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Guidelines on sterilization and disinfection methods effective against human immunodeficiency virus (HIV)

Second edition

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Preface to the second edition

In the past year, considerable additional information has been developed on sterilization and disinfection methods effective against the human immunodeficiency virus (HIV), the causative agent of AIDS.

This second edition of the guidelines takes this new information into account and clarifies several areas of possible confusion for users of the first edition. In this regard, the reader is invited to give special attention to the details of the particular method selected for sterilization or disinfection.

Sincere thanks are due to the scientists and public health workers around the world whose constructive comments were incorporated into the second edition of these guidelines.

Introduction

The human immunodeficiency virus (HIV) can be transmitted from one person to another through the use of non-sterile needles, syringes and other skin-piercing and invasive instruments. Correct sterilization of all such instruments is therefore important to prevent transmission of the virus. HIV is very sensitive to standard methods of sterilization and high-level disinfection; methods designed to inactive other viruses (e.g., hepatitis B virus) will also inactivate HIV.

Heat is the most effective method for inactivating HIV; methods for sterilization and high-level disinfection based on heat are therefore the methods of choice. High-level disinfection by boiling is feasible in most circumstances, as this requires only a source of heat, a container, and water. In practical and field settings, high-level disinfection with chemicals is far less reliable.

These guidelines present sterilization and disinfection techniques relevant to clinical health care settings. Techniques specific for diagnostic and research laboratories working with HIV will be dealt with in separate guidelines to be issued shortly by WHO.

HIV transmission

HIV has been found in various body fluids from persons infected with the virus. However, only blood, semen, and vaginal/cervical secretions have been implicated in HIV transmission. Nevertheless, as all body fluids (including pus and other infected discharges and infected body cavity fluids, such as pleural fluid and cerebrospinal fluid) may contain blood or white blood cells, it is essential that all medical instruments for invasive procedures (including needles and syringes) should be sterilized if at all possible, or at a minimum, given high-level disinfection for each separate patient to prevent transmission of HIV.

Methods for sterilization and high-level disinfection of medical instruments

Sterilization is defined as the destruction of all microbes, including bacterial spores (*Bacillus subtilis, Clostridium tetani*, etc.). High-level disinfection is defined as the destruction of all microbes, but spores may survive if initially present in large numbers.

Items that come into contact with intact skin (e.g., stethoscopes) need to be routinely kept free of visible contamination. This requires intermediate to low-level disinfection or washing with soap and water, depending on the nature and amount of contamination.

Medical instruments that pierce human tissue (e.g., scalpels, needles) must be sterilized between each patient contact. Medical instruments that touch but do not penetrate mucous membranes (e.g., anaesthesia breathing circuits, laryngoscope blades, vaginal specula, flexible fibroptic endoscopes) should ideally be sterilized; if this is not feasible they must receive high-level disinfection.

In some health care settings medical instruments are soaked in a chemical disinfectant or detergent before cleaning and further processing prior to reuse. The aim of such soaking is to loosen or prevent drying of organic material. It should not be viewed as making instruments either safe to handle or safe to reuse without further processing.

Sterilization by steam

Steam sterilization (autoclaving) is the recommended method for reusable medical instruments including needles and syringes (syringes should be made of glass or "autoclavable" plastic). The autoclave should be operated for at least 15 minutes after the load achieves a temperature of 121°C (250°F), equivalent to a pressure of 1 atmosphere (101 kPa, 15 lb/in^2) above atmospheric pressure, and after water vapour saturation. The autoclave must not be overloaded.

An inexpensive autoclave has been developed by WHO and the United Nations Children's Fund (UNICEF). This portable steam sterilizer contains an insert (rack), where needles, syringes and other instruments commonly used in health care settings can be fitted.[a] All autoclaves must be tested for efficacy on a regular basis by the use of biological indicators, autoclave control indicators or such other tests as may be devised to ensure that the contents of the load have been subjected to sterilization conditions.

[a] For more information, contact: Expanded Programme on Immunization (EPI), World Health Organization, 1211 Geneva 27, Switzerland; or UNIPAC (UNICEF Procurement and Assembly Centre), Freeport, DK 2100, Copenhagen, Denmark.

Sterilization by dry heat

Sterilization by dry heat in an electric or gas oven is an appropriate method for instruments that can withstand a temperature of 170°C (340°F). This method is therefore not suitable for reusable plastic syringes. Although an ordinary electric or gas household oven may be satisfactory for dry heat sterilization, it should only be used when devices specifically designed for sterilization (autoclave or steam sterilizer, see above) are not available. The sterilization time by dry heat is two hours once the load has equilibrated to 170°C (340°F).

High-level disinfection by boiling

A high level of disinfection is achieved when instruments are boiled for 20 minutes. This is the simplest and most reliable method for inactivating most pathogenic microbes, including HIV, when sterilization equipment is not available. Boiling should be used only when sterilization by steam or dry heat is not available. Hepatitis B virus is inactivated by boiling for several minutes; HIV, which is very sensitive to heat, is also inactivated by boiling for several minutes. However, in order to be sure, boiling should be continued for 20 minutes.

High-level disinfection by soaking in chemicals

Many disinfectants recommended for use in health care facilities have been found to inactivate HIV in laboratory testing. In practice, however, chemical disinfectants may not be reliable, because they may be inactivated by blood or other organic matter present. Futhermore, they must be prepared carefully. They may also rapidly lose their strength, especially when stored in a warm place.

Chemical disinfection must not be used for needles and syringes. Chemical disinfection for other skin-cutting and invasive instruments should be employed only as the last resort, if neither sterilization nor high-level disinfection by boiling is possible, and then only if the appropriate concentration and activity of the chemical can be ensured and if the instruments have been thoroughly cleaned to remove gross contamination prior to soaking (immersion) in the chemical disinfectant. Removal of gross contamination is necessary because disinfectants will not penetrate into some organic matter, such as clotted or dried blood. Instruments other than skin-piercing instruments should be roughly towelled dry before immersion, since repeated immersion of wet instruments may dilute these solutions beyond their range of effectiveness.

Glutaral (glutaraldehyde) 2% and hydrogen peroxide 6% are the two most commonly used high-level chemical disinfectants.

Glutaral (glutaraldehyde)

Glutaral (glutaraldehyde) is usually available as a 2% aqueous solution that needs to be "activated" before use. Activation involves addition of a powder or a liquid buffer supplied with the solution; this renders the solution alkaline.

Total immersion in the activated solution destroys vegetative bacteria, fungi and viruses generally within 30 minutes. Immersion for as much as 10 hours is required for the destruction of spores (sterilization).

After immersion, all equipment should be thoroughly rinsed with sterile water to remove any glutaral residue. After immersion and rinsing, instruments should be handled only with sterile forceps and gloves and dried only with sterile towels in order to prevent recontamination.

Once activated, solutions should not be kept more than two weeks, though some commercial solutions may remain stable for longer. A solution should be discarded if it becomes turbid.

Stabilized glutaral solutions that do not require activation have been developed recently. However, insufficient data exist for their use to be recommended at this time.

Glutaral solutions are expensive. They give off a toxic, irritant vapour which operators should avoid. Skin contact with the liquid should also be avoided.

Hydrogen peroxide

Hydrogen peroxide is a potent high-level disinfectant whose activity is due to its oxidizing ability.

Immersion of cleaned equipment in a 6% solution provides high-level disinfection in less than 30 minutes. After immersion, all equipment should be thoroughly rinsed with sterile water or wiped with a sterile cloth. After immersion and rinsing, instruments should be handled with sterile gloves and forceps and dried with sterile towels to prevent recontamination.

The 6% solution should be prepared immediately before use from the 30% stabilized solution (1 part of stabilized 30% solution added to 4 parts of boiled water). The concentrated stabilized 30% solution should be handled and transported with care because it is corrosive. It should be stored in a cool place protected from light. Hydrogen peroxide is not suitable for transport and storage in hot climates where there are inadequate facilities for keeping the product cool and hence preventing rupture of unvented bottles.

Because hydrogen peroxide 30% is a strong oxidizing agent, it should not be used on copper, aluminium, zinc or brass.

Field guide to sterilization and high-level disinfection of medical instruments[a]

Medical instruments should be sterilized by heat (steam or dry heat). If sterilization by heat is not possible, high-level disinfection by boiling is acceptable. Chemical high-level disinfection must not be used for needles and syringes. Chemical high-level disinfection for other skin-cutting and invasive instruments should only be employed as the last resort, and only if the appropriate concentration and activity of the chemical can be ensured and if the instruments have been thoroughly cleaned before being soaked in the chemical disinfectant.

Sterilization: inactivates (destroys) all viruses, bacteria and spores	
Steam sterilization under pressure for at least 20 minutes: 1 atmosphere (101 kPa, 15 lb/in²) above atmospheric pressure, 121 °C (250 °F)	In autoclave or WHO/UNICEF type steam sterilizer
Dry heat sterilization: 2 hours at 170 °C (340 °F)	In electric or gas oven
High-level disinfection: inactivates (destroys) all viruses and bacteria, but not spores present in large numbers	
Boiling for 20 minutes	In appropriate container
Immersion in high-level disinfectant for 30 minutes followed by rinsing with sterile water (not acceptable for needles and syringes)	High-level chemical disinfectant, e.g.: glutaral (glutaraldehyde) 2% hydrogen peroxide 6%

[a] A poster containing this information is available, on request, from Global Programme on AIDS, World Health Organization, 1211 Geneva 27, Switzerland.

Decontamination of environmental surfaces with chlorine-releasing compounds

Wiping with an appropriate intermediate to low-level disinfectant is acceptable for surfaces such as table tops.

Most spills of blood in the health care setting should be dealt with by removing visible blood with absorbent material (e.g., paper towelling) and then decontaminating the area by wiping it with an appropriate disinfectant as outlined below. For large spills of blood or for spills of concentrated or cultured material (such as may occur in the laboratory setting), the area should first be covered with paper towelling or other absorbent material and then a disinfectant should be poured over the absorbent material and left for 10 minutes. Next, the whole spill is wiped up with fresh absorbent material and placed in a contaminated-waste container. The surface should then be disinfected with an appropriate intermediate to low-level disinfectant. Gloves should be worn throughout the procedure.

Chlorine-releasing compounds are appropriate disinfectants for the decontamination of environmental surfaces, and sodium hypochlorite is the most widely used compound (see below). Alcohols are not generally considered suitable for this purpose because of their rapid evaporation and because they quickly coagulate organic residue and do not penetrate it.

Sodium hypochlorite

Sodium hypochlorite solutions (e.g., liquid bleach, eau de Javel) are excellent intermediate to low-level disinfectants: they are bactericidal, virucidal, inexpensive and widely available.

However, they have two important disadvantages.

- **They are corrosive.** They will corrode nickel and chromium steel, iron, and other oxidizable metals. Solutions exceeding 0.05% available chlorine should not be used repeatedly for the decontamination of good quality stainless steel equipment. Contact should not exceed 30 minutes. Dilutions should not be prepared in metallic containers as they may corrode rapidly.

- **They deteriorate.** Solutions should be recently manufactured and protected in storage from heat and light. Dilutions should be prepared just before use. Rapid decomposition may be a particular problem in countries with a warm climate.

The three other chlorine-releasing compounds described below are also suitable. They are more stable than sodium hypochlorite solutions and, because of their formulations, can be transported more easily and cheaply.

Calcium hypochlorite

Calcium hypochlorite can be expected to inactivate HIV as it generates hypochlorous acid in solution, and is therefore expected to act in a similar way to sodium hypochlorite. Like sodium hypochlorite, it decomposes gradually if not protected from heat and light but it does so more slowly. It is available in two forms: "high-tested" calcium hypochlorite and chlorinated lime or bleaching powder. A deposit in solutions of calcium hypochlorite is normal.

Sodium dichloroisocyanurate (NaDCC)

Generally formulated as tablets, this substance is much more stable than either sodium hypochlorite solution or calcium hypochlorite. When dissolved in water, NaDCC forms hypochlorous acid; it can therefore be expected to inactivate HIV in much the same way as sodium hypochlorite.

Chloramine (tosylchloramide sodium; chloramine T)

Chloramine is more stable than either sodium hypochlorite or calcium hypochlorite. It should, however, be stored protected from humidity, light and excessive heat. It is available as powder or tablets.

The disinfectant power of all chlorine-releasing compounds is expressed as "available chlorine" (% for solid compounds; % or parts per million (ppm) for solutions) according to the concentration level. Thus,

0.0001% = 1 mg/litre = 1 ppm and 1% = 10g/litre = 10 000 ppm.

In some countries the concentration of sodium hypochlorite solution is expressed in chlorometric degrees (° chlorom.); 1° chlorom. is approximately equivalent to 0.3% available chlorine.

Household liquid bleach generally contains 5% available chlorine.
Eau de Javel (15° chlorom.) contains approximately 5% available chlorine.
Extrait de Javel (48° chlorom.) contains approximately 15% available chlorine.
Calcium hypochlorite contains approximately 70% available chlorine.
Chlorinated lime contains approximately 35% available chlorine.
NaDCC contains approximately 60% available chlorine.
Chloramine contains approximately 25% available chlorine.

The amount of available chlorine required in solutions used for the decontamination of environmental surfaces depends on the amount of organic matter present, since chlorine is inactivated by organic matter such as blood or pus.

Recommended dilutions of chlorine-releasing compounds

	"Dirty" conditions (for flooding the contaminated surface prior to removal of bulk material)	"Clean" conditions (following physical removal of bulk material)
Available chlorine required	0.5% (5 g/litre, 5000 ppm)	0.05-0.1% (1 g/litre, 500-1000 ppm)
Dilution		
Sodium hypochlorite solution (5% available chlorine)	100 ml/litre	10-20 ml/litre
Calcium hypochlorite (70% available chlorine)	7.0/litre	0.7-1.4 g/litre
NaDCC (60% available chlorine)	8.5 g/litre	0.9-1.7 g/litre
NaDCC-based tablets (1.5 g of available chlorine per tablet)	4 tablets/litre	½-1 tablet/litre
Chloramine (25% available chlorine)	20 g/litre	10-20 g/litre[a]

[a] Chloramine releases chlorine at a slower rate than do hypochlorites. Therefore, a higher available chlorine concentration is required in chloramine solutions for the same effectiveness. On the other hand, chloramine solutions are not inactivated by biological materials (e.g., protein and blood) to the same extent as hypochlorites. Therefore, a similar concentration is recommended for both clean and dirty conditions.

Disinfection of living tissues with antiseptics

Antiseptics are germicides that are designed for use on in living tissue, not on instruments or other inanimate surfaces.

Ethanol and 2-propanol

Ethanol (ethyl alcohol) and 2-propanol (isopropyl alcohol) have similar disinfectant properties. They are germicidal for vegetative forms of bacteria, mycobacteria, fungi and viruses after a few minutes of contact. They are not effective against bacterial spores.

For highest effectiveness they should be used in a concentration of approximately 70% (70% alcohol, 30% water); lower and higher concentrations are less effective. Ethanol can be used in its denatured forms, which may be less expensive; these are toxic if consumed.

All alcohols are very expensive if they have to be imported, as they are subject to strict air-freight regulations requiring special heavy packaging. Importation of alcohol is limited in some countries.

Polyvidone iodine (PVI)

Polyvidone iodine (PVI) is an iodophore (a compound that carries iodine) and can be used in aqueous solution. PVI has multiple mechanisms of action, including surfactant (wetting) activity. It is commonly formulated as a 10% solution (1% iodine). It can be used diluted to 2.5% PVI (1 part 10% solution to 3 parts boiled water).

Indicative prices of chemical disinfectants

The choice of disinfectants should be determined by their intended use, effectiveness, stability, availability and price. The cost of their transport between and within countries may add considerably to the overall costs. Solids, tablets or powders that can be diluted locally are always the least expensive to transport.

The price list below illustrates the difference in prices for 1 litre of ready-to-use disinfectant solution and the added cost when disinfectants have to be shipped by air as solids or stock solutions from manufacturing country to importing country.

As examples, the prices in the right-hand column have been estimated on the basis of the average purchase price in Europe in 1987 plus approximate air-freight costs for a distance equivalent to that from Europe to Africa and special packaging costs for inflammable and corrosive substances.

Disinfectant	Price in Europe (US$)	Price for 1 litre of ready-to-use solution (US$)	Price for 1 litre of ready-to-use solution when air-freighted (US$)
High-level disinfectants			
glutaral (glutaraldehyde) (2%)	3.20/litre	3.20 (undiluted)	6.50
hydrogen peroxide (30%)	3.20/litre	0.65 (1:5 dilution)	4.60
Intermediate to low-level disinfectants			
calcium hypochlorite (70% available chlorine)	6.00/kg	0.04 (7 g/litre)	0.13
chloramine (1 g/tablet)	0.02/tablet	0.4 (20 tablets/litre)	0.52
sodium dichloroisocyanurate (1.5 g of chlorine/tablet)	0.07/tablet	0.28 (4 tablets/litre)	0.32
sodium hypochlorite (5% available chlorine)	0.50/litre	0.05 (1:10 dilution)	1.15
Antiseptics			
ethanol (90%)	3.10/litre	2.50 (8:10 dilution)	11.30
polyvidone iodine (10%)	5.00/litre	1.25 (1:4 dilution)	2.10
2-propanol (100%)	4.20/litre	3.00 (7:10 dilution)	10.70

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