24 Infection Control in Operating Rooms: Sterilization and Disinfection Practices

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24.1 Introduction

Operation rooms (ORs) are highly critical patient-care areas, where utmost cleanliness and highest levels of sterilization/disinfection practices must be observed. Apart from a robust engineering standard of OR structure, it is essential that staff should be trained and monitored for observing best practices/protocols for in the ORs in order to prevent surgical site infections (SSIs). Prevention of SSIs requires a multipronged approach involving ventilation engineering, appropriate disinfection and sterilization practices, maintenance of OR discipline and protocols, and continuous education of staff [1, 2].

24.2 Cleaning of Operating Rooms

The inanimate theatre environment usually has a negligible contribution to the development of SSIs. However, the surfaces should be kept free of visible dirt and the floors should be dry. For cleaning of ORs, use only vacuum cleaners or wet mopping. The cleaning equipment for the ORs must be dedicated and kept separate from the outer zone [3–6].

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Although in the absence of visible soiling or contamination, it is logical to perform routine decontamination of these surfaces to recreate a clean environment after each operation, there are no evidence to support routine disinfection of environmental surfaces or equipment between operations [3–7]. When there is visible soiling of equipment or surfaces during an operation, an EPA-approved hospital disinfectant should be used to clean the affected areas before the next operation. It should be ensured that medical equipment left in the OR are covered so that solutions used for decontamination do not contact them [3–6].

Cleaning Schedule At the start of the day, clean floors and all horizontal surfaces (examination couches, operating tables, trolley tops or mayo stands, chairs, lamps, sinks, counters, door handles, shelves, office furniture) and other noncritical surfaces with an EPA-approved detergent/low level disinfectant [3–6]. Between patients, clean operating tables, trolley tops, examination couches, counters, lamps, and any other potentially contaminated surfaces in procedure rooms and operating theatres with a cloth dampened with a low level decontaminator solution (used according to manufacturer's recommendations). Immediately clean spills of blood or other body fluids as detailed below. Mop buckets for spillage should be emptied after each use and kept dry until next use. Lint free cloth is recommended for all operating theatre cleaning.

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Empty the waste and sharps disposal containers when they are three-quarters full. Data does not suggest special cleaning measures or closing of an operating theatre after a dirty or contaminated operation has been done. Thorough, routine disinfection is appropriate to provide a safe environment for subsequent operations given the high frequency of air changes in ORs. At the end of session or day, wet vacuuming of the floor with a hospital disinfectant which is EPA-approved should be done. An appropriate floor-scrubbing machine may also be used. Mops should be hot laundered and dried daily. Horizontal surfaces must be damp-dusted with paper cloths or single-use fabric. The sluice should be cleaned with warm water and detergent. The walls with undamaged surfaces acquire very few bacteria even if left unwashed for long durations. However, they should not be allowed to become visibly dirty and should be washed at least every 3–6 months. If parts of paint peel off, the wall should be repainted [3].

Fumigation Routine fumigation is not advocated in current day OT practices. Thorough washing and disinfection of surfaces, if done everyday after the surgeries, is more beneficial than fumigation.

The amount of equipment in operating rooms should be kept minimal. Equipment should be stored under clean conditions and be disinfected or cleaned regularly. Items should be arranged neatly, so that staff movement is minimal. Placing of trolleys in advance of the procedure involves the risk of contamination. Some of the benefits of UCV air will be negated by not unwrapping instruments in the UCV area or not covering them subsequently [8].

24.3 Sterilization and Disinfection

The protocols for sterilization/disinfection should be based on the classification devised by EH Spaulding, as shown in Table 24.1 [9].

In 1991, the CDC proposed an additional category designated as "environmental surfaces" to the Spaulding's original classification [10] to represent surfaces which do not come in contact with patients and thus have minimal risk for transmitting infections [11]. Environmental surfaces are further divided into clinical contact surfaces (healthcare equipment or high-touch surfaces) and housekeeping surfaces. Clinical contact surfaces are those which can act as reservoirs for microbes with the potential for secondary transmission (through the hands of the healthcare workers (HCW) or through equipment that subsequently contacts the patients (e.g., light switches, telephones, countertop, door knobs, etc.)) [11, 12]. These should be disinfected with an EPA-registered low- or intermediate-level disinfectant.

Blood/body fluids spills must be promptly disinfected and cleaned as per the following methods:

All equipment and surfaces contaminated with blood and other potentially infectious material must be disinfected with an appropriate disinfectant. PPE (gloves, face masks, fluid resistant gowns) must be used for cleaning blood spills. Small spills should be cleaned and disinfected using an intermediate level germicide having a tuberculocidal claim. For decontamination of small spills (<10 ml), if sodium hypochlorite solution is selected, use a 1:100 dilution (a 1:100 dilution of 5.25–6.15% sodium hypochlorite provides 525–615 ppm of available chlorine). If

Table 24.1 Spaulding's classification of devices

Item/device	Definition/intended use	Risk of infection	Reprocessing required	Example
Critical	Medical device intended to enter a normally sterile tissue/vasculature	High	Sterilization	Surgical instruments/ implants/needles
Semi-critical	Devices that are intended to come in contact with mucous membrane or non-intact skin	High/ intermediate	Sterilization desirable HLD acceptable	Respiratory therapy equipment, some endoscopes
Noncritical	Devices that come in contact with intact skin	Low	Intermediate or LLD	BP cuff, stethoscope

spills involve large amounts (e.g., >10 ml) of blood or OPIM, or involves a culture spill in the laboratory, a 1:10 dilution of hypochlorite solution for first application (before cleaning) reduces the risk of infection during cleaning. After the first application, remove the visible organic matter with absorbent material (e.g., single-use paper towels discarded into labeled leak-proof container), and then terminal disinfection with 1:100 sodium hypochlorite may be done [13].

24.4 Cleaning of Medical Equipment

Thorough cleaning, done at the point of use, must precede any disinfection or sterilization process. Cleaning is a form of decontamination, which renders the equipment safe to handle and removes the organic and inorganic matter that shield microorganism, rendering the subsequent sterilization/disinfection ineffective. Thus, cleaning alone (physical scrubbing with surfactants and detergents followed by washing with water) effectively removes a large number of microorganisms from contaminated equipment and surfaces. Cleaning should be done using a detergent/soap and water. A neutral/near neutral pH detergent solution is frequently used because such solutions usually have the best material compatibility and good soil removal. Enzymes (usually proteases) are occasionally added to assist in removing organic material. Neutral pH detergent solutions containing enzymes are the preferable method of cleaning sensitive equipment like flexible endoscope [3, 11–17].

The sterilization and disinfection are essential to render a device or equipment free of microbial contamination and safe for reuse.

24.4.1 Sterilization [11, 14–16, 18, 19]

Sterilization can be attained by either physical or chemical methods. Pre-cleaning to remove all the organic matter must be done for all instruments undergoing sterilization. Equipment which can withstand heat and moisture must be sterilized by autoclaving since it affords a wide margin of safety and allows packaging of loads which is important to prevent post-processing contamination. The FDA has approved a few high-level disinfectants which can be used for chemical sterilization if the exposure time is prolonged. These chemicals must be used as per the manufacturer's instructions for use concentration, contact time, temperature, product compatibility, and shelf life. A disadvantage of chemical sterilization is that items cannot be packed and therefore must be used immediately. The disinfectants also need to be rinsed off thoroughly to prevent toxicity. Moreover, there are no reliable biological indicators for monitoring chemical sterilization.

The resistance to disinfection methods varies among microbes. Accordingly, prions, coccidia, spores, mycobacteria, cysts, small non-enveloped viruses, trophozoites, Gram-negative bacteria, fungi, large non-enveloped viruses, Gram-positive bacteria, and lipid-enveloped viruses represent a descending order of resistance to disinfectants [11, 15, 16].

Sterilization can be done by the following methods.

24.4.2 High-Temperature Sterilization

24.4.2.1 Steam Under Pressure (Autoclaves) [3, 11, 14–16, 18]

It is the most efficient and reliable method of sterilization. It is used for sterilization of all critical and semi-critical items that are heat and moisture resistant (surgical instruments, surgical drapes, some respiratory and anesthetic equipment, microbiological waste, and sharps).

Monitoring of Steam Sterilization Process The residual air detection for vacuum sterilizers is to be done daily by the Bowie-Dick test. For this, commercially available Bowie-Dick type test sheet must be placed in the center of the pack. The test pack should be positioned horizontally in the front, bottom segment of sterilizer rack, adjacent to the door, and over the drain in an otherwise empty chamber and run at 134 °C × 3.5 min. If the

sterilizer fails the test, do not use until remedied. Mechanical and chemical monitoring should be done with each cycle. For biological monitoring, *Geobacillus stearothermophilus* spores 10^5 must be used at least weekly (preferably daily) and with each load of implantable devices. Loads containing implantable devices should ideally be quarantined until the results of biological indicators are available.

24.4.2.2 Flash Sterilization [11, 20–22]

This is a high-temperature, rapid, steam sterilization procedure (132 °C at 27–28 lbs × 3–4 min) of unwrapped items for emergency situations. The items are placed in an open tray or specifically designed, covered rigid container for quick penetration of steam.

It is used for sterilization of heat-tolerant, critical medical devices, which are to be used immediately and cannot be packaged and stored. It may be used in emergencies (orthopedic screws). It should not to be used for implants. For its monitoring, mechanical and chemical tests should be done with each cycle. For biological monitoring, there are no suitable timely indicators. A recently developed Attest rapid readout biological indicator detects the presence of a spore-associated enzyme (α-D-glucosidase) in 1 hour. Use biological indicators at least weekly (preferably with each cycle).

24.4.3 Low-Temperature Sterilization [3, 11, 14–16, 18, 23]

24.4.3.1 Ethylene Oxide (EtO) [11, 14–16, 18]

EtO gas must penetrate the entire load. It should be handled according to strict guidelines. Items must undergo aeration to remove residual EtO. It is used for sterilization of heat and moisture labile critical and semi-critical items and for sterilization of devices containing electronic components. The mechanical of EtO should be done with each cycle (time, temperature, pressure). Chemical monitoring should also be done with each cycle. For biological monitoring, *Bacillus atrophaeus* spores (10^6) should be used at least weekly (if possible daily) and with each load of implantable devices. Loads containing implantable devices must ideally be quarantined until the results of biological indicators are available.

24.4.3.2 Hydrogen Peroxide (H_2O_2) Gas Plasma [11, 15, 16, 23–25]

Gas plasmas are the fourth state of matter. They are generated by exciting a chemical precursor (H_2O_2) under a deep vacuum in an enclosed chamber using radiofrequency/microwave energy. This produces highly reactive and biocidal charged particles, many of which are free radicals. The free radicals react and inactivate essential cellular components (enzymes, nucleic acids) of microbes.

24.4.3.3 Sterrad Sterilizers

The Sterrad sterilizers have been the first plasma phase sterilizer, in use since the 1990s. The initial Sterrad 100 systems could sterilize lumened devices with single lumens ≥3 mm in diameter and ≤40 cm in length. The Sterrad 100 was replaced with the 100 S series, which had an added cycle, with resultant reduced sterilization time. It is used for sterilization of devices which are heat and moisture sensitive (plastic, electronic devices, corrosion-sensitive metals), like arthroscope and its instruments, micro instruments, vascular instruments, spine sets, pneumatic drills, dermatomes, micro and mini drill, implants, urethroscope and its instruments, laparoscope and its instruments, thoracoscope and its instruments, laparotomy set, nephrectomy set, microvascular instruments, dental implants, craniotomy sets, tracheostomy set, image-intensifying cover, retractors, bone nibblers, and ophthalmic instruments. The physical and chemical monitoring is inbuilt with each cycle. For biological monitoring, spores of *G. stearothermophilus* (read at 48 hours) should be used. The system has its own monitor in plastic vials, which should be incorporated at least weekly (preferably daily).

24.4.3.4 Chemical/Liquid Sterilization

These should be considered only if single use is not cost-effective and other sterilization methods cannot be used. Any liquid chemical sterilant

approved by FDA may be used in such situations. The choice should be primarily based on material compatibility, time, use conditions, and cost. Strictly follow the manufacturer's instructions of use. Use the items immediately since once the items are unpacked, they are liable to get contaminated. Another disadvantage is that suitable biological indicators are not available to monitor chemical sterilization.

24.4.3.5 Peracetic Acid (STERIS System-1) [11, 15, 16, 23, 24]

An automated machine using PAA (STERIS-1) has been approved by the FDA for chemical sterilization of medical and surgical equipment. It is a low-temperature chemical sterilization process. It works on the principal of oxidizing agent which denatures proteins, disrupts cell walls, and oxidizes sulfhydryl groups. The time to sterilization is 45 min. It is used for sterilization of medical and surgical endoscope. Chemical monitoring strips which detect the active ingredient (at >1500 ppm) are used as process control. Use manufacturer's clip to hold the strip. *G. stearothermophilus* (10^5) spores are used for biological monitoring, at least weekly, although daily monitoring is ideal.

24.4.3.6 Low-Temperature Sterilization with Ozone [11, 16]

A low-temperature sterilization using ozone has been recently cleared by FDA. It uses medical grade oxygen, water, and electricity. O_2 is energized and split into two monoatomic molecules which react with O_2 to form ozone (O_3). One oxygen atom is loose and is readily available to bind and oxidize cellular components. It is used for sterilization of rigid lumened devices with internal diameter (ID) >2 mm, length ≤25 cm, ID >3 mm, L ≤47 cm, and ID >4 mm, L ≤60 cm.

24.4.3.7 Performic Acid [11, 23]

Endoclens is a new, proprietary liquid chemical sterilization method based on performic acid. This is a fast-acting, sporicidal, automated endoscope reprocessing system. The system provides point of use chemical sterilization of flexible endoscopes.

24.4.3.8 Vaporized Hydrogen Peroxide [11]

It is a rapid, low-temperature sterilization technique based on hydrogen peroxide, which is safe, has a good compatibility, and is easy to use. However, it is not FDA cleared.

24.4.3.9 Disinfection

Disinfection is used to kill organisms present on delicate or heat-sensitive instruments which cannot be sterilized or when single-use items are not available. The level of disinfection varies with the intended use and level of risk of infection associated with its use. Disinfection can be achieved by thermal (pasteurization) or chemical means.

24.4.3.10 Thermal Disinfection (Pasteurization) [3, 11, 14–16, 18]

If an instrument is able to withstand heat and moisture and if sterilization is not required, then thermal disinfection is suitable. Pasteurization is a process of hot water disinfection which is attained through the use of washer disinfectors or automated pasteurizers. Semi-critical items suitable for pasteurization include equipment for respiratory therapy and anesthesia. The degree of disinfection depends on the water temperature and duration of exposure. The items to be pasteurized should be thoroughly cleaned with detergent and water prior to disinfection. They must be totally immersed in water throughout the pasteurization cycle. After pasteurization, special care must be taken to dry and prevent recontamination of the equipment during storage and transport.

24.4.3.11 Chemical Disinfection [3, 11, 18, 26]

Numerous disinfectants are used alone or in combination to serve the purpose of rendering an equipment/surface free of microbes. Commercial formulations of these germicides are unique products, which should be registered with EPA or cleared by FDA. The activity of a disinfectant depends on the temperature, contact time, pH, presence of inorganic or organic

matter, and number and resistance of the bioburden on a surface. Thus, while using the product, the users must comply with the manufacturer's label for use/storage and disposal. HCW must exercise precautions and use appropriate PPE while using disinfectants. There is no single perfect disinfectant. Disinfectants must be used taking into consideration the level of disinfection required, the material compatibility, time required to disinfect, and health hazard. Use only instrument grade disinfectants for equipment and instruments. Household/hospital grade chemicals should be used for noncritical surfaces. Pre-cleaning of instruments must be done to ensure appropriate disinfectant activity. The activity of a disinfectant depends on the chemical composition, concentration, temperature, pH, relative humidity, water hardness, and presence of organic/inorganic matter. A rise in pH improves the action of some disinfectants (glutaraldehyde, quaternary ammonium compounds) but reduces the activity of others (hypochlorites, iodine, phenols). Many disinfectants need dilution prior to use. It is mandatory to follow the manufacturer's instructions exactly as per label regarding its use, dilution, and mixing (higher dilution will reduce activity, and high concentration can damage instruments or cause toxic effects to the users). Use diluted preparations only till recommended shelf life. During use, the minimum effective concentration (MEC) must be regularly monitored depending on the frequency of use.

24.4.3.12 Sterilizing Items Potentially Contaminated with CJD Agents [10, 14–16, 27]

CJD is caused by prions, which resist usual inactivation methods. Human infection with CJD has occurred from iatrogenic exposure of the brain or tissues with CJD-contaminated products and devices (brain electrodes, hormones, grafts, etc.). Specific infection control precautions and decontamination procedures are required to prevent CJD transmission.

Items suspected to be contaminated with prions should be steam sterilized for at least 30 min at 132 °C in a gravity displacement sterilizer. If a prevacuum sterilizer is used, 18 min at 134 °C is effective. Semi-critical and noncritical items may be immersed in 1N NaOH for 1 hour at room temperature and then steam sterilized at 121 °C for 30 min. Alternatively, if the instruments do not tolerate this temperature, they can be cleaned twice, treated with various chemicals such as peracetic acid, iodophor, 3% sodium dodecyl sulfate or 6M urea, and 0.5% sodium hypochlorite (at least 2% chlorine free), and autoclaved at 121 °C for 30 min. Table 24.2 provides the details of liquid sterilants and high-level disinfectants approved for disinfection/sterilization of devices.

Key Points

- Prevention of SSIs requires a multifaceted approach involving ventilation engineering, appropriate disinfection and sterilization practices, maintenance of OR discipline and protocols, and continuous education of staff.
- Prevention of intraoperative infections requires a multifaceted approach involving ventilation engineering, appropriate disinfection and sterilization practices, maintenance of OR discipline and protocols, and continuous education of staff.
- Thorough cleaning, done at the point of use, should precede any disinfection or sterilization process. All equipment and surfaces contaminated with blood and other potentially infectious material should be decontaminated with an appropriate disinfectant.
- The amount of equipment in operating rooms should be kept minimal.
- Sterilization can be accomplished by either physical or chemical methods. The protocols for sterilization/disinfection should be based on the Spaulding's classification.

Table 24.2 Liquid sterilants and high-level disinfectants approved by FDA for processing of medical and dental devices (2009) [19]

Disinfectants	Use dilution	Exposure time/comment
Chemical sterilant (sporicidal)		Sterilization claim
Glutaraldehyde	≥2.4%	10 h at 20–25 °C
		7.5 h at 35 °C
Ortho-phthalaldehyde (OPA)	0.55%	Data not available
Gluteraldehyde with phenol/phenate	1.12%/1.93%	12 h at 25 °C
	0.95%/1.64% [7]	
Hydrogen peroxide with peracetic acid	7.35%/0.23%	3 h at 20 °C
	1.0%/0.08%	
	8.3%/7%	5 h at 25 °C
Hydrogen peroxide	7.5%	6 h at 20 °C
Peracetic acid	0.2%	Only cleared for use with STERIS system
		12 min at 50–56 °C
High-level disinfectants		
Glutaraldehyde (different formulations cleared by FDA)	≥2.0%	5 min at 35/37.8 °C to 90 min at 25 °C
Ortho-phthalaldehyde	0.55%	12 min at 20 °C
		5 min at 50 °C in AER
	0.6%	12 min at 20 °C
Hydrogen peroxide	7.5%	30 min at 20 °C
Hydrogen peroxide and peracetic acid	1.0%/0.08%	25 min at 20 °C
	7.35%/0.23%	15 min at 20 °C
	8.3%/7%	5 min at 25 °C
Hypochlorite and hypochlorous acid	650–675 ppm	10 min at 25 °C
	400–450 ppm	10 min at 30 °C
Glutaraldehyde and phenol/phenate	1.121%/1.93%	20 min at 25 °C
Glutaraldehyde + isopropyl alcohol	3.4%/26%	10 min at 20 °C
Intermediate-level disinfectants		
Ethyl/isopropyl alcohol	70–90%	1–10 min
Sodium hypochlorite	100–1000 ppm available chlorine	30 s–5 min
Phenolic germicide	Manufacturer's product label instruction	~10 min
Iodophor germicide	Manufacturer's product label	~10 min
Low-level disinfectants		
Ethyl/isopropyl alcohol	70–90%	
Sodium hypochlorite	100–1000 ppm available chlorine	≥1 min
Phenolic germicide	Manufacturer's product label	≥1 min
Iodophor germicide	Manufacturer's product label	≥1 min
Quaternary ammonium compounds	Manufacturer's product label	≥1 min

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