to blood

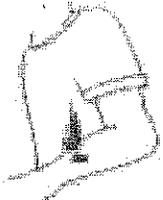
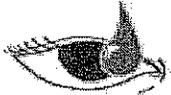
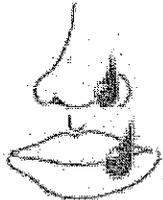
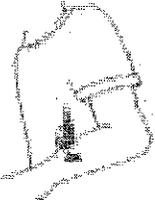
1. Apply first aid care, as appropriate (see Section 4.3.1, below).
2. Notify a supervisor. The health-care worker should report immediately to the medical services and seek advice on the need for PEP for HIV and HBV.
3. Carry out an immediate medical evaluation, including a risk assessment and follow-up care (e.g. counseling and PEP) as appropriate.
4. Complete an exposure form documenting the circumstance and report the exposure in the needle stick injury surveillance system.



4.3.1 First aid

The first aid given is based on the type of exposure (e.g. splash, needle-stick or other injury) and the means of exposure (e.g. intact skin, nonintact skin) (14, 72). Table 4.1 shows the first aid to apply in different situations.

Table 4.1 First-aid care of the exposure site

| Injury or exposure | Management |
|--|--|
| Needle-stick or other sharps injury  | Immediately wash the affected area with soap and water Allow injury to bleed freely |
| Splash of blood and/or body fluids on nonintact skin  | <ol style="list-style-type: none"> 1. Immediately wash the affected area with soap and water 2. DO NOT use disinfectant on skin 3. DO NOT scrub or rub the area |
| Splash of blood or body fluids to eyes  | Flush the area gently but thoroughly with running water or saline for at least 15 minutes while the eyes are open Keep eyelid gently inverted |
| Splash of blood or body fluids to mouth or nose  | <ol style="list-style-type: none"> 1. Immediately spit out the blood or fluids and rinse the mouth with water several times 2. Blow the nose and clean the affected area with water or saline 3. DO NOT use disinfectant |
| Splash of blood and/or body fluids on intact skin  | Immediately wash the affected area with soap and water DO NOT rub the area |



4.3.2 Notification

The health-care worker should report immediately to the medical services and seek advice on the need for PEP for HIV and HBV.

4.3.3 Risk assessment

In managing exposure, the first step is to carry out an immediate medical evaluation, including a risk assessment (72).

To assess the risk of transmission from the exposure:

- determine the risk associated with the exposure by considering the
 - type of fluid (e.g. blood, visibly bloody fluid, other potentially infectious fluid or tissue and concentrated virus);
 - type of exposure (i.e. percutaneous injury, mucous membrane or nonintact skin exposure and bites resulting in blood exposure);
- evaluate the risk associated with the exposure sources by
 - assessing the risk of infection for all bloodborne pathogens using available information (e.g. interview, medical records);
 - perform tests on the source person based on informed consent, but DO NOT test discarded needles or syringes for virus contamination;
- combine the results to evaluate the risk to the exposed person.

Ensure that only a suitably trained person performs the medical evaluation, risk assessment and prescription of PEP.

Where logistic reasons (e.g. testing facilities not being readily available) make it difficult to evaluate the immune status of the person exposed, it may be useful to withdraw and store a blood sample, to help in obtaining baseline information. However, only do this if the exposed person gives informed consent.

Give PEP, even if test results are not yet available.

4.4 Evaluation and management of exposure to HBV

4.4.1 Risk of transmission of HBV

The risk of transmission of HBV is higher than that for HCV or HIV. Among susceptible health workers, the risk of HBV infection after a needle-stick injury involving an HBV-positive source is 23–62% (6, 14).



4.4.2 Management of HBV exposure

PEP for HBV can be highly effective in preventing transmission of the virus after exposure. PEP for HBV is based on the hepatitis B vaccine, either alone or combined with hepatitis B immune globulin (HBIG).

- For PEP to be effective, the initial dose of vaccine must be administered soon after exposure; the longer the gap between exposure and administration of the vaccine, the less effective the PEP.
- Few studies have researched the maximum time after exposure during which PEP is effective, but it is likely to be less than seven days for needle-stick exposures (14).

The steps to take after HBV exposure are to:

- evaluate the exposed person for HBV – assess the person's immunization status for hepatitis B (i.e. by taking their history of hepatitis B vaccination);
- administer HBV PEP for exposures that pose a risk of infection transmission.

WHO has no specific guidelines for HBV PEP; however, it does recommend HBV PEP (73). This document refers to the CDC guidelines (14). As shown in Table 4.2, the regimen recommended for HBV PEP depends on the vaccination status of the exposed person. HBV PEP is safe for pregnant and lactating women.

Table 4.2 Hepatitis B post-exposure prophylaxis and immunization follow-up in occupational settings

| Source of exposure | Action according to vaccination status | |
|---------------------------------|---|------------------------------|
| | Unvaccinated or incompletely vaccinated (< 3 doses) | Vaccinated (3 or more doses) |
| Unknown or hepatitis B positive | Initiate and complete vaccination Give hepatitis B immune globulin (where available) | No PEP |
| Negative | Initiate and complete vaccination | No PEP |

PEP, post-exposure prophylaxis.

4.4.3 Follow-up of HBV exposure

Perform follow-up testing for antibodies to hepatitis B in individuals who receive hepatitis B vaccine in response to an exposure. The recommendation is to test for antibodies 1–2 months after the last dose of vaccine. However, if the person received hepatitis B immune globulin in the previous 3–4 months, it is not possible to use the test for antibodies to hepatitis B to determine the response to the vaccine.

4.5 Evaluation and management of exposure to HCV

4.5.1 Risk of transmission of HCV

The risk of transmission of HCV is relatively low. The seroconversion rate after accidental percutaneous exposure from an HCV-positive source is 1.8% (range: 0–7%), and one study indicated that transmission occurred only from hollow-bore needles. HCV is rarely transmitted from exposure of mucous membranes or nonintact skin to contaminated blood (14, 16).



4.5.2 Management of exposure to HCV

There is no recommended PEP for exposure to HCV-positive blood. Immunoglobulin and antiviral agents are not recommended as PEP, and there is no vaccine against HCV. Instead, the procedure is to identify infection as soon as possible and refer the person for evaluation of treatment options.

There are no guidelines for administration of therapy during the acute phase of hepatitis C. However, a few studies suggest that antiviral therapy might be beneficial when started early in the course of the infection.

The steps to take after HCV exposure are simply to perform baseline testing for antibodies to HCV and for alanine aminotransferase (ALT).

4.5.3 Follow-up of HCV exposure

Perform follow-up testing for individuals potentially exposed to HCV.

- Test for anti-HCV and ALT 4–6 months after exposure.
- Test for HCV ribonucleic acid (RNA) at 4–6 weeks if early diagnosis of HCV infection is desired.
- Confirm repeatedly positive results in anti-HCV enzyme immunoassays (EIAs) with supplemental tests.

If an individual has seroconverted, refer the person to a specialist.

4.6 Management of exposure to HIV

4.6.1 Risk of transmission of HIV

The risk of acquiring HIV infection following an exposure through the skin (i.e. percutaneous) to blood known to be infected with HIV is approximately 0.3% (14). This figure is derived from studies carried out in well-resourced countries with a low background prevalence of HIV. The risk may be greater in countries with higher prevalence or in settings that have limited resources, where the reuse of medical supplies and equipment is higher and overall safety standards are lower.

4.6.2 Management of exposure to HIV

Refer the person exposed to the risk of transmission to a trained person for medical evaluation, risk assessment and prescription of PEP. The decision on whether or not to take PEP should be based on the recommendations shown in Tables 4.3 and 4.4, appropriate information, and counselling on adherence and on the possible adverse reactions to the antiretroviral drugs.



Table 4.3 HIV post-exposure prophylaxis following occupational exposure

| PEP recommended | PEP not recommended |
|--|---|
| <p>PEP is recommended if exposure meets ALL the following criteria:</p> <ul style="list-style-type: none"> • exposure within 72 hours • exposed individual not known to be HIV-infected • source of exposure is HIV-infected or of unknown status • exposure was to one or more of the following <ul style="list-style-type: none"> – blood – body tissues – visibly blood-stained fluid – concentrated virus – cerebrospinal fluid – synovial fluid – pleural fluid – peritoneal fluid – pericardial fluid – amniotic fluid • exposure was through one or more of the following <ul style="list-style-type: none"> – skin penetration with spontaneous bleeding or deep puncture – splash of significant amount of fluid to mucous membrane – prolonged contact of an at-risk substance with nonintact skin • if skin penetration occurred, exposure was from a recently used hollow-bore needle or other sharp object visibly contaminated with blood. | <p>PEP is not recommended if ANY of the following conditions apply:</p> <ul style="list-style-type: none"> • more than 72 hours has elapsed since the exposure • exposed person is already HIV positive • exposure was to body fluids from a person known to be HIV negative (unless this person is identified as at high risk for being recently infected and is within the "window period"^a) • exposure is to noninfectious body fluids (e.g. faeces, saliva, urine or sweat) • exposure does NOT pose a risk of transmission, because <ul style="list-style-type: none"> – only intact skin was exposed to potentially infectious body fluids; – the exposed person is already HIV positive. |

HIV, human immunodeficiency virus; PEP, post-exposure prophylaxis.

^a The window period is the time between the onset of HIV infection and the appearance of detectable antibodies to the virus.

Table 4.4 Evaluation of risk of HIV infection

| Exposure type | HIV status of source | | |
|--|---|---|---|
| | Positive | Unknown | Negative |
| Percutaneous: more severe^a | Recommend two-drug regimen ^b | Consider HIV prevalence in population or subgroup | DO NOT recommend PEP provided there is NO risk that the source person might be in window period |
| Percutaneous: less severe^c | Recommend two-drug regimen ^b | DO NOT recommend PEP | DO NOT recommend PEP |
| Splash^d: more severe^a | Recommend two-drug regimen ^b | Consider HIV prevalence in population or subgroup | DO NOT recommend PEP provided there is no risk that the source person might be in window period |
| Splash: less severe^f | DO NOT recommend PEP. Two-drug regimen optional | DO NOT recommend PEP | DO NOT recommend PEP |

HIV, human immunodeficiency virus; PEP, post-exposure prophylaxis.

^a Injury with large hollow-bore needle, deep puncture, visible blood on device, needle used in artery or vein.

^b In cases where the source person is known to be HIV positive with drug resistance or in settings where the drug resistant HIV prevalence is above 15%, a three-drug regimen with the addition of a protease inhibitor is recommended.

^c Injury with small bore or solid needle, superficial injury.

^d Exposure to nongenital mucous membrane, or nonintact skin exposures.

^e Exposure to large volume of blood or semen.

^f Exposure to smaller volume, or to less infectious fluid (e. g. cerebrospinal fluid) (74, 75).



Testing and counselling

For people potentially exposed to HIV, testing is highly recommended but should never be mandatory (76).

- If testing is available, offer a test, but ensure that the person receives appropriate counseling, with the option to opt out of testing.
- Where possible, also test the source patient, with that person's informed consent.
- DO NOT delay the administration of antiretroviral drugs for PEP while waiting for test results.
- If the test results of the source person are negative, consider stopping PEP.

Issues to raise in PEP counselling include:

- the importance of treatment adherence;
- the importance of HIV prevention in general and at the workplace;
- recommendations on the use of condoms and the avoidance of donating blood, sperm or organs until a test at 6 months after exposure is negative;
- information on contraception for women of childbearing age;
- information on alternatives to breastfeeding for lactating mothers.

Administration of PEP

Do not administer PEP to a person who is HIV positive, because PEP generally includes only two drugs to be taken for only 28 days, and is thus not a treatment for HIV infection. HIV treatment is based on a combination of three antiretroviral drugs taken continuously. If desired, it is acceptable to administer antiretroviral drugs for PEP, and to stop the treatment if the exposed person is found to be HIV positive.

In situations where PEP is required:

- administer the antiretroviral drugs for PEP as soon as possible after the exposure (ideally within 4 hours);
- continue the PEP regimen continuously for 28 days;
- use the two-drug regimen (recommended by WHO) unless there is suspicion or evidence of drug resistance, or unless there are national guidelines on choice of PEP regimen (in which case, follow these in preference);
- evaluate the person taking PEP within 72 hours, to monitor for possible adverse drug reactions and adherence, and follow-up (as described below) for at least two weeks.

HIV PEP standard drug regimen

Table 4.5 shows the WHO recommended two-drug combination therapies for PEP for HIV exposure.

As explained above, in cases where the source person is known to be HIV positive with drug resistance, or in settings where the drug resistant HIV prevalence is above 15%, a three-drug regimen with the addition of a protease inhibitor is recommended. Possible regimens are given in Table 4.6.



Table 4.5 WHO recommended two-drug regimens for HIV post-exposure prophylaxis

| Preferred regimens | Alternative regimen |
|--------------------|---------------------------|
| 1. ZDV + 3TC | 1. TDF + 3TC ^a |
| 2. d4T + 3TC | |

3TC, lamivudine; d4T, stavudine; TDF, tenofovir; WHO, World Health Organization; ZDV, zidovudine.

^a Prescribed in fixed dose combination tablets where possible.

Table 4.6 WHO recommended three-drug regimens for HIV post-exposure prophylaxis

| Preferred regimens | Alternative regimens |
|-------------------------|---|
| 1. ZDV + 3TC plus LPV/r | 1. ZDV + 3TC plus SQV/r or ATV/r or FPV/r |
| | 2. TDF + 3TC plus SQV/r or ATV/r or FPV/r |
| | 3. TDF + FTC plus SQV/r or ATV/r or FPV/r |
| | 4. (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, saquinavir/ritonavir; TDF, tenofovir; WHO, World Health Organization; ZDV, zidovudine.

When giving PEP:

- DO NOT prescribe certain combinations of medication (e.g. didanosine + stavudine) for women of childbearing age unless a pregnancy test is negative;
- DO NOT prescribe non-nucleoside reverse transcriptase inhibitors for PEP;
- ensure that lactating women are aware that antiretroviral drugs are present in breast milk and that the virus itself could be transmitted through breastfeeding;
- when and where alternatives to breastfeeding are feasible, discuss this with the mother.

4.6.3 Follow-up of HIV exposure

An exposed health worker should seek or be referred for medical follow-up (77):

- The aim of follow-up visits is to:
 - support adherence to PEP;
 - prevent or treat side effects of PEP;
 - identify a possible seroconversion.
- Test for HIV antibodies at baseline, 6 weeks and 6 months after exposure.
- Test for HIV antibodies if illness compatible with an acute retroviral syndrome occurs.
- Repeat the test for HIV antibodies at 6 weeks and 6 months after exposure; if seroconversion occurs, refer the exposed person for treatment, care and support.
- Advise anyone who has been exposed to use precautions to prevent secondary transmission during the follow-up period; such precautions include:
 - avoiding pregnancy;
 - seeking safe alternatives to breastfeeding;
 - avoiding blood, tissue or sperm donation, and using condoms for sexual intercourse until a test at 6 months shows that the exposed person remains seronegative.
- Evaluate individuals taking PEP within 72 hours, to monitor for possible adverse drug reactions and treatment adherence. Follow up for at least two weeks.



Reporting of HIV exposure

Reporting of the incident should lead to the evaluation of the safety of working conditions and appropriate measures when relevant. All reports should be strictly confidential.

Prompt reporting of exposures is important to:

- ensure timely and appropriate PEP and follow-up;
- provide information useful for future prevention; for example, information about the circumstances of the exposure can be used to evaluate the occupational health programme and make recommendations for changes in products, practices and policies;
- document the injury in the case of seroconversion;
- monitor the frequency of needle-stick injuries and exposure events by person, place and time, as part of occupational exposure surveillance.

The data collected are of two kinds:

- data for risk assessment and post-exposure management;
- data that describe the circumstances of the exposure; these are used for making recommendations for future prevention.



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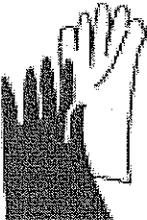
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Annex A: Indications for glove use in health care

| Key elements | Indications | Precautions |
|--|--|---|
| <p>Glove use</p>  | <p>Wear non-sterile, well-fitting, single-use gloves:</p> <ul style="list-style-type: none"> • when handling potentially infectious materials or when coming into contact with contaminated items and surfaces • when there is a likelihood of coming into direct contact with a patient's blood or other potentially infectious materials (e.g. body fluids, moist body substances and saliva [in dental procedures]), mucous membranes and nonintact skin • when performing venepuncture or venous access injections, because of the potential for blood exposure at the puncture site • if the health worker's skin is NOT intact (e.g. through eczema, or cracked or dry skin) • if the patient's skin is NOT intact (e.g. through eczema, burns or skin infections). <p>Change gloves:</p> <ul style="list-style-type: none"> • between tasks and procedures on the same patient, and after contact with material that may contain a high concentration of microorganisms • during a procedure if gloves become visibly soiled, torn or punctured • after contact with each patient. <p>After treatment is complete, and before leaving areas of patient-care activity:</p> <ul style="list-style-type: none"> • remove gloves promptly and discard • perform hand hygiene immediately after removing and discarding gloves. <p>Gloves DO NOT replace the need for hand hygiene.</p> <p>Wear sterile gloves ONLY for procedures where an aseptic technique is required (e.g. intravascular infusion and devices).</p> | <p>When undertaking injections, DO NOT use gloves:</p> <ul style="list-style-type: none"> • for routine intradermal, subcutaneous and intramuscular injections • if the health worker's skin is intact • if the patient's skin is intact. <p>Natural rubber latex allergy is a serious and life threatening condition that affects 8–12% of regular users of natural rubber latex gloves. Health workers and patients with an allergy to natural rubber latex must NOT come into contact with any latex products. Health workers with an allergy should use gloves made from synthetic material.</p> <p>Health workers must NOT:</p> <ul style="list-style-type: none"> • wash or decontaminate gloves for reuse • wear gloves <ul style="list-style-type: none"> – away from the bedside or laboratory bench – at nursing stations to handle phones or charts – to handle clean linen – to clean equipment or patient-care supplies – in hallways or elevators. <p>Gloves DO NOT provide protection against needle-stick or other puncture wounds caused by sharp objects. Needles, scalpels and other sharps should be handled with extreme caution.</p> |



Annex B: 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 afterwards 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 it or by 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.



Glossary

Abscess

A collection of pus (dead neutrophils) that has accumulated in a cavity formed by the tissue on the basis of an infectious process (usually caused by bacteria or parasites) or other foreign materials (e.g. splinters, bullet wounds or injecting needles). It is a defensive reaction of the tissue to prevent the spread of infectious materials to other parts of the body.

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.

Antigen (or immunogen)

Any substance that can be recognized by the adaptive immune system and prompt an immune response.

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 antisepsis 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.



Colour coding

Designation of different colours for the storage of different categories of health-care wastes.

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.

Decontamination

The process of removing pathogenic microorganisms from objects and equipment to make them safe to handle.

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.

Elimination of hazard

Administration of medications by ways other than injection (e. g. use of tablets, inhalers).

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.

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.

Hepatitis D infection

Hepatitis caused by the hepatitis D virus (HDV), a defective virus that needs HBV to exist. HDV is found in the blood of persons infected with the hepatitis B virus.



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;
- use of personal protective equipment.

See also fact sheet 4 of the *Joint ILO/WHO guidelines on health services and HIV/AIDS (77)* 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.

Intravascular

Within a blood vessel.

Intravenous injection

An injection given into a vein.

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 unfixed 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 such as subcutaneous, intramuscular, intravenous or arterial routes, through such events as injections, needle-sticks, cuts or abrasions.

Pathogen

A microorganism capable of causing disease.

Personal protective equipment (PPE)

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

Phlebotomy

The act of drawing or removing blood from the circulatory system through an incision or puncture in order 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.

Proteinaceous

Relating to or of the nature of protein.

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 devices

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.

Syringes with reuse prevention features

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.



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K.S.A. 65-1635

Chapter 65. — Public Health
Article 16. — Regulation of Pharmacists

65-1635. Dispensing and administering of drugs by duly licensed practitioners, nurses and other persons. (a) Nothing contained in the pharmacy act of the state of Kansas shall prohibit any duly licensed practitioner from purchasing and keeping drugs, from compounding prescriptions or from administering, supplying or dispensing to such practitioner's patients such drugs as may be fit, proper and necessary. Except as provided in subsection (b) or (c), such drugs shall be dispensed by such practitioner and shall comply with the Kansas food, drug and cosmetic act and be subject to inspection as provided by law.

(b) Nothing contained in the pharmacy act of the state of Kansas shall be construed to prohibit any nurse or other person, acting under the direction of a duly licensed practitioner, from administering drugs to a patient.

(c) Nothing contained in the pharmacy act of the state of Kansas shall be construed to prohibit any registered nurse, acting under the supervision of a person who is licensed to practice medicine and surgery as of July 1, 1982, from dispensing drugs to patients of such person so long as the principal office of such person is, and as of July 1, 1982, was, located in a city not having a registered pharmacy within its boundaries. For the purposes of this subsection (c), "supervision" means guidance and direction of the dispensing of drugs by the person licensed to practice medicine and surgery who shall be physically present in the general location at which the drugs are being dispensed.

(d) Nothing contained in the pharmacy act of the state of Kansas shall be construed to prohibit a duly registered wholesaler from distributing a prescription-only drug pursuant to a veterinarian practitioner's written prescription or order, where a valid veterinarian-client-patient relationship, VCPR, as defined in K.S.A. 47-816, and amendments thereto, exists, to the layman responsible for the control of the animal.

History: L. 1953, ch. 290, § 21; L. 1975, ch. 319, §21; L. 1982, ch. 262, § 6; L. 1982, ch. 263, § 6; L. 1983, ch. 210, § 1; L. 1997, ch. 2, § 1; L. 1999, ch. 38, § 4; July 1.

**DISPENSING PHYSICIANS
K.A.R. ARTICLE 21**

ARTICLE 21.--DISPENSING PHYSICIANS

- 100-21-1. Definition of dispensing physician.
- 100-21-2. Drug label.
- 100-21-3. Packaging.
- 100-21-4. Record keeping and inventories.
- 100-21-5. Storage and security.

100-21-1. Definition of dispensing physician.

"Dispensing physician" means a person licensed to practice medicine and surgery who purchases and keeps drugs and compounds his or her own prescriptions for the purpose of supplying such drugs to his or her patients.

(Authorized by K.S.A. 65-2865; effective, E-81-11, May 14, 1980; effective May 1, 1981.)

100-21-2. Drug label.

A dispensing physician shall clearly label each drug dispensed. The label shall be typed or machine printed and shall include the following:

- a. The name, address and telephone number of the dispensing physician.
- b. The full name of the patient.
- c. The identification number assigned to the prescription order by the dispensing physician.
- d. The date the prescription was filled or refilled.
- e. Adequate directions for use.
- f. The expiration date of the drug dispensed, if applicable.
- g. The brand name or corresponding generic name and manufacturer or distributors name and the strength, at the discretion of the physician.

(Authorized by K.S.A. 65-2865; effective, E-81-11, May 14, 1980; effective May 1, 1981.)

100-21-3. Packaging.

All oral medications shall be dispensed in child resistant containers in accordance with the poison prevention packaging act of 1970 and in light resistant air-tight containers as required by the United States pharmacopeia. In those cases where a bona fide circumstance exists to make it undesirable to use safety closures, medication may be dispensed in a nonchild resistant container.

(Authorized by K.S.A. 65-2865; effective, E-81-11, May 14, 1980; effective May 1, 1981.)

100-21-4. Record keeping and inventories.

- a. There shall be kept in the office of every dispensing physician a suitable book or file in which shall be preserved for a period of not less than three (3) years, every prescription order

filled or refilled by such dispensing physician, and said book or file of prescription orders shall at all times be open to inspection to proper authorities.

b. Each dispensing physician shall maintain the inventories and records of controlled substances as follows:

1. Inventories and records of all controlled substances listed in schedules I and II shall be maintained separately from all other records and prescriptions for such substances shall be maintained in a separate prescription file:

2. Inventories and records of controlled substances listed in schedules III, IV, and V shall be maintained either separately from all other records or in such form that the information required is readily retrievable from ordinary business records and prescriptions for such substances shall be maintained either in a separate prescription file for controlled substances listed in schedules III, IV, and V only, or in such form that they are readily retrievable from the other prescription records. Prescriptions will be deemed readily retrievable if, at the time they are initially filled the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than 1-inch high and filed either in the prescription file for controlled substances listed in schedules I and II or in the usual consecutively numbered prescription file for non-controlled substances.

c. Inventory requirements. An initial inventory of all controlled substances shall be taken and recorded. Every two years on May 1, a new inventory shall be taken and recorded. The records of these inventories shall be maintained for a period of three years.

(Authorized by K.S.A. 65- 2865; effective, E-81-11, May 14, 1980; effective May 1, 1981.)

100-21-5. Storage and security.

a. All dispensing physicians shall provide effective controls and procedures to guard against theft and diversion of controlled substances.

b. All drugs shall be stored under conditions proper and suitable to maintain their integrity.

(Authorized by K.S.A. 65-2865; effective, E-81-11, May 14, 1980; effective May 1, 1981.)

**CONTROLLED SUBSTANCES LISTED IN
SCHEDULE II
K.A.R. 68-20-19**

68-20-19 Controlled substances listed in schedule II.

(a) Requirements of prescription.

(1) A pharmacist shall dispense a controlled substance listed in schedule II, which is a prescription drug as determined under these regulations, only pursuant to a written prescription signed by the prescribing practitioner, except as provided in paragraph (4) of this subsection.

(2) Any written prescriptions signed by the prescribing practitioner falling under the above provisions of paragraph (1) shall not be filled if submitted more than six months after the original date appearing on the written prescription.

(3) A prescriber may administer a controlled substance listed in schedule II in the course of professional practice without a prescription, subject to K.A.R. 68-20-18.

(4) (A) In the case of an emergency situation, as defined by paragraph (5) of this subsection, a pharmacist may dispense a controlled substance listed in schedule II upon receiving authorization of a prescriber, if all of the following conditions are met:

(i) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period. Dispensing beyond the emergency period shall be pursuant to a written prescription signed by the prescriber.

(ii) The prescription shall be immediately reduced to a hard copy by the pharmacist and shall contain all information required under K.A.R. 68-20-18(c) except for the signature of the prescriber.

(iii) If the prescriber is not known to the pharmacist, the pharmacist shall make a reasonable effort to determine that the authorization came from the prescriber, which may include a call back to the prescriber, using the prescriber's phone number as listed in the telephone directory or other good faith efforts to insure the prescriber's identity, or both.

(iv) Within seven days after authorizing an emergency prescription drug order, the prescriber shall cause a written prescription drug order for the emergency quantity prescribed to be delivered to the dispensing pharmacist.

(B) In addition to conforming to the requirements of K.A.R. 68-20-18(c), the prescription drug order shall have written on its face "Authorization for Emergency Dispensing" and the date of the prescription drug order.

(C) The written prescription drug order shall be delivered to the pharmacist in person within seven days of authorization or, if delivered by mail, it shall be postmarked within the seven-day period.

(D) Upon receipt, the dispensing pharmacist shall attach this written prescription drug order to the pharmacist's record of the emergency prescription drug order.

(E) The pharmacist shall notify the nearest office of the U.S. drug enforcement administration (DEA) if the prescribing practitioner fails to deliver a written prescription drug order to the pharmacist; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescriber.

(5) For the purposes of authorizing a prescription of any controlled substance listed in schedule II of the federal or state uniform controlled substances act, the term "emergency situation" means those situations in which the prescriber determines the following:

(A) That immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user;

(B) that no appropriate alternative treatment is available, including administration of a drug that is not a controlled substance under schedule II of the act; and

(C) that it is not reasonably possible for the prescriber to provide a written prescription to be presented, before dispensing, to the pharmacist dispensing the substance.

(b) A medical care facility or other institution registered with the board shall administer or dispense a controlled substance listed in schedule II only pursuant to a written prescription signed by the prescriber or to an order for medication made by a prescriber that is dispensed for immediate administration to the ultimate user.

(c) Partial filling of prescriptions. The partial filling of a prescription for any controlled substance listed in schedule II shall be permissible, only as provided in this subsection.

(1) Whenever the pharmacist is unable to supply the full quantity called for in a written or emergency prescription and the pharmacist makes a notation of the quantity supplied on the face of the written prescription or written record of the emergency prescription, the pharmacist shall perform the following:

(A) Fill the remaining portion of the prescription within 72 hours of the first partial filling or, if the remaining portion cannot be filled within the 72- hour period, the pharmacist shall notify the prescriber of the situation; and

(B) supply no further quantity beyond 72 hours without a new prescription.

(2) Whenever written, prescriptions for schedule II controlled substances for patients in a long-term care facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities, including individual dosage units, as provided in this subsection. The pharmacist shall record on the prescription whether the patient is "terminally ill" or an "LTCF patient."

(A) For each partial filling, the dispensing pharmacist shall record on the back of the prescription, or on another appropriate, uniformly maintained, and readily retrievable record, the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist.

(B) The total quantity of schedule II controlled substances dispensed in all partial fillings shall not exceed the total quantity prescribed.

(C) These schedule II prescriptions shall be valid for a period not to exceed 60 days from the issue date unless terminated sooner by the discontinuance of medication.

(d) Labeling of substances. The pharmacist filling a written or emergency prescription for a controlled substance listed in schedule II shall affix a label to the package showing the following information:

(1) The date the prescription was filled;

(2) the name, address, and telephone number of the pharmacy dispensing the prescription;

(3) the serial number of the prescription;

(4) the full name of the patient;

(5) the name of the practitioner and either the physician's assistant (PA) or the advanced registered nurse practitioner (ARNP);

(6) the directions for use and cautionary statements, if any, contained in the prescription or required by law;

(7) the brand name or corresponding generic name of the prescription medication;

(8) the manufacturer or distributor of the prescription medication, or an easily identified abbreviation of the manufacturer's or distributor's name;

(9) the expiration date of the prescription medication dispensed, if applicable.

(e) Filing of prescriptions.

(1) All written prescriptions and written records of emergency prescriptions shall be kept in accordance with K.A.R. 68-20-16.

(2) All written or emergency prescriptions for a controlled substance listed in schedule II shall be cancelled on the face of the prescription with the name of the pharmacist filling that prescription.

(3) All written or emergency prescriptions for controlled substances listed in schedule II and filled by a pharmacy intern shall be cancelled on the face of the prescription with the names of the pharmacy intern and preceptor authorizing the filling of that prescription.

(Authorized by and implementing K.S.A. 1998 Supp. 65-4102 and K.S.A. 65- 4123, as amended by L. 1999, Ch. 115, Sec. 15; effective, E-72-24, Aug. 25, 1972; effective Jan. 1, 1973; amended Sept. 9, 1991; amended March 29, 1993; amended March 20, 1995; amended Feb. 5, 1999; amended Dec. 27, 1999.)

INFORMATION CONCERNING PRESCRIPTIONS
K.A.R. 68-20-18

68-20-18 Information concerning prescriptions.

(a) Persons entitled to issue prescriptions. A prescription for a controlled substance may be issued only by a practitioner or mid-level practitioner who meets the following conditions:

- (1) Is legally authorized to prescribe controlled substances in Kansas or any other competent jurisdiction; and
- (2) is either registered or exempted from registration under K.S.A. 65- 4116(d) and amendments thereto.

(b) Purpose of issue of prescription.

(1) To be effective, a prescription for a controlled substance shall be issued for a legitimate medical purpose by a practitioner or mid-level practitioner acting in the usual course of professional practice. The responsibility for the proper prescribing and dispensing of controlled substances shall rest with the prescriber, but a corresponding responsibility shall rest with the pharmacist who fills the prescription. The person filling an unlawful prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of the controlled substance act, K.S.A. 65- 4101, et. seq. and amendments thereto.

(2) A prescription shall not be issued in order for a practitioner or mid-level practitioner to obtain controlled substances for supplying that individual or any other prescriber for the purpose of general dispensing to patients.

(3) A prescription shall not be issued for the dispensing of narcotic drugs listed in any schedule to a narcotic drug-dependent person for the purpose of continuing dependence upon these drugs, except in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program.

(c) Manner of issuance of prescriptions.

(1) Controlled substance prescriptions in schedules II through V shall not be issued on a prescription blank that is preprinted with the name of a propriety preparation or with the strength, quantity, or directions.

(2) All written prescriptions for controlled substances shall meet the following requirements:

(A) Be dated and manually signed on the day issued;

(B) bear the following information:

(i) The full name, address, and registration number of the practitioner or mid-level practitioner;

(ii) the name and address of the patient; and

(iii) the drug name, strength, dosage form, quantity prescribed, and directions for use; and

(C) be written with ink, indelible pencil, or typewriter.

(3) A practitioner or mid-level practitioner shall manually sign a prescription in the same manner as that individual would sign a check or legal document.

(4) The prescriptions may be prepared by a secretary or agent for the signature of a practitioner or mid-level practitioner, but the prescriber shall be responsible if the prescription does not conform in all essential respects to the state and federal law and regulations. A corresponding liability shall rest upon the pharmacist who fills a prescription that is not prepared in the form prescribed by this regulation.

(5) An intern, resident, foreign physician, or foreign medical graduate exempted from registration under K.S.A. 65-4116(d), and amendments thereto, shall include on all prescriptions issued the registration number of the hospital or other institution and the special internal code number assigned to the intern, resident, foreign physician, or foreign medical graduate by the hospital or other institution as provided in K.A.R. 68-20-10. This requirement shall be in lieu of the registration number of the practitioner required by this subsection. Each prescription shall have the name of the intern, resident, foreign physician or foreign medical graduate stamped or

printed on it, as well as the signature of the physician.

(6) An official exempted from registration under K.A.R. 68-20-10 shall include on all prescriptions issued the official's branch of service or agency and the service identification number. This requirement shall be in lieu of the registration number of the practitioner otherwise required by this subsection. The service identification number for a public health service employee shall be that individual's social security identification number. Each prescription shall have the name of the officer stamped or printed on it, as well as the signature of the officer.

(d) Manner of issuance of prescriptions by facsimile.

(1) Controlled substance prescriptions in schedules III through V may be transmitted by telephone by a prescriber or designated agent to a pharmacy for a patient of the prescriber. The transmitted telephone prescription may be by oral, facsimile, or electronic transmission. Prescription orders shall be reduced to hard copy by the pharmacist and, if telephoned by other than the prescriber, shall bear the name of the person so transmitting or telephoning the prescription.

(2) Controlled substance prescriptions in schedule II may be transmitted by facsimile or electronic transmission from the prescriber to a pharmacy. However, when the prescription is actually dispensed, the original written prescription that is manually signed by the prescriber shall be presented, verified against the facsimile or electronic transmission, and retained for filing. Exceptions to this subsection shall be in compliance with K.A.R. 68-20-10a.

(e) Persons entitled to fill prescriptions.

(1) A prescription for controlled substances shall be filled only by the following:

(A) A pharmacist acting in the usual course of professional practice in a registered pharmacy, hospital drug room, or other registered place of employment; or

(B) A pharmacist intern acting under the immediate personal direction and supervision of a licensed pharmacist.

(2) For the purposes of this regulation, an intern shall mean a prospective candidate for examination as a licensed pharmacist who is qualified to receive, and is obtaining, pharmaceutical experience as defined in K.A.R. 68-5-1.

(3) A medical care facility or other institution registered with the board shall administer or dispense directly a controlled substance listed in schedules III and IV and legend V only pursuant to a written prescription signed by the prescriber or to an order of medication made by a prescriber that is dispensed for immediate administration to the ultimate user.

(Authorized by K.S.A. 1998 Supp. 65-4102; implementing K.S.A. 65-4123, as amended by L. 1999, Ch. 115, Sec. 15; effective, E-72-24, Aug. 25, 1972; effective Jan. 1, 1973; amended May 1, 1988; amended Sept. 9, 1991; amended March 29, 1993; amended March 20, 1995; amended Dec. 27, 1999.)

DEA FORMS 41 & 106



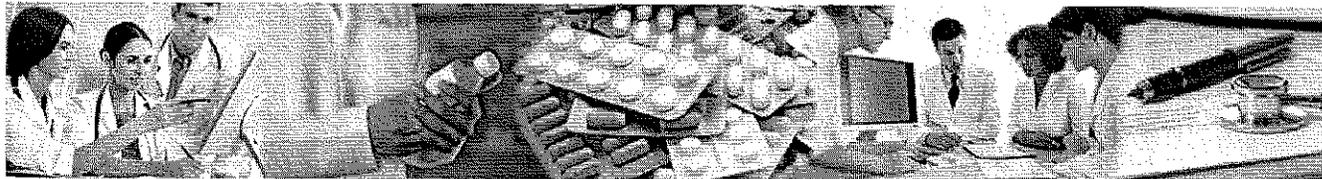
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Inventory of Drugs Surrendered - DEA Form 41

Destruction of Controlled Substances

IMPORTANT NOTICE: Only those persons registered with and authorized by DEA to handle controlled substances may utilize/submit this form.

The instructions provided on the DEA Form 41 are incorrect. Please disregard instruction number 5. That instruction directs the registrant to ship the drugs to the Special Agent in Charge of the DEA office that serves the registrant's area. Registrants should send the forms to DEA as detailed in instruction number 3, and await instructions on how to proceed.

Currently the DEA Form 41 (Registrants Inventory of Drugs Surrendered) is available in PDF format in two ways - 1. As an interactive form which can be completed online and printed on your printer, or 2. As a blank form to be printed on your printer. **This second version is not recommended; fewer errors occur if the form is entered online and then printed.**

This PDF form will print out both the front and back of the official forms.

- [DEA Form 41 - Registrants Inventory of Drugs Surrendered \(PDF\)](#)
- [View Instructions Online](#) - (It is suggested that you view the instructions prior to completing the form)
- [Privacy Act Information for DEA Form 41](#)

- [ARCOS](#)
- [BCM Online](#)
- [Chemical Import/Export Declarations](#)
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INSTRUCTIONS

DEA Form 41 Registrants Inventory of Drugs Surrendered

1. **DO NOT SEND DRUGS TO ANY DRUG ENFORCEMENT ADMINISTRATION (DEA) OFFICE WITHOUT PRIOR WRITTEN APPROVAL.** Drugs are to be destroyed by: (1) shipment to a reverse distributor registered by DEA (may not require the use of this form); (2) the registrant, according to state and local laws, rules and regulations; or (3) the specific instructions of your area Drug Enforcement Office.
2. List the name of the drug in column 1, the number of containers in column 2, the size of each container in column 3, and in column 4 the controlled substance content of each unit described in column 3; e.g., morphine sulfate tabs., 3 pkgs., 100 tabs., 1/4 gr. (16 mg.) or morphine sulfate tabs., 1 pkg., 83 tabs., 1/2 gr. (32mg.), etc.
3. All packages included on a single line should be identical in name, content and controlled substance strength.

Privacy Act Information for DEA Form 41

Authority: Section 307 of the Controlled Substances Act of 1970 (PL-513).
Purpose: To document the surrender of controlled substances which have been forwarded by registrants to DEA for disposal.
Routine Uses: This form is required by Federal Regulations for the surrender of unwanted Controlled Substances. Disclosures of information from this system are made to the following categories of users for the purposes stated:

1. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
2. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.

Effect: Failure to document the surrender of unwanted Controlled Substances may result in prosecution for violation of the Controlled Substances Act.

Under the Paperwork Reduction Act, a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for this burden, to the Drug Enforcement Administration, FOI and Records Management Section, Washington, D.C. 20537; and to the Office of Management and Budget, Paperwork Reduction Project no. 1117-0007, Washington, D.C. 20503.



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Title 21 USC Codified CSA



U.S. DEPARTMENT OF JUSTICE • DRUG ENFORCEMENT ADMINISTRATION
Office of Diversion Control • 8701 Morrisette Drive • Springfield, VA 22152 • 1-800-882-9539

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**U. S. DEPARTMENT OF JUSTICE – DRUG ENFORCEMENT ADMINISTRATION
REGISTRANT RECORD OF CONTROLLED SUBSTANCES DESTROYED
FORM DEA-41**

A. REGISTRANT INFORMATION

| | | |
|---------------------|--------------------------|-----------|
| Registered Name: | DEA Registration Number: | |
| Registered Address: | | |
| City: | State: | Zip Code: |
| Telephone Number: | Contact Name: | |

B. ITEM DESTROYED

1. Inventory

| | National Drug Code or DEA Controlled Substances Code Number | Batch Number | Name of Substance | Strength | Form | Pkg. Qty. | Number of Full Pkgs. | Partial Pkg. Count | Total Destroyed |
|-----------------|---|--------------|-------------------|----------|----------|-----------|----------------------|--------------------|-----------------|
| <i>Examples</i> | 16590-598-60 | N/A | Kadian | 60mg | Capsules | 60 | 2 | 0 | 120 Capsules |
| | 0555-0767-02 | N/A | Adderall | 5mg | Tablet | 100 | 0 | 83 | 83 Tablets |
| | 9050 | B02120312 | Codeine | N/A | Bulk | 1.25 kg | N/A | N/A | 1.25 kg |
| 1. | | | | | | | | | |
| 2. | | | | | | | | | |
| 3. | | | | | | | | | |
| 4. | | | | | | | | | |
| 5. | | | | | | | | | |
| 6. | | | | | | | | | |
| 7. | | | | | | | | | |

2. Collected Substances

| | Returned Mail-Back Package | Sealed Inner Liner | Unique Identification Number | Size of Sealed Inner Liner | Quantity of Packages(s)/Liner(s) Destroyed |
|-----------------|----------------------------|--------------------|------------------------------------|----------------------------|--|
| <i>Examples</i> | X | | MBP1106, MBP1108 - MBP1110, MBP112 | N/A | 5 |
| | | X | CRL1007 - CRL1027 | 15 gallon | 21 |
| | | X | CRL1201 | 5 gallon | 1 |
| 1. | | | | | |
| 2. | | | | | |
| 3. | | | | | |
| 4. | | | | | |
| 5. | | | | | |
| 6. | | | | | |
| 7. | | | | | |

C. METHOD OF DESTRUCTION

| | | |
|----------------------------|------------------------|-----------|
| Date of Destruction: | Method of Destruction: | |
| Location or Business Name: | | |
| Address: | | |
| City: | State: | Zip Code: |

D. WITNESSES

I declare under penalty of perjury, pursuant to 18 U.S.C. 1001, that I personally witnessed the destruction of the above-described controlled substances to a non-retrievable state and that all of the above is true and correct.

| | | |
|---|------------------------------|-------|
| Printed name of first authorized employee witness: | Signature of first witness: | Date: |
| Printed name of second authorized employee witness: | Signature of second witness: | Date: |

E. INSTRUCTIONS

- Section A. REGISTRANT INFORMATION:** The registrant destroying the controlled substance(s) shall provide their DEA registration number and the name and address indicated on their valid DEA registration, in addition to a current telephone number and a contact name, if different from the name on the valid DEA registration.
- Section B. (1) Inventory:** This part shall be used by registrants destroying lawfully possessed controlled substances, other than those described in Section B(2). In each row, indicate the National Drug Code (NDC) for the controlled substance destroyed, or if the substance has no NDC, indicate the DEA Controlled Substances Code Number for the substance; if the substance destroyed is in bulk form, indicate the batch number, if available. In each row, indicate the name, strength, and form of the controlled substance destroyed, and the number of capsules, tablets, etc., that are in a full package (pkg. qty.). If destroying the full quantity of the controlled substance, indicate the number of packages destroyed (number of full pkgs.). If destroying a partial package, indicate the partial count of the capsules, tablets, etc. destroyed (partial pkg. count). If destroying a controlled substance in bulk form, indicate that the substance is in bulk form (form) and the weight of the substance destroyed (pkg. qty.). In each row, indicate the total number of each controlled substance destroyed (total destroyed).
- Section B. (2) Collected Substances:** This part shall be used by registrants destroying controlled substances obtained through an authorized collection activity in accordance with 21 U.S.C. 822(g). In each row, indicate whether registrant is destroying a mail-back package or an inner liner. If destroying a mail-back package, enter each unique identification number separated by a comma and/or as a list in a sequential range and total quantity of packages being destroyed. If destroying an inner liner, enter each unique identification number separated by a comma and/or as a list in a sequential range based on the size of the liners destroyed and the total quantity of inner liners being destroyed. In the case of mail-back packages or inner liners received from a law enforcement agency which do not have a unique identification number or clearly marked size, include the name of the law enforcement agency and, if known, the size of the inner liner or package. **DO NOT OPEN ANY MAIL-BACK PACKAGE OR INNER LINER; AN INVENTORY OF THE CONTENTS OF THE PACKAGES OR LINERS IS PROHIBITED BY LAW AND IS NOT REQUIRED BY THIS FORM.**
- If additional space is needed for items destroyed in Section B, attach to this form additional page(s) containing the requested information for each controlled substance destroyed.
- Section C. METHOD OF DESTRUCTION:** Provide the date, location, and method of destruction. The method of destruction must render the controlled substance to a state of non-retrievable and meet all applicable destruction requirements.
- Section D. WITNESSES:** Two authorized employees must declare by signature, under penalty of perjury, that such employees personally witnessed the destruction of the controlled substances listed in Section B in the manner described in Section C.
- You are not required to submit this form to DEA, unless requested to do so. This form must be kept as a record of destruction and be available by the registrant for at least two years in accordance with 21 U.S.C. 827.

Paperwork Reduction Act Statement: The information collected on this form is necessary for DEA registrants to record controlled substances destroyed in accordance with the Controlled Substances Act (CSA). The records that DEA registrants maintain in accordance with the CSA must be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General. 21 U.S.C. 827. DEA estimates that it will take approximately 30 minutes to complete this form, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The completion of this form by DEA registrants that destroy controlled substances is mandatory in accordance with 21 U.S.C. 827. Please note that an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Comments regarding this information collection, including suggestions for reducing the burden estimate, should be directed to the Drug Enforcement Administration, DEA Federal Register Representative/ODL, 8701 Morrisette Drive, Springfield, Virginia 22152.



Report of Theft or Loss of Controlled Substances Under Controlled Substances Act of 1970

INSTRUCTIONS for Form DEA-106, Report of Theft or Loss of Controlled Substances - Approved OMB Form No. 1117-0001 Expires: 09/30/2014

General Instructions

WHAT'S NEW

Changes to the Controlled Substances Section. The DEA is now requiring registrants to enter the National Drug Code (NDC) of the controlled substances lost or stolen.

Discontinued Fields. With the implementation of the NDC number, DEA will no longer require registrants to enter specific information pertaining to product lost or stolen. Inputting the NDC number will auto-populate all required information needed for data collection and report generation.

Purpose of Form

The DEA-106 is for reporting any theft or loss of controlled substances.

Do not use this form if:

1. You have not previously registered with the DEA,
2. The theft or loss you are reporting is not of a controlled substance, or
3. You want to correct minor inventory shortages.

Additional Information

The online version of Form DEA 106 has 8 sections. What follows is a description of each section and the information you will need to successfully fill out this online form. Please note that for all pages where you are required to supply information, there is a section labeled "Help." For any field on the page for which you require clarification, place the cursor in the field and click. Help text will appear in the Help section.

SPECIFIC INSTRUCTIONS

Section 1. Authentication and Report Selection

You will be asked to enter your DEA Number and your last name or the business name you used to register with the DEA. The name you supply must match exactly the name on your registration. You will be able to choose whether to file a new report or amend a report previously entered.

Section 2. Theft/Loss Details

You will be asked to provide background information relating to this loss or theft incident, such as the date and place, the type (night break-in, armed robbery, etc.), and the estimated value of the controlled substances, etc. Responses may require additional information; for example, indicating that a police report has been filed will open new fields requesting the police department's name and telephone number.

Section 3. Controlled Substances

You will be asked to provide the National Drug Code (NDC) and quantity of the controlled substance being reported as a theft or loss. If the substance is liquid or powder, you will need to enter the total milliliters/milligrams; if tablet, enter the total count of tablets.

Section 4. Signature

You will be asked to supply the name and title of the person filing this report.

Section 5. Theft/Loss Summary

Information regarding the details of the theft or loss will be presented to you for confirmation; changes to the information may be made. You may also change information in the Signature section.

Section 6. Controlled Substances Summary and Certification

Information on the substances will be displayed, and may be changed. Additionally, you will be required to enter the name of the certifying official who attests to the validity of the information included in the report.

Section 7. Submit Report

Submitting the report will generate an amendment key. Please save the amendment key in order to be able to modify information using the online DEA-106 report in the future.

Section 8. Print

You may send a copy of the DEA-106 report to your local printer. DEA regulations specify that you keep a copy of this report for two years.

Please do not use your browser's BACK and FORWARD buttons while navigating this form.

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DEA Forms & Applications

DEA Forms & Applications

REGISTRATION APPLICATIONS AND TOOLS

| | | | |
|---|------------------------------|-----------------------------|---|
| Renewal Registration Applications | Apply Online | ← Online Only | Form 224a, Form 225a, Form 363a, Form 510a |
| New Registration Applications | Apply Online | PDF Version | Form 225, Form 363, Form 510 (Form 224 unavailable in PDF) |
| Duplicate Receipt of Renewal Application | Apply Online | ← Online Only | Request an additional receipt for a previously submitted Renewal Application. |
| Duplicate Certificate Request | Apply Online | ← Online Only | Duplicate Certificates for misplaced, illegible, or destroyed originals. |
| Online Pharmacy Modifications | Apply Online | ← Online Only | Modify your existing Retail Online Pharmacy Information. |
| Registration Change Requests | Apply Online | ← Online Only | Make changes to drug code, schedule, name, or address (<i>address change requires approved state license for the new address first.</i>) |
| Registration Validation | Apply Online | ← Online Only | Allows a current DEA registrant to check the validity of another DEA registrant. |
| Registration for Disposal of Controlled Substances | Apply Online | ← Online Only | Modify eligible DEA registration to collect pharmaceutical controlled substances from ultimate users (e.g., patients); Modify DEA registration to stop being a collector; Modify existing collector registration information. |
| DEA Form 222 – Official Order Forms | Apply Online | ← Online Only | Request Official Order Forms (<i>Schedule I & II Registrants Only</i>) |
| CSOS (Controlled Substance Ordering System) | Apply Online | ← Online Only | Allows electronic orders of controlled substances without the supporting paper Form 222. |

REPORTING FORMS

| | | | |
|---|------------------------------|-----------------------------|--|
| ARCOS EDI Request Form | PDF Only → | PDF Version | Electronic Data Interchange Program Request Form |
| ARCOS PC Field Edit Software Request Form | PDF Only → | PDF Version | Personal Computer (PC) Field Edit Program Request Form |
| BCM Online (Bulk Chemical Manufacturer) | Apply Online | ← Online Only | Bulk Chemical Manufacturer Reports |
| Chemical Import/Export Declarations | Apply Online | PDF Version | Form 486, Form 486a |
| CMEA (Combat Meth Epidemic Act of 2005) | Apply Online | PDF Version | Required Training and Self-Certification |
| DTL (Drug Theft/Loss) | Apply Online | ← Online Only | Form 106 |
| Extortion Scam Online Reporting | Apply Online | ← Online Only | Report criminals posing as DEA Special Agents seeking money. |
| Import/Export Permit Apps & Declarations | PDF Only → | PDF Version | Form 161, Form 161R, Form 357 |
| Import/Export Permit Declaration | Apply Online | PDF Version | Form 236 |
| Inventory of Drugs Surrendered | PDF Only → | PDF Version | Form 41 |
| Quota Applications | Apply Online | PDF Version | Form 189, Form 250, Form 488 |
| Report Suspicious Online Pharmacies | Apply Online | ← Online Only | |

RX Abuse Online Reporting

[Apply Online](#) ← Online Only

To report regarding unlawful or suspicious activities on the Internet only

Submit A Tip To DEA

[Apply Online](#) ← Online Only

To report pharmaceutical drugs (i.e., oxycodone, hydrocodone, etc.); doctors and pharmacies

Submit a Tip to DEA

YERS Online (Year-End Reports)

[Apply Online](#) ← Online Only

Year-End Reports



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Federal Register Notices

National Take-Back Initiative
NFLIS
Publications & Manuals
Questions & Answers
Significant Guidance Documents
Title 21 Code of Federal Regulations
Title 21 USC Codified CSA



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ASA GUIDELINES

GUIDELINES FOR OFFICE-BASED ANESTHESIA

Committee of Origin: Ambulatory Surgical Care

(Approved by the ASA House of Delegates on October 13, 1999; last amended on October 21, 2009; and reaffirmed on October 15, 2014)

These guidelines are intended to assist ASA members who are considering the practice of ambulatory anesthesia in the office setting: office-based anesthesia (OBA). These recommendations focus on quality anesthesia care and patient safety in the office. These are minimal guidelines and may be exceeded at any time based on the judgment of the involved anesthesia personnel. Compliance with these guidelines cannot guarantee any specific outcome. These guidelines are subject to periodic revision as warranted by the evolution of federal, state and local laws as well as technology and practice.

ASA recognizes the unique needs of this growing practice and the increased requests for ASA members to provide OBA for health care practitioners* who have developed their own office operatories. Since OBA is a subset of ambulatory anesthesia, the ASA "Guidelines for Ambulatory Anesthesia and Surgery" should be followed in the office setting as well as all other ASA standards and guidelines that are applicable.

There are special problems that ASA members must recognize when administering anesthesia in the office setting. Compared with acute care hospitals and licensed ambulatory surgical facilities, office operatories currently have little or no regulation, oversight or control by federal, state or local laws. Therefore, ASA members must satisfactorily investigate areas taken for granted in the hospital or ambulatory surgical facility such as governance, organization, construction and equipment, as well as policies and procedures, including fire, safety, drugs, emergencies, staffing, training and unanticipated patient transfers.

ASA members should be confident that the following issues are addressed in an office setting to provide patient safety and to reduce risk and liability to the anesthesiologist.

Administration and Facility

Quality of Care

- The facility should have a medical director or governing body that establishes policy and is responsible for the activities of the facility and its staff. The medical director or governing body is responsible for ensuring that facilities and personnel are adequate and appropriate for the type of procedures performed.
- Policies and procedures should be written for the orderly conduct of the facility and reviewed on an annual basis.
- The medical director or governing body should ensure that all applicable local, state and federal regulations are observed.

- All health care practitioners* and nurses should hold a valid license or certificate to perform their assigned duties.
- All operating room personnel who provide clinical care in the office should be qualified to perform services commensurate with appropriate levels of education, training and experience.
- The anesthesiologist should participate in ongoing continuous quality improvement and risk management activities.
- The medical director or governing body should recognize the basic human rights of its patients, and a written document that describes this policy should be available for patients to review.

Facility and Safety

- Facilities should comply with all applicable federal, state and local laws, codes and regulations pertaining to fire prevention, building construction and occupancy, accommodations for the disabled, occupational safety and health, and disposal of medical waste and hazardous waste.
- Policies and procedures should comply with laws and regulations pertaining to controlled drug supply, storage and administration.

Clinical Care

Patient and Procedure Selection

- The anesthesiologist should be satisfied that the procedure to be undertaken is within the scope of practice of the health care practitioners and the capabilities of the facility.
- The procedure should be of a duration and degree of complexity that will permit the patient to recover and be discharged from the facility.
- Patients who by reason of pre-existing medical or other conditions may be at undue risk for complications should be referred to an appropriate facility for performance of the procedure and the administration of anesthesia.

Perioperative Care

- The anesthesiologist should adhere to the “Basic Standards for Preanesthesia Care,” “Standards for Basic Anesthetic Monitoring,” “Standards for Postanesthesia Care” and “Guidelines for Ambulatory Anesthesia and Surgery” as currently promulgated by the American Society of Anesthesiologists.
- The anesthesiologist should be physically present during the intraoperative period and immediately available until the patient has been discharged from anesthesia care.
- Discharge of the patient is a physician responsibility. This decision should be documented in the medical record.
- Personnel with training in advanced resuscitative techniques (e.g., ACLS, PALS) should be immediately available until all patients are discharged home.

Monitoring and Equipment

- At a minimum, all facilities should have a reliable source of oxygen, suction, resuscitation equipment and emergency drugs. Specific reference is made to the ASA “Statement on Nonoperating Room Anesthetizing Locations.”
- There should be sufficient space to accommodate all necessary equipment and personnel and to allow for expeditious access to the patient, anesthesia machine (when present) and all monitoring equipment.
- All equipment should be maintained, tested and inspected according to the manufacturer’s specifications.
- Back-up power sufficient to ensure patient protection in the event of an emergency should be available.
- In any location in which anesthesia is administered, there should be appropriate anesthesia apparatus and equipment which allow monitoring consistent with ASA “Standards for Basic Anesthetic Monitoring” and documentation of regular preventive maintenance as recommended by the manufacturer.
- In an office where anesthesia services are to be provided to infants and children, the required equipment, medication and resuscitative capabilities should be appropriately sized for a pediatric population.

Emergencies and Transfers

- All facility personnel should be appropriately trained in and regularly review the facility’s written emergency protocols.
- There should be written protocols for cardiopulmonary emergencies and other internal and external disasters such as fire.
- The facility should have medications, equipment and written protocols available to treat malignant hyperthermia when triggering agents are used.
- The facility should have a written protocol in place for the safe and timely transfer of patients to a prespecified alternate care facility when extended or emergency services are needed to protect the health or well-being of the patient.

*defined herein as physicians, dentists and podiatrists

STANDARDS FOR BASIC ANESTHETIC MONITORING

Committee of Origin: Standards and Practice Parameters

**(Approved by the ASA House of Delegates on October 21, 1986, and last amended on
October 20, 2010 with an effective date of July 1, 2011)**

These standards apply to all anesthesia care although, in emergency circumstances, appropriate life support measures take precedence. These standards may be exceeded at any time based on the judgment of the responsible anesthesiologist. They are intended to encourage quality patient care, but observing them cannot guarantee any specific patient outcome. They are subject to revision from time to time, as warranted by the evolution of technology and practice. They apply to all general anesthetics, regional anesthetics and monitored anesthesia care. This set of standards addresses only the issue of basic anesthetic monitoring, which is one component of anesthesia care. In certain rare or unusual circumstances, 1) some of these methods of monitoring may be clinically impractical, and 2) appropriate use of the described monitoring methods may fail to detect untoward clinical developments. Brief interruptions of continual† monitoring may be unavoidable. These standards are not intended for application to the care of the obstetrical patient in labor or in the conduct of pain management.

1. STANDARD I

Qualified anesthesia personnel shall be present in the room throughout the conduct of all general anesthetics, regional anesthetics and monitored anesthesia care.

1.1 Objective –

Because of the rapid changes in patient status during anesthesia, qualified anesthesia personnel shall be continuously present to monitor the patient and provide anesthesia care. In the event there is a direct known hazard, e.g., radiation, to the anesthesia personnel which might require intermittent remote observation of the patient, some provision for monitoring the patient must be made. In the event that an emergency requires the temporary absence of the person primarily responsible for the anesthetic, the best judgment of the anesthesiologist will be exercised in comparing the emergency with the anesthetized patient's condition and in the selection of the person left responsible for the anesthetic during the temporary absence.

2. STANDARD II

During all anesthetics, the patient's oxygenation, ventilation, circulation and temperature shall be continually evaluated.

2.1 Oxygenation –

2.1.1 Objective –

To ensure adequate oxygen concentration in the inspired gas and the blood during all anesthetics.

STANDARDS FOR BASIC ANESTHETIC MONITORING

2.2 Methods –

- 2.2.1 Inspired gas: During every administration of general anesthesia using an anesthesia machine, the concentration of oxygen in the patient breathing system shall be measured by an oxygen analyzer with a low oxygen concentration limit alarm in use.*
- 2.2.2 Blood oxygenation: During all anesthetics, a quantitative method of assessing oxygenation such as pulse oximetry shall be employed.* When the pulse oximeter is utilized, the variable pitch pulse tone and the low threshold alarm shall be audible to the anesthesiologist or the anesthesia care team personnel.* Adequate illumination and exposure of the patient are necessary to assess color.*

3. VENTILATION

3.1 Objective –

To ensure adequate ventilation of the patient during all anesthetics.

3.2 Methods –

- 3.2.1 Every patient receiving general anesthesia shall have the adequacy of ventilation continually evaluated. Qualitative clinical signs such as chest excursion, observation of the reservoir breathing bag and auscultation of breath sounds are useful. Continual monitoring for the presence of expired carbon dioxide shall be performed unless invalidated by the nature of the patient, procedure or equipment. Quantitative monitoring of the volume of expired gas is strongly encouraged.*
- 3.2.2 When an endotracheal tube or laryngeal mask is inserted, its correct positioning must be verified by clinical assessment and by identification of carbon dioxide in the expired gas. Continual end-tidal carbon dioxide analysis, in use from the time of endotracheal tube/laryngeal mask placement, until extubation/removal or initiating transfer to a postoperative care location, shall be performed using a quantitative method such as capnography, capnometry or mass spectroscopy.* When capnography or capnometry is utilized, the end tidal CO₂ alarm shall be audible to the anesthesiologist or the anesthesia care team personnel.*
- 3.2.3 When ventilation is controlled by a mechanical ventilator, there shall be in continuous use a device that is capable of detecting disconnection of components of the breathing system. The device must give an audible signal when its alarm threshold is exceeded.
- 3.2.4 During regional anesthesia (with no sedation) or local anesthesia (with no sedation), the adequacy of ventilation shall be evaluated by continual observation of qualitative clinical signs. During moderate or deep sedation the adequacy of ventilation shall be evaluated by continual observation of qualitative clinical signs and monitoring for the presence of exhaled carbon dioxide unless precluded or invalidated by the nature of the patient, procedure, or equipment.

STANDARDS FOR BASIC ANESTHETIC MONITORING

4. CIRCULATION

4.1 Objective –

To ensure the adequacy of the patient's circulatory function during all anesthetics.

4.2 Methods –

- 4.2.1 Every patient receiving anesthesia shall have the electrocardiogram continuously displayed from the beginning of anesthesia until preparing to leave the anesthetizing location.*
- 4.2.2 Every patient receiving anesthesia shall have arterial blood pressure and heart rate determined and evaluated at least every five minutes.*
- 4.2.3 Every patient receiving general anesthesia shall have, in addition to the above, circulatory function continually evaluated by at least one of the following: palpation of a pulse, auscultation of heart sounds, monitoring of a tracing of intra-arterial pressure, ultrasound peripheral pulse monitoring, or pulse plethysmography or oximetry.

5. BODY TEMPERATURE

5.1 Objective –

To aid in the maintenance of appropriate body temperature during all anesthetics.

5.2 Methods –

Every patient receiving anesthesia shall have temperature monitored when clinically significant changes in body temperature are intended, anticipated or suspected.

† Note that “continual” is defined as “repeated regularly and frequently in steady rapid succession” whereas “continuous” means “prolonged without any interruption at any time.”

* Under extenuating circumstances, the responsible anesthesiologist may waive the requirements marked with an asterisk (*); it is recommended that when this is done, it should be so stated (including the reasons) in a note in the patient's medical record.

BASIC STANDARDS FOR PREANESTHESIA CARE

Committee of Origin: Standards and Practice Parameters

**(Approved by the ASA House of Delegates on October 14, 1987, and last affirmed on
October 20, 2010)**

These standards apply to all patients who receive anesthesia care. Under exceptional circumstances, these standards may be modified. When this is the case, the circumstances shall be documented in the patient's record.

An anesthesiologist shall be responsible for determining the medical status of the patient and developing a plan of anesthesia care.

The anesthesiologist, before the delivery of anesthesia care, is responsible for:

1. Reviewing the available medical record.
2. Interviewing and performing a focused examination of the patient to:
 - 2.1 Discuss the medical history, including previous anesthetic experiences and medical therapy.
 - 2.2 Assess those aspects of the patient's physical condition that might affect decisions regarding perioperative risk and management.
3. Ordering and reviewing pertinent available tests and consultations as necessary for the delivery of anesthesia care.
4. Ordering appropriate preoperative medications.
5. Ensuring that consent has been obtained for the anesthesia care.
6. Documenting in the chart that the above has been performed.

STANDARDS FOR POSTANESTHESIA CARE

Committee of Origin: Standards and Practice Parameters

**(Approved by the ASA House of Delegates on October 27, 2004, and last amended on
October 15, 2014)**

These standards apply to postanesthesia care in all locations. These standards may be exceeded based on the judgment of the responsible anesthesiologist. They are intended to encourage quality patient care, but cannot guarantee any specific patient outcome. They are subject to revision from time to time as warranted by the evolution of technology and practice.

STANDARD I

ALL PATIENTS WHO HAVE RECEIVED GENERAL ANESTHESIA, REGIONAL ANESTHESIA OR MONITORED ANESTHESIA CARE SHALL RECEIVE APPROPRIATE POSTANESTHESIA MANAGEMENT.¹

1. A Postanesthesia Care Unit (PACU) or an area which provides equivalent postanesthesia care (for example, a Surgical Intensive Care Unit) shall be available to receive patients after anesthesia care. All patients who receive anesthesia care shall be admitted to the PACU or its equivalent **except** by specific order of the anesthesiologist responsible for the patient's care.
2. The medical aspects of care in the PACU (or equivalent area) shall be governed by policies and procedures which have been reviewed and approved by the Department of Anesthesiology.
3. The design, equipment and staffing of the PACU shall meet requirements of the facility's accrediting and licensing bodies.

STANDARD II

A PATIENT TRANSPORTED TO THE PACU SHALL BE ACCOMPANIED BY A MEMBER OF THE ANESTHESIA CARE TEAM WHO IS KNOWLEDGEABLE ABOUT THE PATIENT'S CONDITION. THE PATIENT SHALL BE CONTINUALLY EVALUATED AND TREATED DURING TRANSPORT WITH MONITORING AND SUPPORT APPROPRIATE TO THE PATIENT'S CONDITION.

STANDARD III

UPON ARRIVAL IN THE PACU, THE PATIENT SHALL BE RE-EVALUATED AND A VERBAL REPORT PROVIDED TO THE RESPONSIBLE PACU NURSE BY THE MEMBER OF THE ANESTHESIA CARE TEAM WHO ACCOMPANIES THE PATIENT.

1. The patient's status on arrival in the PACU shall be documented.

2. Information concerning the preoperative condition and the surgical/anesthetic course shall be transmitted to the PACU nurse.
3. The member of the Anesthesia Care Team shall remain in the PACU until the PACU nurse accepts responsibility for the nursing care of the patient.

STANDARD IV

THE PATIENT'S CONDITION SHALL BE EVALUATED CONTINUALLY IN THE PACU.

1. The patient shall be observed and monitored by methods appropriate to the patient's medical condition. Particular attention should be given to monitoring oxygenation, ventilation, circulation, level of consciousness and temperature. During recovery from all anesthetics, a quantitative method of assessing oxygenation such as pulse oximetry shall be employed in the initial phase of recovery.* This is not intended for application during the recovery of the obstetrical patient in whom regional anesthesia was used for labor and vaginal delivery.
2. An accurate written report of the PACU period shall be maintained. Use of an appropriate PACU scoring system is encouraged for each patient on admission, at appropriate intervals prior to discharge and at the time of discharge.
3. General medical supervision and coordination of patient care in the PACU should be the responsibility of an anesthesiologist.
4. There shall be a policy to assure the availability in the facility of a physician capable of managing complications and providing cardiopulmonary resuscitation for patients in the PACU.

STANDARD V

A PHYSICIAN IS RESPONSIBLE FOR THE DISCHARGE OF THE PATIENT FROM THE POSTANESTHESIA CARE UNIT.

1. When discharge criteria are used, they must be approved by the Department of Anesthesiology and the medical staff. They may vary depending upon whether the patient is discharged to a hospital room, to the Intensive Care Unit, to a short stay unit or home.
2. In the absence of the physician responsible for the discharge, the PACU nurse shall determine that the patient meets the discharge criteria. The name of the physician accepting responsibility for discharge shall be noted on the record.

¹ Refer to Perianesthesia Nursing Standards, Practice Recommendations and Interpretive Statements, published by ASPAN, for issues of nursing care.

* Under extenuating circumstances, the responsible anesthesiologist may waive the requirements marked with an asterisk (*); it is recommended that when this is done, it should be so stated (including the reasons) in a note in the patient's medical record.

STATEMENT ON NONOPERATING ROOM ANESTHETIZING LOCATIONS

Committee of Origin: Standards and Practice Parameters

(Approved by the ASA House of Delegates on October 19, 1994, and last amended on October 16, 2013)

These guidelines apply to all anesthesia care involving anesthesiology personnel for procedures intended to be performed in locations outside an operating room. These are minimal guidelines which may be exceeded at any time based on the judgment of the involved anesthesia personnel. These guidelines encourage quality patient care but observing them cannot guarantee any specific patient outcome. These guidelines are subject to revision from time to time, as warranted by the evolution of technology and practice. ASA Standards, Guidelines and Policies should be adhered to in all nonoperating room settings except where they are not applicable to the individual patient or care setting.

1. There should be in each location a reliable source of oxygen adequate for the length of the procedure. There should also be a backup supply. Prior to administering any anesthetic, the anesthesiologist should consider the capabilities, limitations and accessibility of both the primary and backup oxygen sources. Oxygen piped from a central source, meeting applicable codes, is strongly encouraged. The backup system should include the equivalent of at least a full E cylinder.
2. There should be in each location an adequate and reliable source of suction. Suction apparatus that meets operating room standards is strongly encouraged.
3. In any location in which inhalation anesthetics are administered, there should be an adequate and reliable system for scavenging waste anesthetic gases.
4. There should be in each location: (a) a self-inflating hand resuscitator bag capable of administering at least 90 percent oxygen as a means to deliver positive pressure ventilation; (b) adequate anesthesia drugs, supplies and equipment for the intended anesthesia care; and (c) adequate monitoring equipment to allow adherence to the "Standards for Basic Anesthetic Monitoring." In any location in which inhalation anesthesia is to be administered, there should be an anesthesia machine equivalent in function to that employed in operating rooms and maintained to current operating room standards.
5. There should be in each location, sufficient electrical outlets to satisfy anesthesia machine and monitoring equipment requirements, including clearly labeled outlets connected to an emergency power supply. In any anesthetizing location determined by the health care facility to be a "wet location" (e.g., for cystoscopy or arthroscopy or a birthing room in labor and delivery), either isolated electric power or electric circuits with ground fault circuit interrupters should be provided.*
6. There should be in each location, provision for adequate illumination of the patient, anesthesia machine (when present) and monitoring equipment. In addition, a form of battery-powered illumination other than a laryngoscope should be immediately available.
7. There should be in each location, sufficient space to accommodate necessary equipment and personnel and to allow expeditious access to the patient, anesthesia machine (when present) and monitoring equipment.

8. There should be immediately available in each location, an emergency cart with a defibrillator, emergency drugs and other equipment adequate to provide cardiopulmonary resuscitation
9. There should be in each location adequate staff trained to support the anesthesiologist. There should be immediately available in each location, a reliable means of two-way communication to request assistance.
10. For each location, all applicable building and safety codes and facility standards, where they exist, should be observed
11. Appropriate postanesthesia management should be provided (see Standards for Postanesthesia Care). In addition to the anesthesiologist, adequate numbers of trained staff and appropriate equipment should be available to safely transport the patient to a postanesthesia care unit.

*See National Fire Protection Association. Health Care Facilities Code 99; Quincy, MA: NFPA, 2012.

GUIDELINES FOR AMBULATORY ANESTHESIA AND SURGERY

Committee of Origin: Ambulatory Surgical Care

(Approved by the ASA House of Delegates on October 15, 2003, last amended on October 22, 2008, and reaffirmed on October 16, 2013)

The American Society of Anesthesiologists (ASA) endorses and supports the concept of Ambulatory Anesthesia and Surgery. ASA encourages the anesthesiologist to play a leadership role as the perioperative physician in all hospitals, ambulatory surgical facilities and office-based settings, and to participate in facility accreditation as a means for standardization and improving the quality of patient care.

These guidelines apply to all care involving anesthesiology personnel administering ambulatory anesthesia in all settings. These are minimal guidelines which may be exceeded at any time based on the judgment of the involved anesthesia personnel. These guidelines encourage high quality patient care, but observing them cannot guarantee any specific patient outcome. These guidelines are subject to periodic revision, as warranted by the evolution of technology and practice.

- I. ASA Standards, Guidelines and Policies should be adhered to in all settings except where they are not applicable to outpatient care.
- II. A licensed physician should be in attendance in the facility, or in the case of overnight care, immediately available by telephone, at all times during patient treatment and recovery and until the patients are medically discharged.
- III. The facility must be established, constructed, equipped and operated in accordance with applicable local, state and federal laws and regulations. At a minimum, all settings should have a reliable source of oxygen, suction, resuscitation equipment and emergency drugs. Specific reference is made to the ASA "*Statement on Nonoperating Room Anesthetizing Locations.*"
- IV. Staff should be adequate to meet patient and facility needs for all procedures performed in the setting, and should consist of:
 - A. Professional Staff
 1. Physicians and other practitioners who hold a valid license or certificate are duly qualified.
 2. Nurses who are duly licensed and qualified.
 - B. Administrative Staff
 - C. Housekeeping and Maintenance Staff
- V. Physicians providing medical care in the facility should assume responsibility for credentials review, delineation of privileges, quality assurance and peer review.
- VI. Qualified personnel and equipment should be on hand to manage emergencies. There should be established policies and procedures to respond to emergencies and unanticipated patient transfer to an acute care facility.
- VII. Minimal patient care should include:
 - A. Preoperative instructions and preparation.

- B. An appropriate pre-anesthesia evaluation and examination by an anesthesiologist, prior to anesthesia and surgery. In the event that nonphysician personnel are utilized in the process, the anesthesiologist must verify the information and repeat and record essential key elements of the evaluation.
- C. Preoperative studies and consultations as medically indicated.
- D. An anesthesia plan developed by an anesthesiologist, discussed with and accepted by the patient and documented.
- E. Administration of anesthesia by anesthesiologists, other qualified physicians or nonphysician anesthesia personnel medically directed by an anesthesiologist. Non-anesthesiologist physicians who are administering or supervising the administration of the continuum of anesthesia must be qualified by education, training, licensure, and appropriately credentialed by the facility.
- F. Discharge of the patient is a physician responsibility.
- G. Patients who receive other than unsupplemented local anesthesia must be discharged with a responsible adult.
- H. Written postoperative and follow-up care instructions.
- I. Accurate, confidential and current medical records.

STATEMENT ON DOCUMENTATION OF ANESTHESIA CARE

**Committee of Origin: Quality Management and Departmental Administration
(Approved by the ASA House of Delegates on October 15, 2003, and last amended
on October 16, 2013)**

Documentation is a factor in the provision of quality care and is the responsibility of an anesthesiologist. While anesthesia care is a continuum, it is usually viewed as consisting of preanesthesia, intraoperative/procedural anesthesia and postanesthesia components. Anesthesia care should be documented to reflect these components and to facilitate review. Documentation may be through a paper record, an electronic system, or a combination, as specified by the practice and the facility where patient care is provided. CMS has separate detailed requirements for the contents of peri-anesthesia care documentation that should be addressed, if pertinent.

The record should include documentation of:

I. Preanesthesia Evaluation*

A. Patient interview to assess:

1. Patient and procedure identification.
2. Verification of admission status (inpatient, outpatient, "short stay", etc.)
3. Medical history
4. Anesthetic history
5. Medication/Allergy history
6. NPO status

B. Appropriate physical examination, including vital signs and documentation of airway assessment.

C. Review of objective diagnostic data (e.g., laboratory, ECG, X-ray) and medical records.

D. Medical consultations when applicable.

E. Assignment of ASA physical status, including emergent status when applicable.

F. Formulation of the anesthetic plan and discussion of the risks and benefits of the plan (including discharge issues when indicated) with the patient or the patient's legal representative and/or escort.

- G. Documentation of appropriate informed consent(s).
- H. Appropriate premedication and prophylactic antibiotic administrations (if indicated).

II. Intraoperative/procedural anesthesia (time-based record of events)

- A. Immediate review prior to initiation of anesthetic procedures:
 - 1. Patient re-evaluation (re-verification of NPO status)
 - 2. Check of equipment, drugs and gas supply
- B. Monitoring of the patient** (e.g., recording of vital signs and use of any non-routine monitors).
- C. Doses of drugs and agents used, times and routes of administration and any adverse reactions.
- D. The type and amounts of intravenous fluids used, including blood and blood products, and times of administration.
- E. The technique(s) used and patient position(s).
- F. Intravenous/intravascular lines and airway devices that are inserted including technique for insertion, and location.
- G. Unusual events during the administration of anesthesia.
- H. The status of the patient at the conclusion of anesthesia.

III. Postanesthesia

- A. Patient evaluation on admission and discharge from the postanesthesia care unit or admission to the intensive care unit.
- B. A time-based record of vital signs and level of consciousness.
- C. A time-based record of drugs administered, their dosage and route of administration.

D. Type and amounts of intravenous fluids administered, including blood and blood products.

E. Any unusual events including postanesthesia or postprocedural complications.

F. Postanesthesia visits.

* See Basic Standards for Preanesthesia Care

** See Standards for Basic Anesthetic Monitoring

**STATEMENT ON THE LABELING OF PHARMACEUTICALS
FOR USE IN ANESTHESIOLOGY
Committee of Origin: Equipment and Facilities
(Approved by the ASA House of Delegates on October 27, 2004, and last amended on
October 21, 2009)**

Rationale:

The practice of anesthesiology requires the administration of a wide variety of potent medications. These medications are often given in high acuity situations and in environments with poor visibility and multiple distractions. Medications with widely differing actions, such as muscle relaxants, vasopressors, and vasodilators, are often used in the course of a single anesthetic, at times simultaneously. It has been recognized for some time that perioperative medication errors are a significant source of morbidity and, rarely, mortality.¹⁻⁴ Interest in medication errors has extended to regulatory agencies, the federal government, and the general public.

Medications are often selected based upon the location and visual features of the container. The recognition and identification of an object depends on shape, color, brightness, and contrast. As these elements become increasingly distinctive, identification of the object becomes faster and more accurate.⁵⁻⁷ Identification of the medication is verified by reading the label. Therefore, although multiple factors contribute to medication errors, consistency and clarity of pharmaceutical and syringe labeling, in accordance with human factors, are important elements in their prevention.

References:

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2. Fasting S, Gisvold SE. Adverse drug errors in anesthesia, and the impact of coloured syringe labels. *Can J Anesth*. 2000; 47:1060-1067.
3. Merry AF, Webster CS. Labeling and drug administration error. *Anaesthesia*. 1996; 51:987-988.
4. *ISO 26825:2008*, Anaesthetic and respiratory equipment – User-applied labels for syringes containing drugs used during anaesthesia – Colour, design and performance.
5. Treisman A. Feature and objects in visual processing. *Scientific American*. November 1986; pp: 114-125.
6. Treisman A. Features and Objects. *Quarterly J of Exp Psychology*. 1988; 40A (vol 2) 201-237.
7. Kosslyn SM. Aspects of a cognitive neuroscience of mental imagery. *Science*. 1988; 240:1621-1626.

NOTES: For referenced ASTM International standards, visit the ASTM Web site www.astm.org or contact ASTM customer service at service@astm.org.

For referenced ISO standards, visit the ISO (International Organization for Standardization) Website at www.iso.org.

STATEMENT ON THE LABELING OF PHARMACEUTICALS FOR USE IN ANESTHESIOLOGY

Statement:

The primary consideration in the design of labels for pharmaceutical containers should be patient safety and the reduction of medication errors. This is particularly true for the potent medications used in the practice of anesthesiology. Therefore, the ASA supports the manufacture and use of pharmaceuticals labels meeting the following standards, which are consistent with those established by American Society for Testing and Materials International (ASTM International) and the International Organization for Standardization (ISO):

1. **Label Content:** The drug's generic name, concentration, and the total volume or contents of the vial or ampoule should be the most prominent items displayed on the label of each vial or ampoule containing pharmaceuticals for use in the practice of anesthesiology. The drug's proprietary name, manufacturer, lot number, date of manufacture, and expiration date should also be included on the label.
2. **Font:** The text on the label should be designed to enhance the legibility, of the drug name and concentration as recommended in ASTM D4267, *Standard Specification for Labels for Small-Volume (100 ml or less) Parenteral Drug Containers* and D6398, *Standard Practice to Enhance Identification of Drug Names on Labels*, and ISO 26825:2008, *Anaesthetic and respiratory equipment – User-applied labels for syringes containing drugs used during anaesthesia – Colour, design and performance*. These standards include recommendations for font size, extra space for separation around the drug name, and use of additional emphasis for the initial syllable, or a distinctive syllable, of similar drug names.
3. **Contrasting Background:** Maximum contrast between the text and background should be provided by high-contrast color combinations as specified in Section 6.3.1 of ASTM D6398. This minimizes the impact of color blindness:

| Text | Background |
|-------|------------|
| Black | White |
| Blue | Yellow |
| White | Blue |
| Blue | White |

4. **Color:** Nine classes of drugs commonly used in the practice of anesthesiology have a standard background color established for user-applied syringe labels by ASTM D4774, *Standard Specifications for User Applied Drug Labels in Anesthesiology* and ISO 26825:2008. For these drugs, the color of the container's top, label border, and any other colored area on the label, excluding the background as required for maximum contrast, should be the color corresponding to the drug's classification. The color would be that established in ASTM D4774 and ISO 26825:2008 and therefore identical to the color of the corresponding syringe label.

**STATEMENT ON THE LABELING OF PHARMACEUTICALS
FOR USE IN ANESTHESIOLOGY**

| Drug Class | Pantone Color |
|--------------------------------------|--|
| Induction Agents | Process Yellow C (RGB 255.255.0) |
| Benzodiazepines and Tranquilizers | Orange 151 (RGB 255.102.0) |
| Benzodiazepines Antagonists | Orange 151 (RGB 255.102.0)/White Diagonal Stripes |
| Muscle Relaxants | Florescent Red 805 (RGB 253.121.86) |
| Relaxant Antagonists | Florescent Red 805 (RGB 253.121.86)/White diagonal stripes |
| Narcotics | Blue 297 (RGB 233.299.227) |
| Narcotic Antagonists | Blue 297 (RGB 233.299.227)/White diagonal stripes |
| Major Tranquilizers and Anti-Emetics | Salmon 156 (RGB 237.194.130) |
| Narcotic/Tranquilizer Combinations | Blue 297 (RGB 233.299.227)/Salmon 156 (RGB 237.194.130) |
| Vasopressors | Violet 256 (RGB 222.191.217) |
| Hypotensive Agents | Violet 256 (RGB 222.191.217)/White Diagonal Stripes |
| Local Anesthetics | Gray 401 (RGB 194.184.171) |
| Anticholinergic Agents | Green 367 (RGB 163.217.99) |

5. Label Enhancements to Reduce Drug Administration Errors:

- **Bar coding:** Essential information, including the drug's generic name, concentration, and volume of the vial or ampoule should be bar coded at a location on the vial or ampoule which will not interfere with the label's legibility, as specified in Section 8 of ASTM D6398.
- **Peel-off labels** which meet the above criteria for user applied labels and can be transferred directly from the vial to a syringe, along with the contents of the vial, should be added to single-dose vials. These labels reduce the chance of labeling errors and are recommended by Section 3.1 of ISO 26825:2008. Once the peel-off label is removed, the name of the drug shall still be visible on the vial beneath where the peel-off label was removed.
- **Label material** shall allow the user to write information on it using a ball-point pen or felt-tip marker without smudging or blurring as specified in Section 2.3 of ISO 26825:2008.

**CONTINUUM OF DEPTH OF SEDATION:
DEFINITION OF GENERAL ANESTHESIA AND LEVELS OF
SEDATION/ANALGESIA***

Committee of Origin: Quality Management and Departmental Administration

**(Approved by the ASA House of Delegates on October 27, 2004, and amended on
October 21, 2009)**

| | <i>Minimal Sedation/Anxiolysis</i> | <i>Moderate Sedation/Analgesia</i> (“Conscious Sedation”) | <i>Deep Sedation/Analgesia</i> | <i>General Anesthesia</i> |
|--------------------------------|---------------------------------------|--|---|--|
| <i>Responsiveness</i> | Normal response to verbal stimulation | Purposeful** response to verbal or tactile stimulation | Purposeful** response following repeated or painful stimulation | Unarousable even with painful stimulus |
| <i>Airway</i> | Unaffected | No intervention required | Intervention may be required | Intervention often required |
| <i>Spontaneous Ventilation</i> | Unaffected | Adequate | May be inadequate | Frequently inadequate |
| <i>Cardiovascular Function</i> | Unaffected | Usually maintained | Usually maintained | May be impaired |

Minimal Sedation (Anxiolysis) is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilatory and cardiovascular functions are unaffected.

Moderate Sedation/Analgesia (“Conscious Sedation”) is a drug-induced depression of consciousness during which patients respond purposefully** to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

* Monitored Anesthesia Care does not describe the continuum of depth of sedation, rather it describes “a specific anesthesia service in which an anesthesiologist has been requested to participate in the care of a patient undergoing a diagnostic or therapeutic procedure.”

** Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

**CONTINUUM OF DEPTH OF SEDATION:
DEFINITION OF GENERAL ANESTHESIA AND LEVELS OF
SEDATION/ANALGESIA**

Deep Sedation/Analgesia is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully** following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

General Anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue*** patients whose level of sedation becomes deeper than initially intended. Individuals administering Moderate Sedation/Analgesia ("Conscious Sedation") should be able to rescue*** patients who enter a state of Deep Sedation/Analgesia, while those administering Deep Sedation/Analgesia should be able to rescue*** patients who enter a state of General Anesthesia.

** Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

*** Rescue of a patient from a deeper level of sedation than intended is an intervention by a practitioner proficient in airway management and advanced life support. The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation (such as hypoventilation, hypoxia and hypotension) and returns the patient to the originally intended level of sedation. It is not appropriate to continue the procedure at an unintended level of sedation.

WHO/SAFE WASTE MANAGEMENT

14

Hospital hygiene and infection control

14.1 Objective

Management of health-care waste is an integral part of hospital hygiene and infection control. Health-care waste should be considered as a reservoir of pathogenic microorganisms, which can cause contamination and give rise to infection. If waste is inadequately managed, these microorganisms can be transmitted by direct contact, in the air, or by a variety of vectors. Infectious waste contributes in this way to the risk of nosocomial infections, putting the health of hospital personnel, and patients, at risk. The practices described in Chapters 6 to 10 of this handbook for the proper management of health-care waste should therefore be strictly followed as part of a comprehensive and systematic approach to hospital hygiene and infection control.

This chapter outlines the basic principles of prevention and control of the infections that may be acquired in health-care facilities (but does not address other aspects of hospital hygiene and safety such as pressure sores and the risk of falls). It should be stressed here that other environmental health considerations, such as adequate water-supply and sanitation facilities for patients, visitors, and health-care staff, are of prime importance.

14.2 Epidemiology of nosocomial infections

Nosocomial infections—known also as hospital-acquired infections, hospital-associated infections, and hospital infections—are infections that are not present in the patient at the time of admission to hospital but develop during the course of the stay in hospital. There are two forms:

- *Endogenous infection, self-infection, or auto-infection.* The causative agent of the infection is present in the patient at the time of admission to hospital but there are no signs of infection. The infection develops during the stay in hospital as a result of the patient's altered resistance.
- *Cross-contamination followed by cross-infection.* During the stay in hospital the patient comes into contact with new infective agents, becomes contaminated, and subsequently develops an infection.

While there is no clinically significant difference between the endogenous self-infection and the exogenous cross-infection, the distinction is important from the standpoint of epidemiology and prevention.

Healthy people are naturally contaminated. Faeces contain about 10^{13} bacteria per gram, and the number of microorganisms on skin varies between 100 and 10 000 per cm^2 . Many species of microorganisms live

on mucous membranes where they form a normal flora. None of these tissues, however, is infected. Microorganisms that penetrate the skin or the mucous membrane barrier reach subcutaneous tissue, muscles, bones, and body cavities (e.g. peritoneal cavity, pleural cavity, bladder), which are normally sterile (i.e. contain no detectable organisms). If a general or local reaction to this contamination develops, with clinical symptoms, there is an infection.

14.2.1 *The transition from contamination to infection*

Whether or not a tissue will develop an infection after contamination depends upon the interaction between the contaminating organisms and the host.

Healthy individuals have a normal *general resistance* to infection. Patients with underlying disease, newborn babies, and the elderly have less resistance and will probably develop an infection after contamination. Health-care workers are thus less likely to become infected than patients.

Local resistance of the tissue to infection also plays an important role: the skin and the mucous membranes act as barriers in contact with the environment. Infection may follow when these barriers are breached. Local resistance may also be overcome by the long-term presence of an irritant, such as a cannula or catheter; the likelihood of infection increases daily in a patient with an indwelling catheter.

The most important determinants of infection, however, are the nature and number of the contaminating organisms. Microorganisms range from the completely innocuous to the extremely pathogenic: the former will never cause an infection, even in immunocompromised individuals, while the latter will cause an infection in any case of contamination. A classification of conventional, conditional, and opportunistic pathogens is given in Box 14.1.

When only a few organisms are present on or in a tissue, an infection will not necessarily develop. However, when a critical number is exceeded, it is very likely that the tissue will become infected. For every type of microorganism, the *minimal infective dose* can be determined; this is the lowest number of bacteria, viruses, or fungi that cause the first clinical signs of infection in a healthy individual. For most causative agents of nosocomial infections, the minimal infective dose is relatively high. For *Klebsiella* and *Serratia* spp. and other Enterobacteriaceae, for example, it is more than 100 000, but for hepatitis B virus it is less than 10.

14.2.2 *The sources of infection*

In a health-care facility, the sources of infection, and of the preceding contamination, may be the personnel, the patients, or the inanimate environment.

The hospital environment can be contaminated with pathogens. *Salmonella* or *Shigella* spp., *Escherichia coli* O157:H7, or other pathogens may be present in the food and cause an outbreak of disease just as they can in a community outside the hospital. If the water distribution system breaks down, waterborne infections may develop. In more sophisticated premises the water cooling system of air conditioning equipment may

Box 14.1 Classification of pathogenic germs¹

Conventional pathogens

Cause disease in healthy individuals in the absence of specific immunity.

Examples:

Staphylococcus aureus, *Streptococcus pyogenes*, *Salmonella* spp., *Shigella* spp., *Corynebacterium diphtheriae*, *Mycobacterium tuberculosis*, *Bordetella pertussis*, hepatitis A and B viruses, rubella virus, rotaviruses, human immunodeficiency virus (HIV).

Conditional pathogens

Cause disease, other than trivial local infections, only in persons with reduced resistance to infection (including newborn infants) or when implanted directly into tissue or a normally sterile body area.

Examples:

Streptococcus agalactiae, *Enterococcus* spp., *Clostridium tetani*, *Escherichia coli*, *Klebsiella* spp., *Serratia marcescens*, *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, *Candida* spp.

Opportunistic pathogens

Cause generalized disease, but only in patients with profoundly diminished resistance to infection.

Examples:

atypical mycobacteria, *Nocardia asteroides*, *Pneumocystis carinii*.

¹Source: Parker (1978).

become contaminated with *Legionella pneumophila*, causing Legionnaires' disease in susceptible patients. Pharmaceuticals may become contaminated during production or preparation; an outbreak of infection with, for example, *Pseudomonas aeruginosa*, *Burkholderia cepacia*, or *Serratia marcescens*, may occur as a consequence. In all these examples, it may be possible to isolate the same causative agent in several patients, which would suggest a common source. All possible measures should be taken to prevent the recurrence of such incidents.

The source of an outbreak of nosocomial infection may also be a health worker who is infected or colonized (a carrier). The symptoms of frank infection will make the potential of transmission apparent to the health worker and/or to managerial staff, and infected personnel are usually dismissed from patient care duties. A symptomless carrier, however, is contaminated or colonized by potentially pathogenic organisms but does not develop any infection. A typical example is *Staphylococcus aureus*, which may be carried in the nasal passages of 30–60% of personnel. Faecal carriage of enteropathogens such as *Salmonella* spp. also occurs frequently, but the prevalence varies according to the region. Other conventional pathogens that can be found in symptomless carriers include *Streptococcus pyogenes*, *Corynebacterium diphtheriae*, *Neisseria meningitidis*, hepatitis B virus, and cytomegalovirus. Contamination of patients by carriers can give rise to an outbreak of disease. Careful investigation and isolation of the same organisms from a cluster of patients should reveal the cause of the outbreak.

The source of most hospital epidemics is infected patients, i.e. patients contaminated with pathogenic microorganisms. These microorganisms are often released into the environment in very high numbers, exceeding the minimal infective dose, and contaminate other patients who subsequently develop hospital-acquired infections.

14.2.3 The routes of transmission

Microorganisms can be transmitted from their source to a new host through direct or indirect contact, in the air, or by vectors.

Vector-borne transmission is typical of countries in which insects, arthropods, and other parasites are widespread. These become contaminated by contact with excreta or secretions from an infected patient and transmit the infective organisms mechanically to other patients.

Airborne transmission occurs only with microorganisms that are dispersed into the air and that are characterized by a low minimal infective dose. Only a few bacteria and viruses are present in expired air, and these are dispersed in large numbers only as a result of sneezing or coughing.

Direct contact between patients does not usually occur in health-care facilities, but an infected health-care worker can touch a patient and directly transmit a large number of microorganisms to the new host.

The most frequent route of transmission, however, is indirect contact. The infected patient touches—and contaminates—an object, an instrument, or a surface. Subsequent contact between that item and another patient is likely to contaminate the second individual who may then develop an infection.

During general care and/or medical treatment, the hands of health-care workers often come into close contact with patients. The hands of the clinical personnel are thus the most frequent vehicles for nosocomial infections. Transmission by this route is much more common than vector-borne or airborne transmission or other forms of direct or indirect contact.

The spread of nosocomial infections is summarized and illustrated in Fig. 14.1.

14.3 The prevention of nosocomial infection

14.3.1 Principles

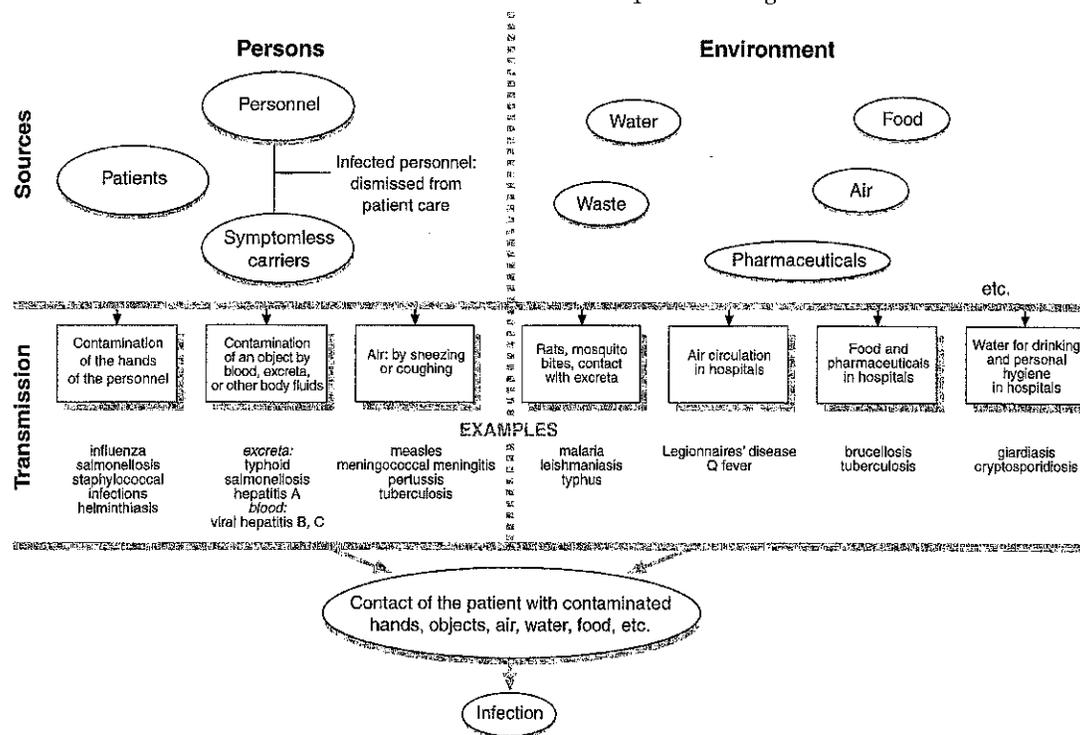
Two basic principles govern the main measures that should be taken in order to prevent the spread of nosocomial infections in health-care facilities:

- separate the infection source from the rest of the hospital;
- cut off any route of transmission.

The separation of the source has to be interpreted in a broad sense. It includes not only the isolation of infected patients but also all “aseptic techniques”—the measures that are intended to act as a barrier between

Fig. 14.1 The spread of nosocomial infections

Notes: Many of the listed diseases can spread by more than one route. The figure shows only a few of the many diseases that may be transmitted within a hospital setting.



infected or potentially contaminated tissue and the environment, including other patients and personnel.

In recent years, increasing attention has been paid to the protection of the personnel, in particular against the transmission of bloodborne infections, e.g. AIDS and viral hepatitis B and C. Preventive measures are known as "universal" or "standard" precautions.

It is impossible to avoid all contact with infected tissue or potentially contaminated body fluids, excreta, and secretions. Even when they are not touched with the bare hands, they may come in contact with instruments, containers, linen, etc. **All objects that come in contact with patients should be considered as potentially contaminated.** If an object is disposable, it should be discarded as waste. If it is reusable, transmission of infective agents must be prevented by cleaning, disinfection, or sterilization.

Despite the continuing concern of hospital managers and all attempts at improvement, many health-care establishments are unable to achieve adequate levels of prevention, particularly in developing countries. An international survey of the prevalence of hospital-acquired infections was conducted in 14 countries in different regions of the world between 1983 and 1985. The results of this survey, which covered 47 hospitals of size

ranging from 227 to 1502 beds (mean 614) showed a wide range of nosocomial infections, with prevalence varying from 3% to 21% (mean 8.4%) in individual hospitals. This work emphasizes the importance of the public health problem.

14.3.2 Isolation of infected patients and standard precautions

The first essential measure in preventing the spread of nosocomial infections is *isolation* of infected patients. The term isolation covers a broad domain of measures. The strictest form of isolation is applied in case of very infectious diseases (e.g. haemorrhagic fever, diphtheria); less stringent precautions can be taken in case of diseases such as tuberculosis, other respiratory infections, and infectious diarrhoea. Isolation of any degree is expensive, labour-intensive, and usually inconvenient or uncomfortable for both patients and health-care personnel; its implementation should therefore be adapted to the severity of the disease and to the causative agent. Disease-specific precautions should include details of all the measures (private room, wearing of masks or gowns, etc.) to be taken in the case of a specific disease caused by a defined organism.

The so-called standard precautions, summarized in Box 14.2, essentially protect health-care workers from bloodborne infections caused by human immunodeficiency virus and hepatitis B and C viruses.

14.3.3 Cleaning

One of the most basic measures for the maintenance of hygiene, and one that is particularly important in the hospital environment, is cleaning. The principal aim of cleaning is to remove visible dirt. It is essentially a mechanical process: the dirt is dissolved by water, diluted until it is no longer visible, and rinsed off. Soaps and detergents act as solubility-promoting agents. The microbiological effect of cleaning is also essentially mechanical: bacteria and other microorganisms are suspended in the cleaning fluid and removed from the surface. The efficacy of the cleaning process depends completely on this mechanical action, since neither soap nor detergents possess any antimicrobial activity. Thorough cleaning will remove more than 90% of microorganisms. However, careless and superficial cleaning is much less effective; it is even possible that it has a negative effect, by dispersing the microorganisms over a greater surface and increasing the chance that they may contaminate other objects. Cleaning has therefore to be carried out in a standardized manner or, better, by automated means that will guarantee an adequate level of cleanliness.

Diluting and removing the dirt also removes the breeding-ground or culture medium for bacteria and fungi. Most non-sporulating bacteria and viruses survive only when they are protected by dirt or a film of organic matter; otherwise they dry out and die. Non-sporulating bacteria are unlikely to survive on clean surfaces.

The effectiveness of disinfection and sterilization is increased by prior or simultaneous cleaning.

14.3.4 Sterilization

Self-evidently, an object should be sterile, i.e. free of microorganisms, after sterilization. However, sterilization is never absolute; by definition,

Box 14.2 Essentials of the standard precautions to be used in the care of all patients

A. Hand washing

- Wash hands after touching blood, secretions, excretions and contaminated items, whether or not gloves are worn. Wash hands immediately after gloves are removed, between patient contacts.
- Use a plain soap for routine hand washing.
- Use an antimicrobial agent for specific circumstances.

B. Gloves

- Wear gloves when touching blood, body fluids, secretions, excretions, and contaminated items. Put on clean gloves just before touching mucous membranes and non-intact skin.

C. Mask, eye protection, face shield

- Wear a mask and eye protection or a face shield during procedures and patient-care activities that are likely to generate splashes or sprays of blood, body fluids, secretions, and excretions.

D. Gown

- Wear a gown during procedures and patient-care activities that are likely to generate splashes or sprays of blood, body fluids, secretions, or excretions.

E. Patient-care equipment

- Ensure that reusable equipment is not used for the care of another patient until it has been cleaned and reprocessed appropriately.

F. Environmental control

- Ensure that the hospital has adequate procedures for the routine care, cleaning, and disinfection of environmental surfaces.

G. Linen

- Handle used linen, soiled with blood, body fluids, secretions, and excretions in a manner that prevents skin and mucous membrane exposures, and that avoids transfer of microorganisms to other patients and environments.

H. Occupational health and bloodborne pathogens

- Take care to prevent injuries when using needles, scalpels, and other sharp instruments or devices.
- Use ventilation devices as an alternative to mouth-to-mouth resuscitation methods.

I. Place of care of the patient

- Place a patient who contaminates the environment or who does not assist in maintaining appropriate hygiene in an isolated (or separate) room.

it effects a reduction in the number of microorganisms by a factor of more than 10^6 (i.e. more than 99.9999% are killed). Standard reference works, such as pharmacopoeias, often state that no more than one out of 1 000 000 sterilized items may still bear microorganisms. It is therefore important to minimize the level of contamination of the material to be

sterilized. This is done by sterilizing only objects that are clean (free of visible dirt) and applying the principles of good manufacturing practice.

Sterilization can be achieved by both physical and chemical means. Physical methods are based on the action of heat (autoclaving, dry thermal or wet thermal sterilization), on irradiation (γ -irradiation), or on mechanical separation by filtration. Chemical means include gas sterilization with ethylene oxide or other gases, and immersion in a disinfectant solution with sterilizing properties (e.g. glutaraldehyde).

14.3.5 *Disinfection*

The term disinfection is difficult to define, as the activity of a disinfectant process can vary widely. The guidelines of the Centers for Disease Control (Garner & Favero, 1986) allow the following distinction to be made:

- *High-level disinfection*: can be expected to destroy all microorganisms, with the exception of large numbers of bacterial spores.
- *Intermediate disinfection*: inactivates *Mycobacterium tuberculosis*, vegetative bacteria, most viruses, and most fungi; does not necessarily kill bacterial spores.
- *Low-level disinfection*: can kill most bacteria, some viruses, and some fungi; cannot be relied on to kill resistant microorganisms such as tubercle bacilli or bacterial spores.

There is no ideal disinfectant and the best compromise should be chosen according to the situation. A disinfectant solution is considered appropriate when the compromise between the antimicrobial activity and the toxicity of the product is satisfactory for the given application. Another consideration may well be the cost. The more active disinfectants are automatically the more toxic ones; potentially toxic products can be applied to inanimate objects or surfaces, whereas for disinfection of human tissues only the less toxic disinfectants can be considered. For antisepsis, different disinfectants are used for application to the intact skin (e.g. alcoholic solutions) and to mucous membranes or wounds (only aqueous solutions of non-toxic substances). Cost is a less important consideration for an antiseptic than for a disinfectant.

The principal requirements for a good antiseptic are absence of toxicity and rapid and adequate activity on both the natural flora and, especially, pathogenic bacteria and other microorganisms after a very short exposure time. Essential requirements for a disinfectant are somewhat different: there must be adequate activity against bacteria, fungi, and viruses that may be present in large numbers and protected by dirt or organic matter. In addition, since disinfectants are applied in large quantities, they should be of low ecotoxicity.

In general, use of the chosen disinfectant, at the appropriate concentration and for the appropriate time, should kill pathogenic microorganisms, rendering an object safe for use in a patient, or human tissue free of pathogens to exclude cross-contamination.

An overview of the characteristics of the main groups of disinfectants is given in Table 14.1.

Table 14.1 *Characteristics of the main disinfectant groups*

| Disinfectants | Bactericidal activity | Tuberculocidal activity | Fungicidal activity | Virucidal activity | Sporicidal activity | Local human toxicity | Applications |
|---|---|-------------------------|---------------------|--------------------|---------------------|----------------------|---|
| Alcohol | Very active | Very active | Very active | Very active | Not active | Moderate | <ul style="list-style-type: none"> • Skin antiseptics • Disinfection of small surfaces |
| Chlorhexidine | Less active against Gram-negative bacilli | Not active | Less active | Not active | Not active | Low | <ul style="list-style-type: none"> • Skin and wound antiseptics |
| Chlorine compounds (chloramine, hypochlorite) | Very active | Active | Active | Very active | Less active | Moderate | <ul style="list-style-type: none"> • Skin and wound antiseptics • Water treatment • Surface disinfection |
| Formaldehyde | Very active | Very active | Very active | Very active | Less active | High | <ul style="list-style-type: none"> • Disinfection of inanimate objects and surfaces |
| Glutaraldehyde | Very active | Very active | Very active | Very active | Very active | High | <ul style="list-style-type: none"> • Disinfection of inanimate objects |
| Hydrogen peroxide | Less active against staphylococci and enterococci | Active | Active | Active | Less active | Low | <ul style="list-style-type: none"> • Wound antiseptics |
| Iodophore | Active | Active | Less active | Active | Not active | Moderate | <ul style="list-style-type: none"> • Skin and wound antiseptics |
| Peracetic acid | Very active | Active | Active | Active | Active | High | <ul style="list-style-type: none"> • Disinfection of inanimate objects |
| Phenolic compounds | Very active | Very active | Very active | Less active | Not active | High | <ul style="list-style-type: none"> • Disinfection of inanimate objects and surfaces |
| Quaternary ammonium compounds | Less active against Gram-negative bacilli | Not active | Less active | Less active | Not active | Low | <ul style="list-style-type: none"> • In combination with other compounds |

14.3.6 *Hand hygiene*

As the hands of health-care workers are the most frequent vehicle of nosocomial infections, hand hygiene—including both hand washing and hand disinfection—is the primary preventive measure.

Thorough hand washing with adequate quantities of water and soap removes more than 90% of the transient, i.e. superficial, flora including all or most contaminants. An antimicrobial soap will further reduce the transient flora, but only if used for several minutes. Hand washing with (non-medicated) soap is essential when hands are dirty and should be routine after physical contact with a patient.

Killing *all* transient flora with all contaminants within a short time (a few seconds) necessitates hygienic hand disinfection: *only alcohol or alcoholic preparations act sufficiently fast*. Hands should be disinfected with alcohol when an infected tissue or body fluid is touched without gloves.

Table 14.2 The main forms of hand hygiene

| Technique | Main purpose | Influence on hand flora | Agents | Rapidity of action | Residual effect |
|----------------------------|----------------------------------|---|---|-------------------------------|-----------------|
| Social hand washing | Cleansing | Reduces transient flora | Non-medicated soap | Slow | Short |
| Careful hand washing | Cleansing after patient contact | Partly removes transient flora | Non-medicated soap | Slow | Short |
| Hygienic hand disinfection | Disinfection after contamination | Kills transient flora | Alcohol | Fast | Short |
| Surgical hand disinfection | Preoperative disinfection | Kills transient flora and inhibits resident flora | Antibacterial soap, alcoholic solutions | Slow (soap) or fast (alcohol) | Long |

During a surgical intervention, a high proportion of gloves becomes perforated. Hands should therefore be disinfected with a long-acting disinfectant before gloves are put on. This will not only kill all the transient flora, but will also prevent the microorganisms of the resident (or deeper) flora from taking the place of the transient flora during the intervention. For this purpose, hands should be washed for 5–10 minutes with an antibacterial detergent containing chlorhexidine or an iodophore, or rubbed twice for 2 minutes with an alcoholic solution of one of these antiseptics.

An overview of the main forms of hand hygiene is given in Table 14.2.

References and suggested further reading

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**USE OF PROPOFOL (DIPRIVAN)
IN OFFICE-BASED SURGERY
KSBHA POLICY NO. 10-03**

| Kansas State Board of Healing Arts | |
|---|---|
| Policy Title: Use of Propofol (Diprivan) in Office Based Surgery | Policy Number: 10-03 |
| Author: Dan Riley | Effective Date: August 20, 2010 |
| Date Authored: August 2, 2010 | Last Modified: |
| Responsible for Updates: ---- | Pending Executive Directory Approval: Yes No |

Purpose:

To assure the use of Propofol (diprivan) in Office Based Surgery is administered in a safe manner.

Authority:

K.A.R. 100-25-3

Policy:

Propofol(diprivan) should not be used in an Office Based Surgery setting unless the following guidelines and protocols are followed **in addition to, or in excess of** the current regulatory guidelines. In all instances propofol must be administered by a licensed CRNA or anesthesiologist with expert training in its administration. **Continuous monitoring** of ECG, pulse oximetry, heart rate, respiration rate and blood pressure must be performed. Patients must be on continuous flow oxygen.

Procedure:

Approved by the Kansas State Board of Healing Arts this 20th day of August, 2010


 Kathleen Solzler Lippert, Executive Director