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**infection control guidelines**

# Hand Washing, Cleaning, Disinfection and Sterilization in Health Care

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# **Infection Control Guidelines**

## **Hand Washing, Cleaning, Disinfection and Sterilization in Health Care**

Health Canada  
Laboratory Centre for Disease Control  
Bureau of Infectious Diseases  
Nosocomial and Occupational Infections

# Introductory Statement

The primary objective in developing clinical guidelines at the national level is to help health care professionals improve the quality of health care. Guidelines for the control of infection are needed to assist in developing policies, procedures and evaluative mechanisms to ensure an optimal level of care. Guidelines facilitate the setting of standards but respect the autonomy of each institution and recognize the governing body's authority and responsibility of ensuring the quality of patient/client care provided by the institution.

The guidelines, whenever possible, have been based on research findings. Where there is insufficient published research, consensus of experts in the field has been utilized to provide guidelines specific to conventional practice. The encouragement of research and frequent revision and updating are necessary if guidelines are to remain relevant and useful.

The Steering Committee acknowledges, with sincere appreciation, the many practising health professionals and others who contributed advice and information to this endeavour.

The guidelines outlined herein are part of a series that has been developed over a period of years under the guidance of the Steering Committee on Infection Control Guidelines. *Infection Control Guidelines for Hand Washing, Cleaning, Disinfection and Sterilization in Health Care* presents an overview and provides recommendations to assist in preventing the transmission of infection in health care facilities. This document is part of the Health Canada series of *Infection Control Guidelines* and is intended to be used with the other *Infection Control Guidelines*, which include the following:

*Preventing the Transmission of Bloodborne Pathogens in Health Care and Public Services Settings* (1997)

*Isolation and Precaution Techniques* (1990) (under revision - to be published March, 1999)

*Preventing the Spread of Vancomycin-Resistant Enterococci* (1997)

*Preventing the Transmission of Tuberculosis in Canadian Health Care Facilities and Other Institutional Settings* (1996)

*Canadian Contingency Plan for Viral Hemorrhagic Fevers and Other Related Diseases* (1997)

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*Foot Care by Health Care Providers* (1997)

*Occupational Health in Health Care Facilities* (1990) (under revision)

*Prevention of Nosocomial Pneumonia* (1990) (under revision)

*Long Term Care Facilities* (1994)

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*Prevention of Surgical Wound Infections* (1990)

*Prevention of Urinary Tract Infections* (1990)

*Perinatal Care* (1988)

*Organization of Infection Control Programs in Health Care Facilities* (1990)

For information regarding these Health Canada publications, contact:

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# Hand Washing and Gloves\*

Disease-causing microorganisms can frequently be isolated from the hands. Hand carriage of bacteria is an important route of transmission of infection between patients or from the health care worker to the patient/client<sup>(1-6)</sup>. Appropriate hand washing results in a reduced incidence of both nosocomial and community infections<sup>(1,7,8)</sup>. Guidelines from national and international infection prevention and control organizations have repeatedly acknowledged that **hand washing is the single most important procedure for preventing infections**<sup>(9-11)</sup>. Despite this, health care providers' compliance with hand washing is poor<sup>(12-14)</sup>.

This section will review the current literature on skin flora, antimicrobial agents used for hand antisepsis, hand washing techniques and other aspects of hand care and protection, and will make recommendations to be applied in the health care setting. Routine hand washing is discussed in this guideline, and the surgical hand scrub is discussed in *Infection Control Guidelines: Prevention of Surgical Wound Infections*<sup>(15)</sup>.

## A. Microbiology of the Skin

Larson has provided an extensive review of the physiologic and bacteriologic characteristics of the skin<sup>(16)</sup>. The finger nail area is associated with a major portion of the hand flora. The subungual areas (located under the fingernail) often harbour high numbers of microorganisms, which may serve as a source of continued shedding, especially under gloves<sup>(17)</sup>.

Artificial nails<sup>(18)</sup> and chipped nail polish<sup>(19)</sup> may be associated with a further increase in the number of bacteria on fingernails.

The microbial flora of the skin consist of resident (colonizing) and transient (contaminating) microorganisms. The resident microorganisms survive and multiply on the skin. Resident flora include the coagulase-negative staphylococci, members of the genus *Corynebacterium* (diphtheroids or coryneforms), *Acinetobacter* species, and occasionally members of the Enterobacteriaceae group<sup>(20)</sup>. Resident skin microorganisms are not usually implicated in nosocomial infections, other than minor skin infections; however, some can cause infections after invasive procedures, when the patient/client is severely immunocompromised or has an implanted device, such as a heart valve or artificial hip.

The transient microbial flora represent recent contaminants of the hands acquired from colonized or infected patients/clients or contaminated environment or equipment. Transient microorganisms are not consistently isolated from most persons. In contrast to the resident flora, the transient microorganisms found on the hands of health care personnel are more frequently implicated as the source of nosocomial infections. The most common transient flora include gram negative coliforms and *Staphylococcus aureus*.

Hand washing with plain soap (detergents) is effective in removing most transient microbial flora<sup>(20-22)</sup>. **The components of good hand washing include using an adequate amount of soap, rubbing the hands together to create some friction, and rinsing under running water.** The mechanical action of washing, rinsing and drying removes most of the transient bacteria present<sup>(23-25)</sup>.

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\* See Appendix 1 for definitions of the following terms: antimicrobial agent, antiseptic, hand wash(ing), hand antisepsis, heavy microbial soiling, plain or nonantimicrobial soap, sharps, surgical hand scrub.

In some studies, air dryers have been shown to reduce the number of organisms on hands after hand washing<sup>(26-28)</sup>. Several studies have demonstrated that air hand dryers are unsuitable for use in critical patient care areas because of the potential for cross infection, either through airborne dissemination or contaminated personnel<sup>(24,29-31)</sup>. Air dryers may be an impediment to hand drying because of the time taken to dry hands and the need to ensure that the equipment is functioning.

## B. Soaps and Antiseptic Agents

The purpose of hand washing is to remove soil, organic material and transient microorganisms from the skin. Few clinical studies have defined the absolute indications for hand washing with plain soaps (detergents) versus hand antisepsis with antimicrobial products. Controlled trials have not documented decreased infection with the use of an antiseptic agent over plain soap for routine hand washing in the general health care setting. The degree of reduction in microbial numbers on the hands of health care providers necessary to protect the recipient of care has not been defined. A few studies have suggested that antiseptic agents may be preferable for the care of patients if there is a possibility of antimicrobial-resistant organisms, such as in intensive care units<sup>(3,32)</sup>, in the presence of antimicrobial-resistant organisms<sup>(33-36)</sup>, and under conditions of heavy microbial soiling (e.g., in the presence of infection or a high level of contamination with organic matter such as feces)<sup>(37)</sup>.

Understanding the distinctive ingredients and uses of the soap and antiseptic products available is important in choosing the appropriate agent for the appropriate situation. If an antiseptic product is used, it should be selected for its chemical composition, its type and spectrum of activity, its onset and duration of activity, the application for which it will be used, its cost, allergenic potential and acceptability to the users. Whatever product is used, it should be applied at the right dilution for the recommended time with standard methods of application.

Antiseptic hand cleansers are designed to rapidly wash off the majority of the transient flora by their mechanical detergent effect and to exert an additional sustained antimicrobial activity on the resident hand flora (Tables 1 and 2)<sup>(38,39)</sup>.

## C. Waterless Hand Scrubs

Several studies have demonstrated superior efficacy of waterless hand scrubs compared with hand washing with

soap and water or chlorhexidine<sup>(36,47-50)</sup>. Alcohol-based compounds for hand antisepsis predominate in several European countries<sup>(51-53)</sup>. Alcohol preparations offer rapid reduction in microbial counts on skin<sup>(54)</sup>; a vigorous, 1-minute rubbing with enough alcohol to wet the hands completely has been shown to be an effective method of hand antisepsis<sup>(20,36,51,55,56)</sup>. Alcohol applications as short as 15 seconds in duration have been effective in preventing hand transmission of gram-negative bacteria<sup>(37,57)</sup>. The advantages of alcohol rubs include the following: (1) they have an immediate and delayed antimicrobial performance, (2) no wash basin is necessary for their use and (3) alcohol rubs can be conveniently available near every patient/client and are more practical when there is insufficient time to wash hands<sup>(42,57,58)</sup>. Alcohol preparations are useful in home care when proper facilities for hand washing may be lacking<sup>(59)</sup>.

A major disadvantage of alcohol for skin antisepsis is its effect on the user. Waterless hand scrubs may have a drying effect on the skin of the hands, and product odours may be irritating for health care workers. The addition of emollients to minimize skin drying increases the acceptability of alcohol-based solutions on the hands<sup>(55)</sup>. The antimicrobial efficacy of alcohols is sensitive to dilution with water, therefore alcohol preparations must be rubbed onto dry hands<sup>(55)</sup>. The activity of alcohol does not appear to be significantly affected by small amounts of blood<sup>(60)</sup>; however, further studies are needed to determine activity in the presence of large amounts of organic matter.

See Table 2 for a description of the antimicrobial activity and uses of antiseptic agents.

## D. Hand Washing Techniques

The absolute indications for and the ideal frequency of hand washing have not been well studied. The indications for hand washing depend on

- (a) the type, intensity, duration and sequence of activity;
- (b) the degree of contamination associated with the contact; and
- (c) the susceptibility to infection of the health care recipient.

**Table 1. Soaps and Antiseptic Agents for Hand Washing**

Product	Indications	Special considerations
<p><b>Plain soap, bar soap, liquid*, granules</b></p>	<p>For routine care of patients/residents/clients<sup>(10,20,40)</sup>                      For washing hands soiled with dirt, blood or other organic material</p>	<p>May contain very low concentrations of antimicrobial agents to prevent microbial contamination growth in the product.                      Bar soap should be on racks that allow water to drain; small bars that can be changed frequently are safest<sup>(11,41)</sup>.</p>
<p><b>Waterless antiseptic agents:</b>                      - rinses                      - foams                      - wipes                      - towelettes</p>	<p>Demonstrated alternative to conventional agents<sup>(42)</sup>                      For use where hand washing facilities are inadequate, impractical or inaccessible (e.g., ambulances, home care, mass immunization)                      For situations in which the water supply is interrupted (e.g., planned disruptions, natural disasters)</p>	<p>Not effective if hands are soiled with dirt or heavily contaminated with blood or other organic material.                      Follow manufacturer’s recommendations for use.                      Efficacy affected by concentration of alcohol in product.                      Hand creams should be readily available to protect skin integrity<sup>(43-45)</sup>.</p>
<p><b>Antiseptic agents</b></p>	<p>Refer to recommendations at end of this chapter.                      May be chosen for hand scrubs prior to performance of invasive procedures (e.g., placing intravascular lines or devices)<sup>(34)</sup>.                      When caring for severely immunocompromised individuals                      Based on risk of transmission (e.g., specific microorganisms)                      Critical care areas                      Intensive care nurseries                      Operating room scrub                      When caring for individuals with antimicrobial resistant organisms<sup>(33)</sup></p>	<p>Antiseptic agents may be chosen if it is felt important to reduce the number of resident flora or when the level of microbial contamination is high.                      Antiseptic agents should be chosen when persistent antimicrobial activity on the hands is desired.                      They are usually available in liquid formulations*.                      Antiseptic agents differ in activity and characteristics<sup>(38,39)</sup>.                      Routine use of hexachlorophene is not recommended because of neurotoxicity and potential absorption through the skin<sup>(46)</sup>.                      Alcohol containers should be stored in areas approved for flammable materials.</p>

\* Disposable containers are preferred for liquid products. Reusable containers should be thoroughly washed and dried before refilling, and routine maintenance schedules should be followed and documented. Liquid products should be stored in closed containers and should not be topped-up.

**Table 2. Characteristics of Antiseptic Agents**

Group and subgroup	Gram-positive bacteria	Gram-negative bacteria	<i>Mycobacterium tuberculosis</i>	Fungi	Virus	Speed of killing sensitive bacteria	Inactivated by mucus or proteins	Comments
Alcohols	Good	Good	Good	Good	Good	Fast	Moderate	Optimum strength 70% to 90% with added emollients (glycerine or cetyl alcohol is less drying), not recommended for physical cleaning of skin; good for hand antisepsis and for surgical site preparation.
Chlorhexidine 2% and 4% aqueous	Good	Good	Fair	Fair	Good	Intermediate	Minimal	Has persistent effect; good for both hand washing and surgical site or preoperative patient skin preparation; do not use near mucous membranes; toxic effects on ears and eyes reported; activity neutralized by nonionic surfactants.
Hexachlorophene 3% aqueous	Good	Poor	Poor	Poor	Poor	Slow	Minimal	Provides persistent, cumulative activity after repeated use (washing with alcohol reduces persistent action), can be toxic when absorbed from skin especially in premature infants; good for hand washing but not for surgical site preparation; limited spectrum of antimicrobial activity.
Iodine compounds, iodine in alcohol	Good	Good	Good	Good	Good	Fast	Marked	Causes skin "burns," but this is unusual with 1% tincture, especially if it is removed after several minutes; too irritating for hand washing but excellent for surgical site preparation.
Iodophors	Good	Good	Fair	Good	Good	Intermediate	Moderate	Less irritating to the skin than iodine; good for both hand washing and surgical site preparation; rapidly neutralized in presence of organic materials such as blood or sputum
<i>Para</i> -chloro- <i>meta</i> -xylenol (PCMX)	Good	Fair*	Fair	Fair	Fair	Intermediate	Minimal	Activity neutralized by nonionic surfactants
Triclosan	Good	Good	Fair	Poor	Good	Intermediate	Minimal	

\*Activity improved by addition of chelating agent such as EDTA.

Note: Some of these agents, such as iodine or chlorhexidine, are combined with alcohol to form tinctures and are available in the combined formulation<sup>(10)</sup>.

Table used with permission of author and publisher<sup>(10)</sup>.

**Table 3. How to Wash Hands**

Procedure	Rationale
Remove jewelry before hand wash procedure <sup>(38,61)</sup> .	
Rinse hands under warm running water.	This allows for suspension and washing away of the loosened microorganisms.
Lather with soap and, using friction, cover all surfaces of the hands and fingers.	The minimum duration for this step is 10 seconds <sup>(25)</sup> ; more time may be required if hands are visibly soiled. For antiseptic agents 3-5 mL are required <sup>(38)</sup> . Frequently missed areas are thumbs, under nails, backs of fingers and hands.
Rinse under warm running water.	To wash off microorganisms and residual hand washing agent
Dry hands thoroughly with single-use towel or forced air dryer.	Drying achieves a further reduction in number of microorganisms <sup>(24,29,38)</sup> . Reusable towels are avoided because of the potential for microbial contamination.
Turn off faucet without recontaminating hands.	To avoid recontaminating hands.
Do not use fingernail polish or artificial nails.	Artificial nails or chipped nail polish may increase bacterial load and impede visualization of soil under nails <sup>(18,62)</sup> .

The efficacy of a hand wash depends on the time taken and the technique. The recommended hand washing technique is outlined in Table 3. It is important to avoid potential microbial contamination by splashing of clothing, other skin surfaces or inanimate items during hand washing.

### E. Compliance with Hand Washing Protocols

Although hand washing is considered the most important single intervention for preventing nosocomial infections<sup>(1-6)</sup>, studies have repeatedly shown poor compliance with hand washing protocols by hospital personnel<sup>(3,12,13,63,64)</sup>. Failure to comply is a complex problem that includes elements of lack of motivation and

lack of knowledge about the importance of hand washing. It may also be due to real or perceived obstacles, such as understaffing, inconveniently located hand washing facilities, an unacceptable hand washing product or dermatitis caused by previous hand washing. A number of strategies have been suggested to improve compliance (Table 4). Long-term success will require development of programs and sustained efforts at promoting compliance with hand washing. Effective interventions will probably be multidimensional, and will require the application of behavioural science theory combined with engineering and/or product innovation<sup>(7,8)</sup>.



**Table 4. Proposed Strategies to Improve Hand Washing Technique and Compliance**

Obstacle	Strategy
Lack of knowledge	Education with supportive literature, videotaped instructions, hand washing demonstrations; frequent refreshers; involvement of personnel in education and feedback <sup>(7,8,65)</sup> Feedback on infection rates <sup>(64)</sup>
Lack of motivation	Direct observation and feedback on regular basis <sup>(65)</sup> ; role models; involvement of staff in studies; application of new technologies <sup>(63,66-69)</sup> Programs on hand hygiene for patients and families <sup>(64,70)</sup>
Availability of hand washing facilities	Hand washing facilities conveniently located throughout the health care setting <sup>(67,68)</sup> A sink accessible to personnel in or just outside every room; more than one sink per room may be necessary if a large room is used for several individuals. Hand washing facilities in or adjacent to rooms where health care procedures are performed Accessible, adequately supplied and proper functioning soap and towel dispensers or hand dryers Faucets with foot, wrist or knee operated handles; faucets with an electric eye are also desirable. Waterless antiseptic agents readily available in wall mounted dispensers, or in small containers for mobile care such as home care and for emergency responders.
Hand washing product	Hand washing products that have a high level of acceptability to staff, with appropriateness, cost, supply, etc., being taken into consideration <sup>(55,59)</sup>
Dermatitis	Lotions to prevent skin dryness Lotion supplied in small, non-refillable containers <sup>(43-45,72)</sup> Compatibility between lotion and antiseptic products and effect on glove integrity Lotions approved by personnel in infection control and occupational health <sup>(73)</sup>

**Recommendations on Hand Washing**

1. Hands must be washed

- (i) between direct contact with individual patients/residents/clients;
- (ii) before performing invasive procedures<sup>(11,20)</sup>;
- (iii) before caring for patients in intensive care units and immunocompromised patients<sup>(11,20)</sup>;
- (iv) before preparing, handling, serving or eating food, and before feeding a patient;

- (v) when hands are visibly soiled<sup>(13,20)</sup>;
- (vi) after situations or procedures in which microbial or blood contamination of hands is likely;
- (vii) after removing gloves<sup>(11,20,74)</sup>; and
- (viii) after personal body functions, such as using the toilet or blowing one’s nose. **Category B; Grade II\***

2. Hand washing should be encouraged whenever a health care provider is in doubt about the necessity for doing so. **Category B; Grade III**

\* See Appendix 2 for the rating system used in these recommendations.

3. As well as between patient/resident/client contacts, hand washing may be indicated more than once in the care of one person, for example after touching excretions or secretions and before going on to another care activity for the same person<sup>(37)</sup>.  
**Category B; Grade II**
4. Superficial contact with an object not suspected of being contaminated, such as when touching or collecting food trays, generally does not require hand washing. **Category B; Grade III**
5. Hand washing facilities should be conveniently located throughout the health care setting. They should be available in or adjacent to rooms where health care procedures are performed. If a large room is used for several individuals, more than one sink may be necessary. Sinks for hand washing should be used only for hand washing and not for any other purpose, e.g., as a utility sink. There should be access to adequate supplies and proper functioning soap and towel dispensers or hand dryers, or liberal use of waterless hand wash agents<sup>(41,68,69)</sup>. **Category B; Grade II**
6. To avoid recontaminating hands, faucets with foot, wrist, or knee operated handles should be installed wherever possible; faucets with an electric eye are also desirable. If automated faucets are not available, single-use towels should be supplied for user to turn off faucets. **Category B; Grade III**
7. Hands should be dried thoroughly with either a single-use towel or electric air dryer<sup>(26,27)</sup>. **Category A; Grade II**
8. Hand lotion may be used to prevent skin damage from frequent hand washing<sup>(55)</sup>. Lotion should be supplied in disposable bags in wall containers by sinks or in small, non-refillable containers to avoid product contamination. Skin lotions for patient and/or staff use have been the reported source of outbreaks<sup>(43-45,72,73)</sup>. **Category B; Grade II**
9. Compatibility between lotion and antiseptic products and lotion's potential effect on glove integrity should be checked<sup>(75,76)</sup>. **Category A; Grade II**
10. Liquid hand wash products should be stored in closed containers and dispensed from either disposable containers or containers that are washed and dried thoroughly before refilling. **Category A; Grade II**
11. Hand washing with plain soap is indicated in routine health care and for washing hands soiled with dirt, blood or other organic material. Plain soap and water will remove many transient organisms<sup>(20-22,40,59,77)</sup>.  
**Category A; Grade II**
12. Hand washing with an antiseptic agent is indicated for the following situations:
  - (i) when there is heavy microbial soiling, e.g., in the presence of infection or a high level of contamination with organic matter such as infected wounds and feces<sup>(36,47,48,78)</sup>. **Category A; Grade II;**
  - (ii) prior to performing invasive procedures (e.g., the placement and care of intravascular catheters, indwelling urinary catheters)<sup>(2,5,6)</sup>.  
**Category A; Grade I;**
  - (iii) before contact with patients who have immune defects, damage to the integumentary system (e.g., wounds, burns), or percutaneous implanted devices<sup>(3,6)</sup>. **Category A; Grade II;**
  - (iv) before and after direct contact with patients who have antimicrobial-resistant organisms<sup>(32,35,36)</sup>. **Category A; Grade II**
13. Hand washing with waterless/alcohol-based agents is equivalent to soap and water, and these agents should be made available where access to water is limited<sup>(42,59,78)</sup>. If there is heavy microbial soiling, hands must first be washed with soap and water to remove visible soiling<sup>(20)</sup>. Hands must be dry before an alcohol-based agent is used because moisture from wet hands dilutes the alcohol. **Category A; Grade II**
14. Compliance with hand washing procedures should be encouraged by involving users as much as possible in product selection, facilities design, studies, application of new technologies, education programs and feedback<sup>(63,64,69)</sup>. **Category A; Grade II**
15. Patients/clients/residents in settings where patient hygiene is poor should have their hands washed. Patients/residents should be helped to wash their hands before meals, after going to the bathroom, before and after dialysis, and before leaving their room. **Category B; Grade III**

## F. Gloves

### i) Glove use

Gloves are worn to

- a. provide an additional protective barrier between health care workers' hands and blood, body fluids, secretions, excretions and mucous membranes<sup>(74,79)</sup>, and
- b. reduce the potential transfer of microorganisms from infected patients to health care workers, and from patient to patient via health care workers' hands<sup>(81)</sup>.

Glove use should be an adjunct to, not a substitution for, hand washing. If hand washing is performed carefully and appropriately by all personnel, gloves are not necessary to prevent transient colonization of health care workers' hands and subsequent transmission to others<sup>(82)</sup>.

In 1987, the Laboratory Centre for Disease Control (LCDC) recommended the use of gloves for specific situations, primarily to protect the health care worker from exposure to bloodborne pathogens<sup>(83)</sup>. Application of universal precautions<sup>(82-84)</sup> significantly increased the use of gloves in the health care setting. Some institutions adopted body substance isolation precautions<sup>(85)</sup>, which expanded the use of gloves to prevent contamination of hands.

### ii) Selection of gloves

**It is important to assess and select the most appropriate glove to be worn for the circumstances.** Selection of gloves should be based on a risk analysis of the type of setting, type of procedure, likelihood of exposure to blood or fluid capable of transmitting pathogens, length of use and amount of stress on the glove<sup>(86)</sup>. Factors such as personal comfort and fit, cost and latex allergy in employees and clients/residents are also important considerations.

### iii) Glove types

Non-sterile gloves sold in Canada must meet the requirements of Health Canada Information Letter No. 777 (April 30, 1990). Health Canada recommends purchasing gloves with the Canadian General Standards Board certification mark, which ensures that voluntary national standards are met during manufacturing. However some types of glove materials are not available in certified brands. The Medical Devices Bureau of Health Canada has an information package on glove quality and certification, and on latex allergy (1-800-267-9675)<sup>(87)</sup>.

Studies have demonstrated varying effectiveness of gloves as barrier protection. Some studies have concluded that latex gloves were associated with less leakage than vinyl gloves<sup>(74,88-92)</sup>. Other studies have shown non-latex gloves to be effective<sup>(79,93-96)</sup>.

### iv) Problems of glove use

Constant use of gloves may cause irritant dermatitis. The cause of the dermatitis may be mechanical irritation from the glove or glove powder; it may also be chemical agents, such as residual soap, trapped between the glove and skin.

Latex allergy is an increasing concern in health care settings because of the potentially serious outcomes in workers and clients who are allergic to latex. Some employees affected by latex allergy may be able to work in an area where others are using low protein, non-powdered latex gloves. Employees and clients who are severely allergic to latex need to avoid all contact with it.

For further information on latex allergy in health care facilities, refer to the Canadian Healthcare Association publication *Guidelines for the Management of Latex Allergy and Safe Latex Use in Health Care Facilities*<sup>(97)</sup>.

### Recommendations on Glove Use

For further information and recommendations on glove use, refer to Health Canada's *Infection Control Guidelines Preventing the Transmission of Bloodborne Pathogens in Health Care and Public Services Settings*<sup>(84)</sup> and the revision of Health Canada's *Isolation and Precaution Techniques*<sup>(98)</sup>.

1. Gloves should be used as an additional measure, not as a substitute for hand washing<sup>(74,99)</sup>. **Category B; Grade II**
2. Gloves are not required for routine patient care activities if contact is limited to a patient's intact skin, e.g., when transporting patients. **Category B; Grade III**
3. Gloves may not be needed for routine diaper changes if the procedure can be done without contaminating the hands with stool or urine. **Category C**
4. Clean non-sterile gloves should be worn
  - (i) if exposure is anticipated to blood and body fluids capable of transmitting bloodborne infection<sup>(84)</sup>,
  - (ii) if exposure is anticipated to potentially infectious material such as pus, feces,

respiratory secretions or exudate of skin lesions<sup>(81,85)</sup>,

- (iii) when the health care worker has non-intact skin on his or her hands. **Category A; Grade II**
5. Sterile gloves must be worn for procedures in which the hands or the instruments being handled are entering a sterile body cavity or tissue<sup>(2,100)</sup>.  
**Category A; Grade I**
  6. The accepted standard should be that medical gloves be worn for all blood collection procedures. However, if phlebotomists choose not to wear gloves routinely, they must be gloved for performing phlebotomy if they have cuts, scratches or other breaks in their skin, or when hand contamination with blood is anticipated. All students or new trainees must wear medical gloves during their training period and in subsequent blood collection procedures<sup>(84)</sup>.
  7. Worn gloves should be changed
    - (i) between patient/client/resident contacts,
    - (ii) if a leak is suspected or the glove tears,
    - (iii) between care activities and procedures on the same patient after contact with materials that may contain high concentrations of micro-organisms (e.g., after manipulating an indwelling urinary catheter and before suctioning an endotracheal tube)<sup>(74,88)</sup>.  
**Category A; Grade II**
  8. Hands must be washed after gloves are removed<sup>(74,86,89,91)</sup>. **Category A; Grade II**

9. Potentially contaminated gloves should be removed prior to touching clean environmental surfaces (e.g., lamps, blood pressure cuffs)<sup>(74,101)</sup>. **Category A; Grade II**
10. Single-use disposable gloves should not be washed or reused. **Category A; Grade II**
11. Disposable, good quality medical gloves made of vinyl, nitrile, neoprene or polyethylene serve as adequate barriers, particularly when latex allergies are a concern. **Category A; Grade II**

The *Health and Safety Act* requires that employers provide appropriate personal protective apparatus<sup>(102)</sup>. They should make suitable gloves available to employees to prevent the transmission of infection to residents/clients/patients. Employees should assess the risk in each procedure, choose gloves that are appropriate to the task, and recommend alternative gloves if the ones available are not adequate<sup>(84,86)</sup>. The following is suggested as a guide.

- (i) If latex gloves are chosen, low protein and unpowdered gloves should be selected.
- (ii) Non-latex gloves should be available for individuals with latex sensitivity.
- (iii) Vinyl gloves should be used for short tasks or for tasks in which there is minimal stress to glove material.
- (iv) For housekeeping activities, instrument cleaning and decontamination procedures, general purpose reusable household gloves (e.g., neoprene, rubber, butyl) are recommended. Medical gloves are not durable enough for these activities.

# Cleaning, Disinfecting and Sterilizing Patient Care Equipment\*

Appropriate cleaning, disinfection and sterilization of patient care equipment are important in limiting the transmission of organisms related to reusable patient care equipment. Decisions concerning the appropriate processes, methods or products are complex, given the many types and compositions of medical devices and the great variety and combination of cleaning, disinfection and sterilization methods available<sup>(103-108)</sup>.

The reprocessing method required for a specific item will depend on the item's intended use, the risk of infection to the patient, and the amount of soiling<sup>(59,109-111)</sup>.

**Cleaning is always essential prior to disinfection or sterilization. An item that has not been cleaned cannot be assuredly disinfected or sterilized.** See Table 5 for examples.

## A. Classification of Medical Devices

In the 1970s, E.H. Spaulding developed a system to classify the cleaning, disinfection and sterilization requirements for equipment used in patient/client care. This system divides medical devices, equipment and surgical materials into three categories based on the potential risk of infection involved in their use<sup>(117)</sup>. The three categories are noncritical, semicritical, and critical. The categories are defined in the glossary at the end of this document.

## B. Cleaning Equipment and Instruments

**Cleaning is an extremely important part of equipment and instrument reprocessing and is**

**necessary to permit maximum efficacy of subsequent disinfection and sterilization treatments.**

Effective cleaning can physically remove large numbers of microorganisms<sup>(118)</sup>. Soil or other foreign materials can shield microorganisms and protect them from the action of disinfectants or sterilants or interact with the disinfectant or sterilant to neutralize the activity of the process<sup>(119-122)</sup>. Organic material left on a medical device is extremely difficult to remove after treatment with glutaraldehyde, which acts as a fixative.

Manufacturers must provide detailed directions for effective cleaning of all reusable products. The method and effectiveness of cleaning an item must be considered prior to purchase. Do not purchase products that cannot be cleaned. If such products are purchased the health care setting has the responsibility to develop detailed cleaning procedures. Effective reprocessing requires rigorous compliance with recommended protocols. Even full compliance with protocols may be insufficient if the method or product selected is inadequate or inappropriate for cleaning and subsequent disinfection or sterilization of a particular device.

Staff responsible for cleaning contaminated health care equipment must be properly trained and conversant with the purpose of their task. They should wear personal protective equipment appropriate to the task to protect themselves from exposure to potential pathogens and chemicals and to protect the integrity of their skin. Employees should also be immunized against hepatitis B<sup>(84)</sup>.

\* See Appendix 1 for definitions of the following items: noncritical items, semicritical items, critical items, biofilm, cleaning, decontamination, disinfection, germicides, low level disinfection, intermediate level disinfection, high level disinfection, sanitation, sterilization.

**Table 5. Reprocessing of Commonly Used Equipment in Health Care Settings in Usual Situations (See the section on Housekeeping for routine environmental cleaning; outbreaks may require special disinfection measures)**

**MANUFACTURERS' RECOMMENDATIONS FOR CONCENTRATION AND EXPOSURE TIME MUST BE FOLLOWED.**

Process	Equipment	Examples of items*	Products or methods†
<b>Cleaning</b> Some items may require low level <b>disinfection</b> ‡	All reusable equipment	All reusable equipment, since such equipment requires cleaning after use and before further disinfection processes are initiated  Certain environmental surfaces (e.g., of dental lamps) touched by personnel during procedures involving parenteral or mucous membrane contact  Bedpans, urinals, commodes  Stethoscopes  Blood pressure cuffs  Ear specula  Hemodialysis surfaces in contact with dialysate	Physical removal of soil, dust or foreign material. Chemical, thermal or mechanical aids may be used.  Cleaning usually involves soap and water, detergents or enzymatic agents.  Quaternary ammonium compounds  Phenolics should not be used in nurseries  Some iodophors  3% hydrogen peroxide
<b>Cleaning</b> followed by intermediate level <b>disinfection</b> ‡	Some semicritical items	After large environmental blood spills or spills of microbial cultures in the laboratory  Glass thermometers  Electronic thermometers  Hydrotherapy tanks used for patients whose skin is not intact‡	Alcohols  Hypochlorite solutions  Iodophors  Phenolics should not be used in nurseries.
<b>Cleaning</b> followed by high level <b>disinfection</b>	Semicritical items	Flexible endoscopes‡  Laryngoscopes‡  Respiratory therapy equipment‡  Nebulizer cups‡  Anesthesia equipment‡  Endotracheal tubes‡  Nasal specula  Tonometer foot plate‡  Ear syringe nozzles  Vaginal specula  Vaginal probes used in sonographic scanning‡  Pessary and diaphragm fitting rings‡  Cervical caps  Breast pump accessories	Items intended for sterilization in the plasma or EO sterilizers must be meticulously cleaned prior to sterilizing <sup>(112)</sup> .  Pasteurization <sup>(113)</sup>  2% glutaraldehyde  6% hydrogen peroxide  Peracetic acid  Chlorine or chlorine compounds

\* For products that appear in two categories, manufacturers' directions differ for length of exposure time and concentration.

† **Manufacturers' recommendations for concentration and exposure time must be followed.**

‡ For guidelines regarding disinfection, refer to comprehensive discussion of disinfection issues<sup>(110,114-116)</sup>.

Process	Equipment	Examples of items*	Products or methods†
<b>Cleaning followed by sterilization</b>	Critical items	All items contacting sterile tissue Surgical instruments All implantable devices Needles and syringes Cardiac and urinary catheters Hemodialysis, plasmapheresis and heart-lung oxygenator surfaces in contact with blood All intravascular devices Biopsy forceps or biopsy equipment associated with endoscopy equipment Bronchoscopes‡ Arthroscopes‡ Laparoscopes‡ Cystoscopes‡ Transfer forceps Acupuncture needles and body piercing objects Neurologic test needles Arterial pressure transducers‡ High speed dental handpieces All instruments used for footcare	Steam under pressure Dry heat Ethylene oxide gas 2% glutaraldehyde 6-25 % hydrogen peroxide Peracetic acid Chlorine dioxide 6-8% formaldehyde

\* For products that appear in two categories, manufacturers' directions differ for length of exposure time and concentration.

† **Manufacturers' recommendations for concentration and exposure time must be followed.**

‡ For guidelines regarding disinfection, refer to comprehensive discussion of disinfection issues<sup>(110,114-116)</sup>.

### i) Sorting and soaking

Unless they can be cleaned immediately, instruments and small items should be sorted and then submerged in water and/or detergent to prevent the organic matter from drying on them. Complete disassembly of each item is necessary to allow effective cleaning. Heavy or nonimmersible items should be wrapped in or covered with a wet towel.

### ii) Removal of organic material

Removal is done with the use of detergents, enzymatic cleaners, or elevated temperature with or without the use of mechanical devices such as washer-sterilizer, ultrasonic cleaner, dishwasher, utensil washer or washer-disinfectors. A detergent is used to reduce surface tension and suspend the soil in water. The detergent selected must be compatible with the subsequent disinfection process because some products can interfere with chemical disinfection or sterilization. An enzymatic solution may be used to help in the removal of protein-

aceous material when plain water and/or a detergent solution is considered inadequate. Combination low level disinfectant-detergent products (also referred to as germicidal detergents) are frequently used to clean items that do not require further disinfection or sterilization (e.g., intravenous [IV] poles, commodes, wheelchairs).

### iii) Rinsing

A thorough rinsing is necessary to remove all the soil and cleaning agent from the items, to avoid spotting and to ensure thorough cleanliness. Depending upon the quality of the available water supply, the final rinse may require distilled or de-ionized water<sup>(119)</sup>. Cleaning agents (i.e., detergents) may also make surfaces slippery or leave residuals that impair equipment integrity and function. When cleaning is to be followed by disinfection, it must be ensured that residuals of the cleaning agent are removed to prevent neutralization of the disinfectant<sup>(120,123)</sup>.

#### iv) Drying

Drying prevents microbial growth. All items that require no further treatment must be dried prior to storage. Immediate drying is necessary to prevent corrosion of stainless steel equipment. While they are drying, the items should be inspected to ensure that they are free of all organic soil, oil, grease, and other matter<sup>(124)</sup>. Post-disinfection flushing of endoscopes with 70% alcohol to ensure thorough drying prior to storage has been recommended<sup>(118)</sup>.

Bacteria grow attached to surfaces because of their hydrophobicity (insolubility in water)<sup>(119,125)</sup>. When nonsterile surfaces are moist or continuously wet, they may become coated with a “biofilm”, which is a layer of bacteria encased in an extracellular substance. Biofilm and its bacteria can be released when disrupted (e.g., in the lumens of endoscopes). Biofilm development may also protect bacteria from subsequent disinfection or sterilization.

Items that require further disinfection or sterilization may also need to be dried, as water may dilute the action of the chemical disinfectant.

### C. Disinfection

Disinfection is required when cleaning processes alone do not render an item safe for its intended use. There are three major methods of disinfection: liquid chemicals, pasteurization and ultraviolet radiation. Failure to use disinfection products or processes appropriately has repeatedly been associated with the transmission of nosocomial infections<sup>(117,126, 127)</sup>. Table 5 shows the cleaning and disinfection levels required for many commonly used items of equipment.

In health care settings, the precise nature of the microbial burden may not be known. In the natural environment, microorganisms are usually found in mixtures. For example, fecal material contains vegetative as well as spore forms of bacteria along with fungi, viruses and protozoa. Therefore, products and procedures selected to disinfect instruments must be known to be effective against pathogens with varying levels of resistance (See Figure 1). The level of disinfection achieved depends on factors such as contact time, temperature, extent of soil, type and concentration of the active ingredients of the chemical disinfectant, and the nature of the microbial contamination<sup>(121,126,128)</sup>.

A variety of factors influence the efficacy of disinfectant processes, including the innate resistance of the microorganisms (Figure 1), the concentration and type of organic and inorganic material present

(cleanliness, presence of biofilm), the intensity and duration of the treatment, the concentration (on initial and repeated use) of the disinfectant, the temperature associated with the process, the contact time associated with the process, the pH of the solution, the hardness of water used as the diluent, and interfering residues that may remain after cleaning<sup>(126,128, 129)</sup>.

#### i) Chemical disinfection

In Canada, chemical disinfectants used in health care settings are regulated by the Health Protection Branch of Health Canada (see the discussion of Registration of Disinfectants in Canada later in this section).

#### ii) Relative resistance of microorganisms

Microorganisms have variable susceptibility to disinfectant agents (see Figure 1). Vegetative bacteria and enveloped viruses are usually the most sensitive, and bacterial spores and protozoan cysts the most resistant. Some pathogens (e.g., *Pseudomonas aeruginosa*) have been shown to be significantly more resistant than their laboratory grown counterparts to a variety of disinfectants in their “naturally occurring” state, (i.e., in body fluids and tissues)<sup>(110)</sup>.

Major classes of disinfectant chemicals and their relative advantages and disadvantages are summarized in Table 6. The manufacturer of the chemical disinfectant will provide instructions for use, including the recommended exposure time. Manufacturers’ recommendations regarding exposure time must be followed.

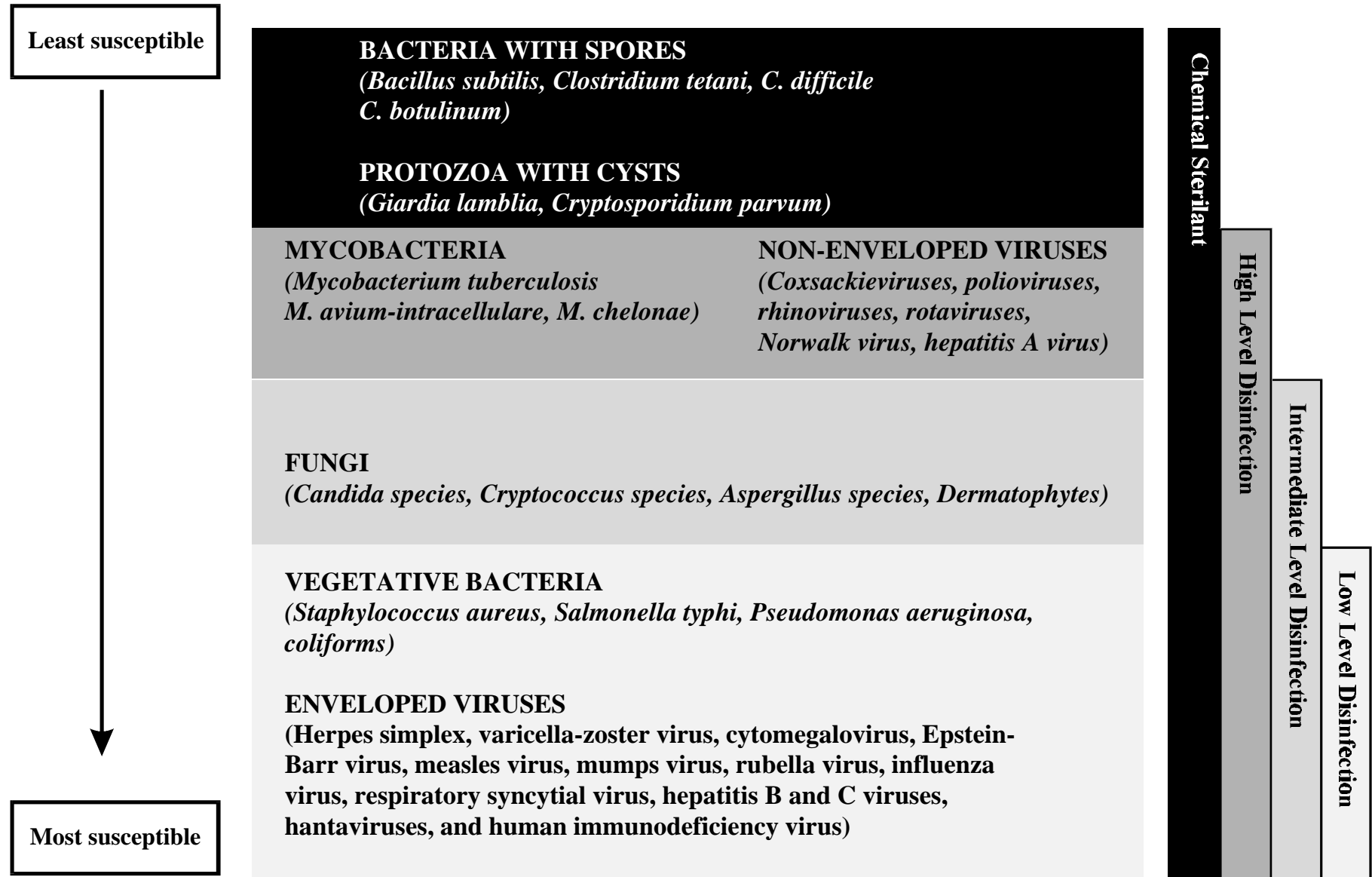
#### iii) Creutzfeldt-Jakob Disease (CJD)

The Laboratory Centre for Disease Control is developing CJD protocols<sup>(134,135)</sup>. The prion that causes Creutzfeldt-Jakob resists normal inactivation methods. Human infection with the CJD agent has resulted from either direct exposure of the brain to the CJD agent (e.g., dura mater graft) or peripheral injection of CJD agent-contaminated product derived from human brain (pituitary hormone). Special CJD-specific infection control precautions are recommended for patients who have developed, are suspected of having developed, or are at substantially increased risk of developing CJD (i.e., persons who have received human pituitary hormone [growth hormone and gonadotrophin] or dura mater grafts, or members of a family in which CJD is recognized as being familial)<sup>(135)</sup>.

Needles, needle electrodes, scalpels, ophthalmic tonometers, autopsy instruments, dedicated equipment cryostats and all other potentially contaminated materials should be sterilized by special procedures.



**Figure 1.**  
**Classes of Microorganisms Ranked in Descending Order from Least to Most Susceptible to Chemical Disinfectants**



**Table 6. Major Classes of Chemical Disinfectants and their Relative Advantages and Disadvantages**

MANUFACTURERS' RECOMMENDATIONS FOR CONCENTRATION AND EXPOSURE TIME MUST BE FOLLOWED.

Disinfectant	Uses	Advantages	Disadvantages
<b>Alcohols</b>	Intermediate level disinfectant Disinfect thermometers, external surfaces of some equipment (e.g., stethoscopes). Equipment used for home health care <sup>(59)</sup> Used as a skin antiseptic	Fast acting No residue Non staining	Volatile Evaporation may diminish concentration Inactivated by organic material May harden rubber or cause deterioration of glues Use in the OR is contraindicated
<b>Chlorines</b> <sup>(131)</sup>	Intermediate level disinfectant Disinfect hydrotherapy tanks, dialysis equipment, cardiopulmonary training manikins, environmental surfaces. Effective disinfectant following blood spills; aqueous solutions (5,000 parts per million) used to decontaminate area after blood has been removed; sodium dichloroisocyanurate powder sprinkled directly on blood spills for decontamination and subsequent cleanup. Equipment used for home health care <sup>(59)</sup> See Table 7 for uses for and dilution of chlorines.	Low cost Fast acting Readily available in non hospital settings	Corrosive to metals Inactivated by organic material Irritant to skin and mucous membranes Unstable when diluted to usable state (1:9 parts water) Use in well-ventilated areas Shelf life shortens when diluted
<b>Ethylene oxide</b>	Used as gas for the sterilization of heat sensitive medical devices	Sterilant for heat or pressure sensitive equipment	Slow acting and requires several hours of aeration to remove residue. One of its carriers (chlorofluorocarbon) is now a restricted chemical.
<b>Formaldehyde</b>	Very limited use as chemisterilant Sometimes used to reprocess hemodialyzers Gaseous form used to decontaminate laboratory safety cabinets	Active in presence of organic materials	Carcinogenic Toxic Strong irritant Pungent odour
<b>Glutaraldehydes</b>	2% formulations — high level disinfection for heat sensitive equipment Most commonly used for endoscopes, respiratory therapy equipment and anesthesia equipment	Noncorrosive to metal Active in presence of organic material Compatible with lensed instruments Sterilization may be accomplished in 6-10 hours	Extremely irritating to skin and mucous membranes Shelf life shortens when diluted (effective for 14-30 days depending on formulation) High cost Monitor concentration in reusable solutions Fixative

<b>Disinfectant</b>	<b>Uses</b>	<b>Advantages</b>	<b>Disadvantages</b>
<b>Hydrogen peroxide</b>	<p>3% — low level disinfectant</p> <p>Equipment used for home health care<sup>(59)</sup></p> <p>Cleans floors, walls and furnishings</p> <p>6% — high level disinfectant</p> <p>Effective for high level disinfection of flexible endoscopes<sup>(132)</sup></p> <p>Foot care equipment</p> <p>Disinfection of soft contact lenses</p> <p>Higher concentrations used as chemisterilants in specially designed machines for decontamination of heat sensitive medical devices</p>	<p>Strong oxidant</p> <p>Fast acting</p> <p>Breaks down into water and oxygen</p>	<p>Can be corrosive to aluminum, copper, brass or zinc</p>
<b>Iodophors</b>	<p>Intermediate level disinfectant for some equipment (hydrotherapy tanks, thermometers)</p> <p>Low level disinfectant for hard surfaces and equipment that does not touch mucous membranes (e.g., IV poles, wheelchairs, beds, call bells)</p>	<p>Rapid action</p> <p>Relatively free of toxicity and irritancy</p>	<p>Note: Antiseptic iodophors are NOT suitable for use as hard surface disinfectant</p> <p>Corrosive to metal unless combined with inhibitors</p> <p>Disinfectant may burn tissue</p> <p>Inactivated by organic materials</p> <p>May stain fabrics and synthetic materials</p>
<b>Peracetic acid</b>	<p>High level disinfectant or sterilant for heat sensitive equipment</p> <p>Higher concentrations used as chemisterilants in specially designed machines for decontamination of heat sensitive medical devices</p>	<p>Innocuous decomposition (water, oxygen, acetic acid, hydrogen peroxide)</p> <p>Rapid action at low temperature</p> <p>Active in presence of organic materials</p>	<p>Can be corrosive</p> <p>Unstable when diluted</p>
<b>Phenolics</b>	<p>Low/intermediate level disinfectants</p> <p>Clean floors, walls and furnishings</p> <p>Clean hard surfaces and equipment that does not touch mucous membranes (e.g., IV poles, wheelchairs, beds, call bells)</p>	<p>Leaves residual film on environmental surfaces</p> <p>Commercially available with added detergents to provide one-step cleaning and disinfecting</p>	<p>Do not use in nurseries</p> <p>Not recommended for use on food contact surfaces</p> <p>May be absorbed through skin or by rubber</p> <p>Some synthetic flooring may become sticky with repetitive use</p>
<b>Quaternary ammonium compounds</b>	<p>Low level disinfectant</p> <p>Clean floors, walls and furnishings</p> <p>Clean blood spills<sup>(133)</sup></p>	<p>Generally non-irritating to hands</p> <p>Usually have detergent properties</p>	<p>DO NOT use to disinfect instruments</p> <p>Non-corrosive</p> <p>Limited use as disinfectant because of narrow microbicidal spectrum</p>

**Table 7. Directions for Preparing and Using Chlorine-based Disinfectants**

Product	Intended use	Recommended dilution	Level of available chlorine
Household bleach (5% sodium hypochlorite solution with 50,000 ppm* available chlorine)	Cleanup of blood spills	Use concentrations ranging from 1 part of bleach to be mixed with 99 parts of tap water (1:100) or one part of bleach to be mixed with 9 parts of tap water (1:10), depending on the amount of organic material (e.g., blood or mucus) present on the surface to be cleaned and disinfected.	0.05% or 500 ppm  0.5% or 5,000 ppm
	To add to laundry water	One part (one 8 ounce cup) of bleach to be mixed with about 500 parts (28 gallons†) of tap water	0.01% or 100 ppm
	Surface cleaning Soaking of glassware or plastic items	One part (one 8 ounce cup) to be mixed with about 50 parts (2.8 gallons) of tap water	0.1% or 1,000 ppm
NaDCC (Sodium dichloroisocyanurate) powder with 60% available chlorine	Cleanup of blood spills	Dissolve 8.5 g in one litre of tap water	0.85% or 5,000 ppm
Chloramine-T powder with 25% available chlorine	Cleanup of blood spills	Dissolve 20 g in one litre of tap water	2.0% or 5,000 ppm

\* Parts per million

† Imperial gallon (4.5 litres)

For further information on uses of bleach in health care refer to article on subject<sup>(131)</sup>.

#### iv) Reuse of chemical disinfectants

Several physical and chemical factors influence disinfectant action, including temperature, pH, relative humidity, and water hardness<sup>(110,128)</sup>. Extremes of acidity or alkalinity can effectively limit growth of microorganisms. Moreover, the activity of antimicrobial agents may be profoundly influenced by relatively small changes in the pH of the medium<sup>(136)</sup>. An increase in pH improves the antimicrobial activity of some disinfectants (e.g., glutaraldehyde, quaternary ammonium compounds) but decreases the antimicrobial activity of others (e.g., phenols, hypochlorites, iodine). The pH influences the antimicrobial activity by altering the disinfectant molecule or the cell surface<sup>(110)</sup>.

Many chemical disinfectants require dilution prior to use. It is mandatory that users follow exactly the manufacturer's directions regarding dilution and mixing. If the concentration of the disinfectant is too low the efficacy will be decreased. If the concentration is too high the risk of the chemical damaging the instrument or causing toxic effects on the user increases.

Once diluted some disinfectants may be used (if handled properly) for a period of days or weeks. Dilutions are inherently unstable once mixed and the manufacturer's directions as to duration of use must be followed.

Glutaraldehydes require special discussion. Glutaraldehydes may be in acidic or alkaline formulations, and are usually purchased in concentrated forms and diluted for use. These dilutions are time limited. During reuse, the concentration of active ingredient(s) in the product may drop as dilution of the product occurs (incomplete drying), and while organic impurities accumulate (incomplete cleaning)<sup>(128)</sup>. Chemical test strips are available for determining whether an effective concentration of active ingredients (e.g., glutaraldehyde) is present despite repeated use and dilution. The frequency of testing should be based on how frequently the solutions are used (e.g., used daily, test daily). The strips should not be considered a way of extending the use of a disinfectant solution beyond the expiration date. The glutaraldehyde solution should be considered unsafe

when the concentration of glutaraldehyde falls below the minimum effective concentration (MEC) for the product or the dilution falls below 1% glutaraldehyde<sup>(110)</sup>.

#### v) Disinfectants and safety

Chemical disinfectants are a double-edged sword. Although their use is necessary in many routine health care settings, the ability of these products to kill infectious agents also makes them potentially harmful to humans and the environment. Although manufacturers continue to work to improve their formulations, it is unrealistic to expect that highly effective disinfectants that are also completely safe will be available in the near future.

Products containing glutaraldehyde require special attention. Glutaraldehydes are used extensively in the disinfection of semicritical instruments because they are noncorrosive and relatively fast acting in addition to possessing a broad spectrum of activity. However, the pungent and irritating nature of glutaraldehyde fumes and the toxic effects of this disinfectant on skin make it a workplace hazard. The expanding use of glutaraldehyde in many health care settings has led to legislation or regulations in some provinces (e.g., British Columbia) that limit workers' exposure to glutaraldehyde fumes, for instance through the installation of fume hoods and extraction fans in units using glutaraldehyde.

#### vi) Registration of disinfectants in Canada

In Canada, the main control of antimicrobials rests on two pieces of legislation. Antimicrobial products that are labelled for use in health care facilities or food processing plants or on medical devices and are produced for the purposes of disease prevention and health preservation are regulated as drugs under the *Food and Drugs Act and Regulations*, which are administered by the Therapeutic Products Programme, Bureau of Pharmaceutical Assessment, Health Protection Branch, Health Canada. Products used for disinfection or antimicrobial purposes in domestic or household applications, non-food industrial applications, etc. are regulated under the *Pest Control Products Act and Regulations*, which are administered by the Pest Management Regulatory Agency, Health Canada.

For disinfectant drugs, manufacturers must obtain a drug identification number (DIN) from Health Canada prior to marketing. To obtain this they must submit a DIN application, with labelling and supporting data (if required) to the Therapeutic Products Directorate for evaluation. For a DIN to be issued, it must be established that the product is effective and safe for its intended use<sup>(137)</sup>.

The extent of premarket assessment of disinfectant products is based on the relative risk associated with the use of the product, which varies depending on the established knowledge of the active ingredients and the proposed uses for the product. On the basis of this premise, disinfectants or sterilants for use on medical instruments undergo a more rigorous pre-market assessment than disinfectants containing well-known active ingredients for use on environmental surfaces such as floors and walls.

Specific efficacy test methodologies and data requirements for disinfectants to be marketed in Canada are recommended by the Canadian General Standards Board. These requirements vary according to the proposed use(s) of the product, resulting in specific test methodologies and test organisms to match specific claims of efficacy. The most stringent requirements exist for sterilants, products that are to be used for the sterilization of critical instruments. High level disinfectants carry less stringent requirements and are labelled for use on semicritical instruments. Low level disinfectants are labelled for the disinfection of noncritical items and environmental surfaces, and thus have the least stringent efficacy requirements.

The label on the disinfectant must clearly indicate the following information: the product name, a quantitative statement of active ingredient(s), its intended use, the area and site of use, and specific directions for use, including the specific types of surfaces/instruments to be disinfected, any dilution procedure required, the mode of application, the contact time, any cleaning and rinsing procedures, the temperature for use and the reuse period. The labelling must also include appropriate precautionary symbols and statements as well as first aid instruction.

The proposed label claims are reviewed, and in order to be considered acceptable they must have been substantiated with data demonstrating with a great level of confidence that the product is effective under the proposed conditions of use. The label claims must not be misleading.

Should there be any questions regarding the label claims, conditions of use, etc., of a product, the reviewing bureau within the Health Protection Branch (Bureau of Pharmaceutical Assessment) should be contacted for verification. See Appendix 3 for information.

## vii) Product labelling

- The product label must have a Drug Identification Number (DIN). The presence of a DIN indicates that, upon review, it has been established that the product is safe and effective for its intended use.
- The product label must be read carefully for instructions on use. Failure to do so often leads to inappropriate use, storage or disposal of the product and may expose the patient as well as the health care worker to an increased risk of infections or toxic chemical effects. Inappropriate storage of chemical disinfectants may reduce their shelf life, and if they become contaminated, may also lead to bacterial growth.
- The product label should include mixing instructions, including concentrations for dilution, and length of disinfection time.
- The product label needs to be read for factors that may influence the activity of the disinfectant, such as temperature, pH, relative humidity and water hardness.

## viii) Pasteurization

Pasteurization is a process of hot water disinfection, which is accomplished through the use of automated pasteurizers or washer disinfectors. Semicritical items suitable for pasteurization include equipment for respiratory therapy and anesthesia.

Exposing respiratory and anesthesia equipment to water above 75°C for 30 minutes is a recognized alternative to chemical disinfection. Items to be pasteurized must be thoroughly cleaned with detergent and water prior to disinfection<sup>(109)</sup>. The items must be totally immersed in water during the pasteurization cycle.

The advantages of pasteurization include its nontoxicity, rapid disinfection cycle, and moderate cost of machinery and upkeep.

The major disadvantages of pasteurization are that (1) it is not sporicidal, (2) it may cause splash burns, (3) there is a lack of standardization of the equipment and (4) there is difficulty validating the effectiveness of the process. The process may be monitored by temperature gauges and timing mechanisms.

Since pasteurization is not a sterilization process, extreme care must be taken to ensure that the process is appropriately performed so that infectious agents considered to be particularly important are inactivated<sup>(138)</sup>. After pasteurization, special care must be taken to dry (residual water tends to collect) and prevent recontamination of the equipment during storage and transport<sup>(138,139)</sup>.

## ix) Ultraviolet radiation

Microorganisms are inactivated by ultraviolet (UV) light in wavelengths within a range of 250-280 nm<sup>(140)</sup>. Modern mercury-vapor lamps emit radiation within that level. Ultraviolet radiation has several potential applications, but its germicidal effectiveness and use is influenced by organic matter, wavelength, type of suspension, temperature, type of microorganism, and UV intensity (which is affected by distance and dirty tubes). The application of UV light in the hospital is limited to the destruction of airborne organisms or inactivation of microorganisms located on surfaces. Ultraviolet germicidal irradiation is a method of air cleaning that can be used to supplement other tuberculosis control measures. Installing ultraviolet lamps in ventilation ducts has two advantages: high levels of UV irradiation may be produced and, since the UV light is in the duct, the risk of human exposure is reduced or eliminated<sup>(141)</sup>. The Health Canada *Guidelines for Preventing the Transmission of Tuberculosis in Canadian Health Care Facilities and Other Institutional Settings*<sup>(140)</sup> concludes its discussion of UV germicidal irradiation by saying that it may be a useful adjunct in ventilation ducts or in high-risk areas, such as bronchoscopy suites, autopsy suites, or other areas where patients with undiagnosed TB may be seen frequently.

No data support the use of UV lamps in isolation rooms<sup>(110)</sup>. Portable ultraviolet light devices should not be used for disinfection purposes in community settings (e.g., of esthetic or body piercing equipment).

UV light may cause skin and eye burns, and may theoretically cause cataracts and skin cancer. Problems have occurred when UV lights have not been installed properly or have not been monitored and maintained correctly<sup>(139,140)</sup>.

## x) Boiling

Boiling is not an acceptable method of sterilization in health care. In home care, boiling has been used to disinfect some items if they do not deteriorate in the process. Home care guidelines should be followed<sup>(59,142,143)</sup>.

The use of boiling water to clean instruments and utensils cannot be called sterilization. Research has shown that boiling water or moist heat at a temperature of 100°C (212°F) is inadequate for the destruction of bacterial spores and some viruses<sup>(144)</sup>. Another major disadvantage of using boiling water to clean instruments and utensils is that the items are not packaged so that they can be stored and transported without contamination.

## xi) Sterilization

All critical items that are in contact with the blood stream, nonintact mucous membranes or normally sterile body sites must be sterile. Sterilization is a process, not just a single event. Appropriate procedures must be followed to achieve and maintain sterility. The sterilization process must be validated and documented.

Table 8 summarizes the advantages and disadvantages of sterilization methods as well as recommended applications and monitoring strategies. Manufacturers of sterilizers should be contacted for specific instructions on installation and use of their equipment. Storage and transportation practices must maintain sterility to the point of use. Manufacturers of sterilizers should be specific as to which devices can be sterilized in their machines, and manufacturers of medical devices and equipment should be specific as to the recommended sterilization methods.

## xii) New technologies

Because of difficulties in disinfecting and sterilizing equipment, such as heat-labile medical devices and devices with small lumens, new technologies are being developed. New technologies will have limited applications (e.g., may not be appropriate for instruments with lumens or may be incompatible with some materials). No single method will work for all hospitals. Policies and procedures must be established to ensure that the reprocessing of equipment follows the principles of infection prevention.

There is controversy about the monitoring of the efficacy of liquid chemical sterilization cycles. Biologic monitoring of liquid chemical sterilization processes using traditional biologic indicators does not appear feasible at this time<sup>(154)</sup>.

## xiii) Monitoring of the sterilization cycle

Monitoring of sterilization cycles can be divided into three distinct methods<sup>(139)</sup>:

- Mechanical:** time and temperature graphs, charts or printouts
- Chemical:** time/temperature and/or humidity sensitive tape, strips or pellets<sup>(155)</sup>
- Biologic:** spore-laden strips or vials<sup>(156)</sup>

Mechanical and chemical monitors merely provide a visible indicator that the conditions required to achieve sterilization, such as time, temperature and pressure, have been met.

Only biologic indicators monitor the actual effectiveness of the sterilization process, which is intended to kill all microbes, including spores<sup>(157)</sup>. An ideal biologic indicator should have the following characteristics: a well characterized organism, widely available, standardized preparation, more resistant to the sterilization process than human pathogens, rapid readout, easy to use, nonpathogenic, and inexpensive<sup>(158)</sup>.

The spores chosen for biologic monitoring must be appropriate for the method of sterilization being monitored<sup>(154)</sup>. For example *Bacillus stearothermophilus* spores are used for steam sterilization and *Bacillus subtilis* for dry heat and ethylene oxide cycles. The frequency of monitoring is indicated in Table 8.

Traditionally, commercially prepared biologic indicators require an incubation time of 24 to 48 hours prior to reading. The recent development of rapid readout biologic monitors, which use fluorometric detection of a spore-bound enzyme at 60 minutes, may offer an alternative to observation of spore growth. Use of rapid readout biologic indicators may enable release of sterilized implants for use or rapid recall of inadequately sterilized devices<sup>(156,157)</sup>. The manufacturer's instructions should be followed in the use of all commercially prepared biologic monitoring systems.

Although indicators are an important part of quality assurance of sterilization processes, the validation of the process and documentation of the operating parameters of the process are of paramount importance. Testing with spore and chemical indicators is only as good as the placement of the spore suspensions or indicators. All sterilization processes should be thoroughly evaluated before being put into service, and at regular intervals afterwards. Autoclaves should be mapped with thermocouples to determine potential cold spots. Filter systems should be tested for leakage. Gas sterilization units should be appropriately validated for such factors as gas concentration, temperature, and relative humidity.

In order to ensure appropriate sterilization processes, health care facility personnel must comply with the manufacturer's recommendations.

The daily operation of the sterilization must be documented by personnel performing the process. This documentation should be reviewed for each operation, and any malfunction should be noted and appropriate action taken to ensure that the product either has been properly treated or is returned for reprocessing<sup>(138)</sup>.

The health care facility should have a protocol on the procedure to follow if monitoring shows equipment failure<sup>(139)</sup>.

**Table 8. Advantages and Disadvantages of Currently Available Sterilization Methods**

MANUFACTURERS' RECOMMENDATIONS FOR CONCENTRATION AND EXPOSURE TIME MUST BE FOLLOWED.

Sterilization method	Parameters	Monitoring/frequency	Use/advantages	Disadvantages
<p><b>Steam</b></p> <p>a) Small table top sterilizers</p> <p>b) Gravity displacement sterilizers including flash sterilizers</p> <p>c) High-speed vacuum sterilizers</p>	<p>Raised pressure (preset by manufacturer) to increase temperature to 121<sup>0</sup> C (133<sup>0</sup> C for flash sterilizers)</p> <p>Time varies with temperature, type of material and whether the instrument is wrapped or not.</p> <p>Steam must be saturated (narrow lumen items may require prehumidification).</p>	<p>Air detection for vacuum sterilizers - daily before first cycle of day</p> <p>Mechanical - each cycle<sup>(103)</sup></p> <p>Chemical - each cycle<sup>(103)</sup></p> <p>Biologic - at least weekly, but preferably daily, and with each load of implantable items (<i>Bacillus stearothermophilus</i> spores). Loads containing implantable devices shall be monitored and, whenever possible, the implantable devices quarantined until the results of the biologic indicator testing are available<sup>(103)</sup>.</p>	<p>Heat tolerant instruments and accessories</p> <p>Linen</p> <p>Inexpensive</p> <p>Rapid</p> <p>Efficient</p> <p>Non toxic</p> <p>Can be used to sterilize liquids</p>	<p>Unsuitable for anhydrous oils, powders, lensed instruments, heat and moisture sensitive materials.</p> <p>Some table top sterilizers lack a drying cycle.</p>
<p><b>Flash sterilization</b></p>	<p>Flash sterilization should be used only in an emergency.</p> <p>Flash sterilization should never be used for implantable devices.</p>	<p>Mechanical - each cycle</p> <p>Chemical - each cycle</p> <p>Biologic - at least once a week but preferably daily<sup>(145)</sup></p>	<p>Not recommended</p>	<p>If the devices are used before the results of biologic indicators are known, personnel must record which devices were used for specific patients, so that they can be followed if the load was not processed properly<sup>(113,145-148)</sup>.</p> <p>Difficult to monitor</p> <p>The efficacy of flash sterilization will be impaired if all the necessary parameters are not met properly (e.g., time, temperature), the device is contaminated with organic matter, air is trapped in or around the device, or the sterilizer or flash pack is not working properly.</p> <p>Sterility cannot be maintained if the device is not wrapped.</p>



Sterilization method	Parameters	Monitoring/frequency	Use/advantages	Disadvantages
<b>Ethylene oxide gas (EtO)</b>	EtO concentration based on manufacturer's recommendation Temperature - variable Humidity 50% Time - extended processing time (several hours)	Mechanical - each cycle <sup>(105)</sup> Chemical - each cycle <sup>(105)</sup> Biologic - each cycle <sup>(105)</sup> ( <i>Bacillus subtilis</i> spores)	Heat sensitive items Not harmful to heat sensitive and lensed instruments	Expensive EtO systems have been changed because of the elimination of CFCs <sup>(149)</sup> . Toxic to humans Environmental hazard when combined with chlorinated fluorocarbons Requires monitoring of residual gas levels in environment Requires aeration of sterilized products prior to use Lengthy cycle required to achieve sterilization and aeration Highly flammable and explosive, and highly reactive with other chemicals Causes structural damage to some devices
<b>Dry heat</b> a) Gravity convection b) Mechanical convection	Temperatures - time 171 <sup>0</sup> C - 60 min 160 <sup>0</sup> C - 120 min 149 <sup>0</sup> C - 150 min 141 <sup>0</sup> C - 180 min 121 <sup>0</sup> C - 12 hours	Mechanical - each cycle Chemical - each cycle Biologic - weekly <sup>(139)</sup> ( <i>Bacillus subtilis</i> spores)	Anhydrous oil Powders Glass No corrosive or rusting effect on instruments Reaches surfaces of instruments that cannot be disassembled Inexpensive	Lengthy cycle due to slowness of heating and penetration High temperatures may be deleterious to material. Limited packing materials Temperature and exposure times vary, depending on article being sterilized <sup>(139)</sup> .
<b>Glutaraldehyde</b>	Time and temperature must be maintained. Sterilized items must be rinsed with sterile water <sup>(116,119)</sup> . Sterilized items must be handled in a manner that prevents contamination from process through storage to use.	None for sterility Monitors available for pH and dilution concentration	Heat sensitive items	Unable to monitor sterilization Handling provides opportunities for contamination. Copious rinsing with sterile water required to remove all residual disinfectant at termination of cycle. Toxicity of chemicals to health care workers and environment Lengthy process (6-12 hours).

Sterilization method	Parameters	Monitoring/frequency	Use/advantages	Disadvantages
<b>Boiling</b>	Not recommended	None	Not recommended	May be used for dedicated equipment for clients receiving home care (e.g., catheters used by one person) <sup>(59,142,143)</sup>
<b>Microwave ovens</b>	Not recommended	None	Not recommended	Unable to monitor Unreliable method <sup>(150)</sup> Home use microwaves unable to achieve sterilization <sup>(150)</sup>
<b>Glass bead sterilizers</b>	Not recommended	None	Not recommended	Unable to monitor Cold spots Inconsistent heating Trapped air <sup>(151)</sup>
<b>Hydrogen peroxide vapour</b>	Time and temperature controlled by cycle	Follow manufacturer's instructions  Spores of <i>Bacillus stearothermophilus</i> are used as biologic indicators.	Heat sensitive items, e.g., endoscopes Noncorrosive due to short contact times required Environmentally friendly byproducts Low toxicity if devices are aerated <sup>(152)</sup>	Limited field trials on efficacy of sterilization Inactivation by highly absorptive materials such as cellulose paper and linen, thus limiting packaging material Inability to enter deeply into small lumens <sup>(153)</sup> Further evaluation of toxicity is required <sup>(152)</sup> .
<b>Hydrogen peroxide</b> a) liquid (6-25%) b) gas plasma	Time and temperature controlled by cycle	Follow manufacturer's instructions	Heat sensitive items e.g., endoscopes Can be applied to metal and non-metal as well as heat and moisture sensitive instruments Rapid Nontoxic Lack of corrosion to metals and other materials (except nylon)	Limitations on length and lumens of devices that can be effectively sterilized <sup>(112,153)</sup> With gas plasma, inactivation of hydrogen peroxide by highly absorptive materials (linen, cellulose paper) <sup>(153)</sup>

Sterilization method	Parameters	Monitoring/frequency	Use/advantages	Disadvantages
<b>Peracetic acid</b>	Time and temperature controlled by cycle	Follow manufacturer's instructions	Heat sensitive immersible items e.g., endoscopes, surgical instruments Rapid Automated Leaves no residue Effective in presence of organic matter Sporicidal at low temperatures	Monitoring of efficacy of sterilization cycle with spore strips is questionable <sup>(154)</sup> Can be used for immersible instruments only Corrosive Material incompatibility with some materials Unstable particularly when diluted In vapour form, PAA is volatile, has a pungent odour, is toxic, and is a fire and explosion hazard.
<b>Combination systems</b> of peracetic acid vapour with mixture of hydrogen, oxygen and inert carrier	Time and temperature vary by cycle	Follow manufacturer's instructions	Heat sensitive items Dialysers Rapid Nontoxic Combination system is less corrosive than peracetic acid alone	Limited field trials on efficacy of sterilization Each type of machine needs to be independently verified for effectiveness

#### xiv) Maintenance of sterility

##### a. Packaging

When the process permits, items to be sterilized should be packaged in appropriate wraps before sterilization. One of the main disadvantages of liquid chemical sterilization is that the items are not wrapped before sterilization yet must be stored and transported in a way that minimizes contamination. Ideally, the selected packaging material should possess the following characteristics: it should allow for adequate air removal, sterilant penetration and evacuation; act as a barrier to microorganisms or their vehicles (e.g., dust, vermin) after sterilization is complete; show temperature stability; be strong enough to withstand normal handling; be flexible to permit sealing, wrapping and unwrapping; allow for aseptic removal of sterilized product; produce minimal linting; contain no toxic ingredients or non fast dyes; and maintain seal integrity without resealing upon opening. In the case of rigid containers, gasket integrity must be proven<sup>(103,105,108)</sup>.

##### b. Storage

Sterilized items — those sterilized in the health care setting and those purchased as sterile — must be stored in a protected area where products are unlikely to become exposed to moisture, dirt, dust or vermin. Shelf life is event related<sup>(103)</sup>. Event-related shelf life practice recognizes that the product should remain sterile until some event causes the item to become contaminated (e.g., a tear in packaging, packaging becomes wet, or dropped)<sup>(160)</sup>. Event-related factors include frequency and method of handling, and storage area conditions such as appropriate location, space, open/closed shelving, temperature and humidity, and freedom from dust, insects, flooding, and vermin<sup>(138,160)</sup>.

Items purchased as sterile must be used before the expiration date if one is given. Culture should be done only if clinical circumstances suggest infection related to the use of the item. If intrinsic contamination is suspected, notify the Bureau of Radiation and Medical Devices, Health Protection Branch, Health Canada, and local and provincial health departments.

Single-use sterile items that are opened but not used may be able to be re-sterilized. However, it is necessary to ensure that the product can withstand the sterilization method chosen, and that this method will achieve sterilization of the device. The Canadian Healthcare Association has identified principles for the reuse of single-use medical devices and various activities that should be considered in the sterilization procedure<sup>(162)</sup>.

#### Recommendations on Cleaning, Disinfection and Sterilization

Each health care setting should have a protocol for reprocessing and maintenance of sterility.

1. Items that are received sterile must be maintained sterile until use<sup>(139,163,164)</sup>. **Category A; Grade II**
2. Reusable items must be thoroughly cleaned before disinfection or sterilization<sup>(110,120)</sup>. **Category A; Grade II**
3. Reusable items must be adequately rinsed and dried before disinfection or sterilization<sup>(119)</sup> and dried before storage. **Category A; Grade II**
4. Manufacturers' written recommendations for use of chemical disinfectant should be followed.
5. Only disinfectants with a DIN should be used (disinfectants approved for use in Canada).
6. Respiratory therapy and anesthetic equipment require, at a minimum, high level disinfection<sup>(113,165-167)</sup>.
7. Critical items must be sterile<sup>(110)</sup>. **Category A; Grade III**
8. Semicritical items should be disinfected as detailed in Table 5<sup>(116,139)</sup>. **Category A; Grade III**
9. The sterilization process must be monitored by biologic indicator testing:
  - for steam sterilizers: at least weekly, but preferably daily. Loads containing implantable devices shall be monitored and, whenever possible, the implantable devices quarantined until the results of the biologic indicator testing are available<sup>(103)</sup>.
  - for ethylene oxide sterilizers: every load that is to be sterilized<sup>(105)</sup>.
  - for dry heat sterilization: at least weekly<sup>(139)</sup>. **Category A; Grade III**
10. The sterilization process must be monitored at each cycle by mechanical and chemical indicators<sup>(139)</sup>. **Category A; Grade III**
11. After reprocessing, sterility should be maintained until point of use<sup>(139)</sup>. **Category A; Grade III**

12. If a health care facility reuses a single-use medical device, an established protocol must be established and followed to ensure a level of safety, following the framework of the Canadian Healthcare Association<sup>(162)</sup>.
13. A procedure for recall of items processed from a load that contained a positive biologic indicator should be established by the institution<sup>(103,105)</sup>. **Category A; Grade III**
14. Flash sterilization is not recommended and should be used only in an emergency, and never for implantable devices. **Category D; Grade III**
15. Microwave ovens, glass bead sterilizers and boiling for sterilization should not be used<sup>(144)</sup>. **Category D; Grade III**
16. A specially trained, knowledgeable person must be responsible for the disinfection and sterilization process. **Category B; Grade III**

# Microbiologic Sampling of Environment

The results of microbiologic sampling have seldom been useful in directing infection prevention and control programs. Before 1970, routine environmental culturing of inanimate objects was a widely practised infection control surveillance activity in hospitals. However, nosocomial infection rates have seldom been associated with documented colony counts on cultures of air or environmental surfaces where reasonable hygiene exists. Meaningful standards for permissible levels of microbial contamination of the environment do not exist<sup>(168)</sup>. By 1988, LCDC strongly recommended that routine culturing of floors, walls, linen, air and infant formula be discontinued<sup>(71)</sup>.

However, microbiologic sampling may be indicated in selected circumstances, such as an outbreak or other unusual increase in nosocomial infection transmission in which environmental reservoirs are implicated. Such culturing should be based on epidemiologic data and must follow a written plan that specifies the objects to be sampled and the actions to be taken, based on culture results<sup>(169)</sup>.

One major exception to the recommendations to avoid routine spot checking is related to routine sampling of all water and dialysate fluid after dialysis. Gram negative bacteria have the ability to multiply rapidly in water and other fluids associated with the hemodialysis system. These fluids do not need to be sterile, but excessive levels of gram negative bacterial contamination have been associated with numerous pyrogenic and bacteremic reactions<sup>(170)</sup>. A quantitative guideline for interpretation of levels of contamination has been proposed<sup>(115,170-173)</sup>.

The issue of microbiologic sampling of hydrotherapy pools and tanks is controversial. These tanks have been associated with infections. Health care settings that use hydrotherapy pools and tanks may wish to conduct

microbiologic sampling as a quality indicator that cleaning and water treatment methods are adequate.

## Recommendations for Microbiologic Sampling

1. Routine culturing of air, environmental surfaces or medical devices, either on a scheduled or periodic basis, is not recommended. **Category E; Grade II**
2. Routine microbiologic sampling of patient care items purchased as sterile is not recommended. **Category D; Grade III**
3. Routine sampling of the water and dialysate fluid after dialysis is recommended. **Category A; Grade II**
  - (a) Dialysate water used to prepare dialysate fluid should be checked microbiologically once a month. The level of contamination should not exceed 200 cfu/mL<sup>(174-177)</sup>.
  - (b) Endotoxin contamination in dialysate water used to rinse and reprocess dialysers, and water used to prepare dialyser disinfectant should not exceed 1 ng (5 endotoxin units [EU])/mL<sup>(178,179)</sup>.
  - (c) Dialysate fluid should be sampled once a month at the end of the dialysis treatment. The level of bacterial contamination should not exceed 2,000 cfu/mL. Machine water should be taken from different machines to ensure random sampling<sup>(174-177)</sup>.
4. In an outbreak, selective environmental microbiologic sampling may be indicated. Sampling should be obtained from the potential environmental sites implicated in the epidemiologic investigation, as suggested by the outbreak organism(s) or patient

characteristics, (e.g., when clusters of infections occur in patients following endoscopy procedures with possible implication of the equipment, then endoscopes should be sampled)<sup>(119)</sup>. **Category A; Grade II**

5. If contamination of a commercial product sold as sterile is suspected, infection control personnel should be notified, suspect lot numbers should be recorded, and items from suspected lots should be

segregated and quarantined. Appropriate microbiologic assays may be considered. The Medical Devices Bureau, Environmental Health Directorate, Health Protection Branch, Health Canada, provincial health authorities, and manufacturers should be notified promptly. **Category A; Grade III**

# Housekeeping\*

Although microorganisms are ubiquitous in health care settings, inanimate materials are seldom responsible for the direct spread of infections. Cleaning and maintenance prevent the build-up of soil, dust or other foreign material that can harbour pathogens and support their growth<sup>(180)</sup>. Although there is virtually no risk of transmitting infectious agents to patients by way of the inanimate environment, soiled items could contribute to secondary transmission by contaminating hands of health care workers or by contact with medical equipment that will subsequently come in contact with patients.

Skin antiseptics, except alcohol, should not be used for cleaning inanimate objects.

Cleaning is accomplished with water, detergents and mechanical action. Cleaning reduces or eliminates the reservoirs of potential pathogenic organisms.

Detergents are adequate for most housekeeping<sup>(59)</sup>. Disinfectants are not usually needed in housekeeping activities in health care settings, but are necessary in specified areas (e.g., surgical suites, ICUs, transplant units, surfaces of dialysis machines). Refer to Table 9 for indications on the use of a disinfectant. Disinfection is accomplished by liquid or powdered chemicals. Levels of chemical disinfection vary with the type of product used<sup>(128)</sup>.

## A. Routine Cleaning

The aim of cleaning is to achieve a clean environment with regular and conscientious general housekeeping. Extraordinary measures do not need to be taken to disinfect the health care environment<sup>(115)</sup>; high level disinfection and sterilization are not used in house-keeping activities. Visible dust and dirt should be removed

routinely with water and detergent and/or vacuuming<sup>(181)</sup>. Duct, fan and air conditioning systems should be cleaned and maintained according to a schedule.

The environment should be kept free of clutter to facilitate housekeeping.

The most frequent source of infection from the inanimate environment is contaminated equipment. Decontamination of patient care equipment is discussed on pages 10-26.

However, environmental water reservoirs have been associated with numerous infections and outbreaks. Examples include faucet aerators, shower heads, sinks, drains, flower vase water, ice machines, water carafes and hydrotherapy baths<sup>(115,173)</sup>. Housekeeping protocols should include careful cleaning of wet surfaces and equipment to prevent the build-up of biofilms.

Hands play a major role in the transmission of human pathogenic microorganisms to susceptible hosts. Hands can acquire known or potential pathogens by contact with objects and animate and inanimate surfaces. Strict adherence to hand washing recommendations (see pages 6-7) is more likely to prevent infections than procedures exceeding routine cleaning of the environment.

**Housekeeping issues concerning the inanimate environment and the transmission of disease may be summarized as follows:**

Prevent objects heavily contaminated with organic material from coming into close contact with portals of entry into the body. For example, patients with non-intact skin, such as those with burns or surgical incisions,

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\*See Appendix 1 for definitions of the following terms: antiseptics, cleaning, disinfection, fomites, sanitation.



**Table 9. Cleaning Procedures for Common Items**

Frequency of cleaning will depend on care setting. In acute care settings equipment should be cleaned between patients. In community settings the frequency of cleaning has not been determined.

Surface/object	Procedure	Special considerations
Horizontal surfaces such as over bed tables, work counters, baby weigh scales, beds, cribs, mattresses, bedrails, call bells	<ol style="list-style-type: none"> <li>1. Thorough regular cleaning</li> <li>2. Cleaning when soiled</li> <li>3. Cleaning between patients/clients and after discharge</li> </ol>	<p>Special procedures sometimes called carbolizing are not necessary.</p> <p>Some environmental surfaces may require low level disinfection (e.g., in nurseries, pediatric settings, critical care, burn units, emergency rooms, operating rooms and bone marrow transplantation facilities).</p>
Walls, blinds, curtains	Should be cleaned regularly with a detergent and as splashes/visible soil occur.	
Floors	<ol style="list-style-type: none"> <li>1. Thorough regular cleaning</li> <li>2. Cleaning when soiled</li> <li>3. Cleaning between patients/clients and after discharge.</li> </ol> <p>Damp mopping preferred</p>	<p>Detergent is adequate in most areas.</p> <p>Blood/body fluid spills should be cleaned up with disposable cloths followed by disinfection with a low level disinfectant.</p>
Carpets/upholstery	Should be vacuumed regularly and shampooed as necessary.	
Toys	Should be regularly cleaned, disinfected with a low level disinfectant, thoroughly rinsed, and dried (between patients in acute care setting).	<p>For pediatric settings, toys should be constructed of smooth, nonporous (i.e., not plush) materials to facilitate cleaning and decontamination.</p> <p>Do not use phenolics.</p>
Toilets and commodes	<ol style="list-style-type: none"> <li>1. Thorough regular cleaning</li> <li>2. Cleaning when soiled</li> <li>3. Clean between patients/clients and after discharge.</li> </ol> <p>Use a low level disinfectant.</p>	<p>These may be the source of enteric pathogens such as <i>C. difficile</i> and <i>Shigella</i><sup>(173)</sup>.</p>

would be susceptible to infection if exposed to patient care equipment contaminated with feces. Ensure contaminated environmental surfaces are clean to prevent the hands of health care workers or patients/residents/clients from becoming contaminated<sup>(25)</sup>.

Ensure that contaminated inanimate environments do not contaminate patients/clients/residents through contact with mucous membranes. The transmission of viral and other infections can be reduced by effective cleaning of environmental surfaces<sup>(101)</sup>. During casual contact, transfer of infectious agents from contaminated surfaces to clean surfaces can readily occur<sup>(101)</sup>, and upon inoculation (contaminated hands touching eyes, mouth, other mucous membranes, etc.) could lead to transmission<sup>(182)</sup>. For example, volunteers in a study infected themselves with respiratory syncytial virus (RSV) after

handling objects from the room of an RSV-infected patient and then touching their noses and mouths<sup>(15)</sup>.

Many human pathogens can remain viable on porous and nonporous inanimate objects from several hours to several days<sup>(25,129)</sup>. Laboratory-based investigations have clearly demonstrated that the spread of many types of infectious agents can be successfully interrupted by their proper cleaning and, when necessary, disinfection<sup>(101)</sup>.

The frequency of cleaning and disinfecting the health care environment may vary according to the type of surface to be cleaned, the number of people and amount of activity in the area, the risk to patients and the amount of soiling. Horizontal surfaces have a higher number of organisms than vertical surfaces, ceilings and smooth intact walls.

For noncritical devices that have contact only with intact skin (e.g., beds, handrails, IV poles, wheelchairs) and for most large environmental surfaces with which humans have little direct contact (e.g., floors, walls, furnishings) routine cleaning is sufficient (Table 9)<sup>(139)</sup>. This can usually be achieved with water and a detergent.

Some environmental surfaces that are frequently touched by health care providers and/or patients, such as call bell lights, surfaces of medical equipment and knobs/handles for adjustment or opening, have greater potential as vehicles for infectious agents. Therefore, careful attention should be paid to the regular cleaning of environmental surfaces that are frequently touched.

For further information on cleaning after the discharge of a patient for whom Contact Precautions have been necessary, refer to Health Canada's *Revision of Isolation and Precaution Techniques*<sup>(98)</sup>.

### Recommendations for Routine Housekeeping

1. Routine cleaning of environmental surfaces and noncritical patient care items should be performed according to a predetermined schedule and should be sufficient to keep surfaces clean and dust free<sup>(115,180,183)</sup>. Surfaces that are frequently touched by the hands of health care providers and clients, such as call bells, surfaces of medical equipment and knobs for adjustment or opening, require frequent cleaning. **Category B; Grade III**
2. Careful mechanical cleaning of environmental surfaces is effective in removing many contaminants from surfaces. **Category A; Grade II**
3. Health care facilities should determine a schedule for cleaning and maintaining ducts, fans, and air conditioning systems<sup>(115)</sup>. **Category A; Grade II**
4. An education program for housekeeping staff should help them to understand the effective methods of cleaning and the importance of their work. **Category B; Grade III**
5. Damp rather than dry dusting or sweeping should be performed whenever possible. Any dry cleaning should be done carefully with a chemically treated dry mop or vacuum cleaner (equipped with exhaust filter) rather than a broom. **Category B; Grade III**
6. Vacuum cleaners should be used on carpeted areas. Expelled air from vacuum cleaners should be diffused so that it does not aerosolize dust from uncleaned surfaces. **Category B; Grade III**
7. During wet cleaning, cleaning solutions and the tools with which they are applied soon become contaminated. Therefore, a routine should be adopted that does not redistribute microorganisms. This may be accomplished by cleaning less heavily contaminated areas first and changing cleaning solutions and cloths/mops frequently. **Category B; Grade III**
8. Wet mopping is most commonly done with a double-bucket technique, which extends the life of the solution because fewer changes are required. When a single bucket is used, the solution must be changed more frequently because of increased bioload. **Category B; Grade III**
9. Tools used for cleaning and disinfecting must be cleaned and dried between uses. **Category B; Grade III**
10. Mop heads should be laundered daily in areas of great activity and at a set interval for areas of lesser contamination. All washed mop heads must be dried thoroughly before storage<sup>(115)</sup>. **Category B; Grade III**
11. Cleaning agents: a detergent is acceptable for surface cleaning in most areas (Table 9). A low or intermediate grade disinfectant, often called a germicidal detergent<sup>(128)</sup> (see Tables 6 and 7 for examples), may be preferable for cleaning in nurseries, pediatric settings, critical care, burn units, emergency rooms, operating rooms, bone marrow transplantation facilities, and surfaces of dialysis machines. **Category B; Grade III**
12. Phenolics should not be used in nurseries (See Tables 6 and 7). **Category A; Grade II**
13. Cleaning and disinfecting agents must be mixed and used according to manufacturers' recommendations. **Category A; Grade III**
14. Protective apparatus: household utility gloves should be worn during cleaning and disinfecting procedures. Manufacturers' directions should be followed for product use to ensure safe handling practices. **Category B; Grade III**
15. Disinfectant fogging should not be done<sup>(184)</sup>. **Category D; Grade III**
16. Health care facilities should develop policies for cleaning schedules and methods, which should include the name of the person who is responsible for housekeeping. **Category A; Grade III**

## B. Special Cleaning

### i) Special organisms of epidemiologic significance

Except during outbreaks, no special environmental cleaning techniques are advocated for organisms such as *Clostridium difficile*, methicillin-resistant *Staphylococcus aureus* or vancomycin-resistant enterococci<sup>(115,185)</sup>. During an outbreak, thorough environmental cleaning and disinfection with a disinfectant that has demonstrated effectiveness against the specific organism may be required<sup>(186,187)</sup>.

### ii) Blood spills<sup>(84)</sup>

Note: Some recommendations are not graded for strength of evidence because they are from previous *Infection Control Guidelines*, which were not graded.

#### Recommendations for Cleaning Blood Spills

1. Appropriate personal protective equipment should be worn for cleaning up a blood spill. Gloves should be worn during the cleaning and disinfecting procedures. If the possibility of splashing exists, the worker should wear a face shield and gown. For large blood spills, overalls, gowns or aprons as well as boots or protective shoe covers should be worn. Personal protective equipment should be changed if torn or soiled, and always removed before leaving the location of the spill, then hands washed.
2. The blood spill area must be cleaned of obvious organic material before applying a disinfectant, as hypochlorites and other disinfectants are substantially inactivated by blood and other materials<sup>(84,109,117)</sup>.
3. Excess blood and fluid capable of transmitting infection should be removed with disposable towels. Discard the towels in a plastic-lined waste receptacle.
4. After cleaning, the area should be disinfected with a low level chemical disinfectant (e.g., chemical germicides approved for use as “hospital disinfectants”, such as quaternary ammonium compounds) or sodium hypochlorite (household bleach). Concentrations ranging from approximately 500 ppm (1:100 dilution of household bleach) sodium hypochlorite to 5000 ppm (1:10 dilution of household bleach) are effective, depending on the amount of organic material (e.g., blood or mucus) present on the surface to be cleaned and disinfected. See Table 7 for directions on the preparation and use of chlorine-based disinfectants. Commercially available chemical disinfectants may be more compatible with certain medical devices that might

be corroded by repeated exposure to sodium hypochlorite, especially the 1:10 dilution<sup>(59,109,133)</sup>. Manufacturers' recommendations for dilutions and temperatures of chemical disinfectants approved for use as hospital disinfectants must be followed.

5. For carpet or upholstered surfaces a low level disinfectant may be used. For home health care, a common supermarket disinfectant may be used.
6. Previous recommendations have suggested that sodium hypochlorite or chemical germicide should be left on the surface for 10 minutes.
7. The treated area should then be wiped with paper towels soaked in tap water. Allow the area to dry.
8. The towels should be discarded in a plastic lined waste receptacle.
9. Care must be taken to avoid splashing or generating aerosols during the clean up.
10. Hands must be thoroughly washed after gloves are removed.
11. For blood spills in clinical, public health or research laboratories, refer to recommendations for laboratories<sup>(188,189)</sup>.

### iii) Surgical settings (modified from Association of Operating Room Nurses<sup>(190-192)</sup>)

#### Recommendations for Cleaning Surgical Settings

For the purposes of this discussion, surgical settings include the operating room, ambulatory surgical units<sup>(148)</sup>, physicians' offices where invasive procedures are done, intravascular catheterization laboratories, endoscopy rooms and all other areas where invasive procedures may be performed.

1. Cleaning procedures should be completed on a scheduled basis, usually daily.
2. Areas outside the sterile field contaminated by organic debris should be cleaned as spills or splashes occur.
3. Surgical lights and horizontal surfaces, equipment, furniture and patient transport vehicles should be cleaned between patients with a clean cloth and a low level disinfectant.
4. Floors should be cleaned with a low level disinfectant/detergent, preferably using a wet vacuum

system between patients<sup>(139)</sup> or, depending on type of procedures carried out, at the end of the day.

5. Counter tops and surfaces that have been contaminated with blood or body fluids capable of transmitting infection should be cleaned with disposable towelling, using an appropriate cleaning agent and water as necessary, (e.g., after each procedure, after treatment of each patient/client, at the completion of daily work activities, and after any spill). Surfaces should then be disinfected with a low-level chemical disinfectant or sodium hypochlorite. Loose or cracked work surfaces should be replaced<sup>(84)</sup>.
6. All other areas and equipment in the surgical practice setting, (e.g., air conditioning grills and/or filters, cabinets, shelves, walls, ceilings, lounges and locker rooms) should be cleaned according to an established routine.
7. Before any piece of portable equipment enters or leaves the operating room, it should be wiped with the approved disinfectant.

# Laundry

The potential for transmission of infection from soiled linen is negligible<sup>(115,172,193-195)</sup>. In fact, there are only a handful of reports suggesting soiled linen as a cause of cross infection. In these studies, there were suspected sources of infection other than the soiled linen<sup>(115,172,193)</sup>. When appropriate precautions are followed by care givers and laundry workers for collecting, transporting, handling, washing, and drying soiled linen, the risk of cross infection can be virtually eliminated<sup>(172,193)</sup>.

All linen that is soiled with blood, body fluids, secretions or excretions or contaminated with lice or scabies should be handled using the same precautions, regardless of source or care setting<sup>(40,115,172,193,196-201)</sup>. If the bag soaks through, an additional outer bag should be used. Recent studies show that the practice of “double bagging” linen from isolation areas or when contamination with certain bacteria or viruses is suspected is not only costly but also unnecessary<sup>(172,193,195,202)</sup>.

Microbial counts on soiled linens are significantly reduced during the mechanical action and dilution of washing and rinsing. With the high cost of energy and use of cold water detergents (which do not require heat to catalyze their actions) hot water washes (>71.1° C for 25 minutes) may not be necessary. Several studies show that low temperature laundering will effectively eliminate residual bacteria to a level comparable with high temperature laundering<sup>(172,193,195)</sup>. When low temperature washes are combined with the addition of bleach (with a total available residual chlorine of 50-150 ppm), residual bacteria on laundry are reduced to below levels found on laundry washed at high temperatures<sup>(172,193)</sup>. See Table 7 for directions on preparing and using chlorine-based disinfectants. Machine drying of linen contributes to a further reduction of residual bacteria<sup>(172,193)</sup>.

Easily laundered clothing should be provided for residents in group facilities or long-term care facilities to avoid the use of garments (e.g., of silk or wool) requiring dry cleaning or other special handling.

The presence of sharps in soiled linens has caused sharps injuries in laundry workers. A needle tracking system may be effective in reducing the number of sharps found in soiled laundry. This approach establishes a system of feedback to personnel deemed responsible for the sharps debris.

## Recommendations for Laundry

### 1. Collection and handling

- a. All soiled linen from health care facilities should be handled in the same way for all patients. **Category A; Grade II**
- b. Linen from persons with a diagnosis of rare viral, hemorrhagic fevers (e.g., Lassa, Ebola, Marburg) requires special handling. For detailed handling instructions refer to Health Canada's *Canadian Contingency Plan for Viral Haemorrhagic Fevers and Other Related Diseases* and, from the Centers for Disease Control and Prevention, *Management of Patients with Suspected Viral Hemorrhagic Fevers*<sup>(203,204)</sup>. **Category B; Grade III**
- c. Linen should be handled with a minimum of agitation and shaking<sup>(172,193,205)</sup>. **Category B; Grade III**
- d. Sorting and rinsing of linen should not occur in patient care areas, except in facilities that use colour-coded, compartmented soiled linen bag carts into which different types of linen are sorted, e.g.,

personal clothing, towels, reusable incontinence products, bedding. **Category B; Grade III**

- e. In community or home settings where clothes and linens are not often soiled with blood or body fluids, sorting of linen may take place in care areas<sup>(193)</sup>. **Category B; Grade III**
- f. Heavily soiled linen should be rolled or folded to contain the heaviest soil in the center of the bundle<sup>(172,193)</sup>. Large amounts of solid soil, feces or blood clots should be removed from linen with a gloved hand and toilet tissue and placed into a bed pan or toilet for flushing. Excrement should not be removed by spraying with water (e.g., from clothing, reusable incontinence pads). **Category B; Grade III**

## 2. Bagging and containment

- a. Soiled linen should be bagged at the site of collection<sup>(172,193,206)</sup>. **Category C; Grade III**
- b. To prevent contamination or soaking through, a single, leakproof bag<sup>(172,195,206)</sup> or a single cloth bag can be used<sup>(205)</sup>. The only indication for a second outer bag is to contain a leaking inner bag<sup>(172,193,195,202)</sup>. **Category B; Grade II**
- c. Use of water soluble bags is not recommended as these require hot water washes that may cause stains to set. Water soluble bags offer no benefit from an infection control perspective and needlessly add to costs<sup>(172,193)</sup>. **Category B; Grade III**
- d. Laundry carts or hampers used to collect or transport soiled linen need not be covered<sup>(193)</sup>. The practice of placing lids on soiled linen carts is not necessary from an infection control perspective<sup>(193)</sup>. **Category B; Grade III**
- e. Bags should be tied securely and not over-filled when transported either by chute or cart<sup>(172)</sup>. **Category B; Grade III**
- f. Linen bags should be washed after each use and can be washed in the same cycle as the linen contained in them<sup>(193)</sup>. **Category B; Grade III**

## 3. Transport

- a. When a laundry chute is used, all soiled linen must be securely bagged and tightly closed. There have been reports of bacteria-laden air being exhausted upwards through these chutes; however, infections have not been associated with chutes<sup>(172,193)</sup>. The

chute should discharge into the soiled linen collection area. Laundry chutes should be cleaned on a regular basis with a diluted germicide compatible with the washing process<sup>(206)</sup>. **Category B; Grade III**

- b. When linens are commercially laundered, adequate separation of clean and dirty laundry in the truck is essential to ensure that there is no opportunity for mixing clean and dirty linens. **Category B; Grade III**
- c. Linen transported by cart should be moved in such a way that the risk of cross contamination is minimized. There is no need to cover carts, although odour control may be a factor<sup>(115,193)</sup>. **Category B; Grade III**
- d. Separate carts should be used for dirty and clean linens. Carts used to transport soiled linens should be cleaned with the cleaning product used in the health care setting after each use. **Category B; Grade III**
- e. Clean linen should be transported and stored in a manner that prevents its contamination and ensures its cleanliness<sup>(115,193,207)</sup>. **Category B; Grade III**

## 4. Washing and drying

- a. If low temperature water is used for laundry cycles, chemicals suitable for low temperature washing at the appropriate concentration should be used. **Category B; Grade III**
- b. High temperature washes (> 71.1° C) are necessary if cold water detergents are not used<sup>(193)</sup>. **Category B; Grade III**
- c. To achieve a level of at least 100 ppm of residual chlorine with household bleach, 2 mL of household bleach should be added for every litre of water. See Table 7 for Directions for Preparing and Using Chlorine-based Disinfectants. **Category B; Grade III**
- d. In institutional laundry areas, addition of a mild acidic “souring” agent neutralizes the alkalinity from the fabric, water and detergent. This shift in pH from approximately 12 to 5 may inactivate any remaining bacteria and reduce the potential for skin irritation<sup>(193)</sup>. **Category B; Grade III**
- e. Use of a commercial laundry detergent with household bleach (according to product instructions and where suitable for fabrics) and a normal machine wash and machine dry are sufficient to clean soiled linen in a community living or home care setting<sup>(40,196-201)</sup>. **Category B; Grade III**

- f. Machine drying or hanging clothing and linens on a clothes line at the home care site is a suitable method for drying. **Category B; Grade III**

### 5. Dry cleaning

Clothing containing blood, body fluids or excrement that is sent to community dry cleaners should be appropriately labelled. Dry cleaning personnel should be knowledgeable of procedures to handle soiled clothing items.

### 6. Sterile linen

Only surgical gowns and linens used in sterile procedures should be sterilized<sup>(193,207)</sup>. Such linens should be steam sterilized following the normal washing and drying cycle to kill any residual spores. Resterilization of previously sterilized linen requires laundering to rehydrate it. Disposable items for use in sterile procedures may be more cost-effective in some situations. The need for sterilizing linens for nurseries and other areas has not been substantiated<sup>(193)</sup>.

### 7. Protection of laundry workers

- a. Workers should protect themselves from potential cross infection from soiled linen by wearing appropriate protective equipment, such as gloves and gowns or aprons, when handling soiled linens<sup>(193,205-207)</sup>. Reusable gloves should be washed after use, allowed to hang dry, and discarded if punctured or torn. **Category B; Grade III**
- b. Hand washing facilities should be readily available. **Category B, Grade II**
- c. Personnel should wash their hands whenever gloves are changed or removed<sup>(84)</sup>. **Category B; Grade II**
- d. Staff in care areas need to be aware of sharps when placing soiled linen in bags. Workers are at risk from contaminated sharps, instruments or broken glass that may be contained with linen in the laundry bags<sup>(172,193)</sup>.
- e. All care givers and laundry workers should be trained in procedures for handling of soiled linen<sup>(193)</sup>. **Category B; Grade III**
- f. Laundry workers, as other health care workers, should be offered immunization against hepatitis B.

# Waste Management\*

The management of waste generated in health care settings has been the subject of much debate in recent years because

- there is a public perception of a higher infection risk from medical as compared with household waste, despite evidence to the contrary;
- environmental concerns have limited the use of incinerator or landfill as a final waste disposal site;
- health care fiscal restraint means that waste management procedures must be based on evidence of risk to workers or the public as well as of decreased risk as a result of the procedures.

The waste management guidelines recommended in this document will be based on the principles of disease transmission and esthetic concerns<sup>(114,208-209)</sup>. The management of waste described in this section will reflect the current understanding of disease transmission and risk, and incorporate an adaptation of the biomedical waste guidelines prepared by the Canadian Standards Association<sup>(210-211)</sup>. Because waste disposal now occurs in many diverse health care settings these guidelines will serve as a reference for both institutional and community health care providers.

The categories of human biomedical waste generated in health care are anatomic, microbiologic/laboratory, blood/body fluid, sharps and isolation waste.

Biomedical waste is not necessarily infectious. Waste documented to be associated with risk of disease transmission are sharps contaminated with blood; as

well, aerosolization of the tubercle bacillus from medical waste has been reported<sup>(212)</sup>. The ability of other waste to cause disease depends upon the virulence of the microorganism, susceptibility of the host, and a portal of entry. Because there are no objective methods to determine infection risk from waste, it has become commonplace to regulate waste when it is suspected of containing pathogens capable of producing disease. This practice is not supported by evidence of risk from waste or of decreased disease transmission associated with these practices<sup>(114,208,209)</sup>.

## A. Public Health Risk

Waste generated in health care settings is no more hazardous than household waste. Data demonstrate that household waste contains 100 times more pathogenic organisms than medical waste<sup>(213)</sup>.

There is no evidence that any member of the public has acquired disease from infectious waste<sup>(114,208-209, 214)</sup>. All reports (except one<sup>(212)</sup>) of disease transmission from biomedical waste have been a result of occupational exposure to contaminated sharps in the health care setting. Laboratory workers have unique exposure risks and have incurred exposures that have resulted in transmission of bloodborne pathogens<sup>(84)</sup>. As out-of-hospital care increases, so will the number of sharps disposed of by health care workers in the community<sup>(148,215)</sup> (refer to Table 10). At present, needles may be disposed of in the household waste stream by recreational drug users or persons requiring home health care<sup>(59)</sup>. Accidental needlestick injuries have been reported in 10% of waste industry workers over one year because of improper disposal of needles in residential waste<sup>(217)</sup>. In

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\*See Appendix 1 for definitions of the following terms: biomedical waste, infectious waste.



**Table 10. Recommendations for Management of Untreated Infectious Waste**

Waste category*	Examples	Colour coding packaging†	Handling disposal‡	Special considerations
<b>Anatomic waste</b>	Tissues Organs Body parts	Sealed impervious containers	Incineration, crematorium	For religious or ethical reasons anatomic waste may be buried in a cemetery.
<b>Microbiologic waste</b>	Diagnostic specimens Laboratory cultures Vaccines	Incineration Autoclavable bags and plastic waste holding bags for general waste	Incineration or decontamination by autoclave for landfill <sup>(211)</sup>	
<b>Blood/body fluid waste</b>	Phlebotomy bottles Drainage collection units Suction containers with blood Placentas from home deliveries	Sealed impervious containers	Sanitary sewer if permitted by local regulatory authorities or incineration	
<b>Other waste</b>	Gloves Sponges Dressings Surgical drapes soiled or soaked with blood or secretions	Impervious waste holding bags or double bag	Landfill	It is inappropriate to specify a minimum thickness of plastic bag as plastic materials vary extensively in their physical and mechanical properties.
<b>Sharps</b>	Needles Blood syringes Lancets Clinical glass	Puncture resistant sharps containers	Incineration or landfill disposal (home health care)	For health care provided in the home use a puncture-resistant container. Glass containers should not be used. The lid should be secured before disposal into household waste. The local municipality or public health department should be contacted before disposal <sup>(59,148,210,215)</sup>
<b>Isolation waste</b>	Lassa fever Marburg virus disease Ebola virus disease	Transport Canada approved, sealed, impervious container	Incineration	Contact the local public health authority <sup>(216)</sup> .

\* As per definitions

† Biohazard symbol is required on all packaging for incineration; colour coding varies provincially and regionally.

‡ All transportation of infectious waste must comply with the *Transportation of Dangerous Goods Act*, Transport Canada<sup>(216)</sup>.

Canada, tracking methods for community-acquired needlestick injuries, both in health care workers and non health workers such as waste industry workers, require further development<sup>(218)</sup>.

Esthetics plays a role in the management of biomedical waste. The waste generated during health care delivery is perceived by the public to pose a threat to health. However, the public perception of hazard does not equate with the actual risk of contracting infectious diseases<sup>(213,219,220)</sup>.

Blood-soaked waste has also received much attention. Increased public concern over bloodborne pathogens has resulted in the erroneous extension of bloodborne pathogen precautions to treat **all** blood/body fluid waste as potentially infectious. Items soaked or dripping with blood, contained in an impervious plastic bag before being sent to the landfill, pose no threat to the public health. Special treatment (e.g., incineration) of blood soaked waste is not required, and has enormous cost and environmental implications<sup>(59,211,221,222)</sup>.

Sharps contaminated with body fluid<sup>(84)</sup> and untreated microbiologic waste<sup>(188)</sup> require special handling and treatment. Sharps must be contained in a puncture-proof container. Sharps and microbiologic waste should be incinerated prior to disposal. Local environmental and health regulatory authorities should be consulted when implementing the waste treatment and disposal recommended in this document.

## **B. Treatment of Waste**

The treatment of infectious waste to render it non-infectious, in some instances, may be stipulated by local regulatory authorities. The principles of appropriate treatment methods follow.

### **i) Chemical decontamination**

Chemical decontamination of infectious fluids is generally not indicated except for the cleanup of blood spills<sup>(84)</sup>. Chemical treatment of sharps, such as adding a disinfectant to a sharps container, does not render sharps safe for further handling.

### **ii) Steam sterilization**

Steam sterilization is most often used for decontamination of microbiologic waste before final disposal in a landfill<sup>(188)</sup>. Steam autoclaving is an appropriate method of treating microbiology laboratory waste<sup>(189)</sup>, blood and body fluid waste (if applicable), and

non-anatomic animal wastes. It must not be used for treating anatomic waste<sup>(210)</sup>. The penetration of steam into the waste is essential for decontamination, and therefore the packaging of waste, and the volume and loading of the autoclave are crucial. Biologic monitoring should be used to confirm that a routine cycle achieves sterilization<sup>(210)</sup>.

## **C. Disposal Methods for Waste**

There are three common methods of waste disposal for biologic waste in Canada, which may vary in availability according to location.

### **i) Landfill**

It is acceptable to dispose of specific categories of waste in a properly managed landfill provided there are procedures in place to protect workers from contact with the waste. Studies have shown that bacteria and viruses in a landfill are significantly reduced in number by processes such as thermal inactivation and adsorption of organic material in the solid waste. The leachate similarly contains relatively low concentrations of pathogenic organisms and therefore poses minimal risk to the surrounding environment<sup>(214)</sup>. It is, however, an overall environmental goal to reduce waste of all types, including waste for disposal into the landfill. The landfill disposal method is inexpensive when compared with incineration<sup>(220)</sup>. Local regulations must be followed.

### **ii) Sanitary sewer**

The sanitary sewer is an acceptable method of disposal of blood, suctioned fluids, excretions and secretions<sup>(210)</sup>. The disposal of such liquids into sanitary sewers must conform to municipal sewerage by-laws and provincial regulations and legislation<sup>(211)</sup>.

### **iii) Incineration**

Incineration is the process that converts combustible materials into noncombustible ash, achieving a reduction of 90% by volume or 75% by weight. The product gases are vented into the atmosphere, and the treatment residue may be disposed of in a landfill. Provincial and territorial regulatory authorities issue requirements for many aspects of incinerator operation and emissions<sup>(210)</sup>.

## **D. Safety for Waste Handlers**

Persons handling infectious waste are at potential risk of exposure to pathogens from sharps or infectious waste leaking from containers.

## Recommendations for Waste Management

1. Local environmental and health regulations should be followed when planning and implementing treatment and disposal policies for biologic waste. **Category B; Grade III**
2. Specific categories of biologic waste may be disposed of in a properly managed landfill provided that there are procedures in place to protect workers and the public from contact with the waste. **Category B; Grade III**
3. Medical waste, (e.g., gloves, sponges, dressings, surgical drapes soiled or soaked with blood or secretions) may be contained in impervious waste holding bags or double bags and may be disposed of in a landfill<sup>(114,208,209)</sup>. **Category B; Grade III**
4. Blood, suctioned fluids, excretions and secretions may be disposed of in a sanitary sewer if local regulations permit. **Category B; Grade III**
5. Anatomic waste, (e.g., tissues, organs, body parts) should be packaged in a sealed, impervious container that is not easily torn or penetrated in transport, and may be disposed of in an incinerator or crematorium (Table 10). **Category B; Grade III**
6. Microbiologic waste, (e.g., diagnostic specimens, laboratory cultures, vaccines) should be packaged in incineration or autoclavable bags and treated by incineration or steam sterilization before disposal in a landfill. Adhere to *Laboratory Biosafety Guidelines*<sup>(188,210)</sup>. **Category B; Grade III**
7. Sharps (e.g., needles, syringes, blades, lancets, clinical glass) should be contained in puncture-resistant sharps containers for transport and treated by incineration or landfill (home health care), depending on local regulations (Table 10)<sup>(211,218)</sup>. **Category A; Grade II**
8. Isolation waste (waste containing pathogens categorized as Risk Group 4 agents such as Lassa fever, Marburg and Ebola viruses) must be contained in a Transport Canada approved, sealed, impervious container for transport and should be treated by incineration. Under the *Transportation of Dangerous Goods Regulations*, Schedule 16, mandated by Transport Canada (TC), any shipment of a Risk Group 4 agent must have a TC approved Emergency Response Assistance Plan in place before shipment<sup>(216)</sup>. The local public health authority must be contacted<sup>(203)</sup>. **Category B; Grade III**
9. A biohazard symbol is required on all waste packaged for incineration. Regulations regarding colour coding may vary provincially. **Category B; Grade III**
10. All transportation of infectious waste must comply with the *Transportation of Dangerous Goods Act and Regulation*, Transport Canada<sup>(216)</sup>.
11. Infectious waste must be stored in a designated location with access limited to authorized personnel. Refrigerated space should be provided for lockable, closed storage of laboratory waste that will be disposed of off site<sup>(188)</sup>. Provincial/territorial regulations for specific storage requirements should be followed. **Category B; Grade III**
12. Health care facilities should choose waste hauling, treatment, and disposal firms carefully since the waste generator is held directly accountable for ensuring that all stages of transportation and disposal are carried out in a safe and legal manner<sup>(188)</sup>. **Category B; Grade III**
13. Written policies and procedures to promote the safety of waste handlers should be established with input from persons handling the waste. **Category B; Grade III**
14. Waste handlers should wear protective apparatus appropriate to the risk, (e.g., protective footwear and heavy work gloves). **Category B; Grade III**
15. Waste handlers should be offered hepatitis B immunization.

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# Appendix 1

## Glossary

**Antimicrobial agent:** a product that kills or suppresses the growth of microorganisms.

**Antiseptics:** chemicals that kill microorganisms on living skin or mucous membranes. Antiseptics should not be used in housekeeping.

**Biofilm:** the process of irreversible adhesion initiated by the binding of bacteria to the surface by means of exopolysaccharide material (glycocalyx). The development of adherent microcolonies leads eventually to the production of a continuous biofilm on the colonized surface. Bacteria within biofilms tend to be more resistant to antibiotics and biocides than cells in batch-type culture.

**Biomedical waste:** defined by the CSA<sup>(210)</sup> as waste that is generated by human or animal health care facilities, medical or veterinary settings, health care teaching establishments, laboratories, and facilities involved in the production of vaccines.

**Cleaning:** the physical removal of foreign material, e.g., dust, soil, organic material such as blood, secretions, excretions and microorganisms. Cleaning physically removes rather than kills microorganisms. It is accomplished with water, detergents and mechanical action. The terms “decontamination” and “sanitation” may be used for this process in certain settings, e.g., central service or dietetics. Cleaning reduces or eliminates the reservoirs of potential pathogenic organisms. Cleaning agents are the most common chemicals used in housekeeping activity.

**Critical items:** instruments and devices that enter sterile tissues, including the vascular system. Critical items present a high risk of infection if the item is contaminated with any microorganisms, including bacterial spores. Reprocessing critical items involves meticulous cleaning followed by sterilization.

**Decontamination:** the removal of disease-producing microorganisms to leave an item safe for further handling.

**Disinfection:** the inactivation of disease-producing microorganisms. Disinfection does not destroy bacterial spores. Disinfectants are used on inanimate objects; antiseptics are used on living tissue. Disinfection usually involves chemicals, heat or ultraviolet light. Levels of chemical disinfection vary with the type of product used.

**Fomites:** those objects in the inanimate environment that may become contaminated with microorganisms and serve as a vehicle of transmission<sup>(115)</sup>.

**Germicide:** an agent that destroys microorganisms, especially pathogenic organisms.

**Hand wash(ing):** a process for the removal of soil and transient microorganisms from the hands.

**Hand antisepsis:** a process for the removal or destruction of resident and transient microorganisms on hands.

**Heavy microbial soiling:** the presence of infection or high levels of contamination with organic material, e.g., infected wounds, feces.

**High level disinfection:** level of disinfection required when processing semicritical items. High level disinfection processes destroy vegetative bacteria, mycobacteria, fungi and enveloped (lipid) and non enveloped (non lipid) viruses, but not necessarily bacterial spores. High level disinfectant chemicals (also called chemosterilants) must be capable of sterilization when contact time is extended. Items must be thoroughly cleaned prior to high level disinfection.

**Infectious waste:** that portion of biomedical waste that is capable of producing infectious disease<sup>(219)</sup>.

**Intermediate level disinfection:** level of disinfection required for some semicritical items. Intermediate level disinfectants kill vegetative bacteria, most viruses and most fungi but not resistant bacterial spores.

**Low level disinfection:** level of disinfection required when processing noncritical items or some environmental surfaces. Low level disinfectants kill most vegetative bacteria and some fungi as well as enveloped (lipid) viruses (e.g., hepatitis B, C, Hantavirus, and HIV). Low level disinfectants do not kill mycobacteria or bacterial spores. Low level disinfectants-detergents are used to clean environmental surfaces.

**Noncritical items:** those that either touch only intact skin but not mucous membranes or do not directly touch the patient. Reprocessing of noncritical items involves cleaning and/or low level disinfection.

**Plain or nonantimicrobial soap:** detergent-based cleansers in any form (bar, liquid, leaflet, or powder) used for the primary purpose of physical removal of soil and contaminating microorganisms. Such soaps work principally by mechanical action and have weak or no bactericidal activity. Although some soaps contain low concentrations of antimicrobial ingredients, these are used as preservatives and have minimal effect on colonizing flora.

**Sanitation:** a process that reduces microorganisms on an inanimate object to a safe level (e.g., dishes and eating utensils are sanitized).

**Semicritical items:** devices that come in contact with nonintact skin or mucous membranes but ordinarily do not penetrate them. Reprocessing semicritical items involves meticulous cleaning followed preferably by high-level disinfection (level of disinfection required is dependent on the item, see Table 5). Depending on the type of item and its intended use, intermediate level disinfection may be acceptable (see Table 5 for examples).

**Sharps:** needles, syringes, blades, laboratory glass or other objects capable of causing punctures or cuts.

**Sterilization:** the destruction of all forms of microbial life including bacteria, viruses, spores and fungi. Items must be cleaned thoroughly before effective sterilization can take place.



## Appendix 2

# Guideline Rating System

The Laboratory Centre for Disease Control (LCDC) Infection Control Guidelines previously used a system for rating guideline statements based on the strength of the evidence<sup>(15,71)</sup>. A more elaborate system of rating has recently been proposed<sup>(223)</sup>, with five categories to rank the strength of the evidence *for* (categories A-C) or *against* (D-E) a statement, and three grades to describe the quality of supportive studies. This system of rating follows the guidelines that have been recently published for clinical practice guidelines. The format uses an evidence-based medicine approach, which stresses the examination of evidence from clinical research, especially randomized studies, and places less emphasis on intuition and recalled experiences.

This new rating scheme, with one modification, is used in this document with appropriate clarification of

evidence described in the text. The modification occurs in Category C with the word “insufficient” replacing “poor” in the original rating scheme. This system is outlined in Table 11.

The information in these guidelines was current at the time of publication; it should be emphasized that areas of knowledge and aspects of medical technology advance with time. Guidelines, by definition, are directing principles and indications or outlines of policy or conduct, which should not be regarded as rigid standards. These guidelines should facilitate development of standards but respect the autonomy of organizations and recognize their governing body's authority and responsibility to ensure the quality of care provided by the institution.

**Table 11: Strength and Quality of Evidence for Recommendations**

Categories for strength of each recommendation	
Category	Definition
A	Good evidence to support a recommendation for use.
B	Moderate evidence to support a recommendation for use.
C	Insufficient evidence to support a recommendation for or against use.
D	Moderate evidence to support a recommendation against use.
E	Good evidence to support a recommendation against use.
Categories for quality of evidence on which recommendations are made	
Grade	Definition
I	Evidence from at least one properly randomized, controlled trial.
II	Evidence from at least one well-designed clinical trial without randomization, from cohort or case-controlled analytic studies, preferably from more than one centre, from multiple time series, or from dramatic results in uncontrolled experiments.
III	Evidence from opinions of respected authorities on the basis of clinical experience, descriptive studies, or reports of expert committees.

## **Appendix 3**

# **Drugs Directorate Guidelines**

For more information regarding disinfectants and for an order form for publications of the Drugs Directorate, including the Drugs Directorate Guidelines, visit the website at the following address:  
[www.hc-sc.gc.ca/hpb-dgps/therapeut](http://www.hc-sc.gc.ca/hpb-dgps/therapeut)

For further information from the Therapeutics Products Programme, Bureau of Pharmaceutical Assessment, Health Protection Branch, Health Canada, telephone (613) 965-6466 and (613) 954-6503.