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Review

Disinfection and sterilisation of healthcare medical devices: A review

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ABSTRACT

Disinfection and sterilisation are critical to ensuring that medical devices (invasive and non-invasive) do not transmit pathogens to patients. All invasive procedures require contact between medical devices and patients' sterile tissue or mucous membranes. Failure to properly disinfect or sterilise medical devices will predispose patients to infectious agents when hosts' immunological barriers are broken. The decision about the method of disinfection and sterilisation should always be based on Spaulding's classification. This classification defines critical, semi-critical and non-critical devices which should be sterilised, high-level disinfected and low-level disinfected respectively. Laboratory staff should always consider the merits and demerits of specific methods when carrying out disinfection and sterilisation. This review article presents the approach for the careful selection and adequate utilisation of disinfection and sterilisation processes. Strict adherence to disinfection and sterilisation guidelines will reduce infections associated with contaminated or improperly disinfected or sterilised medical device.

Keywords: Disinfection, sterilisation, germicides, pathogens, medical device.

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INTRODUCTION

Disinfection and sterilisation are crucial for ensuring that medical and surgical instruments do not transmit infectious agents to patients. Sterilisation of all patient-care equipment is not necessary, therefore, health-care policies must identify, principally on the basis of the devices' intended use, such as cleaning, disinfection or sterilisation.

Several studies in many countries have revealed lack of compliance with established guidelines for disinfection and sterilisation (Zaidi et al., 1995). This lack of compliance with scientifically-based guidelines has led to numerous outbreaks of diseases (CDC, 2005; Weber and Rutala, 2001). This review article presents the approach to the judicious selection and adequate use of disinfection and sterilisation processes. This approach is based on assessing the efficacy and effectiveness of disinfection and sterilisation procedures.

Disinfection: This is a process that eliminates many or all pathogenic microbes except endospores, on inanimate objects. In health-care settings, objects are disinfected by liquid chemicals or wet pasteurisation. Disinfection is not sporicidal but a few disinfectants can kill spores with prolonged exposure times (3 to 12 hours); these are known as chemical sterilants. Chemical sterilants at similar concentrations but shorter exposure periods like 2% glutaradehyde for 20 minutes will kill all microbes except large numbers of endospores hence they are called high-level disinfectants. Intermediate-level disinfectants can kill mycobacteria, growing bacteria, most viruses and fungi but do not necessarily kill endospores. Low-level disinfectants can kill most growing bacteria, some viruses and fungi in a fast period of time (less than 10 minutes).

Cleaning: This is the removal of organic and inorganic matter from objects and surfaces. This is achieved manually or mechanically with the help of detergents or enzymatic products. Thorough cleaning is essential before high-level disinfection and sterilisation. This is because organic and inorganic matters on the surfaces of instruments interfere with the efficacy of these processes. Decontamination removes infectious agents from objects. This renders them safe to handle, use, or discard.

Sterilisation: It is the process that destroys all forms of microbial life. Sterilisation is an absolute term; it means complete absence of life forms including bacterial spores. In health-care facilities, it is achieved through physical or chemical methods.

Terms with the suffix: cide or cidal-killing action are also commonly used. For instance, a germicide is an agent that kills pathogenic microorganisms (germs).Therefore, antiseptics and disinfectants are germicides. Antiseptics are applied on living tissue and skin while disinfectants are applied only on inanimate objects. Disinfectants are not used on living tissues and skin because they can injure or damage them. So, virucide kills viruses; fungicide kills fungi; bactericide kills bacteria; and sporicide kills spores (Tables 1 to 3).

Table 1. Methods of disinfection.

Method	Concentration/level of activity
a. Heat	
Moist heat	75°C to 100°C/30min (high)
b. Liquid	
Glutaraldehyde	2% (High)
Hydrogen peroxide	3-25% (High)
Formaldehyde	3-8% (High/Intermediate)
Chlorine Dioxide	Variable (High)
Peracetic acid	Variable (High)
Chlorine Compounds	100-1000 ppm of free chlorine (High)
Alcohol (Ethyl, Isopropyl)	70-95% (Intermediate)
Phenolic Compounds	0.4-5.0% (Intermediate/Low)
Iodophor	30-50 ppm of free Iodine (Low/Intermediate)
Quaternary Ammonium Compounds (QAC)	0.4-1.6% (Low)

Source: Patrick et al. (2005).

Table 2. Methods of sterilisation.

Method	Concentration/ level of activity
1. Physical sterilants	
a. Steam under pressure (autoclaving)	121°C or132°C at various time intervals
b. Dry heat	1 hour at 171°C
(Hot Air Oven)	2 hours at 160°C
c. Filtration	0.22 to 0.45 um pore size, HEPA*filters
d. Ultraviolet radiation	Different exposure to 254 nm wavelength
e. Ionising radiation	Different exposure to micro or gamma wave
2. Gas vapour sterilants	
a. Ethylene Oxide (ETO)	450-1200 mg/L at 29 to 65°C for 2 to 5 h
b. Formaldehyde Vapour	2 to 5% at 60-80°C
c. Hydrogen Peroxide Vapour	30% at 55-60°C
d. Plasma gas	Highly oxidised hydrogen peroxide gas
3. Chemical sterilants	
a. Peracetic acid	0.2%
b. Glutaradehyde	2%

*High-efficiency particulate air. Source: Patrick et al. (2005).

Table 3: Clinical use of disinfection and sterilisation.

Commonly used disinfectant/method of sterilisation	Clinical use
Chlorhexidine	Disinfect hands prior to surgery
Iodopho	Disinfect surgical site before surgery
70% Ethanol	Disinfect skin before venipuncture
	Disinfect stethoscope
Tincture of iodine	Disinfect skin prior to blood culture
	Disinfect catheter before insertion
Thimerosal, Chlorhexidine,	
Hydrogen peroxide	Cleanse wounds
Silver sulfadiazine	Cleanse burn wounds
Hypochlorite (Bleach, clorox)	Disinfect area (Clean-up of blood spill from hepatitis B or C patients)
Ethylene oxide or glutaradehyde	Sterilise surgical instruments
	Heat-sensitive materials (Endoscopes)
Autoclave	Sterilise non-heat sensitive materials
Filtration	Sterilise intravenous solutions
Ultraviolet light	Disinfect air in operating room
Benzalkonium chloride (Lysol)-QAC	Disinfect floor of operating room
Thimerosal	Preservatives in vaccines

Source: Warren (2012).

Factors affecting the efficacy of disinfection and sterilisation

The activity of germicides against microbes depends on a number of factors, some of which are intrinsic qualities of the organism; others are chemical and physical environment. Awareness of these factors would lead to better use of disinfection and sterilisation processes. These factors are:

- Number and location of microbes
- Innate resistance of microbes
- Concentration and potency of disinfectants
- Physical and chemical factors
- Organic and inorganic matter
- Period of exposure
- Biofilms
- Relative humidity of sterilisation process (e.g. ETO)

Methods of disinfection and sterilisation

There are three major methods of disinfection and sterilisation. Each method is subdivided into various forms as listed below:

1. Physical Agents
A. Heat

i. Dry heat
- Incineration - Sterilisation
- Hot air oven - Sterilisation

ii. Moist heat
- Boiling water - Disinfection
- Hot water - Disinfection
- Pasteurisation - Disinfection
- Autoclaving- Sterilisation

B. Radiation
i. Ionising radiation
- X-ray, cathode and gamma rays- Sterilisation

ii. Non-ionising radiation
- UV- Disinfection

2. Chemical Agents
i. Gases- Disinfection and Sterilisation
ii. Liquids
- Animate (Antisepsis)
- Inanimate (Disinfection and Sterilisation)

3. Mechanical Removal Methods
Filtration
- Air (Disinfection)

- Liquids (Sterilisation)

Rational approach to disinfection and sterilisation

Earle H. Spaulding, more than 50 years ago, devised a rational approach to disinfection and sterilisation of patient- care items and equipment (Spaulding, 1968). This approach is so clear and logical that it has been kept, remodified and successfully used by experts when planning methods for disinfection and sterilisation (Simmons, 1983). Spaulding believed that the nature of disinfection and sterilisation could be understood readily if medical instruments and items were divided into three (3) categories - Critical, Semi-critical and Non-critical based on the degree of risk of infection involved in the use of the items. This terminology is employed by CDC in "Guidelines for Environmental Infection Control in Health-care Facilities (CDC, 2003)," Guidelines for the Prevention of Transmission Human Immunodeficiency Virus (HIV) and Hepatitis B Virus (HBV) to Health-care and Public Safety Workers (CDC, 1989)" and Guideline for Hand washing and Hospital Environmental Control (Garner and Favero, 1986).

Critical items: These are instruments that touch places where no single microbe should exist (sterile tissues and vascular system). They carry a high risk of infection if they are contaminated with any microorganisms, including bacterial spores. Therefore, instruments that enter sterile tissue or the vascular system must be sterile because any microbial contamination could lead to infection. These objects are surgical instruments, cardiac and urinary catheters, implants, as well as ultra-sound probes used in sterile body cavities. These devices should be sterilised with steam. However, heat-sensitive ones should be treated with ETO, hydrogen peroxide gas plasma or with liquid chemical sterilants if other methods are unsuitable. Tables 4 and 5 list several germicides that are categorised as chemical sterilants while table 6 is a list of some advantages and disadvantages of common sterilisation techniques.

Table 4. Methods for disinfection and sterilisation of patient-care items and their applications.

Process/method	Spectrum of activity	Health-care application
Sterilisation		
High temperature	Destroys all microbes and bacterial spores	Critical and semi-critical items
Low temperature	Destroys all microbes and bacterial spores	Heat-sensitive critical and semi-critical items
Liquid Immersion	Destroys all microbes and bacterial spores	Heat- sensitive critical and semi-critical immersibles
High-level disinfection		
Automated heat and liquid immersion	Destroys all microbes, except high number of spores	Heat-sensitive semi- critical items.
Intermediate-level disinfection		
Liquid contact	Destroys vegetative bacteria, Mycobacteria, most viruses and fungi, not endospores	Non-critical item with visible blood
Low-level disinfection		
Liquid contact	Destroys vegetative bacteria, few fungi and viruses, not Mycobacteria and spores.	Non- critical items with no visible blood

Source: Kohn et al. (2003).

PROPERTIES OF AN IDEAL DISINFECTANT

- Broad spectrum: Should have wide spectrum of activity
- Fast acting: Should destroy microbes in a short time
- Not inactivated by organic matter: Should be active in the presence of organic matter.
- Should be active in any pH
- Should be stable
- Should be easy to use
- Should have long shelf-life
- Should be odourless: Have a pleasant odour
- Solubility: soluble in water
- Economical: Not costly
- Availability: Readily and easily available
- Environmentally friendly: Not harmful to the environment
- Cleaner - Should have good cleaning properties

Table 5. Some advantages and disadvantages of disinfectants (sterilants/high-level disinfectants).

Sterilisation method	Advantages	Disadvantages
Peracetic acid/ hydrogen peroxide	No activation No significant odour/ irritation Limited use in clinic	Problem of material compatibility
Glutaradehyde	Good material compatibility Not costly Commonly used in clinics	Ability to damage the skin or eye Respiratory irritation from vapour Offensive odour Slow activity on Mycobacteria Allergic contact Dermatitis Vapour control
Hydrogen peroxide	Does not require activation No problem of disposal Inactivates Crypto-sporidium Rich literature about clinical use	Problem of compatibility Terrible eye damage with contact
Orthophthaladehyde	Fast acting high-level disinfectant Odour not significant No coagulation of blood or tissue fixation	Stains surfaces Excess exposure may cause hypersensitivity in patients with bladder cancer
Peracetic acid	Fast sterilisation time (30-45 minutes) Fully automated Rapidly sporicidal No hazardous effects under normal conditions Enhanced removal of organic material and endotoxin Standardised cycle	Material incompatibility Only immersibles More costly No sterile storage Serious eye and skin damage Small number of items processed in a cycle.

Source: CDC (2008).

Table 6. Some advantages and disadvantages of common sterilisation techniques.

Sterilisation method	Advantages	Disadvantages
Steam	Non-toxic Easy to conduct Rapidly microbicidal Rapid cycle time Least affected by organic and inorganic soils	Destroys heat-sensitive items Repeated exposure damages micro-surgical items Moisture cause items to rust
Hydrogen peroxide	Environmentally friendly No toxic residues Used for heat and moisture sensitive items Easy to operate	Not suitable for cellulose gas plasma Not suitable for some devices Requires synthetic packaging Toxic at levels above 1ppm
100% Ethylene oxide (ETO)	Good penetrating power Simple to operate and monitor Useful for most items	Requires aeration time to remove residue Lengthy cycle/aeration time Toxic, a carcinogen and flammable
ETO mixture	Cycle is easy Compatible with many medical items	Toxic Lengthy cycle time

Table 6. Continues.

Peracetic acid	Rapid cycle time	No sterile storage
	Environmentally friendly	Serious eye and skin damage
	Flows through endoscopes	Used for immersibles only
	Enhance salt, protein microbe removal	

Source: CDC (2008).

Resistant	**Level**
Prions	Prion reprocessing
Bacterial spores	Sterilisation
Coccidia (Cryptosporidium)	Disinfection
Mycobacteria	High
Non-lipid or Picornaviruses	
Fungi	Intermediate
Vegetative bacteria	Low
Lipid or medium –sized viruses (HIV, HSV, HBV)	Susceptible

Figure 1. Decreasing order of resistance of microbes to disinfection and sterilisation (disinfection levels indicated). Source: CDC, 2008 (Updated May, 2019).

- Should have high penetrating power
- Should be non-toxic, non-allergenic, non-irritative or non-corrosive
- Efficacy: Should not be lost on reasonable dilution
- Should not leave non-volatile residue or stain.

There is no ideal disinfectant with all these properties. However, the level of disinfection attained depends on a number of factors like contact time, temperature, type and concentration of the active ingredients, the presence of organic matter and the size and type of microorganisms (microbial load). Figure 1 illustrates the decreasing order of resistance of microorganisms to disinfection and sterilisation.

CONCLUSION

Disinfection and sterilisation when done effectively can guarantee safe usage of both invasive and non-invasive medical devices. The method of disinfection and sterilisation to be employed should depend on the use of the medical item. Critical items should be sterilised before use; semi-critical items should undergo high-level disinfection and non-critical items should undergo low-level disinfection. Items with visible blood should be cleaned before high-level disinfection. It is recommended that the current disinfection and sterilisation guidelines should be strictly adhered to.

REFERENCES

Centres for Disease Control (**CDC**), **1989**. Guidelines for prevention of transmission of human immunodeficiency virus and hepatitis B virus to health-care and public safety workers. MMWR, 38:1-37.

Centres for Disease Control (**CDC**), **2005**. *Pseudomonas aeruginosa* infections associated with transrectal ultrasound-guided prostate biopsies—Georgia, 2005. MMWR, 55:776-777.

Centres for Disease Control (**CDC**), **2003**. Guidelines for Environmental Infection Control in Health-care Facilities. MMWR, 52 (No.RR-10): 1-44.

Centres for Disease Control (**CDC**), **2008**. Guideline for Disinfection and Sterilisation in Healthcare Facilities (Updated May, 2019). cdc.gov/infectioncontrol/guidelines/disinfection/.

Garner JS, **Favero** MS, **1986**. CDC guidelines for the prevention and control of nosocomial infections. Guideline for handwashing and hospital environmental control. Am J infect Control, 14: 110-129.

Kohn WG, Collins AS, Cleveland JL, Harte JA, Eklund KJ, Malvitz DM, **2003**. Guidelines for infection control in dental health-care settings. MMWR Recomm Rep, 52: 1-67.

Patrick RM, Ken SR, Michael AP, **2005**. Medical Microbiology. 5thEd. Elsevier Mosby, Philadelphia Pennsylvania, pp. 90.

Simmons BP, **1983**. CDC guidelines for the prevention and control of nosocomial infections. Guideline for hospital environmental control. Am J Infect Control, 11: 97-120.

Spaulding EH, **1968**. Chemical Disinfection of Medical and Surgical Materials. In: Lawrence C, Block SS, eds. Disinfection, sterilisation, and preservation. Philadelphia: Lea & Febiger 517-531.

Warren L, **2012**. Review of Medical Microbiology and Immunology. 12thEd. McGrawHill, New York. pp. 99.

Weber DJ, **Rutala** WA, **2001**. Lessons from outbreaks associated with bronchoscopy. Infect Control Hosp Epidemiol, 22: 403-408.

Zaidi M, Angulo M, Sifuentes-Osornio J, **1995**. Disinfection and sterilisation practices in Mexico. J Hosp Infect, 31: 25-32.

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