Major Review

The Operation Theatre : Basic Architecture

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Introduction

Cleanliness of the hospital environment is the best starting point to achieve the highest patient safety mandate. There is a need to decrease the bio-burden present in the environment in an operating room. A systematic method of cleaning will decrease the possibility of the transmission of pathogens.

Florence Nightingale, "The Lady with the Lamp," and Joseph Lister (1827–1912), a professor at London's King College Hospital were one of the first persons to realize the importance of sterilization. Joseph Lister successfully introduced carbolic acid (phenol) to sterilize surgical instruments and to clean wounds.

During the 1990s, the US Department of Labor, Occupational Safety and Health Administration (OSHA) passed a regulation known as the Blood Borne Pathogen Standard. The standard required institutions to implement policies and procedures for the identification of potential exposure to blood borne pathogens. The Association of peri Operative Registered Nurses (AORN) developed "Recommended Practices for Environmental Cleaning in the Surgical Practice Setting," which was approved by AORN's board of directors and became effective from January 1, 2003.

Asepsis in Operation Theatre

Aseptic technique is a set of specific practices and procedures performed under carefully controlled conditions with the goal of minimizing contamination by pathogens.

The Operation Theatre: Basic architecture

The design and location of OT complex is one of the most important components of OT asepsis. OT complex is located away from the inpatient area, often in a blind wing or on the top or bottom floor. It is a scientifically planned barrier system, such that it keeps the flow of traffic from clean areas to dirty ones and never vice versa. It consists of 4 zones:

A. Outer zone

Areas for receiving patients relatives, toilets, administrative function.

B. Restricted Zone

- Changing room
- Patient transfer area
- Stores room
- Nursing staff room
- Anaesthetist room
- Recovery room

C. Aseptic Zone

- Scrub area
- Preparation room
- Operation theatre
- Area used for instrument packing and sterilization.

D. Disposal Zone

Area where used equipments are cleaned and bio-hazardous waste is disposed.

Marble or polished stone flooring is the preferred type with glazed tile walls. No false ceiling is permissible. The OT needs to be well ventilated such that it prevents any deposition of dust particles. Air circulation with a laminar air flow system through High efficiency particulate air filter (HEPA) (0.3µm) serves the best purpose. As per US Public Health services minimum requirements for OT air are 25 changes per hour, positive pressure compared with corridors, temperature between 18 & 24º C and humidity of 50 to 55%.[1]

Cleaning and Disinfection of OT

Cleaning, disinfection and sterilization are the cornerstones in ensuring operation theatre asepsis.

Cleaning

General Cleaning:

General cleaning involves scrubbing with detergents and rinsing with water. This is the first step, albeit very important, before any disinfection measure can be undertaken. Spot cleaning of walls and ceiling should be undertaken as needed everyday. Open shelves need to be cleaned daily with a detergent while closed cabinets may be cleaned once weekly. The floor should ideally be sprayed and wet vacuum pick up used after each surgical procedure and at the end of the days' schedule.

All horizontal surfaces in the OT (e.g. furniture, surgical lights, and equipment) should be damp-dusted with an Environmental Protection Agency (EPA) registered disinfectant like lysol brand deordorizing disinfectant cleaner

and clorox disinfecting spray III at the end of each case and cleaned thoroughly at the end of the day. The lights and other portable equipment should additionally be steam cleaned weekly. Similarly, anesthesia equipment needs to be cleaned and processed according to AORN's recommended practices. The sink area should be cleaned several times daily and kept as dry as possible

The outside of autoclaves should be cleaned daily while the inside surface is cleaned weekly. Soiled linen should never be left on the floor or transported on a trolley used for other purposes. Liquid waste material such as the contents of suction bottles should never be disposed off in a scrub sink or utility sink but only into a container meant for the purpose.

Cleaning before subsequent surgery

For each subsequent surgical case, a safe environment needs to be re- established. Preparation of the OT should involve visual inspection and spot cleaning of visible contamination. Walls, doors, surgical lights and ceilings should be spot cleaned in the event of being soiled with blood, tissue or body fluids. Visibly soiled areas on the floor should be cleaned using a new or freshly laundered mop head and an EPA- registered hospital-grade germicidal agent. The OT bed should be moved to check for such items as sponges and instruments that may have fallen into open spaces. Data does not support cleaning the entire floor after each case.

Terminal Cleaning

Because a clean surgical environment assists in the reduction of microorganisms, each surgical procedure room and scrub/ utility area should be terminally cleaned at the end of the day's schedule. An EPA-registered agent lysol brand deordorizing disinfectant cleaner and clorox disinfecting spray III and mechanical friction needs to be used to clean all surfaces, including the surgical lights, all furniture, scrub and utility areas, scrub sinks etc.

Disinfection of the OT

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 glutraldehyde based and orthopthaldehyde 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.

Chemical Disinfection

a)Formaldehyde fumigation

Commonly used to sterilize the OT.

Requirement *(For an area of 1000 cubic feet)*

- 500 ml of 40% formaldehyde in one liter of water
- Stove or hot plate for heating formalin
- 300 ml of 10% Ammonia

Procedure

Close all doors & windows air tight and switch off fans and A.C.

Heat formalin solution till boiling dry

Leave the OT unentered over night

Enter the OT next day morning with 300ml of ammonia

Keep the ammonia solution for 2-3 hrs to neutralize formalin vapours

Open the OT to start surgery

Advised fumigation at weekly intervals

Mode of Action

Formaldehyde inactivates microorganisms by alkylating the aminoacid and sulfhydryl groups of proteins and ring nitrogen atoms of purine bases.

Disadvantages

OSHA indicated that Formaldehyde should be handled in the workplace as potential carcinogen and set an employee exposure standard for Formaldehyde that limits an 8-hour time- weighted average exposure concentration of 0.75ppm.

b) Commercially available disinfectant

Baccilocid rasant

A newer and effective compound in environmental decontamination 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: Glutaral 100 mg/g, benzyl-C12-18-alkyldimethylammonium chlorides 60 mg/ g, didecyldimethylammonium chloride 60 mg/g.

Advantages

- Provides complete asepsis within 30 to 60 minutes.
- Cleaning with detergent or carbolic acid not required.
- Formalin fumigation not required.
- Shutdown of O.T. for 24 hrs not required.

c) Aldekol

A new method of fumigation has been evolved using 'Aldekol', a mixture containing 6% formaldehyde, 6% glutaraldehyde

and 5% benzalkonium120 chloride

Disinection by radiation

Ultraviolet radiation

- Daily U.V. Irradiation for 12 -16 hrs
- To be switched off 2 hrs before

Processing of Equipment, Instruments and Other Reusable Items

Steps involved are

1. Decontamination of Equipment, Instruments, and Other Reusable Items

Immediately after use, all surgical instruments, reusable gloves, and other items that have been in contact with blood or other body fluids should be placed in a plastic bucket containing a solution of 0.5% chlorine for 10 minutes.[2] After 10 minutes, the items should be removed from the chlorine solution and rinsed with water or cleaned immediately

2. Cleaning of Equipment, Instruments, and Other Reusable Items

The instruments and other items should be scrubbed vigorously with a brush (a tooth brush is a good option) in lukewarm water with detergent to remove all blood, tissue, and other residue. Cleaning instruments with ultrasonic cleaner is used for cleaning of micro surgical instruments and instruments with hinged areas and serrated edges, endoscopes or other lumened devices such as phaco or irrigation & aspiration hand pieces.

3. Sterilization and high level disinfection of equipments

Sterilization is complete destruction of all microorganisms, both the vegetative forms and their spores. It is the terminus of the continuum where risk of contamination is, effectively, reduced to the lowest practical point. Although sterilization is the safest and the most effective method for the final processing of instruments, often sterilization equipment is either not available or not suitable. In these cases, High Level Disinfection is the only acceptable alternative.[3] The threat of infection by spores or prions does not exist in all circumstances so sterilization of all items used on or by patients is unnecessary. The system used to determine whether items should be cleaned, disinfected, or sterilized was given in 1968 by Earl Spaulding According to the Spaulding system, the level of processing required is based on the nature of the item and the manner in which it is to be used.[4]

1). Items that enter sterile tissue or the vascular system are categorized as critical and should be sterile when used. Examples of critical items include most of the surgical instruments, catheters, needles, implants, etc

2) Items that come in contact with non intact skin or mucous membranes are considered semi critical and should receive a minimum of high-level disinfection immediately before use. This includes the anesthesia equipment, respiratory therapy equipment etc.

3) Items that come in contact only with intact skin are categorized as noncritical items and should receive intermediate-level disinfection, low-level disinfection, or cleaning. This is explained as intact skin acts as an effective barrier to most organisms.

(1) Examples of noncritical items include the tourniquets and blood pressure cuffs, linens, etc.

Methods of High Level Disinfection of equipments

Physical methods

• HLD by Boiling:

Boling destroys all vegetative forms of bacteria, viruses (including HBV, HCV and HIV), yeasts and fungi, but does not kill all endospores reliably. 20 minutes of immersion time is needed, after the water has started boiling. Once the instruments are dry, if any pooled water remains in the bottom of the container, remove the dry items and place them in another high-level disinfected container that is dry and can be tightly covered. If stored in an ordinary covered container, the objects can be used for up to 24 hours only.

• HLD by Steaming (moist heat)

Essentially all vegetative forms of bacteria are killed by moist heat at temperatures of 60– 75 0C within 10 minutes [5] Hepatitis B virus, which is one of the most difficult viruses to kill, is inactivated in 10 minutes when heated to 80 0C. In contrast, although many types of spores are killed when boiled at 99.5 0C for 15 to 20 minutes, Clostridium tetani spores are quite heat-resistant and can even survive boiling for up to 90 minutes.The highest temperature that boiling water or low-pressure steam will reach is 100 0C (212 0F) at sea level. Because the boiling point of water is 1.1 0C lower for each 1,000 feet in altitude, it is best to boil or steam items to be high-level disinfected for a minimum of 20 minutes

• High level disinfection only by chemical method

Although a number of disinfectants are commercially available in most countries, four disinfectants— chlorine, glutaraldehyde, formaldehyde and peroxide— are routinely used as high-level disinfectants. These chemicals can achieve high-level disinfection if the items being disinfected are thoroughly cleaned before immersion.[6,7] A high-level disinfectant should be selected for use based on the characteristics of the items to be disinfected, the physical area and the skills of personnel available to do the procedure.[8,9]

A brief review of each of the above agents is provided here:

Chlorine solutions
are fast acting, very effective against HBV, HCV and HIV/AIDS, inexpensive and readily available (CDC 1987; WHO 1989).[10,11,12]

Formaldehyde
(8%), which is inexpensive and readily available, is an effective high-level disinfectant (HLD) but, the vapours are very irritating and it is classified as a potential carcinogen. Do not dilute with chlorinated water as a dangerous gas (bis-chloromethyl-ether) can be produced.

Glutaraldehydes
are less irritating than formaldehyde, but staff and clients still need to be protected from the fumes when mixing and using these solutions

Hydrogen Peroxide
(H2O2), which must be diluted to a 6% solution, often is available locally and is less expensive than other chemical disinfectants. The 3% H2O2 solutions used as antiseptics, however, should not be used as a disinfectant. The major disadvantage of peroxide is that it is highly corrosive and should not be used to disinfect copper, aluminum, zinc or brass.

Alcohols and Iodophors
Although alcohols and iodophors are inexpensive and readily available, they are no longer classified as high-level disinfectants. Alcohols do not kill some
viruses and are not sporicidal. Pseudomonas species have been shown to multiply in iodophors. [13]

Sterilization of equipment

Steam Sterilization (Autoclaving)
Steam sterilization (frequently referred to as autoclaving) depends on the use of steam above 100 0C. Temperatures ranging from 121-134 0C at pressures of 15-30 psi are generally recommended. Steam readily penetrates all wrapped materials with the destruction of all viruses and bacteria, including the most resistant spores. [14,15] It acts by denaturing the major cell constituents. Minimum holding times for the sterilization of medical equipment are 15 minutes at 121 0C, 10 minutes at 1260C, and 3 minutes at 1340C.

Flash Sterilization
It is a method of emergency sterilization. The equipments to be decontaminated are kept at 132º C at 30 lbs of pressure for 3 minutes.

Chemical Sterilization (Liquids)
The use of chemical solutions as a sterilization technique for surgical equipment is frequently employed, but it should be stressed that most solutions only disinfect and do not guarantee sterility. When the necessity for maintaining sterility is a critical factor, as in the implantation of prosthetic devices, indwelling catheters or vascular access ports, disinfection in chemical solutions is not recommended. [16]

Glutaraldehyde(2%)
It is suitable for instruments that cannot be autoclaved like sharp cutting instruments, plastic & rubber items, and endoscopes. It is effective against vegetative pathogens in 15 minutes and resistant pathogenic spores in 3 hrs. It is not recommended for lumen containing instruments such as irrigating cannulae as the residual glutaraldehyde, even after rinsing, causes corneal edema, endothelial cell damage and uveitis. The recommended time period for effective sterilization is 8- 10 hours. Articles can then be stored in a covered sterile container for up to 7 days.

Chemical Sterilization (Gas)

Ethylene Oxide (E. T. O.)
E. T. O. kills micro organisms by alkylating their DNA. Widely used for re -sterilizing 'packaged heat sensitive devices' like sharp knives and blades.
It is non-corrosive and safe for most plastic and polyethylene materials. Thus, it is the preferred method for sterilizing heat labile tubings, vitrectomy cutters, cryoprobes, light pipes, laser probes, diathermy leads, cannulated instruments like endoscopes etc. However, it is not applicable to liquids or to articles in impervious packaging material.

A typical ETO sterilization cycle includes

1. Packing of the articles to be sterilized.
2. Arranging and loading the sterilizer.
3. Air removal with a vacuum pump.
4. Heating to the required temperature (45 0C– 55 0C).
5. Steam humidification maintained at a relative humidity of 60 %.
6. Exposure to the ETO at 5 psi for 12 hours or at 10 psi for 6 hours.
7. Gas removal by 70 psi vacuum.
8. Air flush by filtered air repeated 4 times to re -establish atmospheric pressure.
9. Aeration to elute residual ETO - Articles should be well aerated prior to use to minimize the potential for tissue toxicity.

Ethylene oxide gas is a potential carcinogen and mutagen and represents a potential occupational health hazard for personnel operating the sterilizers.

Sterilization by radiation

Gamma irradiation

This is a method for cold sterilization with high penetrating power which is lethal to DNA.

Sterilization methods of choice for articles during ocular surgery

1. Linen (Gowns, Caps, Masks, Drapes)- Autoclaving.
2. Glassware (Syringes) - Dry heat sterilization, or use disposables from reputed firms.
3. Metal instruments- Autoclaving.
4. Plastic instruments/ Components- Ethylene oxide sterilization, formalin chamber.
5. Sharp edges instruments (e.g. Vannas scissors, keratome) ETO/ Hot air oven/ Chemical disinfection.
6. Sutures (including monofilament nylon) - Can be autoclaved.
7. Diathermy, Cautery electrodes- Autoclaving.
8. Endoilluminators/ probes- Ethylene oxide sterilization.
9. Silicone oil/ buckles/ sponges- Autoclaving.

Monitoring

Surveillance of Operation theatre: Microbiological monitoring

Swabs are collected from various locations in the OT and cultured as described. The areas 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.

The swabs obtained are cultured for aerobic (Chocolate agar) and anaerobic (Robertson's Cooked Meat Medium) growth. [13]

Evaluation of Quality of air in OT

Settle plate method: One plate of blood agar and Sabouraud's dextrose agar (SDA) is placed in the center of the OT (Close to operation table) and the lid is kept open for 30 min. Blood agar is then incubated at 37° C for 48 hrs,& SDA at 27° C for 7 days. Colony counts of bacteria and fungi are reported.[5]

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.

Testing efficacy of autoclaves

Biological indicators (BI) containing bacterial spores are used for monitoring the efficacy of sterilizers. Commercially available spore strips (Hi- Media, Mumbai and by Cole Palmer, India) impregnated with spores of Bacillus stereothermophillus are used. For ETO sterilizer, the biological indicator is a Bacillus subtilis spore.

Principles of sterile technique in OT

- All items in a sterile field must be sterile.
- Sterile packages or fields are opened or created as close as possible to time of actual use.
- Moist areas are not considered sterile.
- Contaminated items must be removed immediately from the sterile field.
- Only areas that can be seen by the clinician are considered sterile, i.e., the back of the clinician is not sterile.
- Gowns are considered sterile only in the front, from chest to waist and from the hands to slightly above the elbow.
- Tables are considered sterile only at or above the level of the table.
- Nonsterile items should not cross above a sterile field.
- There should be no talking, laughing, coughing, or sneezing across a sterile field.
- Personnel with colds should avoid working while ill or apply a double mask.
- Edges of sterile areas or fields (generally the outer inch) are not considered sterile.
- When in doubt about sterility, discard the potentially contaminated item and begin again.
- A safe space or margin of safety is maintained between sterile and nonsterile objects and areas.
- When pouring fluids, only the lip and inner cap of the pouring container is considered sterile. The pouring container should not touch the receiving container, and splashing should be avoided.
- Tears in barriers are considered breaks in sterility.

Legal responsibility

In each hospital, an interdisciplinary team should meet periodically to discuss the process of cleaning the operating rooms. Role of Microbiology Departments lies in identifying the pathogens, monitoring of antibiotic therapy and proper education on specimen collection and transportation. They should also be updated with information on common antibiogram patterns, and communicate the same to the clinical staff. They maintain data on hospital infection and surveillance of the Hospital environment. The team must consider changes needed in the cleaning protocol in response to rising infection rates with increased multidrug-resistant bacteria or newly emerging pathogens.

Importance of Staff Education cannot be over emphasized. They need to be well trained in a scientific manner with specific duties and responsibilities allotted to each. Written policies and protocols lay the groundwork for all personnel to have the same understanding of the outcome expected.

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