

Current Concepts in Operative Room Sterilisation

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Endophthalmitis is the most dreaded complication of any intraocular surgery. The source of these infections can be endogenous or exogenous. By sterile environment in operation theatres major part of such exogenous infections can be controlled. OT should be divided into four zones named protective, clean, aseptic and disposal zones. Proper ventilation, air circulation, temperature, maintenance of sterile environment in operation theatres plays key role in prevention of such infections. Steps for maintaining sterile environment include cleaning and disinfection of operation theatres by various means like chemical disinfection or disinfection with ultraviolet radiation. Along with this surgical instruments also can be a source of exogenous infections. So cleaning, lubrication, packing and sterilisation of instruments are essential for prevention of surgical site infections.

Keywords : • operating room • sterilisation • operating theatre • fumigation • OT structure • ventilation

Surgical site infections (SSIs) are the second most common cause of hospital acquired (Nosocomial) infections. These complications of surgical procedures cause considerable morbidity. The source of SSIs may be endogenous or exogenous, which includes surgical personnel, the operating room environment (including air), and tools, instruments, and materials brought to the sterile field during an operation. By maintaining sterile environment in operation theatre we can control major part of exogenous infections. Joseph Lister (1827–1912), a professor at London's King College Hospital was one of the first persons to realize the importance of sterilization. He applied Pasteur's germ theory of disease that invisible microbes caused disease to surgery, thus found modern antiseptic surgery. Aseptic technique is a set of specific practices and procedures performed under carefully controlled conditions with the goal of minimizing contamination by pathogens.

Basic Architecture of Operation

Theatres:-

Four zones can be described in an OT complex¹, based on varying degrees of cleanliness, in which the bacteriological count progressively diminishes from the outer to the inner zones (operating area) and is maintained by a differential decreasing positive pressure ventilation

gradi-ent from the inner zone to the outer zone.

(1) Protective zone: It includes change rooms for all medical and paramedical staff with conveniences, transfer bay for patient, material & equipments

- Rooms for administrative staff
- Stores & records
- Pre & post-operative rooms
- Sterile stores

(2) Clean zone: Connects protective zone to aseptic zone and has other areas also like Stores & cleaner rooms

- Equipment store room
- Maintenance workshop
- Kitchenette (pantry)
- Firefighting device room
- Emergency exits
- Service room for staff
- Close circuit TV control area

(3) Aseptic zone: Includes operation rooms (sterile)

(4) Disposal zone: Disposal areas from each OR & corridor lead to disposal zone

Operation Theatre

The number & size of operation theatres can be as per the requirement but recommended size is 6.5 m x 6.5m x 3.5 m. Main doors to the OT complex has to be of adequate width (1.2 to 1.5 m). The doors of each OT should be spring loaded flap type, but sliding doors are pre-ferred as

no air currents are generated. All fittings in OT should be flush type and made of steel. The surface / flooring must be slip resistant, strong & impervious with minimum joints (eg. mosaic with copper plates for antistatic effect) or joint less conductive tiles/terrazzo, linoleum etc. The floor / wall junction shall be formed using a continuous coved section to allow ease of cleaning, and avoid stasis of water or contaminants. Presently the need for antistatic flooring has diminished as flammable anaesthetic agents are no longer in use. Walls- Laminated polyester or smooth paint provides seamless wall; tiles can break and epoxy paint can chip out. Collusion corners to be covered with steel or aluminium plates, colour of paint should allow reflection of light and yet soothing to eyes. Light colour (light blue or green) washable paint will be ideal. A semi-matt wall surface reflects less light than a highly gloss finish and is less tiring to the eyes of OT team. One operation table per OT is recommended. Electric point: Adequate electric points on the wall (at < 1.5 m height from the floor). Electrical wiring shall be supplied in twin and earth within recessed plastic or metal conduit. IPS / UPS systems shall be provided and located in the plant-room. Recessed sealed Fluorescent fittings are advisable for all areas, generally prismatic controlled and dimmable to theatres.

Basic care of Operation theatres

I. VENTILATION

The principle of ventilation in the operating room (OR) is the delivery of positive pressure filtered air in a vertical unidirectional flow over the operating table. The current United States Public Health Service minimum requirements for optimum OR air is as follows: temperature between 18-24°C, humidity 55-80%, and 25 changes per hour.^{2,3} Laminar airflow curtains or a radial exponential airflow pattern away from the operating field are especially helpful. In the surgical OR providing facilities for most forms of surgery, the recommended bacterial count of air should not exceed 1/ft³ (35.5/m³).⁴ Air entering the OR from filters should not contain more than 0.5 /m³ of bacteria-containing particles. Furthermore, the bacteria-containing particles of air within 30 cm of the operation site should not exceed 10/m³, and should not be more than 20/m³ in the rest of the OR.

II. CLEANING

Cleaning is most important in maintenance of operation theatres even more than sterilisation and disinfection as it removes contaminants, dust, and organic matter. By keeping the floor clean and dry, bacteria are reduced. Dry areas cause natural death of bacteria except spores. Floor should be cleaned with vacuum cleaner or wet mops. Brooms are not recommended it increases bacterial flora in environment. A simple detergent reduces flora by 80 %. Addition of disinfectant reduces to 95 %. Roofs should not be disturbed unnecessarily, use of ceiling fans should be avoided as they cause aerosol spread. Cleaning of roofs is recommended only when remodeling or accumulation of dust. Walls should be washed with water and disinfectant

weekly. In between operative procedures, spot cleaning of operation tables, theatre equipment with disinfectant solution is recommended. In case of spillage of blood / body fluids decontamination with bleaching powder/chlorine solution should be done. Wastes should be discarded in prescribed plastic bags. Soiled gowns must not be discarded in the operation theatre. At the end of the day Cleaning of all the table tops sinks, door handles with detergent / low level of disinfectant, floors with detergents mixed with warm water and Finally mop with disinfectant like Phenol in the concentration of 1 : 10 should be done. Cleaning schedule for is described in (Table 1).

Air conditioners filter to be removed and washed with soap and water weekly is recommended.

Name	Disinfection method	Frequency	Other considerations
Floor	Disinfectant cleaning Pesticide spray	Twice/Thrice a day Once a week	Do not sweep or dry dust
Walls	2% Bacillocid	Once in 2 weeks	
Fans	Wet mops with water	Once in 2 weeks	
Air conditioner	2% Bacillocid Vacuum cleaning	Once in a week	Before restart call technician
Refrigerator	Defrost and clean with soap solution	Once in 2 weeks	
Sinks	Cleaning solution	Once in a week	

III. DISINFECTION

There are three levels of disinfection: High, intermediate, and low.

High- level disinfection kills all organisms, except high levels of bacterial spores and prions, and is effected with a chemical germicide cleared for marketing as a sterilant by the Food and Drug Administration like glutaraldehyde based and ortho-phthaldehyde based agents (available in India) .

Intermediate - level disinfection kills mycobacteria, most viruses, and bacteria with a chemical germicide registered as a tuberculocide by the Environmental Protection Agency (EPA).

Low- level disinfection kills some viruses and bacteria with a chemical germicide registered as a hospital disinfectant by the EPA.

A. Chemical disinfection:

Formaldehyde fumigation : Commonly used to sterilize the OT. For an area of 1000 cubic feet we require 500 ml of 40% formaldehyde in one litre of water, Stove or hot plate for heating formalin and 300 ml of 10% Ammonia, All doors & windows should be closed air tight and fans and A.C. switched off and Formalin solution be heated boiling dry . OT to be remain sealed over night Neutralisation of formaldehyde vapors is done with 300ml of ammonia for 1 litre of formaldehyde used, then OT can be Opened to start surgery fumigation is advised at weekly intervals

Mechanism of action - Formaldehyde inactivates microorganisms by alkylating the amino acid and sulfhydryl groups of proteins and ring nitrogen atoms of purine bases. Occupational Safety and Health Administration OSHA

indicated Formaldehyde as potential carcinogen and limits an 8-hour time-weighted average exposure concentration of 0.75ppm.

Other Agents

Ecoshield- stabilized hydrogen peroxide 11% w/v and 0.01% w/v, diluted silver nitrate solution

Aldekol- Formaldehyde 6%, Glutaraldehyde 6% and Benzalkonium chloride 5%. For 4000 cft 325 aldekol in 350 ml of water is sprayed for 30 minutes. OT must be Closed for 2 hrs.

Bacilloid rasant : A newer and effective compound with very good cost/benefit ratio, good material compatibility, excellent cleaning properties and virtually no residues. It has the advantage of being a Formaldehyde-free disinfectant cleaner with low use concentration. Active ingredients are Glutaral 100 mg/g, benzyl-C12-18-alkyldimethylammonium chlorides 60 mg/ g, didecyldimethylammonium chloride 60 mg/g. This provides complete asepsis within 30 to 60 minutes. Cleaning with detergent or carbolic acid is not required.

Bacillol - contains ethanol, 2-propanol, 1-propanol can be used as spray for surface disinfection, and does not act on spores. It is used for instant disinfection.

B. Ultraviolet radiation

Daily U.V. Irradiation for 12 -16 hours is recommended and is to be switched off 2 hrs before entering OT

Microbiological Monitoring :

Swabs are collected from various locations in the OT every 2 week and cultured on blood agar. The areas to be swabbed include:

1. Operation table at the head end
2. Over head lamp
3. Four Walls
4. Floor below the head end of the table
5. Instrument trolley
6. AC duct
7. Microscope handles

Monitoring of air quality

- **Settle plate method:** Blood agar and Sabouraud's dextrose agar (SDA) is placed and lid is kept open for 30 min. Colony counts of bacteria and fungi are reported.

- **Slit sampler method** (from given volume): Very Effective, highly sensitive. Fixed volume of air is sucked and bacterial counts are made.

Bacterial colony count of more than 10 per plate and fungal colony of more than one per plate are considered unacceptable

Surgical Instruments

Preparation of Instruments for Sterilization

The American Operating Room Nursing (AORN) Recommended Practices Committee⁵ has provided guidelines for the care and cleaning of surgical instruments. First step is separation of sharp instruments from the blunt

instruments then should be dismantled as soon as possible after their use. Cleaning is removal of all dirt and organic matter from the instrument to be processed. This can be done by washing the instruments with sterile distilled water or mechanical with ultrasonicator.

1. Manual cleaning includes rinsing with cold water to remove protein materials, then brushing of items followed by rinsing in clean water and drying. Mechanical cleaning is preferred as it minimises handling and decreases risk of exposure to infectious materials. In ultrasonicator sound waves pass at frequency of 100,000 Hz in liquid and generate submicroscopic bubbles which later implode and create minute vacuum that lifts particles from instruments.⁶ After removing the instruments from ultrasonic cleaner, instruments are washed in four basins containing mineral water and dried with sterile towel

2. Lubrication: Lubrication is essential every time instruments are processed which helps instruments remain clean by preventing build-up of "baked-on" protein and mineral deposits, and permits a more effective detergent cleaning.⁷

3. Packaging: Most items to be sterilized should be packaged or wrapped to prevent subsequent contamination by dust, dirt, and microorganisms.

Types

Sterilisation wraps: Sterilisation wraps^{8,9} (woven and non woven fabrics) are available in various sizes, grades, and materials. They are used for trays, mesh containers, cassettes, and racks, as well as single items

Peel pouches are used when visibility of the instrument is critical for its effective use.

Rigid containers: These are specially designed heat-resistant metal, plastic or anodized aluminum receptacles used to package items, usually surgical instruments, for sterilization. The lids and/or bottom surfaces contain steam- or gas permeable

4. Sterilization

After decontaminated instruments are assembled, packaged, and labeled, they are ready to be sterilized. Sterilization is a process which achieves the complete destruction or killing of all microorganisms, including bacterial spores. Preferred methods of sterilisation for various types of instruments are summarised in (Table 2).

Sterilization is principally accomplished by:

- Steam under pressure (Autoclave)
- Dry heat (Hot air oven)
- Chemical agents such as ethylene oxide or low temperature methods
- Chemical sterilant as glutaraldehyde 2 %

Table 2: Various sterilisation methods with their advantages, disadvantages and preferred use

Method	Time	Advantage	Disadvantage	Suitable for
Autoclave	~ 45 min	Kill spores, can sterilise liquids	Items must be heat and moisture resistant	Gowns, dressings, drapes, Metal instruments
Hot air oven	1.5 to 2 hrs	Not much pressure build up	Prions not killed every time	Metal instruments, swabs
Ethylene oxide	5 psi- 12 hrs 10 psi- 6 hrs	Low temperature	Explosive, long duration	Heat labile tubings, cryo and laser probes
Plasma system	Short cycle 74 min.	Low temperature	Specific packaging needs	Same as ETO
Gluteraldehyde	Vegetative pathogens- 15 min. Spores- 3 hrs	For heat labile equipments	Irritant	Metal instruments, Plastic Glass

A. Steam Under Pressure

Autoclave: Autoclave sterilisation¹⁰ is safe method of sterilization; it kills bacteria, spores, viruses and fungus.^{11,12} For this, all items are arranged inside autoclave in a way that allows steam to circulate freely. STACKING must not be done. Gloves must be worn while handling the instruments to avoid infective material & cuts. Then the time duration, temperature and pressure is adjusted. Timing should begin after the autoclave reaches the desired temperature and pressure. Autoclave should be opened once pressure gauge reads "o". All items must be dried before use. Wet packs must be considered non-sterile. Labelling must be accurate with contents, date of processing and expiration date.

Autoclaved instruments should be used within 48 hours. The water should be drained out daily to avoid settling of salt on the instruments and in the chamber. The autoclave should be serviced once in 6 months

Flash or high speed autoclave: For Flash or high speed autoclave¹³, the instruments are first cleaned in clean sterile water or distilled water. These are type of gravity downward displacement autoclaves, which fills with steam and displaces air downward and forces it out of drainage valve. The canulas should be cleaned separately with RL solution. The cleaning water should be changed after cleaning 4 or 5 sets.

B. Dry heat sterilisation

Less preferred in recent era, but indicated for reusable glass, metal instruments, oil, ointments and powders. All items should be cleaned and dried and then put in metal container and heated upto holding temperature (141-180°) and kept for recommended time (3 hrs to 30 min.). items are allowed to cool inside oven upto room temperature and then can be used or stored.

C. Low temperature sterilisation

This is used for heat- and moisture sensitive medical devices. The types include:

- ETO sterilisation
- Plasma sterilisation

ETO (Ethylene oxide) sterilisation: This is an alkylating agent which reacts with DNA and destroys the ability

of microorganisms to metabolize or reproduce. This was a method of choice for many heat- and moisture-sensitive devices but new methods of low temperature sterilisation are now often used as substitutes. Effective EO sterilization depends on concentration of sterilant, relative humidity, temperature and exposure time. For ETO sterilisation after loading the steriliser, air is removed with vacuum followed by heating upto 45-55°c with relative humidity of 60%. Required exposure to ETO is upto 12 hours if 5psi and 6 hrs if 10 psi subsequently gas removal by vacuum and flushing with air 4 times.

Hydrogen peroxide Plasma sterilisation: Plasma is defined as highly ionised gas composed of ions, electrons, and neutral particles. Plasmas are generated by introducing a precursor gas or vapor (e.g., hydrogen peroxide or peracetic acid) into a chamber under low-vacuum conditions and then exciting the gas or vapour with microwave or radiofrequency energy.¹⁴ The cycle time is approximately 75 minutes. They have special packaging needs as Cellulose-containing wrappers are incompatible with hydrogen peroxide processes because they absorb the peroxide and do not allow effective penetration. Commercially available nonwoven polypropylene wraps and poly olefin pouches are material of choice.¹⁵

D. Chemical sterilisation

Cidex (gluteraldehyde 2%) is used for chemical sterilisation which is commonly used to sterilise the instruments in between cases, four trays are used, one for keeping Cidex solution and then three trays for sterile water. Sharp instruments to be kept in activated solution of Cidex (2% Gluteraldehyde) for 15 minutes and then washed 3 times with sterile water, kept in the three trays. Effective against vegetative pathogens in 15 minutes and for spores 3hours. Spores in 3 hrs. Gluteraldehyde is an irritant to eyes and can cause allergic dermatitis or asthma so handling should be with gloves, apron and mask worn. Once mixed, they are usually good for up to 14 days. Solutions should be replaced any time they become cloudy.

Other Specifications

1. All items must be labelled with the date of sterilisation.

2. Every sterilised item has an expiry date.
3. Items must be inspected before use to ensure that there are no tears, punctures, open seams, moisture, soiling from being dropped on the floor, etc.
4. Once a package has been opened, it is no longer considered sterile, whether or not its contents are used.
5. Don't store non-sterile items along with sterile items.
6. If the sterility of an item cannot be assessed, it must be re-sterilised or discarded.

A well done surgery can be spoiled by infection. Infection increases the cost both for the patients and the hospital. OT sterilisation and proper instrument maintenance can provide an infection free environment and quality care for patients.

Financial & competing interest disclosure

The authors do not have any competing interests in any product/ procedure mentioned in this study. The authors do not have any financial interests in any product / procedure mentioned

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