COC - CME Series 2

HANDBOOK ON
OPERATION THEATRE & ASEPSIS



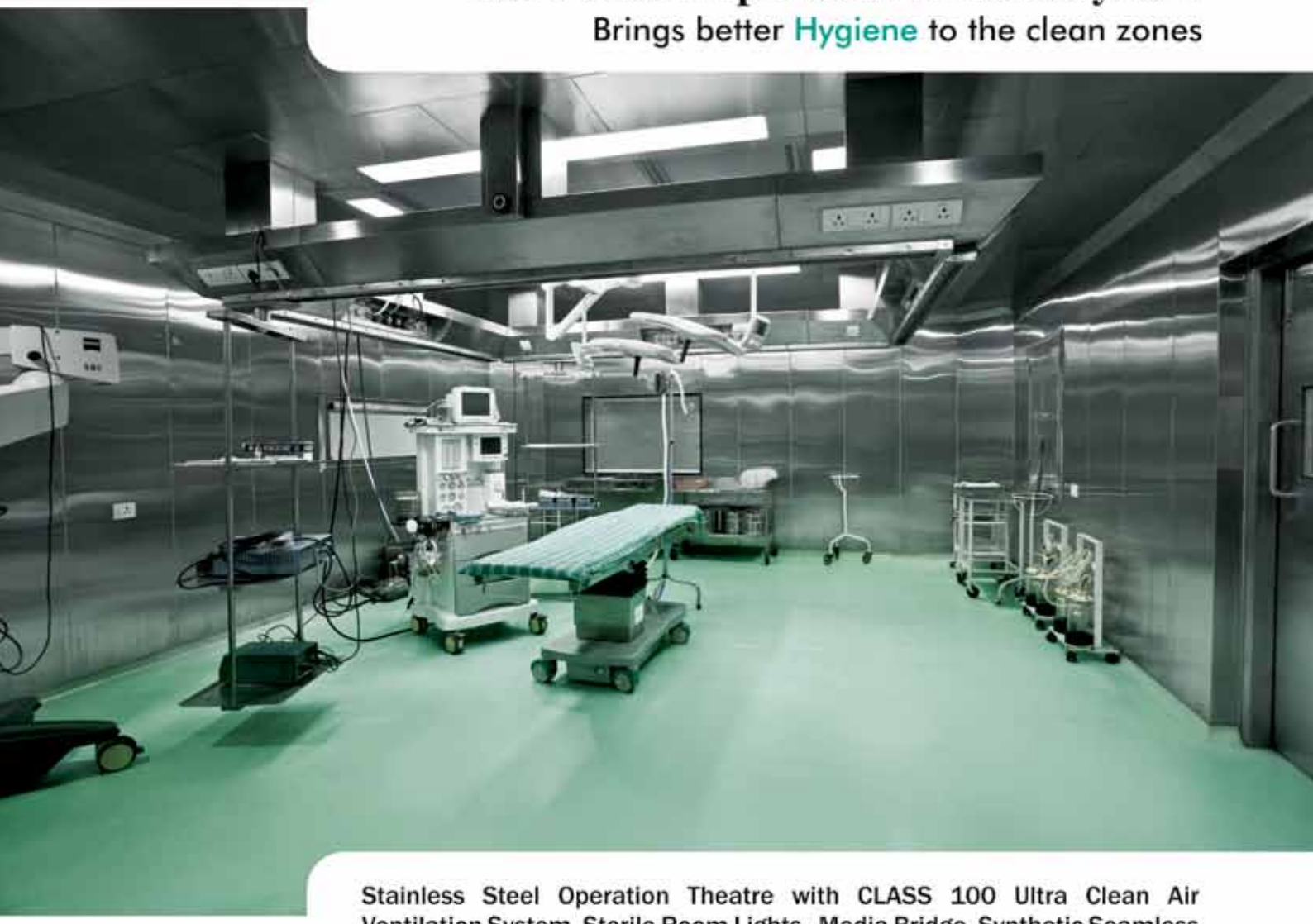
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Editors
Dr. S. SASIKUMAR MS, DO, PGDHHM
Dr. P.I. MOHAN MS, DOMS

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In Association with

KERALA SOCIETY OF OPHTHALMIC SURGEONS



FOREWORD

Dear Friends,

Greetings to you all!

Any professional association becomes relevant when it aims for the overall well being of its members. Number one priority, of course, is the professional front. KSOS has been in the forefront of medical fraternities in trying to improve the professional excellence of its members. Apart from its annual conference, which is a clinical feast, it sponsors innumerable regional CMEs on various aspects of our profession. Bringing out CME series is yet another activity which is of immense significance for the practicing Ophthalmologist. In spite of the 'digital revolution' books still rule the roost as the number one reference/ instruction source in our set up.

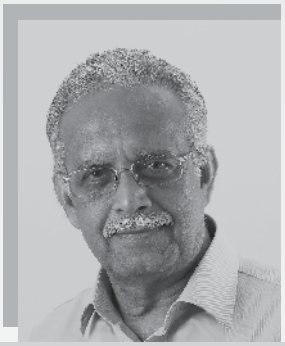
COC has done its share in all this. We are proud to have contributed several previous CME series for KSOS. Here we are with a revised and improved version of a previously popular book, 'Hand book on Operation Theatre Asepsis'. We do hope all the members of KSOS can make use of it.

I thank all the people involved in its conception and execution.

Wishing you all the very best,

Dr. R.R.Varma
President, COC 2011-13





EDITORS' NOTE

22nd November 2013

Infection following intraocular surgery is a catastrophe and prevention should be the "mantra" to counter it. We have great pleasure in bringing out the revised edition of the much popular book on operation Theatre & Asepsis brought out by The Cochin Ophthalmic Club in the year 2006

The visual outcome after an intraocular surgical intervention depends on many factors. The skill of the surgeon and the assistants are only a part of the process. There are other factors like disinfection, cleaning & packing of surgical instruments, sterilisation, and storage of sterilised packs; which play an important role in determining the end result. The chapters in this handbook describe all these points in detail.

Equally important is the operation theatre environment, especially its design. Another area often neglected is CSSD/TSSU. It is imperative to have strict protocols and discipline in our OT complex. There are a lot of misconceptions about the methodology of microbiological surveillance in OT. We have to protect ourselves and other patients by observing universal precautions in handling blood and body fluids; and community at large by complying with hospital waste management regulations as per the Supreme Court order. We have included chapters on the above mentioned subjects. Although this book was initially intended for ophthalmologists and eye hospitals, the coverage of many of the topics will cater to the needs of multispeciality hospitals also.

The All India Ophthalmological Society (AIOS) have brought out certain guidelines in managing and preventing endophthalmitis, which is included. All said and done, we presume that you will have a lot of questions to ask. We hope that you will find the answers in the chapter "FAQs".

"Vows made in storm are forgotten in calm". Nowhere is this true than in the case of Infection control. The initial enthusiasm, mostly a knee jerk reaction, dies down once the hue and cry comes down and the onus of infection control gradually passes on to the OT staff. If the reader could gather sufficient information from this book to set his priorities right, we would consider our efforts fruitful.

Wishing you happy reading.

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GUEST EDITORIAL

It is an honour and privilege to pen down a guest editorial for the revised edition of this 'Handbook on Operation Theatre & Asepsis'.

Post operative endophthalmitis is the one nightmare of any operating Ophthalmologist. Once faced with the situation, most of us are groping in the dark, and we find many a career doomed. With the indications of Cataract surgery changing from blindness control to refractive lens exchange, the pressure on the surgeon is quite high. An increase in the number of Intravitreal injections by the Retinologists means that the traffic in the operation theatre is on the rise. It is human nature to be complacent when the numbers go up.

On the other hand, the patient awareness is very high, and they have all information available at their fingertips. There is significant consumer activism too. As in the past, the surgeon could not just wash off his or her hands, pleading ignorance. "Where on earth do I get to know about asepsis?" This complete manual on Operation Theatre practises is an answer to this question. Right from Operation Theatre design, through microbiological surveillance, etiquette, handwashing, scrubbing and gowning to instrument sterilisation, waste management and finally the All India Ophthalmological Society (AIOS) guidelines on endophthalmitis, this is as good as a textbook on this subject. The book ends with a series of frequently asked questions (FAQs).

The scientific committee of the Kerala Society of Ophthalmic Surgeons (KSOS) is indeed happy to team up with the Cochin Ophthalmic Club (COC) in publishing this book. This is being released as the CME series publication of the KSOS for the term 2011-'13. I congratulate the COC, its President Dr. R.R. Varma and Secretary Dr. S. Sasikumar and Dr P.I.Mohan, past president of KSOS for the effort they have put in for making this a complete Operation Theatre manual.

Dr. Thomas Cherian
Chairman, Scientific Committee
KSOS 2011-13

ACKNOWLEDGEMENTS

At the beginning of this project, we were unsure of the content of the handbook, especially its quality and scientific data. We were blessed to have a group of experts in the field to contribute chapters in the book. We sincerely thank all the authors for taking an extra effort and time to realise this venture.

We owe immense gratitude to Dr Rajiv Sukumaran who has helped us in editing. We are grateful to Kerala Society of Ophthalmic Surgeons, especially the Scientific Committee Chairman, Dr Thomas Cherian for associating with the COC for this project.

M/s AMENSCO and M/S Lysoform Rushail Pharmadin Pvt Ltd have sponsored this book; we express our gratitude to them. Mr Ramachandran of Arceeyem printers has printed this book beautifully on time and we thank him for his co-operation.

This would not have materialised without the whole hearted support of the Cochin Ophthalmic Club. We are thankful to the President, members and the Executive committee of COC for their support.

Dr. Sasikumar S

Dr. Mohan P I

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Planning of an Operation Theatre

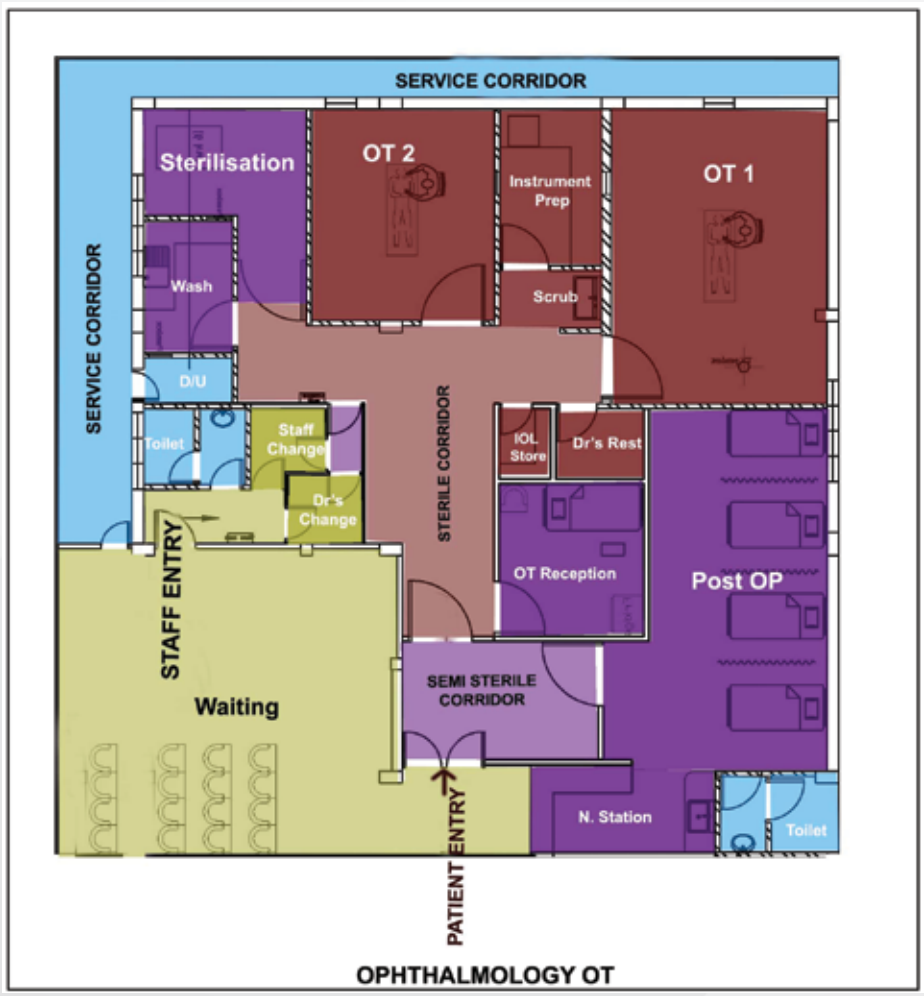
***Binoy B Raj MSc, DME & **S. Sasikumar MS, PGDHHM**





An Operation Theater complex(OT) will have operating rooms (OR) along with their ancillary facilities like reception, changing rooms, pre-anaesthetic rooms, Theater Sterile Supply Unit (TSSU), Sterile supply Preparation rooms, Store and Recovery Room. The OT should be planned to minimise infection introduced through personnel, environment, building, service, equipments, linen and instruments. Along with the high degree of asepsis it should also provide safety to patients and staff and ensure optimum utilisation of staff, facilities and time.

One should always keep the patient as the focus of planning and design of an OT. The surgeon and the support staff should be involved in the planning stage itself to evolve a design suitable to



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that particular hospital and setup. Remodelling an existing OT will consume relatively more time and money and one may end up compromising on several aspects. Provision should be made in the initial stages for possible future expansion. One can visit other efficiently designed OTs before planning one for them. However duplicating the same need not be suitable in a new setup.

A minimum area of 800-1000 sq ft is needed for a good Eye OT Complex and 150-200 sq ft for an OR.

Location

OT complex is always preferred in areas with less traffic to reduce sources of infection. Upper floor of the building is ideal to provide high ceiling to accommodate air conditioner ducts and ventilating units. Dedicated Air Handling Unit (AHU) can be mounted on to the ceiling of any rooms/corridor of Protective or Disposal Zone of the OT complex. It is always better to avoid areas which can produce excessive humidity, direct sunlight and dust. Toilets and plumbing lines above the OT have been notorious to produce damp ceiling and walls if proper care is not taken during the concreting of the roof. OT built in proximity to the TSSU/Central Sterile Supply Department (CSSD), Surgical wards , ICU will increase the efficiency.

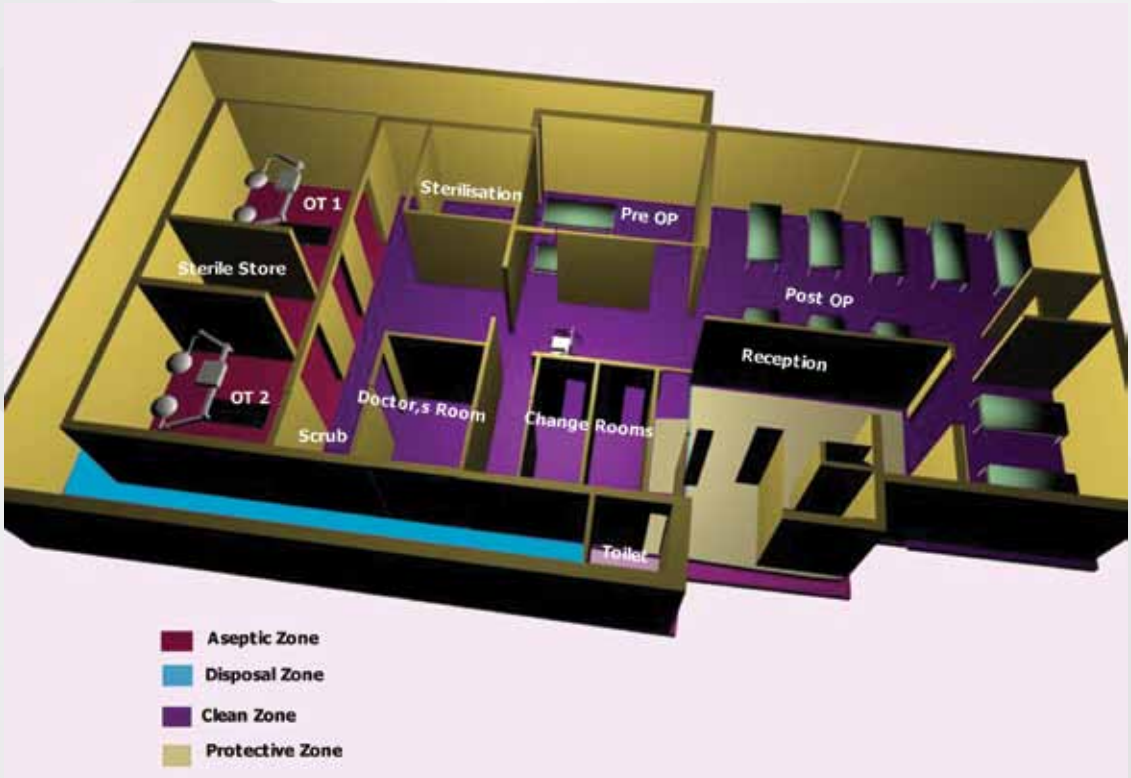
Zoning

Majority of surgical sepsis during surgery was airborne. To reduce this, OT should be divided into various areas or zones of various degrees of cleanliness with an aim to reach absolute asepsis in the operating field.

4 Zones are defined in the OT .

- Protective Zone
- Clean Zone
- Sterile Zone
- Disposal Zone

Zoning minimises the risk of hospital infection, minimises the unproductive movement of staff, supplies and patients and increases the optimum utilisation of staff and other facilities ensuring a smooth work flow.



Zoning in an OT

Protective Zone includes

- Separate entrance hall
- Reception area
- Waiting area for patients and relatives
- Changing rooms
- Store
- Trolley bay
- Electrical control room

Clean Zone includes

- Preoperative and Recovery rooms
- Staff work room
- Autoclave room
- Scrub and Gowning rooms

Sterile zone

- Operating room
- Sterile trolley preparation area
- Sterile store

Disposal zone

- Disposal Corridor
- Dirty wash up area
- Janitors closet

While considering the workflow, four separate streams of traffic must be considered which involves patient, Staff, Supplies and Waste. Incoming and Outgoing traffic in each streams should not meet.

Ancillary rooms

- Changing room
- Premedication room
- Store and Sterilisation room
- Scrub area
- Sterile preparation area
- Staff and Doctor's Room
- Pantry
- Toilet

Toilet should be provided only in the Protective Zone. No staff should enter the toilet in OT clothes, but regrettably this practice has never been rigorously followed in most hospitals.

Protective Zone

The entrance and passage to the reception should be clearly identifiable. The colour should be warm and soothing. For many patients entering the Hospital itself, leave alone the OT, is an unpleasant thought. They will defer hospital visits and surgery solely for this reason. The lighting should be appropriate especially in the waiting area. Audiovisual aids can be used to enable the relatives spend their time in a relaxed manner. In addition to the physical space of the facility, the emotional and spiritual aspect of the patient and relatives should be taken into consideration to provide the right ambience that instils confidence in them.

Service access for collection and delivery of laundry and disposal of hazardous waste should be considered during planning.

The recovery room should be adjacent to the sterile corridor. It would be more economic to have the recovery and preoperative room managed by a single nursing station. The area allocated for each bed, inside the cubicle should be a minimum of 80 sq ft, allowing for at least 3 ft on all sides for work space and circulation. It is enough to have two beds per OR in the recovery. Indirect lighting is ideal keeping the light levels lower over recovery beds and higher at the Nursing station. Provision should be given for AC ducts, electrical conduits and medical gas piping.

There should be separate changing rooms for male and female and adequate storage space should be provided there.

Clean Zone

The Recovery rooms, TSSU, Scrub and gowning areas are located in the Clean Zone.

Sterile or Aseptic Zone

Includes the Operating Room and sterile preparation room. Multiple barriers should be provided from the Protective Zone to the Aseptic Zone to minimise contaminants from the exterior reaching the OR. Keeping these doors in a zig-zag manner, subject to availability of space, will hinder direct flow of air from outside.

Sterile trolley preparation room should be planned adjacent to the OR.

Disposal Zone

It would be ideal to have a disposal corridor where dirty items can be taken out without disturbing any other zones.

OT design by type of corridors

Single corridor or L-shaped design may be used for small OTs. It may extend staff movement distances and there is a possibility of mix up of traffic.

Double corridor and U or T shaped suites take up more space but the corridors reduce the travel distance and improves efficiency and economy.

A peripheral corridor, if feasible would be ideal for movement of patients and the Central one for movement of surgeons and support staff.

A dirty corridor for waste disposal would eliminate any chance of mix up of clean and dirty items on the OT.

Types and Layout of OT

Single OR suite

This is mostly restricted to single specialty low volume setup. Basic facilities like changing room, scrub area, sterile supply room along with limited ancillary accommodation will be provided other than the OR.

Twin OR suite

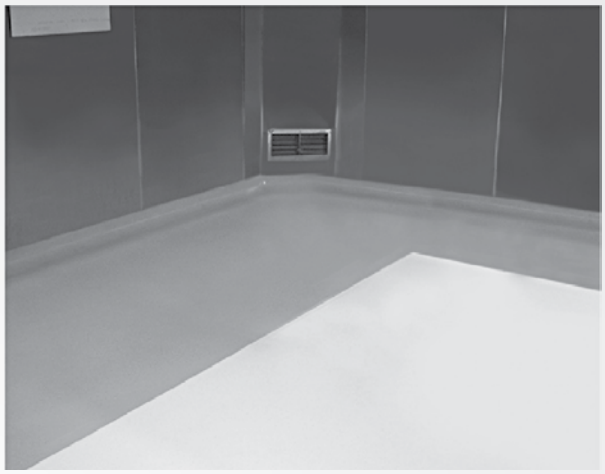
This has shared accommodation such as scrub up and gowning area, sterile supply area, premedication or preparation room. In OTs with single or shared accommodation all operations will have to be postponed in the event of a closure of the complex for cleaning or maintenance. Twin OT and Multi suite OT with separate ancillary facilities are preferable in multispecialty hospitals.

Structural Finishes And Services In OT

An OT should be planned in the right location and constructed with the right material in right specifications.

Walls and Floor

Columns should be made flush with the inside phase of the wall. Walls and floor should be hard, impervious, joint-less, washable and easily disinfected. Normal tiled walls can harbour microbes in the porous grout lines. This can be avoided by leaving a space of 4 mm between tiles by providing a spacer and later filling up the gap with epoxy. It is better to lay joint-free tiles also this way. Special cladding sheets made for modular OTs, special antifungal paints for clean room application, Epoxy, 0.5 mm vinyl sheets, Stainless Steel (SS), Courrien sheets are the other options for walls. It is better to avoid all materials that are porous as they can retain moisture.

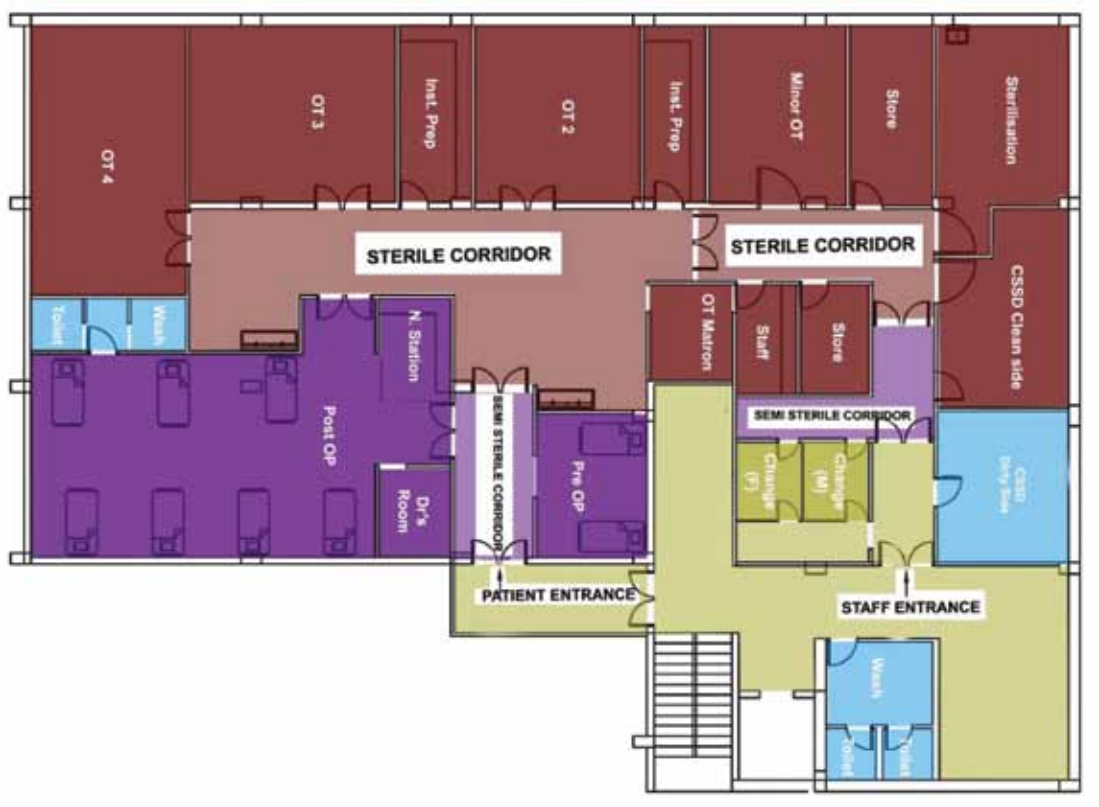


Epoxy floor and SS wall

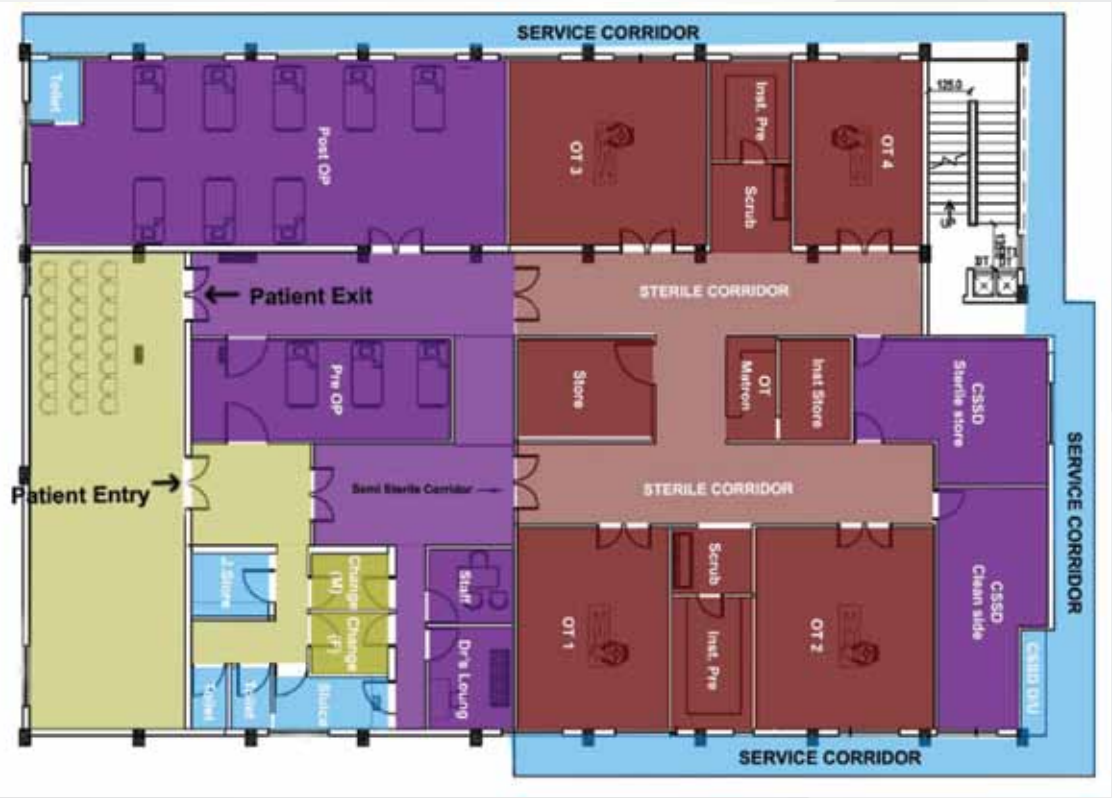
A major source of dust in OT is the horizontal surfaces and cracks in walls, floor and ceilings. Care should be taken to avoid horizontal surfaces like ledges, shelves and skirting in the operating rooms. Coving of the corners reduces the chance of dust collection. Viewing cabinets and switches should remain flush with the wall. If any wall of the theatre is exposed to outside weather, plastering should be done by adding water proofing compound to protect the wall from dampness. Do not incorporate unnecessary cabinets, shelves and furniture in the ORs. Conductive flooring is mandatory if flammable anaesthetic gases are used.



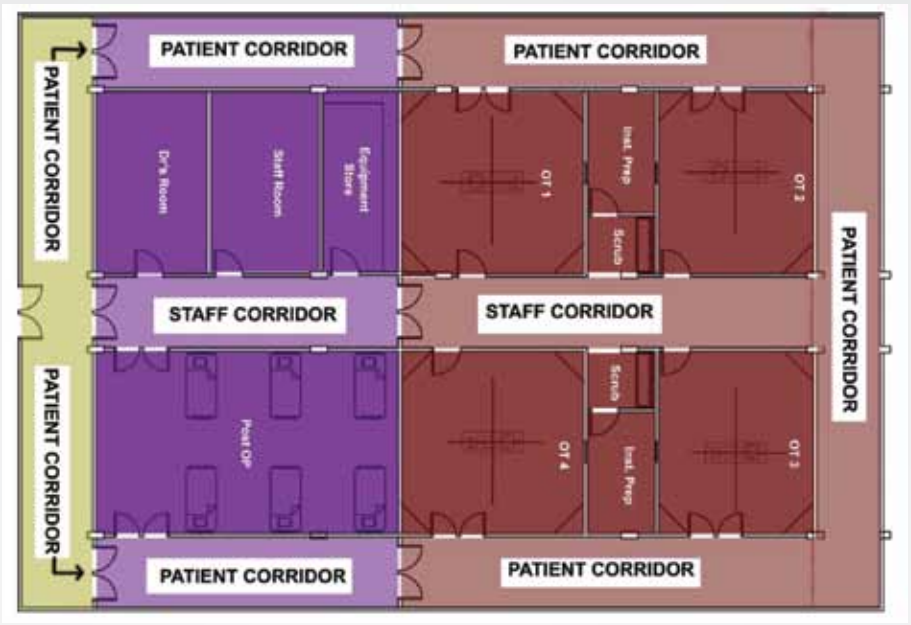
Stainless Steel wall with coving



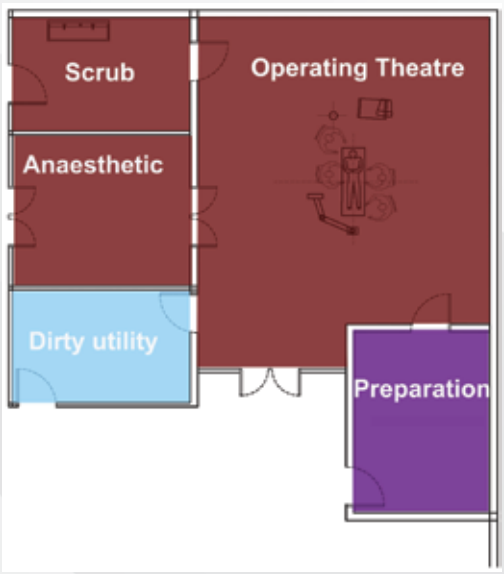
Single Corridor System



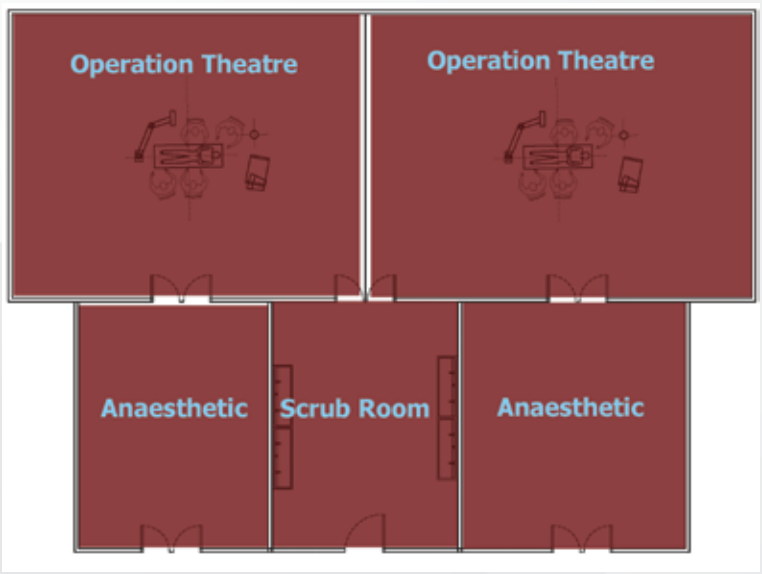
Double Corridor System



Sepatate Staff & patient Corridor



Single suit OT



Twin Suit OT

Ceiling

Ceiling should have minimum number of open joints, fissures or crevices. False ceiling can cover up the AC ducting work, electrical cables and medical gas piping. It would also reduce both the running and capital cost of AC by reducing the volume of the room as well as insulating the room from overhead heat load if the OT is in the top floor. False ceiling should be hermetically sealed to ensure pressure control inside the OR without leakage above it.

Materials like gypsum that can retain moisture should never be used for false ceiling especially in areas where the relative humidity is high.

Ultra clean OTs will have stainless steel or special metallic ceiling with vertical laminar flow (VLF) units. AC ducts, VLF and High Efficiency Particulate Air (HEPA) filter will take up approximately 60 cm above the false ceiling. Hence a height of 3.9 M(12.8Ft) is needed for the concrete ceiling.



S.S. ceiling with HEPA Filter



ACP(aluminum Composite panel) ceiling

False ceiling materials available and their merits and demerits are listed below

Material	Merits	Demerits
Gypsum Board/Plaster Of Paris	Cheap, readily available	Porous, retains humidity and vulnerable to fungus. Not recommended for OT
Cement based (Eboard, V board) within aluminium frame	Cheap, readily available	More joints, difficult to bend to form round corners. Not recommended for OT
PVC strips	Cheap, readily available	Not fire proof, Once dismantled, reassembling to previous finish is not easy
Aluminium composite panel with silicon joint (ACP)	Large sheets are available, can be bent to form round corners	Very skilled labour required to make proper joints with silicon
Powder coated Aluminum strips clip-in	Long sheets are available	Can't be bent to form round corners
One side 50mm EPS TF(Expanded poly sterile – Tested for Fire). Other side imported GI , coated polyester painted sheet machine made panels	Large sheets are available, High thermal insulation	Very skilled labour required to make proper joints.
Calcium Silicate board with epoxy coating	Large sheets are available, form a seamless finish	Difficult to bend to form round corners
0.8mm stainless steel sheet(304 grade)	Large sheets are available, form a seamless finish ,can be bend to form round corners	Ideal, Very expensive. Very skilled labor required to make proper joints.



Manifold pendant



Swing doors



Sliding Door HPL (High Pressure Laminate)



Hermetically sealing sliding door



Barriers to OR

Modular OT consisting of prefabricated interlocking components form the frame work which can be assembled onsite in a seamless finish.

BUILT IN FITTINGS

Manifold Pendants

Manifold pendants carrying electrical lines and gas piping can be attached to the ceiling to avoid tubes and cables occupying floor space. The pendants should be located 60 cms from the end of the table and 60 cms away from it. They should be 1.9 M (6.3ft) above the floor level. Ceiling mounted Operating microscope can also save floor space. This will help the personnel clean the floor without much displacement of the properties inside. Apart from Electrical and medical gas, 2 Data port, 1USB, 1 High Definition Multimedia Interface (HDMI), 1 TV port, 2 Optical fibre can be provided in the pendants considering the future communication /broad casting /Education/training/ Electronic Medical Records (EMR) needs.

Doors

Swing doors displace more air. Hermetically sealed sliding doors run on nylon wheels within the door track and moves in three directions to form a seal against the floor at the bottom and against the frame on both sides and at the top causing minimal displacement of air. The main door of the OR should be of 1.5 m clear width and 2.13 m (7ft) height. It should be protected up to a height of 1.25m with rubber, PVC or stainless steel. A minimum door opening of 90 cm is necessary for hygienic movement of staff dressed in sterile outfits. Vision panels should be fixed on doors so that staff can see what is happening inside without actually opening the door. Door closing mechanism should not be mounted on the floor as the same can become a breeding ground for micro organisms. Instead either top spring or hinges can be used. There should not be many doors in the OR - other than the main door, one for movement of dirty linen is sufficient.

As already mentioned, the OT complex should have several barriers between the Protective zone to the aseptic zone.

Temperature & Humidity

To prevent hypothermia, a temperature of 24-26°C is required, but ideal working temp is 20-22°C. Humidity should be 45-55%. If humidity is more, the microscope optics can get fogged. Adjusting the ventilation best controls temperatures & humidity. Factors like the walls facing the sun, frequent opening of the doors of the OR can affect the temperature control inside the OR.

Electrical connections

OT's have many electro – medical equipments which need power. 4 power outlets (duplex type) should be provided near the anesthesiologist's location. At least 3-4 sockets should have Uninterrupted Power Supply (UPS) (unit should preferably be kept outside the OT complex). The electrical sockets should be made flush with the wall and located 45cm above the floor level. Bus bar system for electrical plugs sockets provide flexibility to relocate sockets in the theatre. If OT electrical points are distributed between two or more distribution boards (DB) one can ensure stable supply in the event of repair and maintenance of one DB.

There should be Captive power produced by a Generator, which could take the full load including AC and TSSU. It should ideally be provided with Auto Main power Failure Panel (AMFP) so that alternate power takes over as soon as the main supply fails.

Earth Leakage Circuit Breakers (ELCB) should be used to prevent shocks. Earthed equipotent bonding of all exposed metal work should be provided. Dedicated earthing with suitably rated conductor for the UPS is a must in the theatres.

Illumination

Light source for General surgery should produce >40,000 lux at the incision site although general lighting intensity may vary from 500 to 2000 lux. Eye operations are usually carried out under the microscope and the need for overhead operation lamps is very minimal. At least one overhead lamp should be connected to the UPS.

Plumbing and sanitation

Sewage shafts should not pass through the operation room. The entire shafts passing through these areas should have impervious lining to prevent contamination. Plumbing fixtures above the OT also should be avoided. Scrub units should have continuous clean running water. Final surgical hand washing may

be done in filtered / boiled and cooled water. The working height of the scrub station should be 96 cm (3.2 ft) with water source 25 cm higher. A 3-station scrub and gowning area require about 11 sq. M space. Care should be taken to prevent splashing by providing appropriate sloping of the walls of the scrub area. Elbow/knee/ photoelectric cell operated scrub stations ensure hygienic hand wash without body contact.



SS Scrub with water filter

Periodic monitoring and documentation of the quality of OT water supply is mandatory.

Ventilation

No area of the hospital requires more careful control of Indoor Air Quality (IAQ) than does the operating or surgical suite. The air-conditioning systems serving the operating rooms require careful design to reduce to a minimum the concentration of airborne organisms.

Air conditioning is the simultaneous controlling of dry bulb temperature, relative humidity, cleanliness, odour, noise, and pressure inside a conditioned area. By using normal split A/C and adding more doors to OT complex we are cutting the fresh air supply which contain sufficient oxygen

A normal split A/C doesn't supply fresh out door air (filtered or unfiltered).

Modern operation theatre ventilation design is based on clean room technology

Cleanroom

A cleanroom is an environment, typically used in manufacturing or scientific research that has a low level of environmental pollutants such as dust, airborne microbes, aerosol particles and chemical vapors. More accurately, a cleanroom has a controlled level of contamination that is specified by the number of particles per cubic meter and by maximum particle size. The outside air would be considered about class 5,000,000 and an operation theater would be Class 1000. The contaminated outside air after passing through a series of varying grades of filters would yield class 1000 at the supply air grill level.

ISO and US FED STD 209E cleanroom standards

CLASS		Number of Particles per Cubic Meter by Micrometer Size					
ISO	US FED	0.1 micron	0.2 micron	0.3 micron	0.5 micron	1 micron	5 microns
ISO 1		10	2				
ISO 2		100	24	10	4		
ISO 3	1	1,000	237	102	35	8	
ISO 4	10	10,000	2,370	1,020	352	83	
ISO 5	100	100,000	23,700	10,200	3,520	832	29
ISO 6	1,000	1,000,000	237,000	102,000	35,200	8,320	293
ISO 7	10,000				352,000	83,200	2,930
ISO 8	100,000				3,520,000	832,000	29,300
ISO 9					35,200,000	8,320,000	293,000

Filtration of air is achieved by means of filter called HEPA filter (High Efficiency Particulate Air) which removes particles up to 0.3 micron size at 99.97% efficiency for keeping the air dust-free. All Clean Air contacting surfaces should be hard, impervious and should not generate dust. Clean air contacting surfaces are Walls, Floor, Ceiling, Door, AC Ducts – supply & return(Use Aluminum or SS ducts), AHU – Coil, Blower, Fan, Furniture, Fabric etc.

All materials should be clean room grade as per GMP standard

Air changes

The air inside the OR will accumulate the anesthetic gases and expired air from the occupants. This has to be exchanged frequently to bring in fresh air. If the air is exchanged once every hour the contamination can be reduced by 63% and 2 changes can reduce it by 86%. 10 changes will reduce the contaminants by 99%. According to NABH guidelines Ophthalmology OT is classified under General OT and thus 25 air changes per hour is mandatory out of which 4 should be the fresh air component. A judicious mix of outside air and inside air can be arranged to increase the efficiency of the system while providing adequate oxygen and retaining the reduced temperature of the inside air. But now a days people are going in for stricter parameters for Ophthalmology OT that suits a super specialty OT.

Overall principles

The function of operating theatre ventilation is to prevent airborne microbial contaminants from entering surgical wounds. Under normal circumstances, the main source of airborne microbial contaminants is microscopic skin fragments shed off by staff in theatre. A proportion of these skin fragments will be contaminated with micro-colonies of bacteria resident, or perhaps transiently present, on that individual's skin. Whilst individuals will have different dispersion levels, overall dispersion is increased with movement and numbers of individuals present.

Other sources of airborne micro-organisms are usually less significant. These include improperly-filtered outdoor air, contaminated fabrics worn by theatre staff and backtracking of contaminated air from outside the theatre. The patient is not usually a significant source of airborne contamination; their movement is usually minimal. However, there exists the potential that power tools can create an aerosol from the tissues and any micro-organisms within them.

Airborne micro-organisms can enter surgical wounds by one of two routes: they can either fall directly into wounds or they can land on exposed instruments, and possibly surgeons' hands, and can later be transferred into the wound. The significance of this latter route will vary with the area of exposed instruments and the duration of their exposure, but is thought usually to exceed the contribution of direct wound contamination.

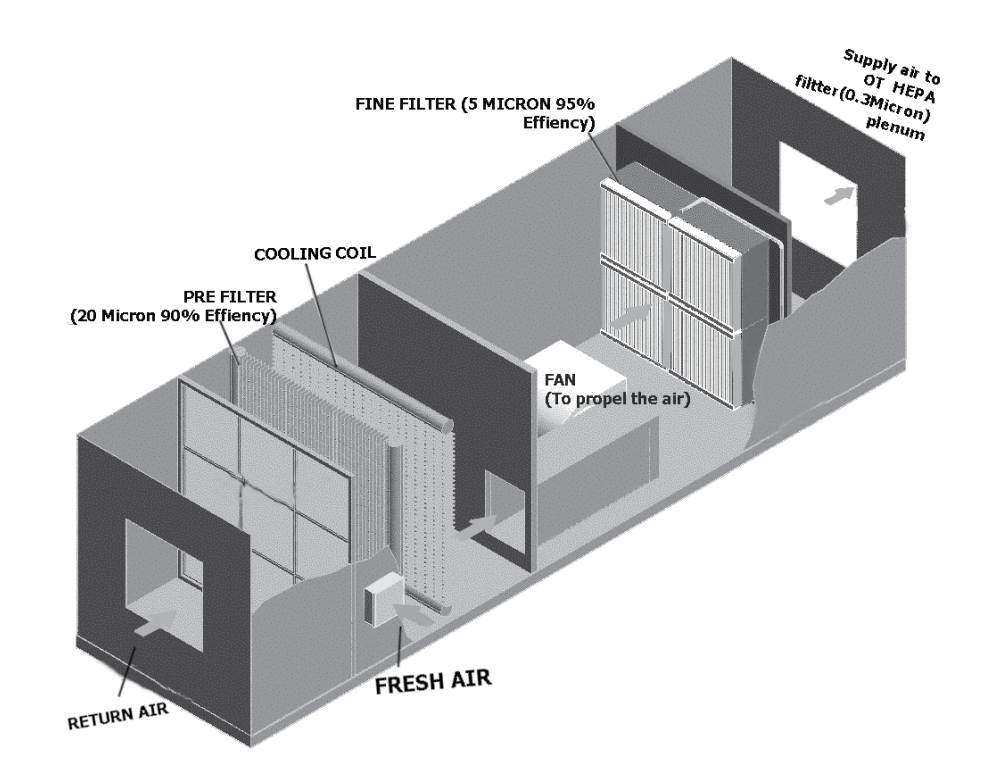
Objective of OT ventilation and its achievement

	Objectives:	Achieved by
1	To dilute the pollution generated by the operating team and patient in the theatre.	1) Filtration of air(20 mic Pre filter with 90 % efficiency , 5 mic Fine filter with 95% efficiency and HEPA filter with 99.97% efficiency) 2) dilution of contaminated air in the theatre (adding clean out door air)
2	To prevent less clean air from neighboring rooms entering the operation theatre.	maintaining +ve pressure inside OT
3	To create airflow pattern that carries contaminated air away from the operating table.	providing Laminar flow
4	To provide a comfortable environment for the operating team and patient	Proper air conditioning with controlled temperature, humidity and ventilation.

Laminar Air flow system

Normally there will be turbulence of air in the room. This will increase the chance of mixing up of clean and contaminated air. In the Laminar Air flow system HEPA filtered, cool air descends in a unidirectional pattern along parallel lines over the surgical area which prevents contaminated air from entering the area. Laminar Flow is restricted to an area in the center of the operating room (Room within the room principle). The flow of air is 0.1 to 0.3 meters per second and not perceptible by theatre staff. Laminar flow is broken around obstacles, such as operating lights, but quickly reforms

Parts of the Air distribution System



AHU Section

Air Handling Units

The Air Handling Unit (AHU) is a centrifugal type fan that pumps air. The fan is usually located in the Air Handler/Water Coil Cabinet. Its purpose is to create a pressure differential so that the air from the conditioned space is drawn to the unit. The air is passed through 20 micron 90% efficiency Pre filter first to remove the dust particles and then over the cooling coils or chilled water tubes where the heat is rejected. This cooled and dehumidified air is then drawn into the suction side of the fan and discharged back into the conditioned space through a HEPA filter. A damper arrangement (Valve) in the suction side of the AHU is kept a little open to draw in fresh air.

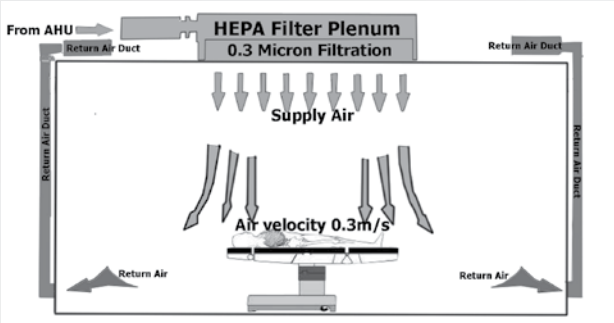
Ducting

Ducts are usually aluminium sheets or stainless sheet, shaped into rectangular boxes or round tubes. They are used to distribute the cool air from the air Handling Unit (AHU), uniformly through out the building to be air conditioned. They start at the AHU, or the packaged air conditioner, and travel to the spaces to be conditioned carrying the cool air. Galvanised iron ducts should not be used for operation theatre ventilation use.

Laminar flow plenum

This is the delivery end of supply duct which will be mounted in the ceiling above the surgical table . HEPA filters are mounted inside this plenum. The air velocity

should average 0.38ms-1 at the surgical table position which is barely perceptible by the person.



Vertical Laminar Flow (VLF)

Return Air

Since a substantial amount of energy goes into cooling the air in the first place it is a practice to recycle the air. The air is therefore brought back to the AHU, or the packaged air conditioner, using return air ducts. It is common to route the return air through the gap between false ceiling and the main ceiling, a space referred to as a Plenum. But this false ceiling plenum system is not at all recommended for operation theatre ventilation, instead a separate return air duct has to be provided. Return air should be taken from four corners of or the OT at a height of 15 cm from finished floor level which will ensure that filtered air from top mounted filter flows down to the surgical area. Providing return air filters of 10 micron 90% efficiency will increase the life of HEPA filter.

Fresh air Intake

A certain volume of fresh, outside air is sucked into the building near the AHU. This air is usually drawn in through a 'damper' which is adjusted to allow the specified volume of air into the building.

Positive air pressure

To prevent infiltration of air of questionable quality into the operating rooms from adjoining rooms, air pressure inside the OT must be maintained at a positive level with respect to any adjoining room. The air distribution system must be carefully balanced after installation to ensure that air movement is from clean to dirty areas and not the reverse.

Monitoring

We should carry out airflow visualisation (smoke testing) to rule out turbulent airflow in the theatre, particularly around the position of the operating table (a puff of smoke should disperse within seconds of creation).

Airflow visualisation should also be used to establish that air flows in the desired direction between rooms in the suite (with all doors closed):–

- from the theatre into
  - the anaesthetic room
  - the disposal room
  - the corridor
- from the anaesthetic room and scrub area into the corridor
- air should either flow from the preparation room into the theatre if it is used for lay-up or they should be at equal pressure if used as a sterile pack store (i.e. no direction of flow between them) and should flow into the corridor from the preparation room.

Choosing the right equipment

As an example, window or small split ACs ,if used in a hospital, are best for patient's rooms or examination room but certainly not for an operating room unless only the very minor type of surgery is performed there.

An economical and yet acceptable air-conditioning system for an operating theatre where even major surgeries can be performed, can be designed and installed using a direct expansion system of 5 to 30 ton capacity with an AHU using recommended air filters and fresh air quantity.

Co-ordination between architect and engineer

The vertical and horizontal distribution of air supply system is a major design issue requiring co- ordination between the architect and the air conditioning engineer. It would be advisable to select the basic system during the early phase of building design. This is because ducting requires taking the optimum route in the space between the false ceiling and the main ceiling avoiding obstructions such as beams, columns and partition walls.

Noise & Noise control in Air conditioning

Ducts are fitted with sound attenuators which work some what like the mufflers in the exhaust pipe of a car. In addition acoustic insulation is used on some

portions of the duct, near the AHU discharge, where it is most prone to make noise. Acoustic insulators are prone to attract dampness which is a precursor of fungal growth. This has to be taken into account while planning. Use of a low noise backward curved fan reduces the noise significantly.

Commissioning

Commissioning must occur before an operating theatre is first used and after any substantial modifications that may affect airflow patterns in pre-existing theatres (as part of a re-commissioning process).

Validation of system is to be done as per ISO 14664

standards and necessarily includes:

1. Air velocity at outlet of terminal filtration unit / filters

2. Validation of HEPA Filters by appropriate tests like DOP (Di Octyl Phthalate) on-site

3. Air particulate count

4. Temperature and Humidity check

5. Pressure Differential levels of the OT with relation to ambient / adjoining areas

6. Air Change Rate Calculation•

Commissioning check list for Operation theatre

1) Commissioning of AHU

a) Check the prefilter

b) Check the Fine filter

c) Check the airflow CFM(Cubic Feet per minute)

d) Check Temperature

e) Check Humidity

f) Check Noise level

g) Check Static pressure

h) Dry run the AC for minimum 6 hours

2) Clean the AHU Room

3) Clean the area above the false ceiling of sterile corridor

4) Clean the rooms adjacent to operation theatre

5) Clean the wall and floor of sterile corridor

6) Initial pre-cleaning of the environmental surfaces for ensuring visible cleanliness

7) Precleaning of OT interior

a) Check all the room lights

b) Check all the electrical sockets

c) Check the medical gas points

d) Check the OT light and camera

e) Check Data POINT

f) Check voice POINT

g) Check SCP(Surgical Control Panel)

h) Check Scrub sink

i) Check the wall panel joints

j) Check the ceiling panel joints

8) HEPA filter mounting

9) Class Validation of Ultra clean Ventilation

10) Initial fumigation of area above the OT false ceiling

a) Install all OT equipments and check

b) Disinfect all the OT equipments

11) Initial fumigation of area above the sterile corridor

12) High level disinfection of AHU and AHU room

13) High level disinfection of Operation theatre

14) Fumigation of AC ducts

15) High level disinfection of Sterile corridor and adjacent areas

16) Microbiological risk assessment



Exhaust fan covered with wiremesh

Internal Air Quality specification. in OT

No of air changes	Minimum 25/hr
Temperature	20-22 deg Celsius
Relative Humidity	45 to 55%
Minimum size of the air supply area	120 cm L x 120 cm B
HEPA filter	0.3 micron @ 99.97% efficiency
Pressure inside the OR	+15 pa
Fresh air quantity	16- 20%
No of R/A opening (15 cm from FFL)	4 nos
Height at which the HEPA filters are fixed	270-300 cm from FFL
Height of the Operation theatre table	90 cm
Air velocity at the Operation theatre table	0.3 m/s
Suitable pre filtration	Pre filter 20 micron @ 90 % efficiency, Fine Filter 5micron @ 95% efficiency and activated carbon filter for absorbing odour and VOC

Dos and don'ts

No Toilets beyond the Reception area.

No staff should use the toilet in OT clothes

No toilets above OR

No exposed plumbing lines in sterile area

No Window AC in theatre

No UPS and battery in sterile area

No Windows in Theatre

No unnecessary furnitures and storage spaces in the Aseptic Zone

No ceiling fans for the ORs as they will create more turbulence.

No exhaust fans for OR. If kept in other areas it should be covered with wire mesh

No floor drain

General Lighting which works on ballast should not be connected to UPS, as it will pollute the purity of the output supply of UPS

Summary

An Operation Theater should be designed in consultation with the users. Replicating another successful model may not be possible always since the final design is influenced by the availability of space, financial status, the shape of the building and the interest of the decision makers.

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CSSD Design

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Location

The Central Sterile Supply Department, as its name indicates, is to be located at the centre of all service stations, where the supply of sterile materials is to be dispatched. The major beneficiary of CSSD supplies is obviously, the surgical areas of the hospital and the location of CSSD could be in proximity to that unit. In some hospitals, the planners and architects recommend that this department may be considered part of theatre complex, to make effective transport of materials in a protective and isolated manner. Such units are known as TSSU (Theatre Sterile Supply Unit) and they are ideally not intended to supply materials to any other clinical unit of the hospital other than operation theatre. As hospitals in India do not have a uniform standard in construction, and mainly depends on the need and objectives of its promoters, it is quite obvious that CSSD planning do not get the priority that is required; when compared with other areas in the hospital.

It is exciting to observe that during recent years, some clinical personals, especially surgical experts are also taken into confidence before finalising the plan of theatre units and its supportive units like CSSD, due to which the gap is being narrowed. However, if finance is a concern, one is likely to end up with constraints in space for the effective service of sterile goods. At the present scenario, in which the cost of the land is steadily shooting up, open land to construct hospitals to feed the demand of the patient community, is becoming scarce in metros and major cities. The only option is to go for multiple floors, resulting in vertical type of hospitals with as many elevators as possible for the transport of patients and public.

In those hospitals where there is constraint for space in the same floor even to accommodate the OT and its ancillary rooms, it is better to locate the CSSD in the adjacent floor and a dump waiter may be installed, which is basically a dedicated elevator that carries materials between the OT and CSSD through a shaft in an isolated environment. It is ideal to have two dump waiters opening diagonally opposite to each other to transport clean and sterile articles separately.

The location of CSSD also should be influenced by the easy transportation of laundered linen, raw material transaction from the general stores and similar feeding areas.

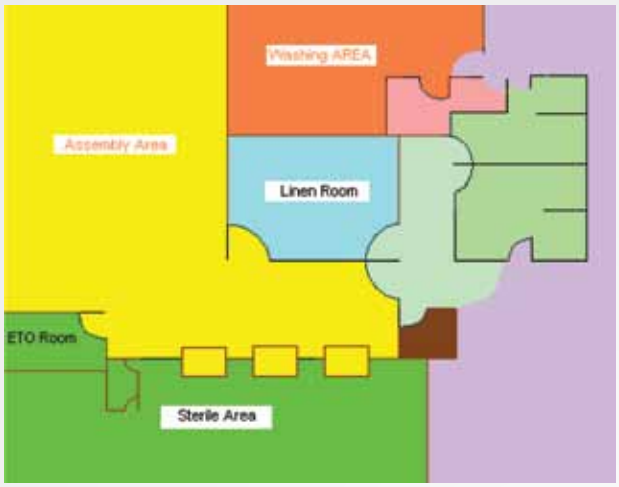
Areas of CSSD

An obvious and quite common question being asked by hospital planners is about the exact requirement of space that is necessary for developing a CSSD. The thumb rule which is adopted by almost all the CSSD professionals across the globe is to reserve 100 sq.ft. area for every single bed. But this is not a hard and

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fast rule. In hospitals catering to medical patients or minor surgeries this calculation may result in wastage of space. It is prudent to allocate space for CSSD taking into account the future expansion.

Area of demarcation



Based on the functions being carried out in the department, CSSD is divided in to three zones - washing area, assembly area and sterile storage area. These zones should be kept isolated from each other and personal movements should be minimised to the possible limit.

Washing Area



Washing area is also being identified as receiving area or dirty area to make a clear understanding for what it is meant for. Personal Protective Equipment (PPE) should be worn by the personal working at this area for their safety. As there is possibility of water spillage during the washing process, the floor should not be made of smooth tiles to avoid accidental fall. Generally most of the CSSD's opt for dull Kota tiles for flooring in this area. It is advised to place smooth tiles on the walls with minimum joints for effective cleaning. Unlike the Operating room, this area should be negatively pressurised in order to contain aerosol within the area itself.

All the furniture needs to be made of stainless steel so that it can be cleaned and disinfected effectively. Washing area needs to have a separate stainless steel table trolley to transport materials from one point to another. One can go for more number of trolleys depending on the volume of materials to be processed and availability of space. But for collecting used materials from various patient units, a separate trolley with closed shelves or a table trolley with closed canisters is recommended. A designated area should be earmarked for parking this trolley and should be cleaned and disinfected after every collection of materials. It is wise to get an intercom point in this area to control movement of staff in and out.



Covered Trolley



Drying Cabinet

Direct entry from the collection area into the assembly area also should be discouraged. For transferring materials from this area to the assembly area, it is advised to install one pass box on the wall.



Pass Box

Storing facility is to be provided for cleaning solutions, disinfecting agents, cleaning accessories and also for holding perforated trays for placing instruments during cleaning process. Provision of PPE to be replenished with adequate stock in appropriate glass cabinets or wall mounted shelves as per the convenience and space availability.



Priority for the floor utilisation should be given to mechanical washing equipment and wash sinks. Adequate space should be provided for the connection of utilities and drains and its maintenance. On the manual washing sink, provision for air jet, water jet and flexible water flusher need to be arranged. One of the sinks or a plastic canister could be used for storing disinfectant solution for terminal disinfection. As the water quality is not guaranteed, it is advisable to go for a separate demineralised water plant for CSSD. Final rinsing of all instruments should be carried out with demineralised water to avoid damage of instruments due to mineral deposits on it. If such a unit is approved for CSSD, a line could be connected to the sterilizer water boiler for long life of heating elements.

Part of the washing area could be converted as trolley wash area in order to wash and disinfect all the trolleys on a regular basis in the most effective manner. Provision should be made for a janitor's room and facility for cleaning OR chappals. Waste management protocols should be observed in the area as per CDC guidelines. Hamper bags should be provided for collecting soiled linen.

Assembly Area



Various surgical items like instruments, linen, dressing materials and other materials are getting assembled and made up in the form of sets or packs in this area and hence the name. This area is a clean area with positive pressure, and should have no access from the receiving (washing) dirty area. It is advisable to keep a change room, shoe rack with separate provision for street and clean shoes, employee lockers, hand washing arrangement and display of clean uniform at the entry point of this area. Floor can be made of smooth tiles or of vinyl flooring. Walls could be painted with washable paints. False ceiling may be made of Plaster of Paris or any other materials with minimum joints (gypsum board with concealed ceiling). Good lighting could be done throughout this area with additional lights at the instruments processing area. Open windows should not be provided at CSSD in any of the areas. However, air tight and permanently locked glass windows may be provided at assembly area in order to have an additional advantage of natural day light. Assembly area and the storage area should be positively pressurised, in such a way that the air flows from sterile to assembly area and then on to the dirty washing area. To achieve perfect

cleaning and disinfection, stainless steel furniture should be provided in this area. However, wooden tables and shelves with high quality of lamination are also acceptable. Depending on the availability of space, one can give provision to put more tables to increase the output in case of an emergency. Couple of S.S.table trolleys are recommended to transport instruments and also to hold it. The number of trolleys can be increased, based on the demand of work and availability of space to move easily.



Storage

As far as storage is concerned, clear bifurcation needs to be done on the materials to be stored before planning cupboards or shelves in the assembly area. Materials which are required quite often and those which are absolutely clean should only be brought to the assembly area for packing. The rest of the bulk supplies and raw materials should be stored away in a separate safe storage area close to the exit point of the department. Avoid unnecessary furniture in the CSSD area. The chair for technicians can be with castors, back rest but without arm rest for easy movements. Area should be earmarked for placing the following equipment or furniture.



- Drying cabinet
- Basket trolley hold
- Autoclave loading trolleys
- Storage cupboards or shelves
- Communication boards
- Washer disinfector unloading trolleys (if it is provided with a drying facility)
- Sealing machines
- Non-woven wrapper sheet dispenser trolley / Linen wrappers storage
- Poly propylene reels dispenser
- Computers and its related parts
- Intercom points at convenience
- Provision for check lists
- Dust bins
- Key box
- First Aid Box
- Hold for temporary storage (like spare instruments)



Washer disinfector

- Dressing materials storage
  (in case to be added in any pack)
- Provision of accessories (To be added during preparation of a pack, like needles pkt.)
- Storage space for tools such as scissors, tape dispensers, lubricating oil
- Provision for record keeping
- Labelling guns
- To hold PCDs(Process Challenge Devices)
- Provision for other labelling accessories

Other than Instrument processing area, Assembly area should have one or two pre designed areas such as Linen Room and Sterilization Area.

Linen Room should be an enclosed room with an easy access to the common corridor. The linen should be packed in a separate area in order to avoid micro lint (which may contain microorganisms) sticking on to the instruments. The easy access to the corridor will help the laundry staff to deliver clean linen directly to the linen packing area without entering any other area of CSSD. Along the walls of the linen room, there should be SS wire racks to hold clean linen prior to packing. Rest of the space other than space for an easy trolley movement could be occupied by a large table for the technicians to make the packs on it. It is useful to identify stains on the washed linen provided the table top is acrylic with background illumination. One hamper bag for collecting rejected linen for rewash and another for collecting linen for mending is desirable close to the working area. One table trolley could be parked in the room to collect packs whenever they were made.

The area in front of the sterilizer panel to operate the machine is called sterilization area. Enough space should be provided here for free 360 degree rotation of the autoclave loading trolley (without any pillar or columns).

One should think about the space for printer, in case the sterilizer does not have a printing system incorporated. As per the manufacturer's recommendation, space should be provided on either side of the sterilizer for the maintenance of the machine. As the machine acts like a barrier between assembly area and sterile storage area, it is highly recommended to erect an air tight stainless steel panel along both front and back panels of the sterilizers and the space developed in between can be used by the maintenance engineers to safely carry on their activities away from the reach of operators. Stainless steel cladding gives a better aesthetic look to that area. Continual observation should be made at this area flooring to confirm that it does not become moist by collecting water due to leakage or due to steam condensation. Also all the electric connections and devices should be insulated effectively to avoid accidents. A proper monitoring system should be adopted to check leakage of utilities such as steam, water, power or compressed air and it should be documented for prompt corrective and preventive action

For the hospital which has an ETO sterilizer, it is advisable to plan a separate enclosed cabin as a precautionary measure, since ethylene oxide is a toxic gas. The area of the cabin should be such that the space around the machine should be adequate enough to carry on maintenance activities and optimum space left in front of the operating panel for easy loading and unloading of the load. Compressed air line with minimum of 7 Kg pressure will be required for accomplishing adequate aeration at the end of the cycle. A copper piping may be required to route the exhaust of the machine till the top of the building in order to execute mandatory safe disposal of chemical in a systematic order. While routing the pipe, the most important point to be considered is that it should have minimum bends on its entire length. Hence it is advised that the location of ETO steriliser should be as close as to the boundary wall of the building or at least close to a safe shaft.

Sterile Storage Area

As the sterile materials are collected and stored in this area, the environment should be as good as that of Operation Theatre and the same precautions are to be taken while entering it. Keep limited and restricted entry to this area. So a change room is to be planned at the entry point from assembly area. By following a double door concept, the space between the assembly and sterile storage can be converted into a change room. The following furniture could be thought of in the change room.

- Small shoes rack for different size of design of slippers

- Lockers for storing personal belongings
- Intercom point
- Computer point (if space available to make issue entries)
- Holders to hang clothes
- Shelf for storing sterile clothes and cap mask
- Adequate bins to collect used clothes and cap masks / waste
- Hand rub to disinfect hands (wash basin not advised as it may cause splash of water)
- Manometer to monitor air pressure in sterile storage area



Just like the sterilization area, sterile storage area also needs 360 deg rotational spaces for unloading trolleys at the back side panel of sterilizer. There should be a suitable place for basket collection trolley in order to stack the empty baskets and in turn shift it to the assembly area. The open racks for storing sterile goods should be made of stainless steel wire mesh in order to avoid collection of condensed steam from the pack beneath it resulting in wetting the packs. Shelves should be at least 8 – 10 inches above the floor level, minimum 18 inches below the ceiling level and at least 2 inches from the walls. The racks identified for storing materials should be clearly labelled as per the storage and appreciable if the red level number of each items got displayed along with the label. Red level is the minimum number which confirms 'no crisis' situation in sterile supplies and to be replenished on an emergency basis.

Air Handling Unit (AHU) for sterile area could be planned separately with an uninterrupted supply of fresh air from a HEPA filter of 0.3 micron, creating a positive pressure of 0.1 mm of Hg level with 10 or more air changes per hour. The temperature of the area should be maintained at 18 to 22^{0}C with relative humidity between 35 and 50 per cent.

As mentioned earlier, if the hospital is of a vertical type and CSSD happened to be in a different floor, then operation theatre supplies could be dispatched through a dump waiter made of stain less steel. It should have double door, one on the elevator itself and the other one to open to access the elevator. The double door system confirms not only safe movement but transportation in a hygienic environment. There can also be a pass box to supply materials to the rest of the hospital. As like collection of dirty materials, CSSD can plan out a distribution system as well, with a clean but enclosed SS trolley with adequate slots to carry all the required materials to shift to the various patient floors.

The flooring of sterile storage area could be made as joint-less as possible and highly recommended for epoxy flooring with side covings in order to accomplish high standard of cleanliness. The walls should be very smooth and painted with antibacterial material. The ceiling also can be with minimum joints and false ceiling can be made of Aluminium sheets with joints filled up with silicon sealant. Lights should be provided adequately with concealed fitting on the ceiling. It is advised to keep minimum gaps for any electrical or other fittings so that the area remains isolated from the rest of the environment.

As far as other furniture and fittings are concerned, the following points may be thought of

- A table close to the issue box to do the paper work
- Computer point for issuing materials through system
- Intercom point
- Electrical points at a good distance
- Humidity meter and Thermo meter to monitor relative humidity and Temperature of sterile storage area

- Holder for fixing check lists (To avoid using adhesives)

In addition to all these, for better housekeeping purposes, a separate mop and bucket with a proper identification has to be reserved for sterile storage area and it could be stored at a designated area outside the sterile storage area.

Other areas in CSSD

Staff Room

There can be a separate staff room. The following features can be part of this room.

- Employee lockers
- Sitting arrangement
- Table
- Wash rooms
- Separate room for refreshments
- Provision of uniforms and changing facility
- Mirror
- Waste and Linen collection bins
- Additional chairs to receive visitors

This area should be close to the main door. Hand washing facility should be very close to staff room.

Manager cabin

This should be close to the main door. The visitors need not change for accomplishment of office related activities. Besides a table and few chairs, think of accommodating a shelf for storing manuals, important records and agreements, display of certificates and mementoes etc. It is advisable to have a meeting space separately.

CSSD Sub stores

This area should have an easy access to the main corridor. While designing a sub store, keep in mind the volume of materials to be stored at the peak requirement. To avoid dumping of materials and spending time in segregating and searching, it is advised to accommodate adequate storing racks at the time of planning itself. In addition to racks, few lockable cupboards could be placed with facility for storing instruments and other valuable materials. One table and few chairs for staff to keep inventory are to be provided. One computer point and adequate number of electrical points are recommended. Couple of trolleys for transporting purpose and distribution of materials are to be planned. Lighting should be good enough to identify the correct product description.

Safety Measures

The following safety points may be taken in to consideration while designing a CSSD

- All electrical panel should be enclosed and sealed
- All the doors, especially those leading to the common corridors should have a locking facility and the keys should be identified by a perfect coding system and stored in a box by arranging in an order
- ETO exhaust line to be taken to top-most floor and further 7-8 ft high of the terrace level with a diffuser attached to the vent so that ETO gas will be further diluted before leaving it in the environment. One should ensure that no building is close by at a distance of minimum 15 ft.
- ETO should have a separate cabin and it should remain closed at any point of time. If possible that area should be negatively pressurised
- Separate loading and unloading trolleys should be provided along with the sterilizers.
- Adequate training should be given to the staff about the usage of dump waiter. It should be meant for only material transportation.
- Washing area flooring should be rough enough to prevent fall due to spillage of water or other chemicals. Always insist to use trolley with a cloth on it for any sort of wet instruments transportation within the area.
- Follow manufacturer's warnings and advises while installing and operating the equipments.
- Personal Protection Equipments should be worn by the staff working in the washing area for their own protection.
- Insist for a sharp container station for collecting all type of sharps and broken glasses. Do not give an opportunity to discard in a wrong bag or left behind at the work station.
- All steam lines should be properly insulated at the time of installation with trap and return lines fixed as per the engineer's advice. Do not give any chance for

overshooting pressure or condensate leakage from the steam inlets.

- The area of sterilizer maintenance should be properly sealed off and entry should be limited to the concerned engineers and technical staff only.

- Entry to the entire CSSD should be limited to authorized personnel only .

Theatre Sterile Supply Unit (TSSU)

As I mentioned at the beginning, TSSU is a concept of providing sterile services within the Theatre complex itself and only for the OT. The staff working in TSSU needs to change on to surgical scrubs prior to entering the department like any other OT staff. Ideally TSSU doesn't require a separate washing and sterile storage area as it will be taken care of by the OT Dirty Utility area and sterile materials stores (clean utility area). So there is no independent action by TSSU like CSSD does. Washing equipment could be kept at the Dirty Utility(DU) of operation theatre, and instruments after cleaning could be transported to TSSU like what was explained between washing area and assembly area in CSSD. Many hospitals especially in abroad has gone for tunnel washer, in which the instruments immediately after surgery will be loaded from the DU.

The photograph below shows one of such tunnel washers in which we can load materials with organic soil on it like we do in washer disinfector. It undergoes various processes in which the instruments get rinsed first, decontaminated, cleaned and disinfected and finally get dried up.



Basically in TSSU, the focus is more in to running sterilizers and arranging and packing instruments, the way surgeons want it.

The most advantage of TSSU is high standard of co-ordination between the sterile service personnel and the theatre staff including surgeons. So communication gap in processing surgical supplies will be almost zero. Another advantage is that no paper work is required as the area is considered as part of theatre complex and staff working may be part of theatre staff reporting to a common authority. Third advantage is space saving. But skipping of separate CSSD to end up with a TSSU is applicable only in small type of hospitals or hospitals which conduct minor type of surgeries only.

But we should not forget the disadvantages of having only a TSSU in a hospital avoiding the concept of a separate CSSD.

The most important disadvantage is control of transport of contaminated and sterile goods. Another one is ignoring sterile supplies to all the other areas of the hospital like ICU , Emergency and wards. As the steam supply leakage is a common feature with sterilizers, one can expect a temperature and humidity fluctuation in OT which is a risk in infection point of view. Accountability, sterility assurance and documentation are other areas which need to be looked in to, because there will be a tendency that TSSU job is every body's duty but nobody's responsibility.

Microbiological Surveillance of Ophthalmic OT





***Aroma Oberoi, MD & **Sangeetha Mohan, MD**

Microbiology and Ophthalmology are interrelated. There are various bacterial, viral, parasitic and fungal diseases affecting the eye. Bacteria are prokaryotes and maybe divided into Gram positive and Gram negative according to the staining properties by the Gram stain.

Common Ocular pathogens

Bacteria

Classification –based on Gram Staining

Gram Positive	Gram Negative
Cocci Staphylococcus spp Streptococcus spp Enterococcus spp	Neisseria spp
Bacilli Corynebacterium spp Propionibacterium spp Bacillus spp Mycobacterium spp	Pseudomonas spp Enterobacter spp Haemophilus spp
Filaments Nocardia spp Actinomyces spp	

Staphylococcus species :

Staphylococci inhabit the skin, skin glands and mucous membranes. They are spherical gram positive cocci arranged in grape like clusters. Staphylococci secrete a variety of extracellular proteins including toxins, enzymes and enzyme activators which help in colonization and in disease. Staphylococcus aureus is important as a pathogen. Some Coagulase negative staphylococci also produce infections. Biofilm formation helps in protecting the bacteria from antibacterial agents and helps in colonization and resistance of infections.

Streptococcus species :

Streptococci inhabit the mucous membranes of the normal upper respiratory tract and female genital tract. They are gram positive cocci arranged in pairs or chains. They are classified based on their ability to hemolyse 5% blood agar .Also they can be classified according to the carbohydrate antigen on the cell wall called lancefield groups. Virulence factors of the pathogenic beta hemolytic streptococci , Streptococus pyogenes include the M and the M like proteins, pyrogenic exotoxins, streptolysin, deoxyribonucleases, C5a peptidase and hyaluronidase. M proteins help the bacteria to resist phagocytosis by neutrophils. Streptolysin lyses erythrocytes, platelets, neutrophils. Deoxyribonucleases cause depolymerisation of DNA. C5a peptidase cleaves and destroys the function of C5a, an important chemoattractant of neutrophils. Hyaluronidase breaks down the hyaluronic acid of the tissues favouring the spread of infection along the intercellular spaces.

Streptococcus pneumoniae is gram positive lanceolate shaped diplococcus which has a polysaccharide capsule that resists phagocytosis by macrophages and neutrophils. Pneumolysin, a membrane damaging toxin has cytotoxic and complement activating properties. It is immunogenic. Autolysins may also contribute to virulence by releasing bacterial components in infected tissues.

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Enterococcus species :

Enterococci are gram positive cocci that are seen in pairs or short chains. They are commensals in gastrointestinal tract, genital tract and saliva .

Enterococcus faecalis is the commonly isolated species from human diseases.

Neisseria species :

Neisseria gonorrhoeae is a kidney-bean shaped gram negative diplococcus seen intracellularly within the neutrophils . Virulence factors include pili, trilaminar outer membrane, Opacity associated protein, IgA1 protease and endotoxin.

Corynebacterium species :

Corynebacteria are gram positive , pleomorphic bacilli that form cuneiform arrangement. C.diphtheriae possess metachromatic granules and are exotoxin producing bacilli. Other species called diphtheroids are not associated with infections usually.

Propionibacterium species :

They are normal inhabitants of the skin. They are thin, gram positive bacilli . P.acnes might be an eye pathogen causing post operative endophthalmitis .

Bacillus species :

Sporogenous bacilli are classified into aerobic bacilli and the anaerobic clostridia. The spores are ubiquitous found in soil, water, dust. B. cereus may produce toxins damaging ocular tissues.

Pseudomonas aeruginosa :

Pseudomonas is gram negative bacilli which are found in water, soil or other moist environments. P .aeruginosa has virulence factors like exotoxin A, proteases, elastases, hemolysins, enterotoxin, pili and slime layer. The toxins can disrupt protein synthesis and damage cell membranes of ocular cells. Proteases degrade the corneal stromal extracellular matrix.

Enterobacteriaceae :

This family of gram negative bacilli include Escherichia coli, Klebsiella spp, Enterobacter spp, Citrobacter spp, Serratia spp, Salmonella spp, Shigella spp and Proteus spp.

The factors which cause pathogenicity include pili, adhesins, cytolysins and toxins.

Haemophilus species :

These commonly inhabit the human upper respiratory tract and mouth. Haemophilus species are small gram negative coccobacilli showing pleomorphism. H.influenzae have polysaccharide capsule which acts as a virulence factor.

Mycobacterium species :

They are gram positive, irregularly stained, acid fast bacilli. Mycobacterium tuberculosis causes posterior uveitis . Cultured on Lowenstein Jensen medium. They are intracellular pathogens. Atypical mycobacteria cause ulcerative keratitis. (M. fortuitum, M .chelonei)

Nocardia species :

N.asteroides are partially acid fast and gram positive thin branching filamentous bacteria. Causes keratitis.

Actinomyces species :

They are gram positive thin, filamentous branching bacteria which are non acid fast. Colonizes mouth, intestines, genital tract. Cause canaliculitis.

Chlamydia species :

They are obligate intracellular parasites of humans with tropism for squamous epithelial cells and macrophages of respiratory and gastrointestinal tracts. They occur in two forms, the Elementary body (EB) and the Reticulate body (RB). The EB is infectious. The Chlamydia trachomatis A, B, Ba and C serotypes cause endemic blinding trachoma. The serotypes D,E,F,G,H,I,J,K cause inclusion conjunctivitis.

Spirochetes :

Spirochetes are spiral bacteria with endoflagella. They are visualized under dark field microscopy in clinical specimens. Treponema pallidum causes venereal syphilis. It has regular spirals and is actively motile. Can be detected by silver impregnation methods also.

Fungal agents :

The fungi are eukaryotes with chitin and polysaccharides in their cell walls. They are classified into Yeasts and Yeast like and Molds (Filamentous) .

Yeasts	Molds (Filamentous)	
Candida spp Cryptococcus neoformans	Septate Fusarium species Aspergillus Curvularia	Aseptate or sparsely septate Mucor Rhizopus Absidia

Yeasts :

Candida species are isolated from gastrointestinal, genital tracts , oropharynx and the skin. The mannan protein helps candida in adhesion.

Cryptococcus neoformans may cause disease in immunocompromised patients in the brain, optic nerve, eye, lung, skin and prostate.

Filamentous fungi :

The septate filamentous fungi which cause corneal infections are Fusarium species, Curvularia, Aspergillus spp, Phialophora, Paecilomyces. These infections occur after injury to cornea with vegetative matter.

The aseptate or sparsely septate molds include Mucor, Rhizopus, Absidia in class Zygomyctes, order Mucorales. In the immunocompromised, these fungi cause life threatening infections of the paranasal sinuses , brain and orbit. They are angioinvasive and also sometimes neuroinvasive. In diabetes mellitus these are common. Affected tissues are necrosed by the fungal invasion.

Pneumocystis jiroveci (carinii) has been placed back in the fungal kingdom and is found in HIV infection causing choroiditis.

Parasites

Protozoa:

Acanthamoeba species infect human cornea and brain. Diagnosis is made by looking for the trophozoites or cysts in the tissues.

Toxoplasma gondii cause chorioretinitis.

Leishmania species: Cutaneous leishmaniasis is transmitted by bite of its vector, female sandfly. The intracellular parasites are seen by Giemsa or immunofluorescent stains.

Helminths:

Microfilariae of Onchocerca volvulus cause Onchocerciasis. They cause keratitis, anterior uveitis, chorioretinitis .

Loa loa microfilariae also migrate through connective tissues and maybe seen under the conjunctiva.

Dirofilaria of animals may become adults in man without producing microfilariae. They include Dirofilaria immitis (parasite of dogs) and Dirofilaria repens. D.repens have been reported from subcutaneous tissue of eyelids and palpebral conjunctiva.

Ocular larva migrans by non human nematodes like Toxocara canis and Toxocara cati maybe caused in older children.

Larval stage of Taenia Solium, cysticercus cellulosae may form in eye and orbit to cause cysticercosis when man accidentally ingests the ova of the cestode.

Arthropods :

Phthiris pubis: this is crab louse seen in pubic hair. Can cause blepharoconjunctivitis.

Demodex species: They inhabit the superficial hair and eyelash follicles ,sebaceous and meibomian glands.

Fly larvae :

Ophthalmomyiasis is external or internal infestation with fly larvae. The maggots feed on the living or dead tissues.

SPECIMEN COLLECTION

Eyelid specimens

For microbial cultures maybe taken by swabbing the abnormal area with a sterile swab followed by direct inoculation of culture media.

Conjunctival specimens :

One must debride enough surface epithelial cells to see intracellular microbes. Sterile Dacron swabs (more preferred than cotton) moistened slightly with medium like thioglycollate broth can be used for recovery of microbial specimens. Immediate inoculation onto pre warmed solid enriched media like blood agar, chocolate agar and Sabouraud`s agar yield better results. When collection of specimen is planned, the Ophthalmologist should send a request

to Microbiology lab from where fresh media can be taken. Swabbing should be done preferably before topical anaesthetic agents are instilled into the eye.

Corneal specimens :

Material for culture from corneal ulcer can be obtained by scraping the lesion with Kimura spatula, sterile needle or scalpel (blunt). The specimen is inoculated onto media. It is inoculated by making C-shaped streaks on the culture medium taking care not to plough deep into it. Best is to directly inoculate the specimen at the bed side. Or it can be transported to the laboratory between two sterile glass slides (one for microscopy and other for culture). Some material is put onto glass slides for Gram stain to look for bacteria and lactophenol cotton blue preparation or 10% KOH preparation to look for fungal hyphae.

Corneal biopsy also may be taken in some cases. It may be divided into two, one for histopathology and one for microbiology.

Fluids :

Aqueous and Vitreous specimens maybe collected in sterile syringes and since the material is so minimal in amount, it may be inoculated into medium like Thioglycollate broth or brainheart infusion broth instead of solid media. The medium is incubated at 37^0C and then later subcultured onto solid medium like Blood agar, Mac Conkey`s agar and Sabouraud`s Dextrose agar.

Microbiologic Surveillance

Surgical procedures are some of the most invasive procedures that occur in a hospital. At every step of the surgical process, there are opportunities for transmission of pathogens that could result in infection. In Ophthalmology Operation Theatres utmost care must be taken to prevent transmission of infection to the patient. It is a highly specialized area where strict asepsis needs to be maintained. Post surgical infections are a significant health risk to patients. One of the most dreaded complications is post operative endophthalmitis. Since it is difficult to get adequate antimicrobial intraocular concentration of drugs via parenteral, oral or peribulbar route, strict aseptic precautions for prevention of endophthalmitis is of paramount importance. Source of infection may be endogenous or exogenous. Factors affecting the rate of post surgical infection are effective sterilization & disinfection procedures, good surgical technique, theatre design, bacterial contamination of theatre air, OT discipline , movement of staff, judicious use of prophylactic antibiotics and flow of traffic from one zone to another. The OT environment plays an important role in the onset and spread of infection.

The Microbiology laboratory conducts and monitors regular surveillance in operation theatres.

Air Surveillance of Operation Theatre :

Scope: to detect bacterial count in the OT air and to determine the presence of pathogens like Staphylococcus aureus.

Factors influencing: Number of persons present, body movements, disturbances of clothing.

Methods :

- Settle plate method
- Slit sampler method (from given volume)
- Particle counter (non viable count)

Settle plate method

if done and interpreted properly, this can can give a very good judgment of the environment of the Ophthalmology OT.

Air sampling is done by keeping Blood agar and Mac Conkey`s agar settle plates. Blood agar will pick up both bacteria and filamentous fungi like Aspergillus, Rhizopus .

Mac Conkey`s agar is good to differentiate gram negative bacilli helping in the identification. Fresh plates need to be kept for exposure in the OT. Multiple plates are kept in different areas of the OT at around 2 1/2 feet height and results interpreted as a whole instead of assessment from a single plate. Usually the corners and the OT table head end are the areas chosen. The time of exposure is 30 minutes. After that all the plates are closed and incubated at 37^0C for 24 hours. At this time control plates from the same batch of the prepared Blood agar and Mac Conkey`s agar should be incubated along with test plates. This is to avoid misinterpretation that can occur sometimes due to plate contamination. After 24 hours the reading is taken. Control plates are checked first. If no bacterial growth is present in them, the reading is taken from test plates. The mean colony forming units (CFU) from all the culture plates are taken. The accepted limit

in an OT during surgery is 180 CFU/m^3. If the culture plate used is of diamater100mm (10cm), according to its area (.0078m2) and exposure to air for 30 minutes, it should not have more than 12.6 colonies. So, 10 to 12 CFU can be taken as the limit in an Ophthalmology OT.

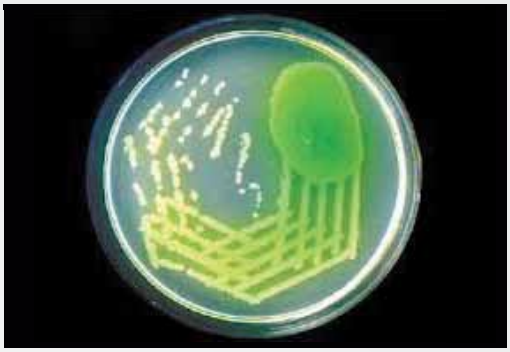
Pathogens, commensals and saprophytes are isolated by the settle plates. Gram staining and biochemical tests are performed according to standard microbiological techniques to identify and confirm organisms. The common organisms isolated in culture are Staphylococcus aureus, Coagulase negative staphylococcus, Pseudomonas species, Escherichia coli, Enterobacter species, Klebsiella species, Filamentous fungal colonies like Aspergillus, Rhizopus and Aerobic spore forming bacilli. The colonies are counted and interpreted along with recommendations. Presence of pathogens like Staphylococcus aureus should be taken as unsatisfactory. It should be mentioned in the report that it is pathogenic.



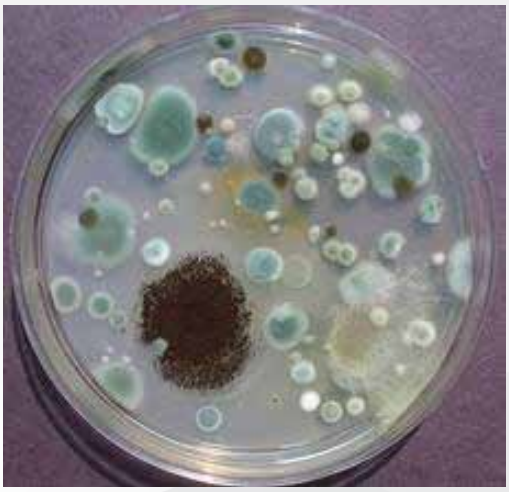
Air sampler



Staph Aureus



Pseudomonas



Settle Plate - Sabouraud`s Dextrose Agar showing Fungal colonies



Settle Plate- Blood agar showing fungal colonies

If the CFU is more than 12, it should be clearly mentioned in the report as "Bioload above acceptable limits"and if CFU is less than 10-12, it may be mentioned as "Bioload within Acceptable Limits."Against non pathogens like Aerobic Spore forming bacilli, it should be mentioned that they are non pathogenic. Against filamentous fungi, opportunistic pathogen should be written. Presence of fungus is considered alarming .

Along with the Surveillance report, appropriate recommendations should be added: Do frequent cleaning, disinfection and sterilization, clean the Airconditioner filters, reduce human traffic in OT etc..

Air Sampler :

Now air samplers are available with which we can adjust the volume of air being checked. Manufacturer`s instructions are to be followed strictly. The agar strips have to be placed inside the sampler with all sterile precautions. The air sampler is placed in the center of the OT secured on a trolley and it is switched on. OT doors need to be closed. Sampling volume needs to be more than 0.25m3 (250L) and optimally around 1m3 (1000L).

After the sampling is over, the agar strips are removed carefully, labeled and sent to Microbiology lab for processing. Strips are incubated at 37^0C and reading taken after 24hours.

Another method of surveillance is swabbing the important areas of the OT.

Swabs moistened with Nutrient broth are used to sample from surfaces or equipments. These are further subcultured on to Blood agar and Mac Conkey`s agar. The areas to be swabbed are operation table head end, operating microscope head, table top where instruments are kept, wall near electrical switches and floor near the table.

Swabbing of airconditioner filters need to be included for checking for presence of fungus. The HEPA filter vents also can be swabbed.(Even settle plate method can be used for these. Close to the outlet vent Blood agar and Sabouraud`s Dextrose agar plates can be held for 30mts and the CFU taken. These swabs can be cultured on Blood agar and Sabouraud`s Dextrose agar. If presence of fungus is there, the report needs to go as early as possible and corrective measures taken.

Filters of Individual A/C units can be soaked in dilute disinfectant solution(preferably aldehyde based) after washing with flowing water to remove all dirt and dust. Then it has to be dried thoroughly before replacing. Wet mopping can be done on the entire A/C unit. Centralised A/C ducts have to be cleaned regularly by the high dusting team of the hospital. They can use vacuum cleaners to suction out all the dirt and dust at the outlets of the A/C vents. Such times OTs need to be closed as there is danger of dispersal of large number of fungal spores and bacteria carrying dust particles. Robotic cleaning devices are available to clean the ducts. Once in six months the entire ducting system should be ideally fumigated after thorough cleaning.

Unnecessary culturing of various surface areas lead to confusion and meaningful interpretation becomes difficult. Routine test for anaerobes is not essential.

There are no national guidelines on frequency of OT surveillance. But there is enough evidence to support the undertaking of Microbiological air sampling in OT as part of vigilance and safety of the OT. A practical approach for our hospitals will be once a month air surveillance along with swabbing of important areas and checking of airconditioner units four times a year or more times in humid weather.

Along with the surveillance report, appropriate recommendations should be added.

Regular discussion with the microbiologists is a must-do in ophthalmology set ups.

Stress should be laid on frequent cleaning (wet mopping) with clean water, which itself will reduce the bacterial loads. After which the disinfection and sterilization can be more effective.

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Cleaning and Packing of Instruments and Linen



Neena Kulkarni MSc(Microbiol)

Cleaning Of Surgical Instruments

After completion of surgery the instruments must be rinsed with cold water (not saline which would cause rusting of instruments) immediately to avoid drying of blood and other body fluids. Hot water (above 50 degree) will cause coagulation of proteins and fixing of organic material which in turn makes cleaning a difficult process. These instruments are then sent to the CSSD for thorough cleaning and further reprocessing. The instruments must be transported to the CSSD under covered conditions to avoid the spread of infection. In large hospitals, dumb waiters (small designated lifts to transport material only) are used to prevent infection in corridors, staircases and lifts. If closed trolleys, covered containers and carts are used for transportation they must be considered contaminated and should be cleaned periodically.

At CSSD, the instruments must be checked for proper count and examined for any obvious damage and sorted for manual cleaning or cleaning by use of mechanical equipment.

Every item used, or that which has come in contact with the used item must be considered contaminated and potentially infectious. Decontamination at CSSD will render the instrument safe to handle. The bioburden or the microbiological load actually depends on the number and type of microorganisms that are present on the instruments. Efficiency in the process of reducing the bioburden would depend on:

- Complexity of the device to be cleaned, i.e. whether it has hinges, lumens, ratchets, rough surfaces, teeth etc.
- What kind and how much of debris (organic soil) is present on the device
- Also the number and type of microorganisms present
- Decontamination method including manual or mechanical cleaning and the chemicals used

It is very difficult to confirm cleaning by quantitative methods. Hence it is essential to verify that the cleaning process has been effective in removing all visible soil from every surface (external and internal) of the instrument / device, by visual inspection. When items are clean and free from dirt, soil and oil, water will run off in sheets. If the item is dirty, droplets or beads will form on the object. However a visual examination will only confirm removal of gross soil but not of microscopic contamination.

Efficacy of manual cleaning will depend on personnel performing the job whereas in automated cleaners it may be affected by size of the load, loading pattern, water pressure, water quality, cleaning chemicals used as well as type and quantum of soil. Even after excellent cleaning there may still be a surviving microbial population depending on initial bioburden.

Today cleaning is considered the most important process in the CSSD reprocessing cycle. It is a pre requisite to sterilization. The sterilization equipment manufactured expects a clean load as an input, to provide a sterile load as output. The tiniest particle of contaminant on an instrument may protect a huge population of pathogenic bacteria by preventing access to the sterilant and in turn causing the instrument to become a potential threat to patient safety.

Standard Precautions must be used while cleaning the contaminated devices. Personnel protective gear, environmental control and safe practices are key features of the decontamination process.

The safety gear includes attire such as a gown or apron that prevents any strike-through of moisture, gloves with long and well fitting cuffs to avoid water entering

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from over the wrist while cleaning the instruments; and a face mask with a shield in case of any possibility of splashing or aerosol creation, to prevent contact with eyes, nose and mouth. If the cleaning involves large amounts of water (e.g. washing of trolley), rubber or plastic boots may be used. A cap to protect and hold hair in place is commonly used.

The area designated for decontamination must be separate from other areas to avoid spread of infection. Also ventilation and air conditioning must be so designed to minimize the risk. The air pressure within this area must be negative as compared to surrounding areas to avoid air from flowing outwards. The air should be directly exhausted with no recirculation. It is important to have at least six total volume air changes per hour with 100% fresh air. Proper lighting will enable proper checking of the medical devices to be cleaned. Following facilities are required for effective cleaning of the surgical instruments and other reprocessible devices:

- Facility of clean cold and warm water, preferably demineralised
- Jets with pressurized air and water flow mechanisms
- Appropriate perforated baskets to hold instruments while cleaning
- Equipment such as ultrasonic cleaners, washer disinfectors
- Array of soft bristle brushes with varying length and diameter to enable cleaning the multiple devices
- Dryers using hot air to enable quick and efficient drying (Wiping is a time consuming process; but when employed, to avoid fibres from getting deposited onto instruments we must use non fibre shedding absorbent material).

Safe work practices involve minimum and careful handling of the used devices and instruments. Extra caution while handling sharps such as scissors, needles, blades etc. is mandatory to avoid injuries. Also delicate instruments must be handled with care. While placing the instruments in perforated trays for washing, care must be taken to keep heavy instruments below and lighter ones on top. Also, the instruments should be clamped in such a way that there is maximum exposure to enable proper cleaning. While cleaning lumens or cannulated instruments, high pressure air jets, water jets and long soft bristle brushes must be used for effective cleaning. Instruments made of two or more parts must be disassembled for better cleaning, but taking care to reassemble them correctly is very important.

In case of devices that cannot be submerged in liquids, alternate methods of wiping with detergent impregnated wipes followed by wet wipes may be used. Dried blood may be removed by judicious use of hydrogen peroxide since over exposure can cause corrosion.

IFU (Instructions for Use) should be strictly followed. Thus the item (product) you clean, the method of cleaning (procedure) as well as the cleaners (catalyst) used must be in conjunction with the manufacturers' recommendations.

Proper waste segregation and disposal of waste in appropriate predefined coloured liners or bins is important to prevent spread of infection and needle stick injuries.

Manual cleaning is generally performed for delicate instruments. This should be done in a sink with a drain stopper or in a basin containing water and cleaner. Items must be scrubbed with a soft bristle brush as use of hard bristles or abrasive powders can damage the instruments. The items should not be rinsed under running water as this would create aerosols, which is a hazard that can cause spread of infection.

The most commonly used equipments for cleaning instruments are ultrasonic washers and washer disinfectors.

Ultrasonic cleaners use the energy from high frequency sound waves created by transducers placed in the bottom or on sides of the sink like chamber. The chamber is filled with water and cleaner through which the waves pass. This makes the liquid vibrate very fast. Due to this, small gas bubbles develop, become larger and implode. The implosion thus draws out tiny particles of dirt from crevices such as the hinges and serrations on instruments; resulting in thorough cleaning of especially hard to reach areas where manual scrubbing would not be possible. It has a brushing effect, more efficient than manual cleaning. Advanced versions of this machine have a separate chamber for rinsing and also an additional swinging mode to increase cleaning efficiency.

To prevent spillage, noise and aerosol formation in the unit, it should have a lid. The instruments are placed in wire mesh trays which in turn are placed in the chamber. The cycle time, temperature, and cleaners to be used would depend on manufacturers' recommendations.

Washer - Disinfectors are machines that include a pre rinse, followed by washing and a sustained rinse. The last part of the cycle is a rinse with hot water at temperatures above 80 degrees. Thus, as the name suggests the instruments are thermally disinfected. The equipment has special adaptors for attachment of different kinds of devices like tubings, instruments with lumens or for those that are used in minimally invasive surgeries. Also the equipment is programmable with respect to concentration of cleaning agent, number of rinse cycles, and other treatments post washing, like use of lubricant / neutralizer. Hence, appropriate program is selected as per the load configuration. These washers have provision of recording and printing cycle parameters thus allowing documentation. Though not very commonly used, chemical indicators to monitor cleaning are available; these assist in the proper control mechanism required for quality assurance.

Since water alone cannot clean the instruments which may have substances like oils, fats and proteins; use of cleaning agents such as detergents and enzymatic cleaners are mandatory. Detergents are known to lower surface tension and dislodge, disperse and remove soils from surfaces being cleaned. While using them in turbo cleaners, non or low foaming types are preferred. Enzymatic cleaners are biological catalyst molecules which help break down or digest large organic molecules like proteins, fats and starch into smaller ones. Compatibility of the various cleaning chemicals with materials being cleaned is very important.

Chemical indicators to check efficacy of cleaning machines are available and use of these assist the validation of cleaning protocols.

Depending on the use of the device, 'Spaulding Classification' is a basis to decide if the item needs to undergo low level disinfection, high level disinfection or sterilization to be safe for reuse. Material compatibility will then decide the method of disinfection or sterilization that is selected.

- **Critical (sterile):** Instruments or items that are introduced directly into the bloodstream or other normally sterile areas of body e.g. Surgical instruments, cardiac catheters, implants etc.
- **Semi-critical (high-level disinfected):** Instruments that come in contact with intact mucous membranes e.g. Non invasive endoscopes, endotracheal tubes, anasthesia circuits, etc.
- **Non-critical (low-level disinfected or clean):** Instruments or items that either touch intact skin or do not ordinarily touch the patient e.g. BP cuffs, crutches, ECG, etc.

After a thorough cleaning of reprocessible devices such as surgical instruments, tubings, kidney trays, bowls, basins etc. They are transported to the Assembly area or Preparation area either through a hatch or a covered trolley. Ideally the assembly area is the adjacent room. If so the items may be passed through a passbox. This is the area where clean instruments are inspected for cleanliness as well as functionality. The instruments are sorted, checked and assembled for sterilization as per priority. This depends on the number and type of available sterile sets within the CSSD and requirements from Operation Theatre, ICU, Catheterization Laboratory or other areas.

Facilities required are as follows:

- Adequately lit workstations with comfortable and height adjustable chairs.
- Holders for accessories such as indicators, cutters as well as appropriate wrapper storage facility.
- Computer and Printer for lists or pre printed list with storage for the same

AAMI (Association for the Advancement of Medical Instrumentation) states that providing "adequate space for supplies and equipment and designing the layout to facilitate the flow of work through the various steps of preparation contributes to the efficiency and accuracy of the sterile processing staff." Consumables such as wrappers, sealing tape, tip protectors, labels, cutters, etc. must be available at each work station. Heat sealers, battery chargers, incubators for checking biological indicators must be close to the work stations when required.

Usage of a computerized tracking system supports prioritizing. Also, a pictorial depiction of various

instruments along with names and catalogue numbers is a boon while assembling the instrument sets. The instrument arrangement in a standardized manner assists in increased efficiency of OR. Placing the instruments in the sterile field before surgery thus becomes easy.

The clean instrument sets are assembled in a tray with a liner if being sterilized by steam. The liner protects instruments from damage and has a wicking effect which assists in condensate removal. This reduces the possibility of 'wet pack' problems.

The list or count sheet that is used while assembling the set must be signed by the personnel packing the set. The user too checks the set before returning it to the CSSD. While receiving or assembling a set, if any damaged, broken, or missing instrument is identified; informing the CSSD supervisor and OR in charge is very important. The designated personnel can then replace the instrument if available in stock, or else request for procurement of the same. The CSSD personnel are also responsible for liasioning with instrument manufacturer for repairs (if possible) of instruments.

After confirming the specialty of instrument set i.e. Ophthalmology, Neurology, Cardiac, Orthopaedics etc. the appropriate count sheet is used carry out a thorough check of each instrument. The quantity and quality of instruments must be checked to avoid inconvenience during surgery or any other intended use. Magnifying glass is used to check the micro instruments; allowing replacement or removal in case of damages such as cracks, broken tips, or non alignment.

A sterile set is always opened when it has to be used on the patient and any unavailability or non functional instrument can be the cause of major problems during surgical procedures. Any inadequacy must be communicated to the user in advance, so that alternatives can be devised.

Qualitative Inspection of Instrument

Surgical instruments are broadly classified according to their application:

Artery (haemostatic) forceps clamp vessels for control of blood flow. Inspection of the ratchet, which is the mechanism to close the jaws of the clamp, is very important. The tips of jaws must match without an overlap. The opening and closing must be a smooth movement. Serrations or teeth must neither be dirty nor must they be worn out. Another check of the locking mechanism is done by tapping both rings gently on the palm while locked on the first ratchet. It should not spring open. Ring-handled instruments should be opened to examine box locks and pivots, checking for cracks or misalignment.

Needle holders are designed to hold suture needles to suture surgical wounds. They should hold needles securely based on the size the instrument is designed for. If the needle is loose in the jaws of a locked needle holder, the instrument should be repaired. They also have a 3 to 4 ratchet closure or spring lock mechanism. The jaws can be straight, curved, or angled. The surface of the jaws may be smooth or gritted and can be made of stainless steel or tungsten carbide. Other checks are similar to Haemostatic forceps.

Scissors are used to cut tissue, sutures and other material in the surgical field. They have two cutting blades. When the scissor is in the closed position, at least the tip end of the blades should be touching each other. They are available in various blade shapes e.g. straight, curved or angled and features such as serrated, knife edge or with tungsten carbide inserts. Inspect the cutting blades for burrs and chips. Test for smooth cutting action by opening and closing the scissors. Inspect the hinged area for surgical debris and stress cracks. To test for sharpness, 1/3rd length of the tip should give 2-3 consecutive clear cuts on latex sheet (like a glove) or pressed damp cotton. For micro scissors, a plastic bag of less than 20 microns can be used.

Forceps (Toothed or Plain) are used to manipulate and hold tissue. The teeth on the tissue forceps should mesh with each other in case of a toothed forceps. Inspect serrations on the jaw for cleanliness and see that they are not worn out. Inspect the proximal end for cracks and dirt.

Retractors are used to hold aside tissue for exposure and visualization of the surgical tissue deeper areas. They can be manual (hand held) or mechanical (self retaining). The instrument may be made of more than one part which must be checked. Retractor must be checked for any metal flaking off, burrs or dented edges. For self retaining retractors, inspect the prongs and close the retractor to insure proper

alignment. Inspect for surgical debris, stress cracks, smooth action and proper fixation.

Suction Tubes are used to extract (via suction) blood and solutions out of the surgical sites for enhancing visualization. Examine the entire device for dents, punctures or irregular bends. Run the stylet through to ensure the tube is unclogged and clean. In case of any joint between the tip and suction body, perform a check to confirm attachment. If the device has a removable tip (E.g. Yankauer's), make sure that the tip is secured after cleaning.

Endoscopic instruments (instruments for minimal invasive surgery) are used to perform surgeries using small key holes, versus the open, large incision technique. These instruments are designed with or without insulation. The insulated ones conduct electricity to the working distal tip. The insulation of these instruments is very susceptible to pin holes, cracks, tears and overall loosening. The electricity that escapes through these insulation failures can cause burns, infections and extended recovery times to the patient. The inspection should start at the distal tip and end at the collar. The insulation should fit tightly against the metal collar. This union should be tight and snug and visibly show no spaces. If the insulation slides, is chipped, cracked or nicked, then the instrument should be sent for repairs.

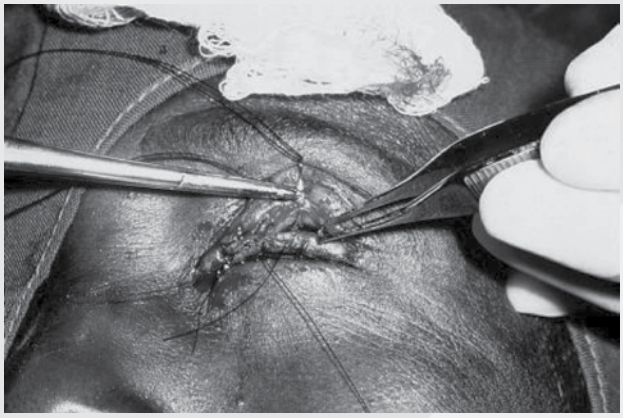
Microsurgical Instruments (small and delicate instruments used in cataract and other ophthalmic or microvascular surgeries) such as micro and suture tying forceps, simcoe cannula, phaco tubings should be routinely examined by trained and qualified staff for any defects. Suture tying forceps should not produce cross action, lest it will cut fine sutures while tying the knot.

Inspect irrigator/aspirator tips, preferably under lighted magnification, before sterilization. Fine instruments with teeth, serrations or points should be examined for chips, missing teeth or sharpness. Also it is important to check cannulae and tubings for dents, cracks and blockages before sterilization. Most ophthalmic surgeons are now discontinuing the use of reusable 27 g cannulas and have switched to using disposable cannulas. Also we must focus on rinsing the Phaco and I+A handpieces immediately after use, by the surgeon stepping on the pedal. In addition, adequate flushing with deionized water and minimum use of chemicals is important while cleaning these instruments.

During the procedure of cleaning intraocular instruments the personnel should carefully wipe the instruments with a damp, lint-free cloth. As the instruments are very delicate, one must be careful to not bend the tips of forceps or cause misalignment of locking mechanisms of needle holders such as Castroviejo needle holders or bend delicate retractors. Diamond/gem blades should be rinsed clean immediately after use to avoid tissue adhering to blade surfaces - outer surface of handle should be wiped clean and not immersed in fluids if such is specified by manufacturer.

Trocars and procedural needles should not have burrs on the sharp cutting edge or scratches or bends in the shaft. Needles can be checked for sharpness by running the tip on a gauze piece. The threads will get pulled in case the needle tip is hooked or improper.

Power Instrument cords should have no cuts or cracks. The same should be visually inspected, and while packing or storing, they should be minimally coiled. Motorized hand pieces of drills and saw should never be submerged in any fluid. These hand pieces must be cleaned manually. Following manufacturers' instructions for checking, cleaning, and lubrication of all parts is mandatory.



Needle holder tips must meet, allowing the suture to be held securely

Summarizing all of the above; every item must be inspected to verify cleanliness and also tested to verify functionality. The instrument must perform effectively every time it is used e.g. cutting edges are sharp, tips are aligned, and all moving parts

operate smoothly. When the instrument or device is disassembled for cleaning, it should be reassembled to perform the functionality testing. The GOLDEN RULE is manufacturer of each instrument / device should provide the specifications, methodologies, and tools needed to perform proper cleaning and functionality testing. This has to be diligently followed by personnel responsible for reprocessing them.

All instruments with moving parts must be lubricated as per manufacturers' instructions. Water soluble lubricants (instrument milk) may be used after the cleaning process. The lubricant could be used in a bath wherein instruments are dipped for specific period. Also, if washer disinfectors are used for cleaning the lubrication could be programmed as part of the washing cycle. Thus the lubricant could be pumped into the machine during the end of the washing cycle. Manually spraying lubricants at specific joints is also a valid method of lubrication. However, lubricants which inhibit the passage of steam e.g. oil, paraffin should not be used. Only steam penetrable lubricants and sprays should be used while preparing instrument sets that would be sterilized by steam.

Surface changes such as corrosion / rusting, discolouration and pitting can be observed on the surgical instruments. These could be caused by:

- Inadequate cleaning, rinsing and drying
- Using tap water
- A malfunctioning autoclave.

Most instruments are made from stainless steel. Stainless steel does not usually rust. However, it can corrode if it is washed in saline or left to soak for a long period of time in any liquid. Once the instrument has started to rust it will become weak, and the rust will eventually destroy and break the instrument (metal fatigue). Rust commonly occurs on chrome or nickel-plated instruments. When the plating wears off, the carbon steel is exposed and is further corroded by autoclaving and washing. If this occurs the instruments cannot be sterilized properly. Inexpensive instruments tend to rust more easily as the stainless steel is of a poorer quality.

While cleaning the instruments water used may contain chlorides, also the soil on instruments such as blood, pus or other body fluids that contain physiological salt, naturally contains chlorine. These chloride ions being very reactive can cause corrosion of any metal instruments which is visible as minute holes in the steel, known as "Chloride induced pitting". These holes may harbor micro organisms as well as induce 'stress' which would further damage the instrument. It is thus essential that any chloride and other ions are removed during the final rinse of instruments. Use of distilled water for the rinsing has thus proved beneficial in avoiding damage of the instruments.

Sodium nitrate is an anti-rusting agent and can be used in conjunction with the lubricant or on its own.

Instruments not rinsed thoroughly after chemical sterilization will stain. Manufacturer's recommended soaking times must not be exceeded. Thorough inspection may reveal stains or discolouration of the metal. Some stains can be rubbed off with a rubber eraser, but it may leave a rough surface. Contact with hydrochloric acid and iodine should be avoided.

Instrument Repair

While inspecting instruments, if any damage is discovered they should be removed out of circulation and sent for repairs. The repairs may be carried out by the original manufacturer or by other well equipped service providers. The choice would depend on cost factors and other logistics. Some repairs are of an expected type, the classic example is scissors or bone cutters that get blunt over a period of use. A preemptive periodic program for sharpening activity can be planned without affecting routine work.

Preparation Of Instrument Sets for sterilization

While preparing the set it is necessary that it is a complete set both qualitatively as well as quantitatively. Absence of any important instrument can affect the surgery outcome or cause misuse of an existing instrument. This in turn can damage the instrument permanently. Effective sterilization depends not only on the correct operation of the sterilizer, but also on correct methods of assembling, packing and arrangement of load in the sterilizer.

The arrangement of instruments must permit air removal which will ensure contact of the sterilant with all the surfaces of the device. Overcrowding will cause increased metal mass and inhibit vaporization of condensate after the steam sterilization exposure

time that may result in 'wet packs'.

Protect the instruments from damage and facilitate handling, transport and aseptic presentation. Sharp and micro instruments should be protected by means of holders, silicon mats, tip guards or foam which is permeable to the sterilant being used.

Reviewing the instrument sets periodically enables addition of any new requirement and removal of those that are not used. Contents of the pack should be as per the users' requirements. For the same procedure / surgery the set should be uniform. If, due to a surgeon's preference or an unusual situation, an additional device is required, this should be packed separately. Also surgeons should examine micro instruments such as intraocular instruments under the microscope prior to each use and reject any instrument that shows signs of residual debris or defects.

Instruments should be sterilized in a stainless steel, heat tolerant plastic or aluminum tray which has a perforated or wire mesh bottom and lid. The perforations optimize air removal and sterilant penetration. Rubber tubing should be laid out in a manner that will avoid any kinks. Glass jars and cans with lids are hazardous. It is difficult for steam to enter and displace the air through the one opening. If lids are used, they must be left off and wrapped beside the jars in the package. Peel Pouches should not be used inside instrument trays as while handling these may not stand on edge. Maximum weight of any set should not exceed 10 to 12 kg. (22 to 25 lbs).

A very common container used to assemble instruments and linen required for a particular surgery is an S.S. drum. This kind of container is considered out-dated today for the following reasons:

- The lid is fixed with the help of a single hinge which is vulnerable to breaking after few uses.
- The portholes have to be opened before sterilization and closed after sterilization which allows for human error of either being not done.
- There is a tendency to fill up the drum too tightly which in turn compromises sterilant penetration.
- Difficult to validate shelf life

During expansions or in case of increased requirements it would be appropriate to invest in perforated trays or wire baskets where the instrument placement would allow effective sterilization.

However, if the existing S.S. drums must be put to use a viable option is to keep portholes permanently open and then consider the drum to be a container with perforations. Instruments and other requirements could be placed in the drum (allowing for proper sterilant penetration i.e. not too tightly packed) followed by wrapping with linen or other non woven wrappers similar to other instrument trays.

While preparing a pack that has basins nested one inside the other, the diameter of each should be at least one inch apart and an absorbent towel placed between each. As steam contacts the basin, it is cooled and forms droplets. The towels between the basins absorb the moisture and facilitate drying. The weight of the wrapped basin sets should not exceed 3kg.

PACKING AND PACKAGING MATERIAL

The packaging material selected must be suitable to wrap and hold the article being sterilized, allow proper sterilization followed by sterility maintenance and finally aseptic delivery to point of use. The merit of packaging material will depend on how effectively and efficiently the above is achieved. Thus the minimal operational requirements are:

- It must be permeable to the sterilizing agent (steam, dry heat, ethylene oxide, or gas plasma)
- It must have excellent barrier qualities
- It must allow adequate air removal from packaging and contents
- It must allow adequate release and removal of the sterilizing agent at the end of the cycle
- It must withstand the physical conditions (temperature, moisture, pressure or vacuum) of that particular process
- It must be compatible with the sterilization process chosen
- It must be sufficiently strong to contain contents during sterilization and further handling
- It must provide a tamperproof closure or seal

- It must be tear, puncture and abrasive resistant
- It must not contain any toxic materials or dyes which may cause reaction to personnel handling
- The packaging material must allow the package to be opened with minimum risk of contamination by fall-out of particulate matter or lint and allow aseptic removal of the contents to a sterile field

Since a wide range of packaging materials are available in varying sizes and configurations it is important to analyse the feasibility of the product to be used. This would differ for different facilities depending on type of workload and quantum of reprocessing done in CSSD.

Manufacturers of the packaging types must demonstrate by scientific evidence that the material is suitable for the specific sterilization methods for which it is recommended and that it does provide an effective barrier to contamination after use.

The Food and Drug Administration (FDA) classifies sterilization packaging as Class II medical device.

Types of Packaging Materials

Flat wrappers, pouch packages and rigid containers are the various options available today to package a device or a set of instruments prior to sterilization.

One of the most versatile wrapping materials is flat wrappers or sheets. The material should be large enough to cover the area to be draped. There are two methods of double wrapping, sequential and simultaneous. Sequential is the method of wrapping one after the other and simultaneous in which both the layers are folded together (most often stitched together). The basic premise is to provide a tortuous path to bacteria, a tamper proof closure, and a package that can be aseptically presented

Flat wrappers are available in both reusable textiles and disposable nonwoven materials.

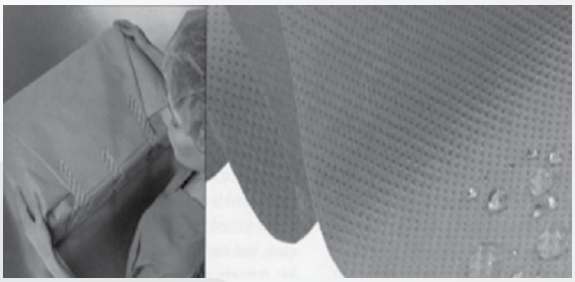


Linen

Reusable textiles have evolved from 140 thread count 100% cotton muslin to the 100% polyester. The newly found textiles are excellent in the barrier properties and hence do not allow fluid penetration or microbial migration. However, the effectivity of this reusable packaging depends on material performance which in turn depends on how it is reprocessed i.e. laundered. Since each textile differs it will have to be laundered as per manufacturer's instructions. The instructions must also specify inspection criteria, number of reuses, any other instructions for wrapping, securing and labeling of the pack e.g. some manufacturers recommend bands to secure packs instead of adhesive tapes as they may leave residues on the material.

The disposable non woven wrappers include a range of paper wraps to synthetic spunbonded polyolefin.

Paper is a non woven material that lacks the flexibility of non woven fabrics. It has an extensive "memory" that makes presentation of packaged contents difficult. However, paper pouches have good barrier properties and are commonly used to pack very lightweight items such as dressings or instruments that are packed separately.



Non Woven Material

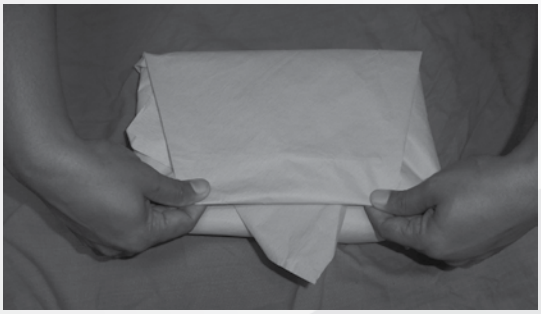
The other non woven material is made by a process wherein a mix of synthetic, textile, inorganic and cellulosic fibres are pressure bonded to form sheets. This means that the fibers are not woven together, but sealed together. These sheets are designed as single use products and are known to have excellent barrier properties. Non wovens generally have the flexibility and handling qualities of muslin but can be torn or punctured by sharp edges. Also these are not very suitable for heavy items exceptions being the thicker (high GSM) and heavier variety. The non woven sheets are compatible to sterilization methods used in hospitals such as steam, LTSF and EO. In case of sterilization by vaporized Hydrogen peroxide the

non cellulosic variety must be used. These wrappers have an advantage of being virtually lint free and resist liquid penetration. However, retention of water caused by steam condensation can result in a wet pack.

Manufacturers must inform regarding recommended storage conditions, inspection criteria and instructions for wrapping, securing and labeling. Rubber bands, safety pins, paper clips, staples or other sharp objects should not be used to secure packages as they can puncture packing material and thus compromise barrier properties.



Paper



Medical Grade Paper

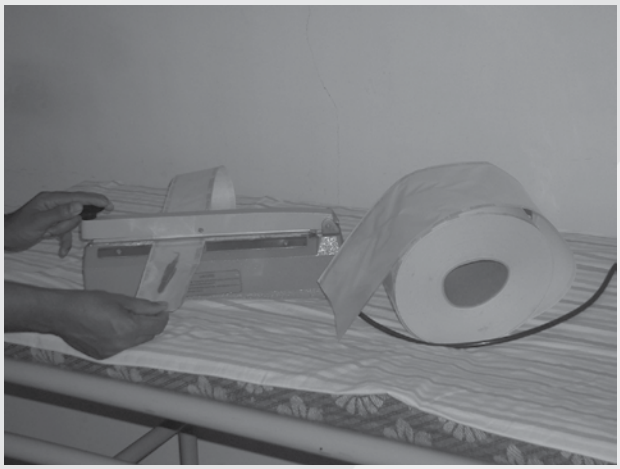


Paper Plastic

Pouch packages are of three types: paper, plastic and paper plastic films. The paper pouches can be used for lightweight items to be sterilized by Steam and EO. Only plastic is generally used for EO and gas plasma. They have a minimum of 2 – 3 mil (20-30 microns) thickness. Before sealing, as much air as possible should be removed to avoid bursting open of packets during sterilization.

The Paper Plastic type is used for sterilization by Steam and EO. They consist of one layer of paper or plastic and one layer of plastic composite transparent film which is heat sealed along the lengthwise edges or tubes dispensed in rolls and reels. They are also available in pre defined sizes with three sides sealed to form a pouch. After filling it with the item to be sterilized the open side is sealed by use of an adhesive tape or mechanical pressure and use of heat. In case of heat sealing the seal should be continuous. Small unsealed areas can be flaws if they transverse the entire band and render the contents open to environment. Options are available between ribbed (multiple narrow) and solid (one broad) seals. To ensure proper sealing, seal checks are available which can be tested periodically.

Rolls or reels are designed to allow the user to cut the desired length and then seal both sides to contain the device to be sterilized. In addition to excellent barrier property there is an in built advantage of being able to see the contents of the package.



Autoclavable Roll

Chemical indicators are printed along the length of the roll and also on the pouches to indicate whether sterilized by steam or EO. These are very basic Class 1

indicators that only differentiate packed goods from those that have exposed to a sterilization cycle. Other specific indicators are used to validate the sterilization cycle.

If a product is to be steam sterilized the packaging must have paper at least on one side to enable sterilant permeability. Paper plastic pouches must only be labeled on the plastic side (as writing on the paper side may cause damage to the package or may leak the ink to the contents) or beyond the seal on paper side. These pouches are called peel pouches as they are peeled open for aseptic presentation of its content. Double pouching is not necessary for sterility maintenance but may be required for aseptic presentation e.g. if several small items are packed in one pouch peeling it open in a sterile field may cause the items to fall out of the sterile field. Item should be placed in the pouch so that the end of the item to be grasped will be presented to the user on opening the pouch.

While placing pouches in a sterilizer it is recommended that they are placed vertically (stands to support pouches are available) as this would optimize air removal, sterilant penetration and drying or aeration.



Rigid Containers

Reusable Rigid Containers are available in various sizes and designs of box like structures with sealable, removable lids with perforations. They are constructed of anodized aluminum, stainless steel, high temperature plastics or combinations of these. The perforations in the top and bottom surfaces are covered internally by sterilant permeable microbial filters. These filters are made of single use materials held in place by retention plates or reusable valves which allow sterilants to enter during sterilization phase and close during drying phase. Unless specified by manufacturers these should not be used in gravity displacements, steam sterilizers. These must have an inner tray to facilitate aseptic handling. All containers incorporate a locking mechanism and external handles. This locking mechanism has to be tamper proof to highlight any unintended opening of a sterilized container and which must result in reprocessing the set.

The manufacturers of the containers and manufacturers of automated washers must collaborate to develop procedures for optimum cleaning of the instruments along with the containers. Also inspection criteria for gaskets, filters, locking mechanisms and expected outcomes must be specified. Specific challenge packs for validation of the container systems must be used to ensure Sterilization Assurance Levels.

Packaging

Sterility maintenance is mandatory as use of unsterile item can cause great harm to a patient. However it is impossible to give a single recommendation regarding shelf life of in house sterilized items. The variables such as barrier quality of wrappers, methods of transport, storage conditions etc differ from one facility to another.

Generally shelf life is as follows: (storage should be ideal – refer chapter CSSD design)

Linen* packed trays or sets	7 days
Medical grade paper packing	1 month
Non woven packing material	3 months
PVC peel pouch packing	1-2 year

*thread count 140

The above is a guideline and should be validated at site before implementation. Thus one must assess his or her facility to develop a system ensuring sterility till the point of use. Collaboration with infection control, risk management, material management, training of end user along with situational analysis and a rational approach is important to standardize expiration dates.

Today the world is moving towards event related shelf life where an expiry date is not allocated to any item. The handling, storage conditions and other events with regards to a sterile pack are parameters that

decide whether the pack is sterile. The key lies in the level of quality consciousness and perfectly controlled environment that the facility can assure.

If reusable woven materials are used for draping the sterile field, to absorb condensate in steam-sterilized instrument trays or to wipe instruments, they should be laundered and rinsed thoroughly between each use to eliminate surgical compounds, debris, and cleaning agents.

Inadequate rinsing of high pH detergents used in institutional laundering can leave chemical residues that could be transferred to intraocular instruments. Laundry procedures should be reviewed and monitored to ensure delivery of residue-free, reused woven materials; otherwise disposable, chemical, and lint-free materials should be used.

All woven materials used in intraocular surgery or instrument management should be lint free.

Recall

Every pack has a label that states contents, sterilization and/or expiry date and batch no along with a chemical indicator affixed.

In the event of evidence of a sterilization process failure, after items have been released, there must be a recall procedure in place to enable a rapid recall of all items suspected to be non-sterile.

A recall notice should:

- Identify the persons or department for which the notice is intended
- State the batch information being recalled
- Communicate regarding area where products must be collected
- Information regarding quantity to be retrieved
- Identify CSSD personnel who would record details of products received
- Include the action to be taken by persons receiving notice - e.g. return or hold for collection by CSSD staff

Proper documentation of recall:

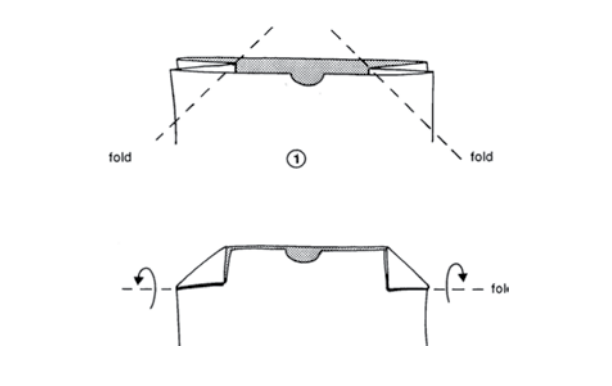
- Why the recall
- When the recall
- Extent of recall i.e. how many products to be recalled
- Success rate i.e. how many actually located
- Number of patients potentially exposed
- The actions taken regarding patient involved
- Where applicable, the actions taken to prevent this happening again

Some facilities carry out a mock recall periodically as a method to audit adherence to protocols.

Sterilising department records must be kept for a period of time not less than that defined by state or local regulations or policy.

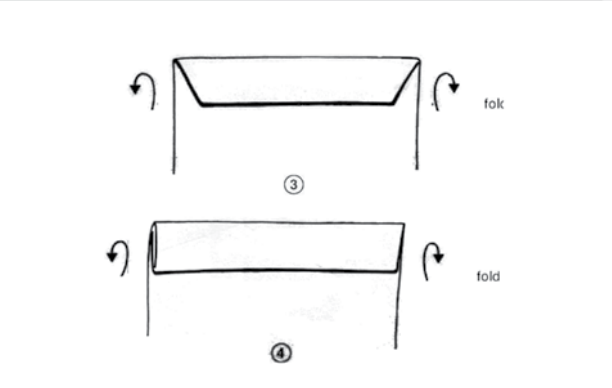
Pictorial Representation Of Packaging Non Rigid Systems

Sealing Plain Closure Bag



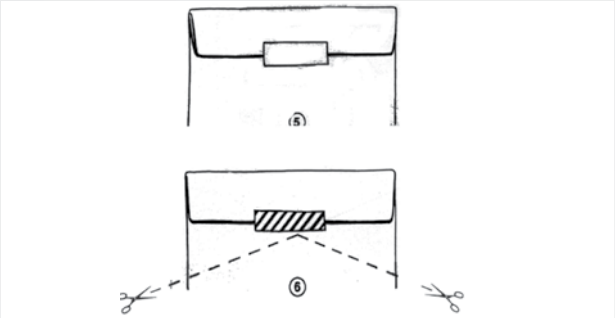
The corners at the open end of the bag are folded diagonally.

Sealing Plain Closure Bag



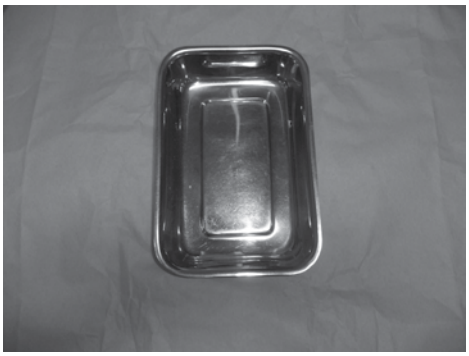
• *The top of the bag is then folded over three times in succession to create a tortuous path.*

Sealing Plain Closure Bag



- *The folds are then secured with a piece of autoclave tape.*
- *Never use staples as it will penetrate the paper.*
- *The bag can then be opened either with scissors or torn open for non critical uses.*

Oblong / Parcel Method



- *Firstly, place contents approximately in centre of wrap.*
- *Then, get the long edges of contents aligned with long edges of wrap.*
- *One of the long edges of wrap is folded over wrap contents to overlap the centre line and the edge of the wrap is turned back on itself.*

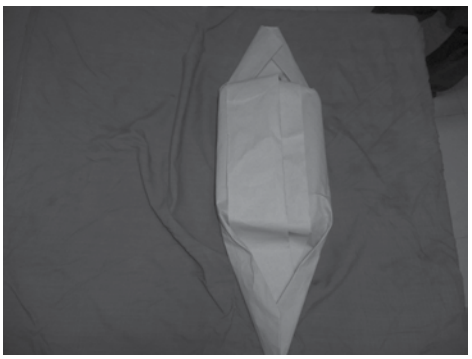
Oblong / Parcel Method





- *The opposite side of the wrap is then folded over pack contents and edge turned back on itself.*
- *The ends beyond the short side of the contents are then folded to a point and each is then folded over the contents.*

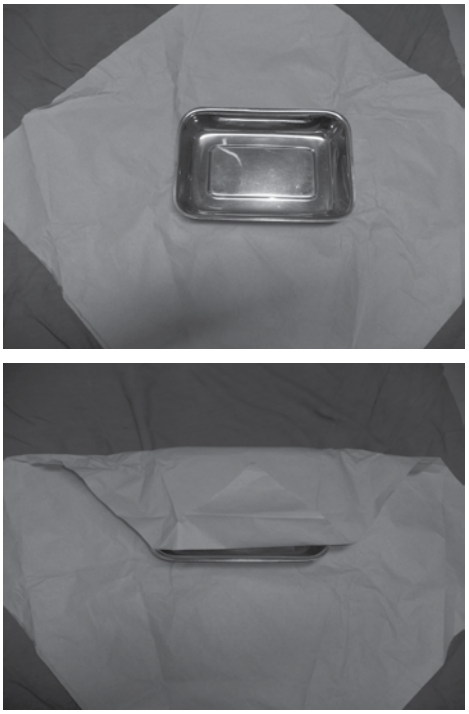
Oblong / Parcel Method





- *The wrap is secured by autoclave tape or can be tied with tape or cord.*
- *Secondary wrapping layers should follow the same procedure.*

Envelope Method



• *Place contents diagonally and slightly off centre*
• *Fold the section of wrap with the shorter corner to pack length over the contents by bringing the corner to centre*

Envelope Method



• *Repeat this step with the corners to the left and the right of the first folded corner.*
• *In each case the corner is folded back to provide a flap for opening.*

Envelope Method



• *Finally the larger fold is brought over the top and tucked in under the earlier folds with a corner protruding to allow aseptic opening.*
• *The envelope fold if properly done is quite secure but can be secured by tape or by tying if required.*

Linen Packs

CSSD prepares and sterilizes linen packs required to drape over the patient, create a sterile field and to be worn by surgeons or other personnel performing surgeries and other invasive procedures in the Operation Theatre, ICUs, and other patient care areas. Linen is also used as a wrapper to pack instrument sets as well as linen packs.

The first reusable material used in Operation Theatre was a muslin fabric known as T-140 where 'T' stands for type, meaning the sum of yarn in both weaving directions (i.e. warp and weft) is 140 per square inch. Developments include more closely woven, improved barrier properties and various microbiocidal coatings etc. Along with muslin which is 100% cotton; now a mix of cotton and polyester is available.

Reprocessing linen in the hospitals involves laundering and sterilization which reduces the effectiveness of properties such as water repellency, impermeability, microbial barrier etc. How many times a linen can be resterilized would depend on various factors. The initial quality of the linen, the way it is handled and also how it is laundered. A 140 thread count sheet would survive approximately 50 cycles of laundering and sterilization.

Technological advancement in the field of textile engineering now provides linen with certified no of reuses by the manufacturer.

Tests such as 'hydro static pressure test' and 'water-resistance impact penetration test' performed at independent laboratories are carried out to assess

the linen. Linen should be of the low linting type i.e. shedding of fibres should be absolutely minimum.

Linen should be packed in a clean, well lit and well ventilated, segregated area. The segregation would prevent the spread of lint to other areas of CSSD. Since lint can be a carrier of microorganisms and dust particles etc., the containment is necessary. Laundered linen received in CSSD should be kept in open shelves for ease of placement and retrieval, as would be required routinely. The reserve stock must be maintained in cupboards with appropriately labeled shelves for proper inventory management.

Fundamentally the linen packs should be assembled so that the item to be used first at the place of use is the last item to be placed in the pack, (i.e. on top). Folding surgeons' gowns inside out enables aseptic gowning procedures. Streamlining of surgical linen system and standardization of packs is very important in a healthcare facility. Different packs will have different numbers and types (dimensions) of sheets (e.g. Bed sheet, Draw sheet) or linen items (e.g. bags to hold defibrillator paddles or cautery). Master lists should be used as a guide while preparing a pack. Patient drape sheets, bed sheets, gowns, and other heavy linen are not included in the basic pack but packed separately as these would increase the size and weight of the pack. The basic packs can be prepared surgery wise e.g. 'orthopaedic pack' or 'endoscopy pack' as per the requirements from departments being serviced.

All linen, whether being used as a patient drape or as a wrapper for sterile supplies; must be inspected for holes, tears, stains, adhesive material or other defects. There should be no loose, unstitched ends. While preparing a pack linen should be laid out loosely, and the layers crisscrossed, so that the linen pack does not form an impermeable dense mass which during steam sterilization may prohibit steam penetration. Gauze and other absorbent items such as mops should be placed near the centre of the pack; as being light and porous, they admit the steam through themselves for contact with heavier articles on either side. Wrappers are used to provide protection against contact contamination as well as to serve as an effective dust cover. They must be large enough to cover the item, without excessive bulk and to provide a sterile field if necessary.

The packs must be secured using adhesive tape with a chemical indicator affixed. These packs are then labeled and the expiry dates marked after which they are sterilized. Packages must not be packed too tightly as it would hamper air removal as well as steam penetration. No package should be above the maximum size (12" x 12" x 20") and weight should not exceed 10 Kg.

Ideally all linen that has been sterilized should be laundered prior to being re-sterilized in order to prevent super heating of excessively dry linen. It is advantageous to have colour code for drapes and wrappers. The linen used as drapes is generally green but using a different colour for wrappers will help in segregation of wrappers from drapes. Thus any linen pack or instrument set will not get packed in a sheet that may at some time have been used as a drape. This thus reduces the damages in wrappers which are unavoidable in drapes due to use of towel clips or other pointed holders.

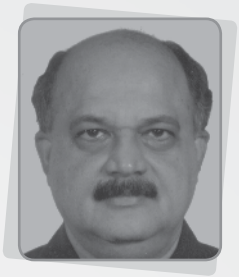
Reusable textiles must be routinely inspected with established criteria for repairs. The check should be with regards to functionality as well as appearance. If high functionality is maintained i.e. gowns and drapes are of correct dimensions fewer would be the no of repairs. At times it is practical to convert a big sheet to a smaller sheet if there is a tear or damage in a relatively new sheet at one extreme end. For other tears ideally stitching or darning is not recommended as repair methods of this type would cause many more small holes. Heat sealable patches using same material or material with greater barrier may be used. They should be placed on both sides of the fabric whenever possible. In case of a two ply construction the patch should be applied on the front side of the tear.

Periodic reviewing of linen (deemed unfit for use) to repair, convert or condemn it must be done by a group of personnel representing departments such as laundry, operation theatre, other patient care areas, CSSD and materials. This is an effective tool for proper inventory control. After the linen review appropriate stock replenishment is required to continue routine work.

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Sterilization Methods and Validation



Sojan Ipe MS(Neuro)

Sterilization is an uncompromising terminology which means destruction of all forms of microbial life including bacteria, viruses, fungi and spores; or in terms of their ability to reproduce. Whereas Disinfection is a process that reduces the number of pathogenic microbes to an acceptable level, not necessarily bacterial spores. In this chapter we are dealing with various sterilization methods.

The objective of sterilization is to reduce the risk of a patient acquiring nosocomial infection. The purpose is to render instruments, dressings, implants and other medical devices sterile to ensure that these items do not transfer any microorganisms into patient's body. Introduction of even a few microorganisms can lead to full blown infection in a few hours. Sterilization should provide the highest level of assurance that an object is free of all viable microorganisms.

Microorganisms vary in their susceptibility to disinfection or sterilization process (Table -1). Lipid containing (Lipophilic) viruses and the vegetative forms of most bacteria are relatively susceptible. Acid-fast bacteria, non-lipid (Hydrophilic) viruses and fungi are less susceptible while bacterial spores are more resistant to the process. Prions, an infectious agent which are proteins in a misfolded form, are highly resistant.

No one should think in terms of partial sterilization. It is either sterilization or disinfection at varying levels as listed in table 1:– High, intermediate or low levels.

Sterility Assurance Level (SAL): The concept of what constitutes 'sterile' is measured as a probability of sterility for each item to be sterilized. This probability is referred to as the Sterility Assurance Level (SAL) of the product. It is defined as the probability of a single viable microorganism occurring on a product after sterilization.

SAL is normally expressed as 10^{-n}. If the probability of a spore surviving were one in a million, SAL would be 10^{-6}. To call an item sterile you must achieve a Sterility Assurance Level of 10^{-6}. This means that if you start a sterilization process with 1 million microorganisms, all except one would be eliminated. That must be the guarantee given by definition. If there are 100

Sterilization		
Prions	prion is a protein in a misfolded form; an infectious agent, not a microbe	
Spores	Bacterial	Geobacillus Stearothermophilus, Bacillus Atrophaeus and Subtilis, Clostridium Sporogenes
	Fungal	Spores of Penicillium, Aspergillus
High Level Disinfection		
Mycobacterium		TB Bacilli var. Bovis, Non-tuberculous Mycobacterium
Intermediate Level Disinfection		
Hydrophilic Virus	Non-lipid or Small Viruses	Poliovirus, Coxsackievirus, Rhinoviruses
Low Level Disinfection		
Vegetative	Fungi	Trichophyton, Cryptococcus, Candida
	Bacteria	Pseudomonas, Staphylococcus, Salmonella, Enterococci
Lipophilic viruses	Lipid or medium sized	Herpes Simplex Virus (HSV), Cytomegalovirus (CMV), Respiratory Syncytial Virus (RSV), Hepatitis B&C(HBV,HBC), Human Immunodeficiency Virus (HIV)

Table – 1: List of microbes and Prions in the descending order of resistance against sterilization

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million to start with 100 spores may remain. That is the reason why you must clean an instrument well prior to sterilization, to reduce the biological burden. If anyone thinks that a clump of dirt or clotted blood can be sterilized, you are wrong.

Cleaning and packing of instruments and linen are all explained in the previous chapter. One must have a clear understanding about the Spaulding Classification of Medical Devices to select ideal sterilization method for a given instrument. Medical Devices that come in contact with body tissues and fluids are considered as critical items. Such items including surgical instruments, biopsy forceps, implanted devices, etc must be sterilized. Sterilant does not penetrate blood, pus, oil or grease left on the surface of the instruments. Always leave space between packs to allow free passage of sterilant. Therefore, sterilizer chamber should not be packed tightly and the packs should not touch the chamber wall.

The spore (Fig-1) contains a chromosome, two cell membranes, cortex, spore coat, and a surrounding cell wall (exosporium). Spores are likely the most resistant forms of life known. Some spores can survive boiling for 2 hours and in alcohol for 20 years. If spores are given adequate exposure to nutrients, temperature, moisture and light at any point of time, they revive.

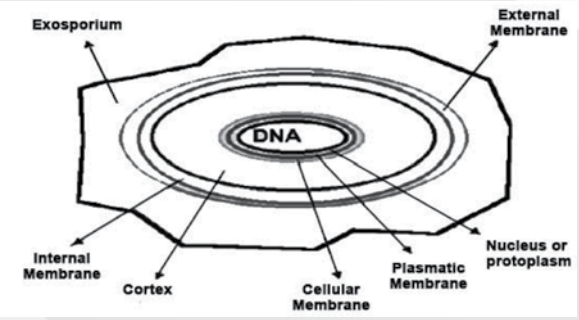


Figure – 1: Structure of spore

You must render an item free of all living microorganisms including spores at the end of a sterilization process. After sterilization there must a guarantee that the material provided is free of all viable microorganisms including spores to the tune of SAL10^{-6}.

Physical and Chemical agents

There are several physical agents like heat (Steam or Dry Heat), ionizing radiation (Gamma or Electron Beam), microwave, etc in use and other chemical agents like Formaldehyde, Ethylene Oxide Gas (EO), Ozone and liquid chemicals like Gluteraldehyde or Ortho-pthalaldehyde(OPA). In addition there are some new generation agents using Peracetic acid gas and Hydrogen Peroxide gas plasma as sterilant.

Dry heat is used for sterilizing anhydrous materials like certain oils, paste, grease and powders which cannot be sterilized by steam because it will not penetrate the substance. Dry heat sterilizers will not be considered in this chapter.

Low Temperature Steam-Formaldehyde gas sterilizers and Ozone also are not considered since there is no satisfactory marketing support in India. Peracetic acid gas plasma was removed from market because of the reports of destruction of cornea of patients when ophthalmic surgical instruments were processed using this system. Ionizing radiation is used in manufacturing facilities for disposable items. Gluteraldehyde and OPA are chemical agents used for high level disinfection and are included in another chapter.

We will discuss various steam sterilization techniques, and low temperature sterilization with Ethylene Oxide and Hydrogen Peroxide gas plasma.

Steam Sterilization – Autoclave

Overview: Steam sterilization is the oldest, cost effective, readily available nontoxic and the most understood method of sterilization of items that can withstand heat and moisture. Most medical and surgical devices used in healthcare facilities are made of materials that are heat stable. The basic principle of steam sterilization is to expose each item to direct steam contact at the required temperature and pressure for a specified period of time.

Mode of action: Destruction of the microorganisms is dependent on temperature/pressure, saturation of the steam and the time of exposure. Steam kills microbes by denaturation of enzymes and coagulation of structural protein in the cell.

The common sterilization temperature is either 121^{0}C or 134^{0}C and must be maintained for a minimum specified time to kill the microbes. The sterilization cycle varies between 1/2 an hour to 1½ hours depending on the type and size of the sterilizer. Understanding how a steam sterilizer is designed and how the sterilizer works is fundamental to using that machine properly.

Understanding steam: when water reaches 100^{0}C on boiling, the water evaporates. The steam thus formed is having the same temperature as water which is the saturation temperature at atmospheric pressure. The heat that the steam carries is called the latent heat of vaporization.

The saturated steam at 100^{0}C is not high enough to kill resistant microbes. To raise the temperature of the saturated steam to the required temperature, the pressure inside the autoclave chamber is proportionately increased. The pressure inside the chamber is raised to 1.2 kg/cm^2 (15-PSIG) for achieving 121^{0}C saturated temperature or to 2.2 kg/cm^2 (30-PSIG) for 134^{0}C.

When steam comes in contact with a cold object, steam gives up the latent heat to the object and changes back to liquid water. Thus condensate is formed. This condensate and the steam are both at the saturation temperature for the saturated pressure. During condensation the volume occupied by the steam is decreased which is made up by steam injected from the steam jacket around the chamber in an autoclave and the condensate is drained.

The quality of steam is important. Once the maximum amount of liquid water has been vaporized at a given temperature and the water exists only as vapor, it is referred to as saturated steam. Saturated steam, as it condenses provides the maximum amount of heat transfer to the objects being sterilized. Steam should not contain more than 3% moisture, which is the entrapped liquid component of water. The dryness fraction of steam should be >=97%. If steam is too wet the packs undergoing sterilization will be damp at the end of the process. Wet or damp articles at the end of steam autoclaving show that the drying cycle was ineffective to achieve the required SAL.

Factors affecting steam sterilization: Three factors are critical to ensure steam sterilization: (1) Temperature/Pressure (2) Steam and (3) Time. We keep referring to parameters of Temperature/ Pressure, Saturation of Steam and Time of exposure as TST. All sterilization failures can be traced back to one or more of these factors not being adequate. Techniques for cleaning, drying, packing of items and loading the sterilizer are all meant to ensure that these three factors are adequately achieved during sterilization with steam.

Time: when a large number of microbes are exposed to steam at a constant temperature, all the microbes do not die at the same time. This time varies from one microbe to another. This means that the rate of kill is proportional to the time of exposure. The time taken for achieving the SAL of 10^{-6} is called the 'Kill Time'. The Kill Time is the component that is scientifically determined. It is the time required to kill all microorganisms at a specific temperature. The minimum timings required by steam sterilizer for killing Geobacillus Stearothermophilus are:

- 12.0 minutes at 121^{0}C (250^{0}F)
- 0.9 minutes at 132^{0}C (270^{0}F)
- 0.5 minutes at 135^{0}C (275^{0}F)

Notice the indirect relationship between time and temperature; the higher the temperature, the shorter the time required to kill. 'Kill time' for Stearothermophilus is selected because the time required to kill all other spores found in hospital items are much shorter.

Temperature: Increasing temperature dramatically reduces the time need to achieve sterilization. For Stearothermophilus twelve minutes would be required at 121^{0}C and only less than a minute is required above 132^{0}C. The range of temperature/pressure against time, are determined by deactivation of one million highly resistant bacilli. The standard recommended kill time for hospital cycles are 15 to 20 minutes at 121^{0}C or 3.5 to 7 minutes at 134^{0}C; therefore having a tremendous safety factor.

If the bio-burden on the instruments is high due to improper cleaning, the proposed time and temperature are not enough to achieve the required SAL of 10^{-6}. Remember that all the microbes do not die at the same time during a sterilization process; the rate of kill is proportional to the number of organisms at the start of a time period.

Saturated Steam: The importance of moisture in the sterilization process is illustrated by the comparison of saturated steam and dry heat sterilization times at a common temperature. Geobacillus Stearothermophilus spores will be killed in12 minutes at 121^{0}C when saturated steam is used, but it takes more than 6 hours when these spores are exposed to dry heat. Air is a poor conductor of heat. You can keep your hand inside an oven for longer time than over

steam coming out of a kettle. The steam carries latent heat across air and as it touches your skin the heat is released by condensation of steam; but inside an oven the radiated heat takes longer time to 'burn' the skin.

The enhanced killing time of steam is due to the effect of moisture on reducing the temperature required to denature or coagulate proteins. In case of dry heat, microbes are dehydrated before the temperature rises enough to cause the protein to denature. And also, air is a poor conductor for dry heat but steam can penetrate the items freely to transfer the heat for sterilization.

Practical points: Inadequate air removal is the greatest impediment to steam sterilization. Air is a barrier for steam penetration. Trapped air in the sterilization chamber can inhibit steam from contacting surfaces of items to be sterilized. Therefore, transfer of latent heat does not occur on the surface of items and instead dry heat condition prevails. Methods for removing air prior to steam sterilization will be considered later in the chapter.

Choose the appropriate packaging material that allows the steam to penetrate effectively. Steam can effectively penetrate cloth, paper, polyester and polypropylene (PP) but not polythene. Devices should be packed loosely and the sterilizer chamber loaded with gaps, so that the steam can pass around and penetrate through each package.

It is important to assure good steam quality. The source of steam must be external to the sterilization chamber. If water and steam remains in the same chamber the resultant steam will be 'wet'. RO water, distilled water, de-ionized water or even rain water may be used to produce high quality >97% dry saturated steam. Tap water should not be used because of the possible dissolved chemicals, gases and salts. Scaling can occur on the sterilizer surfaces and instruments when the water pH is low and corrosion of metallic surfaces occur when the pH is high.

Steam sterilization cycle phases: As you have already read the removal of air from the chamber and load is absolutely critical to accomplishing steam sterilization. Air can be allowed to leave the chamber passively or be actively removed. Hollow, porous (linen and other dressing materials) and packed load types have one thing in common; air is trapped inside these instruments and fabrics, resulting in air pockets that prevent the full penetration of steam. It is known that spores can survive at 134^{0}C in 'air pockets' because steam cannot penetrate these areas. Steam should act evenly on the entire surface of all items in the pack for the kill to occur.

The solution is to remove the air completely to maximize steam penetration to instrument components. Fractioned prevacuum air removal from the autoclave chamber eliminates air pockets from all load types allowing complete steam penetration. There are two basic types of steam autoclaves used in health care settings today:

(1) Gravity air-displacement autoclaves

(2) Dynamic air removal autoclave (either prevacuum or with steam pressure pulse)

All steam cycles undergo 4 phases:

(1) Conditioning (air removal) phase

(2) Come-up (warming up) phase

(3) Exposure (holding time)

(4) Post-conditioning (Exhaust/Drying)

Phase I – Conditioning (Air Removal). In a gravity air-displacement autoclave (Fig-2) conditioning is done by gravity air removal.

The basic principle is that the density of air is 1.6 times greater than that of steam. Steam enters from the top backend of the chamber and remains on top. Air will settle to the bottom of the chamber, to be evacuated as more steam is introduced into the sealed sterilizing chamber. The air outlet is placed at the front lower end of the chamber. As steam fills air is removed passively by gravity displacement. In gravity displacement, it is critical that all packages and all items that can entrap air because of their construct should be arranged in a manner that will allow air to flow out of them in a downward direction, under the influence of gravity.

In a dynamic air removal cycle, air is actively removed from the chamber and the load. The two types using this technique are the prevacuum and the pulsing gravity sterilizer (Steam Flush Pressure Pulse-SFPP).

In prevacuum, steam is injected into the chamber with drain valve open to purge air from the chamber. Then the drain is closed and more steam is let in to the chamber under pressure when a mixture of steam and remaining air occurs. Then the drain is opened

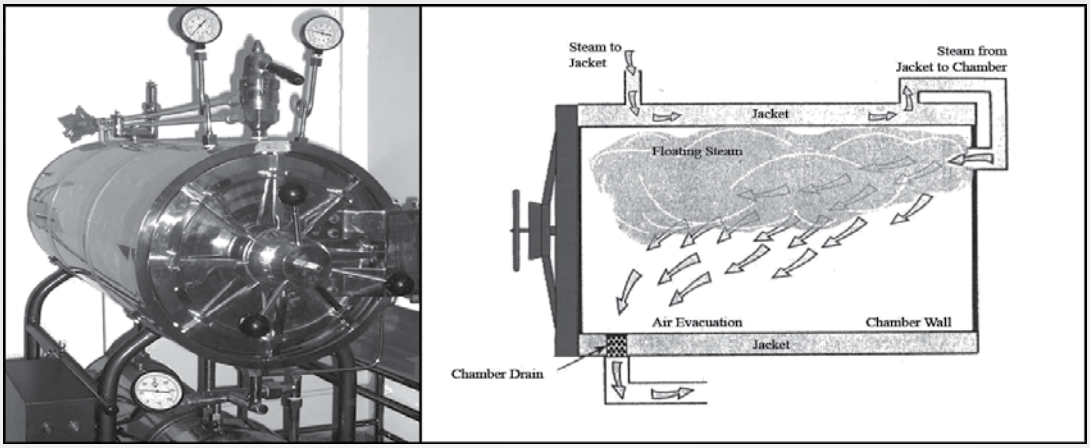


Figure – 2: Steam entry and Air removal in a Gravity Air-displacement Autoclave

allowing the pressurized steam/air mixture to rush out, aided by a vacuum pump. This sudden escape of gases causes the pressure inside the chamber to drop below atmospheric pressure to create vacuum, thus the name prevacuum (Fig-3). This process is repeated 3 or 4 times until all the air is removed allowing effective steam penetration. Prevacuum sterilizer is efficient in air removal and hence is not as dependent on the positioning and makeup of the load as in a passive gravity sterilizer. Pulsing gravity sterilizers - SFPP model use the introduction of pulses of steam to aid in air removal but do not use a vacuum pump at the end of each pulse. Air is removed by purging steam through the chamber with a series of steam pressurization. This process is repeated 3 to 4 times because complete air removal is not possible at one go. With each cycle of steam flush and pressure pulse the air fraction decreases. These repeated steps, allows complete air removal. The main difference from prevacuum is that in SFPP the conditioning pulses are always in the positive pressure range with no vacuum created and consequently no chance of air to leak back into the chamber.

Phase II – **Come-up (Warming Up)** is that point within the cycle after air removal, in which steam injection is taking place in an attempt to raise the chamber temperature to the desired set point, typically 121^{0}C or 134^{0}C (Fig-3). The steam gives up its latent heat to the 'cold load' which begins to warm. After losing heat the steam condenses to water which is removed through the drain. To raise the temperature of the steam to the desired level the pressure inside the chamber is appropriately raised. More steam comes in to replace condensed steam and this process continues till the whole load inside the chamber reaches the selected saturated temperature and pressure. Now the come-up phase ends and exposure begins.

Phase III – **Exposure** or the "holding Time" is the term used to indicate that the chamber is maintained

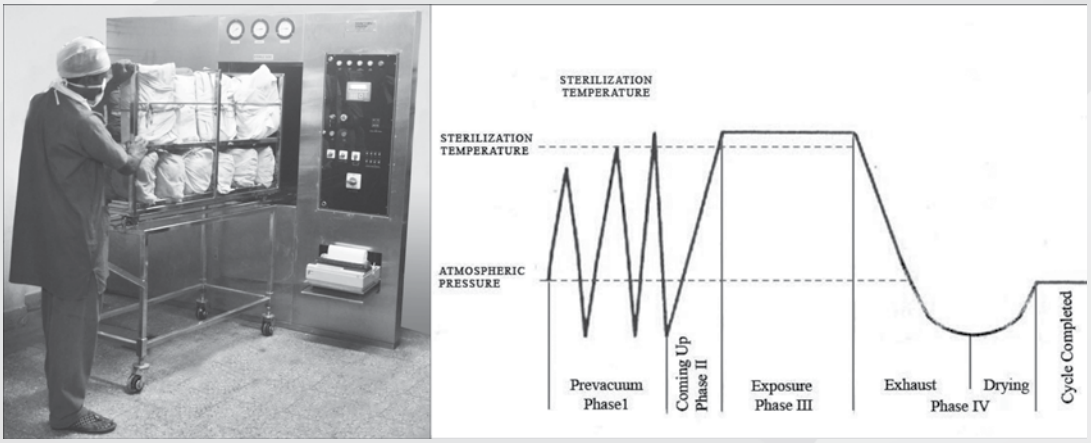


Figure – 3: Typical Prevacuum Dynamic air removal Cycle

at the desired temperature for a specific period of time. The time equals the prescribed 'Kill' time against the temperature. Typical minimum exposure time for gravity displacement autoclaves are 3.5 minutes at 134^{0}C or 15 minutes at 121^{0}C. This time can be lengthened to 'over kill' but never shortened. Typical over kill safety factor is approximately 50% of minimum exposure time. Some recommendations for over kill are for 7 to10 minutes at 134^{0}C or 20 to 30 minutes at 121^{0}C in a gravity machine where there are more chances of incomplete air removal. This may be calculated and monitored manually in manual machines or by programming the computerized control panel in automated equipment.

Phase IV – Post-conditioning (Exhaust / Drying): The objective of post-conditioning is to cool and dry the objects within the chamber and return the chamber to ambient conditions (Fig-3). At the end of adequate 'exposure' the chamber is still under steam pressure. This needs to be exhausted after cutting off the source of steam and opening the discharge line, manually or automatically. As the steam rushes out, a mild natural vacuum is created inside the chamber. Air is gradually let in at the end of exhaust through air filters. The chamber now comes back to atmospheric pressure.

Just as the steam transferred heat energy and formed condensate during the heat up phase, energy must be supplied back into the condensate to vaporize back into steam. Heat to evaporate the remaining condensate must come from the residual heat in the items or heat transferred from the chamber walls. Jacket heat for this reason is maintained during the drying phase. Make sure that the items are dry when packed and loaded in the sterilizer to minimize condensate pooling. The condensate pooling can be minimized by placing absorbent linen at the bottom of the instrument trays. The absorbent material will act as a wick, increasing the surface area of the condensate, so that it can be vaporized effectively by the heat energy.

It can be very difficult to remove moisture from items within a loaded chamber with packs containing filters and tubing, by the above mentioned phenomena alone. In large instruments with lumens, the condensate will collect in the inner surface. In these cases, the drying phase may need to be extended to vaporize the condensate.

This deficiency in a manual gravity autoclave is solved in a pre-post vacuum sterilizer by a vacuum pump and a water ejector for complete drying. Based on the combined operation of heat and vacuum air-removal, the left-over moisture will quickly evaporate from the chamber. The low pressure in the chamber caused by the vacuum reduces the boiling temperature and the moisture evaporates faster. The chamber is continuously evacuated during the drying phase to remove steam from the chamber and the load. Finally, dry air is passed into the chamber through a bacteria free air filter for final drying and breaking of the vacuum.

The load should be left inside the sterilizer until all the steam has escaped. Remove items only after initial cooling and drying. Condensation becomes more serious with packaged loads, when moisture can remain after the cycle ends. A moist load does not guarantee sufficient SAL. Damp packs at the end of sterilization are susceptible to recontamination because bacteria can be transported through the packing by the wicking action of packing material. For this reason items should not be kept on a cold metal surface until the packets are cold and dry.

Prions: A short discussion on prions may be appropriate at this level of knowledge. A prion is an infectious agent (not a microorganism) composed of a protein in a misfolded form. Prions are not alive but can hijack the functions of a living cell to cause diseases like Creutzfeldt-Jakob Disease (CJD), Kuru, etc. in humans. This altered structure of protein are resistant to denaturation by standard sterilization techniques used in hospitals by chemical and physical agents. Hence prions are more resistant than spores to sterilization.

Iatrogenic CJD have been described in humans from the use of contaminated intracranial electrodes and contaminated tissue grafts (cornea and dura grafts) in the US, UK and Germany. Prions are shown to bind tightly to the surface of medical devices and it is difficult to remove by cleaning. Neurosurgical instruments used in brain parenchyma are at high risk after using it on CJD patients. Brain, dura mater, spinal cord, posterior eye, corneal transplants and pituitary tissue are considered as high risk tissues for

transmission of CJD. The current recommendations are to use disposable instruments as far as possible for surgeries on known CJD patients. Reused instruments after surgery, before drying must be soaked in Sodium Hydroxide for one hour at room temperature and autoclaved with prevacuum steam sterilizer at 134^{0}C for 1 hour. Fortunately, as of today, no proven cases of CJD have been reported in India.

Flash sterilizers

"Flash" steam sterilization was originally designed for an unwrapped object at 132^{0}C for 3 minutes from where the name was derived. It should be used only

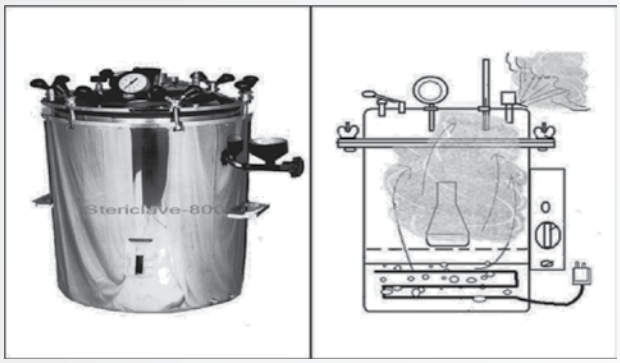


Figure – 4: Cross section of a basic Vertical Steam Sterilizer

in urgent, unplanned or emergency situations for immediate use of an instrument when time does not permit a regular wrapped cycle. Flash takes less exposure time since the chamber is small which takes less heating time. Air removal is not complete and there is no drying time. Instruments are unwrapped, wet and hot at the end of the cycle. Hence chances of staff and the patients getting burns are to be addressed. Flash should not be used for reasons of convenience to save time or as an alternative to purchase additional instrument sets for saving cost. It should not be used for routine sterilization of packed instrument sets.

Items to be flashed are placed in an open tray or containers to allow rapid penetration of steam. The possibility of contamination of processed item is high during transportation to the operating room (OR). The longer a sterile item is exposed to air, the greater the number of microbes that will settle on it. Hence place the flash unit in close proximity to the OR to facilitate aseptic delivery to the point of use.

Though historically these facts are true for gravity displacement flash autoclaves, at present modern pre-post vacuum flash units are available for wrapped items. After understanding the technology behind each autoclave design, you can modify the protocols in your practice.

Vertical Autoclaves

Vertical sterilizer (Fig-4) can be considered as a large pressure cooker where water and steam are inside the same chamber. Water remains at the bottom of the sterilizer. Steam is generated by heating the water. Pressure gauges, temperature gauges and exhaust are fixed at the top on the lid. Since the water is boiling below, droplets of water will enter the steam. The steam thus formed will always be wet. Moisture content will then be more than the prescribed 3% for saturated dry steam for autoclaves.

Air removal in vertical sterilizers is done by dilution technique. When air and water are heated together at temperatures above boiling, the air and steam mix. As vaporization proceeds, air and steam are vented from the top of the chamber. The amount of air removed is a function of the amount of air-steam mixture allowed to escape. This 'bleeding' process is continued until the air is completely removed. The load is then exposed to steam for the "kill time". Knowing the other techniques of air removal described before, it is an inefficient method for air removal before sterilization.

Items for sterilization will be kept on racks above the boiling water inside the chamber and hence condensation and re-vaporization of wet steam can never be complete, leaving the items wet at the end of sterilization. These items cannot be packed in linen or stored for later use. The technique of air removal will not work efficiently for wrapped packs and complex instruments with lumen. Vertical sterilizers are generally used for disinfecting contaminated load from micro-laboratories and other areas of the hospital and not recommended for surgical instruments.

Note: This discussion is not for modern prevacuum vertical sterilizers available commercially for sterilization for all types of loads.

Low Temperature Sterilization Techniques

Since 1950 there has been an increase in medical devices and instruments made of plastic material, which are heat and moisture sensitive. Sterilization temperature is kept below 60^0C during low temperature techniques. Ethylene oxide (EO) gas has been used as a low temperature sterilant instead of steam. Within the past two decades, a number of new low temperature sterilization systems are in the market – Hydrogen Peroxide Gas Plasma, Peracetic Acid Gas Plasma, Steam-Formaldehyde gas sterilizers and Ozone. This section reviews low temperature sterilization techniques used with EO and H_2O_2. The other techniques are not prevalent in India.

I : Ethylene Oxide Sterilizers

Overview: Two types of EO gas sterilizers are available, 100% EO and EO mixed with stabilizing gases like Carbon Dioxide or Hydrochlorofluorocarbons (HCFC). Sterilization with 100% EO is preferred. EO is a colorless gas that is inflammable, explosive and toxic. EO is having the maximum diffusion rate with an ability to penetrate more than steam or hydrogen peroxide gas plasma. It can be used to sterilize items sensitive to moisture and heat including most plastic or rubber products such as catheters, resuscitation bags, anesthesia masks and fiberoptic instruments. Non-heat-sensitive items like surgical instruments, paper, cotton, linen can also be sterilized using EO. However items that can be autoclaved with steam should not be considered for EO.

Mode of action: The microbicidal activity of EO is the result of alkylation of proteins and genetic material. Alkylation is effected by substitution of hydrogen group atom with an alkyl group, which prevents normal cellular metabolism and replication of the organism. Extremely dry organisms may not be destroyed by this process. Hence relative humidity during the sterilization process is important which enhances EO penetration and aids in the chemical alkylation process.

Factors affecting EO sterilization: four main processing parameters affect the inactivation of microorganisms by EO:

(1) Gas concentration

(2) Relative humidity

(3) Temperature and

(4) Exposure time.

Make sure that items are absolutely dry before packing them for EO sterilization. Humidity and temperature are controlled such that moisture does not condense during sterilization. Water droplets are detrimental since dissolved EO can dry up and form ethylene glycol which is a noxious product and also will prevent surface contact with EO for sterilization. EO can effectively penetrate all packing materials used for steam - cloth, paper, polyester, polypropylene (PP) and also polythene, provided humidification is done adequately.

Gas Concentration: EO concentration in hospital processing cycle, are commonly from 450 to 750 mg/liter. As gas concentration is increased at a given temperature and relative humidity level, the microbial inactivation rate also increases significantly.

Relative humidity (RH): The moisture content (humidity) is necessary for the alkylation reaction for the sterilization process. Moisture carries EO to reactive sites and microbes need to be hydrated to make it susceptible to the bactericidal effect of EO. Approximately 35% RH at the site of microbial reaction is optimal for effective inactivation. In practice within EO chamber humidity is kept at a higher level between 40% and 80%. This level ensures the driving force to 'push' the moisture through packing and products to achieve a minimum 35% RH at the site of microbial inactivation. Humidification also assists in heating the materials to be sterilized to the processing temperature

Temperature: EO cycles are performed in a temperature range of 37^0C to 60^0C. The inactivation level will increase and the permeability of EO increases with rise in temperature. Typically, Warm Cycle is done at 55^0C and a Cold or Cool Cycle at 37^0C in hospitals.

Exposure Time: in general there is a direct relationship between the first three parameters and time required to achieve lethality. Higher the EO concentration, RH and temperature lower the exposure time for the kill. The Exposure time ranges between 2 and 5 hours, typically 2 hours for Warm cycles and 5 hours for Cold (Cool) cycles.

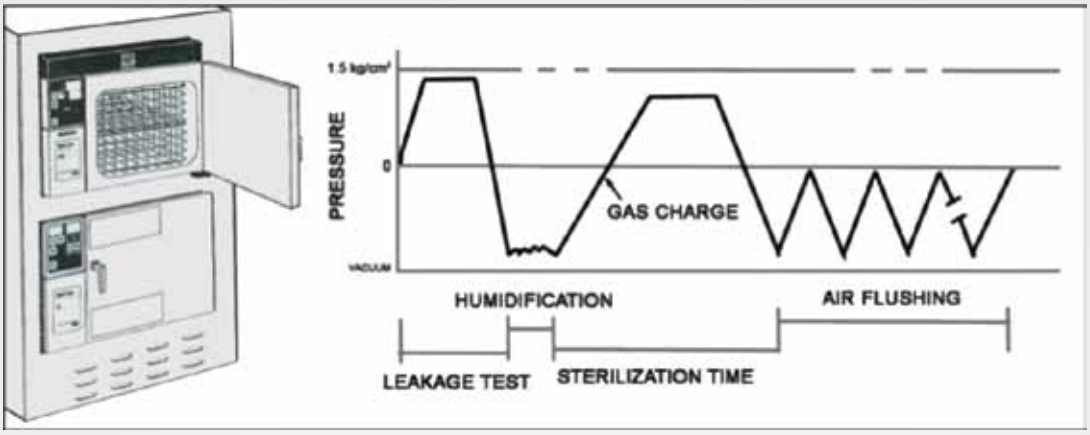


Figure – 5: EO sterilizer with aeration chamber and EO Gas Sterilization Cycle

EO sterilization cycle phases:

The basic EO sterilization cycle consists of four phases (Fig-5). The four phases are (1) air removal, (2) steam injection and conditioning dwell, (3) EO injection and gas dwell, and (4) gas purging and air filling.

During the first phase air is evacuated from the sterilization chamber using repeated vacuum and injection of steam for humidity. Once the air removal is complete, during the second phase more steam is injected for the humidity to reach >50% and the temperature is built up to the desired level of either 37^{0}C for cold cycle or 55^{0}C for warm cycle. The moisture in the chamber also allows easier absorption and desorption of the EO gas in and out of the products. Dwell means the holdup time. During the third phase, EO gas is injected to the warm and humid chamber to build up the desired concentration. The concentrated gas is held in the dwell phase for a period of time to achieve the validated sterility assurance level. During the last phase the gas remaining in the chamber is washed off using purges of filtered ambient air. The chamber after the final evacuation is brought back to ambient conditions.

Heated Aeration: EO is absorbed by many materials during sterilization. Mechanical aeration for 8 to 12 hours at 50^{0}C to 60^{0}C allows desorption of toxic EO residual contained in exposed absorbent material. The sterilized load is then transferred to a heated aeration chamber where it remains for a period of time in circulated heated air. Some models of EO sterilizers combine sterilization and aeration in the same chamber as a continuous process. The total sterilization cycle with aeration will be 10 to 12 hours for warm cycle and 14 to 16 hours for cold cycle. The items should be stored at ambient room temperature for another 24 hours before release for use, to be on the safer side. Hence one of the major disadvantages is the prolonged throughput time of the instruments. If the aeration chamber is separate, the sterilizer can be reloaded immediately for saving time for the next batch of instruments.

EO has one distinctive advantage over steam and the other low temperature alternatives that it has the maximum diffusion rate with an ability to penetrate into lumens less than 1mm and the internal configurations of complex devices, there by contacting all surfaces to achieve sterilization. It is compatible with a wide variety of packing and product material and having superior inactivation properties.

The main disadvantage is the lengthy cycle time as discussed before and its potential hazard to patient and staff. Chronic inhalation has been linked to formation of cataracts, cognitive impairment and poly-neuropathies. There are reports of hematologic changes, spontaneous abortions and various cancers. EO should be considered as a potential human carcinogen. Hence extreme care must be taken to meet all the installation requirements to exhaust the gas during sterilization and aeration.

II: Hydrogen Peroxide gas plasma sterilizers

Overview: This system uses a completely new technology introduced during mid 1990s. Gas plasma has been referred to as the fourth state of any 'matter'- solids, liquids, gases and plasma (Fig-6). Plasma consists of a reactive cloud of ions, electrons and neutral atomic and molecular species.

Plasma is generated under low pressure (vacuum) by applying a strong Radiofrequency (RF)

electromagnetic field. Inside the enclosed chamber of plasma sterilizer a deep vacuum is generated to facilitate maximum dispersion of the H_2O_2 vapor around the items after air removal. RF Emissions are

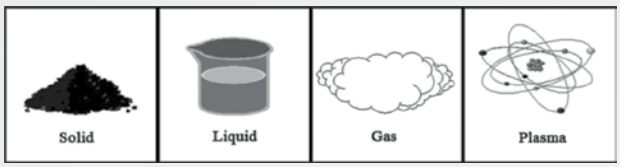


Figure – 6: Four states of any 'matter'

applied to hydrogen peroxide gas to excite the gas molecules to produce charged particles (plasma), many of which are in the form of free radicals (Fig-7). A free radical is an atom with an unpaired electron. In their quest to find another electron they form highly reactive species and cause damage to surrounding molecule. The peroxide also absorbs RF and gives off Ultra Violet (UV) light. The process does not produce any harmful substances; water and oxygen are the final by-products.

Mode of action: The inactivation of microorganisms is done by oxidation by free radicals dispersed in the plasma. These highly reactive species can be atomic or molecular radicals e.g.Nascent Oxygen (O^{nasc}), hydroxyl (-OH) or hydroperoxyl (-OOH) respectively (Fig-7). The free radical are capable of causing erosion of the cell membrane, enzymes and nucleic acids of the microorganism, atom by atom, through a process called etching. Etching spreads from the absorption of reactive species from the plasma by the microorganism with which they subsequently undergo chemical reactions to form volatile compounds. This process yields small molecules – Oxygen and water vapor are the final by-products.

Destruction of microbes is also done by UV irradiation of genetic material of the micro organism causing lesions in the DNA strands (Fig-7). Erosion of the microorganism is done through a process called intrinsic photodesorption. The photon induced desorption resulting from UV photons break the chemical bonds of proteins which in turn inhibits the microbe's ability to replicate.

Gas plasma cycle phases:

The system is fully automated with a cycle time of 55 minutes for short and 72 minutes for extended cycles depending on the model (Fig-8). The operating temperature is below 50^{0}C. Small capacity models are available with shorter cycle time of 28 and 38 minutes.

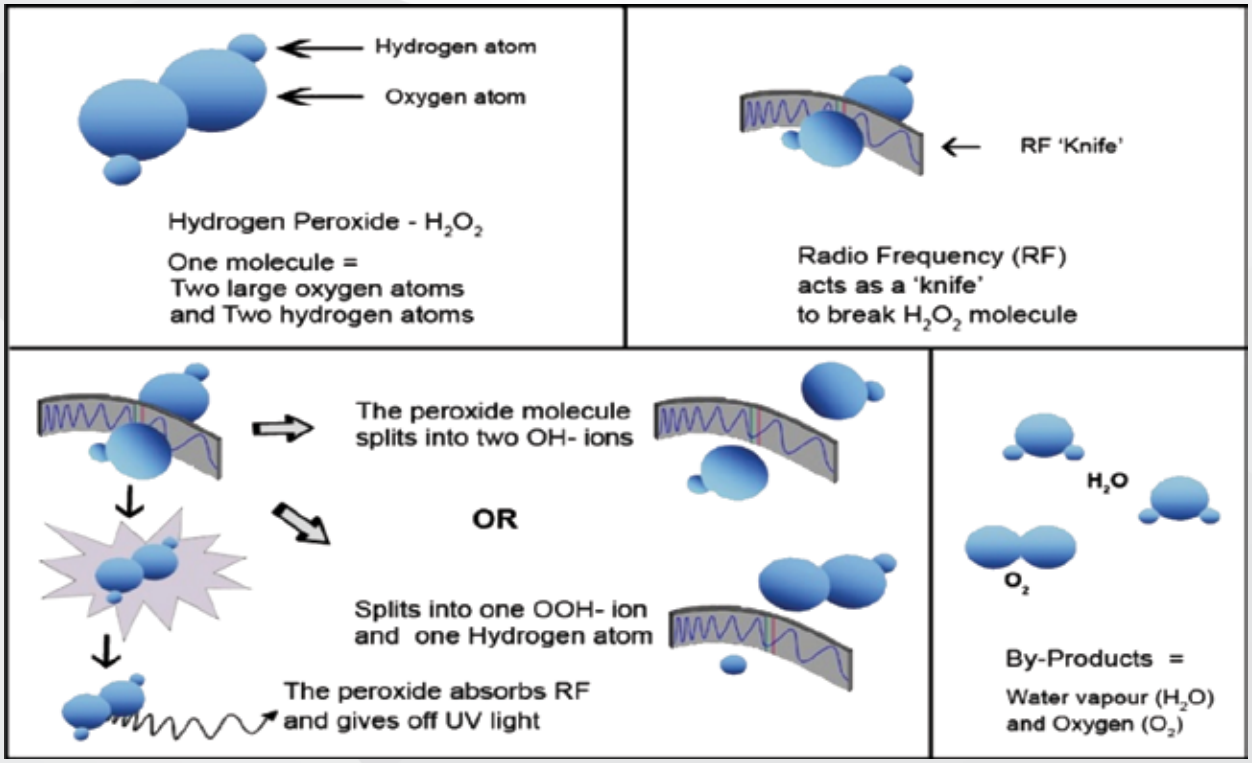


Figure – 7: Hydrogen Peroxide Gas Plasma Sterilization development



Figure – 8: Hydrogen Peroxide Gas Plasma Sterilizer

There are 5 phases:

1) Vacuum phase: This stage is meant for removing air and moisture completely from the chamber to facilitate maximum dispersion of H_2O_2

2) Injection Phase: 1.8ml of 58% solution of H_2O_2 is let into the chamber and vaporized to a concentration of 6 mg/liter.

3) Diffusion phase: allows the gas to diffuse throughout the chamber and exposes all surfaces of the load with the sterilant.

4) Plasma phase: during which vapor is converted into plasma with application of required Radiofrequency (RF) energy.

5) Air flush phase: to remove excess gas by series of vacuum and filling of air through HEPA filters.

The sterilization process is compatible with a wide variety of heat and moisture-sensitive surgical and medical items that are resistant to oxidation like metals, plastic, rubber, etc. Tubular items like rigid and flexible endoscopes can be processed. Cellulose, paper, cotton, linen and any material that absorbs H_2O_2 cannot be processed. Items can only be wrapped with Polypropylene (PP) or Polyethylene (PE-Tyvek® pouches). Items must be absolutely dry before processing. Presence of moisture will break (abort) the cycle automatically during the vacuum phase. It is not approved for tubular items longer than 1 meter and with lumen less than 1mm.

The by-product of the cycle is water and oxygen which are nontoxic and hence there is no need for aeration. The items are cold and can be dispersed for immediate use or for storage. Compared to the EO system the greatest advantage of this process is that the residue is nontoxic and the throughput of items is high, due to the short cycle time of less than an hour.

Sterilization Process Monitoring:

Since the first steam sterilizer was created by Charles Chamberland in 1880, researchers have worked on methods to monitor sterilization process. It was not until 1950's that biological and chemical indicators were used regularly. It is necessary to employ monitors to give assurance that the parameters of sterilization have been met. Validation does not assure that the items are completely sterile, but it furnishes a documented proof of the ongoing effectiveness of the sterilization process under the operating conditions prevailing inside that autoclave. Chemical Indicators, biological indicators and readings of mechanical monitors should be incorporated into the sterility assurance programme of every health care facility.

All Steam autoclaves, regardless of the type (Gravity, Prevacuum or with Pressure Pulse) must maintain adequate Temperature/Pressure, Saturated Steam and Time for assurance of sterilization. Ethylene Oxide sterilizers require four parameters in sufficient quantities to kill microbes – Relative humidity, Gas concentration, Temperature and Time. Hydrogen Peroxide Gas Plasma must maintain required concentration of H_2O_2 vapor and sufficient time for sterilization.

I : Mechanical Indicators

Monitoring of a steam cycle is done by recording the parameters using the chamber and jacket pressure gauge, Temperature gauge and the time maintained during a cycle as shown by the mechanical monitoring devices mounted on the autoclave. Typically, the temperature in a sterilizer is measured in the chamber draining pipe. This is because that location is cooler than the temperature inside the chamber. At the other end of the spectrum is the computer controlled automated equipments designed for hospitals, which has sophisticated pressure transducers, thermal sensors, precise timing capability and multiple means of recording actual cycle information for record keeping.

Useful Terminology

Exposure or Process Control to identify processed from unprocessed packs at a glance. It is monitored by indicator tapes pasted over the packs or printed on peel pouches to assure that each pack has been exposed to the sterilization process.

Pack Control - various indicators can be used inside the packs, trays, containers and inside the peel pouches.

Load Control is the process by which a load inside the sterilization chamber is monitored and released based on the results of an indicator in a test pack. Class 5 or Class 6 Chemical Indicators or Biological Indicator can be used as load controls.

Equipment Control reveals if the sterilizer is operating to the set conditions of air removal or leaks, time, temperature/pressure, moisture conditioning and sterilant exposure

Record Keeping to assist in documenting the sterilization process. Each pack should be labeled so that it can be traced back through records in the event of a problem.

II: Chemical Indicators (CI)

According to ISO standards there are Six Classes of CIs with specific performance requirements for each. They are designed to respond with a chemical change to one or more of the physical conditions within the sterilizing chamber. All chemical indicators will change color to the extent that a color blind person should be able to read.

Class 1 is basic chemical indicators called process or throughput indicators used as Process Control. They are either tapes or indicators printed on paper or plastic peel pouches (Fig-9) which changes color on exposure to the sterilant. Color change indicates that those items were processed but does not guarantee sterility since it does not read concentration of the sterilant or the time of exposure. Available for Steam, EO and H_2O_2 Plasma



Figure – 9: Class 1 indicators

It is convenient to record the following technical data regarding the pack on this tape for future reference:- Date of sterilization and expiry date, name of instrument set, code number of the technician involved in packing and sterilization and the sterilization cycle/ batch number.

Class 2 is used as Equipment Control for air removal tests in prevacuum steam sterilizers. These indicators relates to Bowie Dick (BD) test sheets type or Helix Type. A satisfactory test indicated that air and other non-condensable gases like Carbon Dioxide removal was complete and the steam penetration had occurred evenly. BD test must be done in a prevacuum sterilizer chamber after installation, at calibration, after repair and daily prior to first batch of the day. BD test does not determine if the parameters of time and temperature of sterilization have been met.

BD Test sheets - Pre-assembled BD packs are commercially available. To reduce the cost a test pack can be handmade. 30 numbers of freshly laundered huckaback towels are folded in thirds and assembled to measure approximately 9x12 inches and 12 inches high. A BD type test sheet is placed in the centre of the pack.



Figure – 10: BD test sheet Pass and Failed with air pocket

The test pack is placed horizontally in an empty sterilizer on the front bottom shelf over the drain. Testing is done with 134^{0}C for 3.5 minutes. If the air removal was complete and the steam penetration

was uniform then the indicator sheet must show a uniform color change at the end of the test. If there are 'spots' of incomplete color change, it indicates air pockets present in the chamber due to incomplete air removal during pre-vacuum phase or air has entered the chamber through leaks in the system (Fig-10). If the test fails the autoclave must be shut down for maintenance service.

BD Test Helix Type - Alternative indicators like BD Simulation Test Helix type constitute an entity of their own (Fig-11). Helix test ensures air removal from the load inside the sterilizer chamber. The helix is 1-½ meters long Teflon tube with a metal chamber attached to one end. Chemical indicator strips of specific type can be loaded into this helix chamber. The air from the helix tube must be removed during the prevacuum phase of the autoclave for the steam to reach the helix chamber containing the CI to cause the color to change.

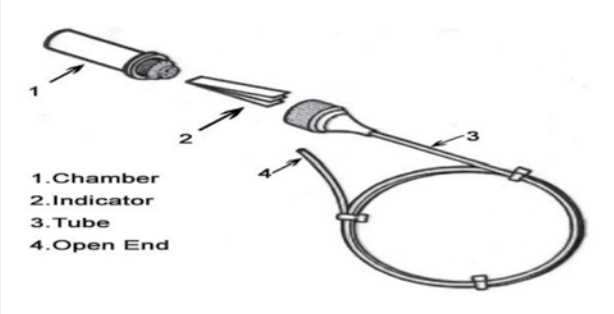


Figure – 11: BD Test Helix Type

Validation is obtained by color change of indicators if all conditions of TST are met. The greatest advantage is that the tubing with the chamber is reusable 1000 times by only changing the CI inside the chamber; hence very economical compared to BD test sheets. Class 2 indicators are not used with EO or Plasma

Class -3 is single parameter indicator used as Pack Controls available only for steam. These indicators react to one of the critical process parameters of steam sterilization cycle as per the stated value (SV) printed on the indicator. An example is the temperature tube that contains a chemical which changes color when an appropriate temperature is achieved. It does not state that the temperature obtained was maintained for adequate period of time. These can be used as pack controls to determine whether appropriate temperature was achieved in the centre of a large pack.

Class -4 chemical indicators

Class 4 is multi-parameter strip indicators, which responds to more than one critical parameter as stated on the CI strip (Fig-12). They are sterilant specific and are available for steam, EO and H_2O_2. They may respond to all parameters but only at a specific temperature. This combination of sterilant specific ink for visual color change and specified temperature provides a good indication of sterilization parameters. These are used as pack controls to indicate that sterilant penetrated to the point of placement for the specified period of time. Typically they are more accurate than Class 3 but less sensitive than Class 5 or class 6. Since the color change is gradual all along the strip, there can be a doubt whether the change of color was completed or not.



Figure – 12: Class 4 multi-parameter chemical indicator strips.

Class -5 Integrators – These indicators are known as 'Integrators' meaning that they combine many parameters simultaneously. In the case of steam sterilizers these indicators integrates time and temperature on exposure to steam. One type of Class 5 CI is having a steam and temperature sensitive chemical contained in a paper wick inside a foil laminate envelope. Steam enters at the permeable side of the device. The chemicals melt and migrate along the paper wick. The distance depends on the exposure to steam, time and temperature (Fig-13).



Figure – 13: Integrating Class 5 indicators

The migration is visible through a window marked unsafe (reject) to safe (accept) levels of autoclaving. If the color does not enter the SAFE window, then critical parameters of TST were not met during the sterilization cycle. It can be used for 121^{0}C and 134^{0}C steam sterilization Cycles. Similar Class 5 integrating indicators are available for EO also.

There are different types of Class 5 Indicators. The strip type (Fig-14) is having different patches sensitive to varying time of sterilization.



Figure – 14: Class 5 Chemical Indicator strip type

Class -5 Steam Chemical Integrating Indicators are used for Pack Control for monitoring conditions inside a pack. Class 5 do not replace the use of Biological Indicators (BI) but can be correlated to the performance of BI. Hence it can be used as a Process Challenging Device (PCD) for Load Control inside the chamber to release processed items, except implants. Class 5 indicators are available only for steam and EO.

Class 6 Emulators - They are named Emulators since it can mimic the functions of a Biological Indicator. It reproduces results better than Biological Indicators. This class of indicators can be used in place of the BI in many applications, thereby reducing the overall cost of sterilization.

Class 6 indicators are chemical indicators (Fig-15) with the added advantage that they change color more abruptly. The indicator will not react until approximately 95% of the cycle is complete. Abrupt color changes lead to less confusion because the chances of having an indicator that is in transition between pass and fail is reduced. The TST control changes color only when all critical parameters for steam are met. Stated Value (SV) of 134^{0}C for 7 min (± 25sec) and 121^{0}C for 20 min (± 72secs) or 134^{0}C for 3.5 min and 121^{0}C for 15 min are available.



Figure – 15: Class 6 Emulating Chemical Indicator

With Biological Indicator (BI) 'kill' occurs at 134^{0}C in steam at 1.8mins. Class 6 with SV of 3.5 min is twice that timing that generates BI kill. Twice the BI kill is the sterilization goal of every sterilization cycle to achieve SAL 10^{-6}. Hence the reliability of an emulator is actually better than the result from BI. If one uses Class 6 with an SV of 134^{0}C for 7 min or 121^{0}C for 20 min the Emulation (imitation) ensures 'over kill' as in extended steam cycles. The user may choose the Emulator by selecting the SV which is most appropriate for their application. Class 6 indicators are available only for steam and used as Pack Control or Load Control.

III: Biological Indicator (BI) functions as integrators of the physical and chemical parameters that result in a reduction of viable population of microbes to the desired SAL. To obtain a sterile product, the sterilization process must kill the most resistant microbes in the most inaccessible site within the load. The spore population in a BI should be in greater number and more resistant than the population of microbes found on the product being sterilized. It is a preparation having 1 million population of a specific microorganism resistant to a particular sterilization process. Each BI device typically contains 1 million Geobacillus Stearothermophilus for steam and H_2O_2 plasma cycles; and Bacillus Atrophaeus for EO. It is used to assist in the qualification of the physical operation of sterilization. There are two forms of Biological Indicators – Spore strips and Ampoules. BIs provide a direct measure of sterilization effectiveness, which is either Growth or No-Growth.

BI strips and discs: Each BI strip is made with special filter paper inoculated with 1 million sterilant specific spores. This type of BI is placed in the centre of a surgical linen pack in case of steam or EO. The BI strips or discs after sterilization are sent to the microbiology lab for culturing to determine if any viable spores survived. Disadvantage is that the result will be available only on the 3rd day. Strips and discs are cheaper than ampoules. BI strips for H_2O_2 plasma are sealed inside peel pouches to be kept along with the load.

BI Ampoule for steam and EO consist of a spore strip carrying 1 million spores packaged in a vial with a sealed ampoule of growth medium combined with a pH indicator (Fig-16).



Figure – 16: Biological Indicator Ampoule type

The ampoule can be kept in the middle of a 16 towel pack during sterilization. The BI ampoule is 'activated' by crushing the ampoule after sterilization, there by releasing the growth medium to provide a growth environment. The 'activated BI' is then incubated for 48 hours to allow any viable organisms to grow. A color change after activation and incubation gives an evidence of a microbial growth. No color change if there is "No-Growth" i.e. a negative response which shows that necessary conditions for sterilization were met. A positive BI test indicates sterilization process failure. BI Ampoule for checking H_2O_2 plasma sterilization is sealed in a peel pouch and kept inside the chamber during sterilization.

Another type of self-contained BI ampoule can be used in a rapid detection system. Fluorescence occurs when a viable BI is exposed to UV light. A special instrument is used to detect the presence or absence of fluorescence. The results can be "read" in 3 hours which is a great advantage but obviously a more expensive method.

BI tests are done after installation, for requalification after repair, once a day or week as per the hospital protocol for validation and with every load containing implants.

Use of Chemical Indicators: When considering which class of indicator to use, you must consider your external and internal chemical monitoring needs for your various sterilization systems (Table-2).

External indicators are simply used to distinguish between processed and unprocessed items. A Class 1 indicator should be placed on each package that is intended for sterilization.

Internal indicators need to be used within each package that will be sterilized. Depending on the complexity of the pack and devices within them, any Class of CI can be used except Class 2 which is meant for air leak tests. All internal CIs should be placed in an area of the package that is determined to be the least accessible to sterilant contact. This may not always be in the center of the package.

Process challenge packs using Class 5 Integrator or Class 6 Emulator or Biological Indicator can be kept outside the packs to monitor sterilization load. Results of external Class 1 indicator and challenge packs with CIs can be read at the end of each cycle. BI results are available only after 48 hours of incubation. Hence items in a load with BI challenge pack can be released only after two days when the result is ready.

Conclusion: Just because one has imported computerized expensive sterilizer with a graphical print out, it does not guarantee the sterility of the materials inside the processed pack. The process of sterilization is complicated and its success depends on so many factors like proper cleaning, drying, packing, loading as well as maintaining critical parameters during the sterilization cycle. No chemical, biological or mechanical monitor will tell you if an item is sterile. It can only aid in the determination of whether conditions of sterilization have been met during a cycle.

Because of dramatic changes in the field of sterilization, it is imperative that the professional responsible for and involved with processing have a solid scientific understanding of the basic principles of sterilization to the present clinical situation. It is only through integration of all aspects that we can ensure delivery of sterile devices in a safe and cost effective manner to health care professionals involved in reducing the risk of a patient acquiring nosocomial infection.

Class	Critical Parameter	Placement	Control Type	Frequency	Information
Class 1	Exposed to Sterilant	Outside pack	Exposure Control	Each pack	Processed v/s Unprocessed
Class 2 BD Type	Air Removal	Empty Load	Equipment Control	Daily	Efficacy of air removal
Class 2 Helix PCD	Temp/Steam Air Removal	Outside	Equipment and Load	Daily	air removal and TST
Class 3	Temperature	Inside pack	Pack Control	Large Packs	Exposure inside
Class 4	Temp/ Sterilant	Inside pack	Pack Control	Each Pack	>1 critical parameter
Class 5 Integrator	Temp/Steam/Time	Inside or Outside	Pack/ Load Control	Each pack and Load	On All parameters
Class 6 Emulator	Temp/Steam/Time	Inside or Outside	Pack/ Load Control	Each pack and Load	On All parameters
Biological Indicator	All parameters	Outside	Load Control	Specific Load	On All parameters

Table – 2: Recommendations for use of various Chemical and Biological Indicators



Disinfection

P.I. Mohan, DOMS, MS

We have come a long way in understanding nosocomial infection. Prevention of hospital acquired infection requires thorough knowledge of infectious agents (virus, bacteria, fungi), the areas of colonisation, and the mode of transmission (air, contact – direct & indirect) susceptibility of the host.

The transmission from patient to healthcare worker and thereafter to another patient can be through direct contact or through indirect contact via diagnostic equipments. Equipments and instruments if used without proper disinfection or sterilisation will cause contamination with microorganisms.

Personal hand hygiene before and after touching the patient, thorough hand disinfection before any invasive procedure, surgical hand scrub prior to surgical procedures, disinfection and sterilisation of all materials and instruments for non invasive and invasive procedures are mandatory to prevent and control nosocomial infection.

Disinfection prevents infection by killing microorganisms in vegetative state. However, it does not kill spores. The agent is usually a chemical; it can be a physical agent. It is used only in inanimate objects, not on human body.

Definitions

Antiseptic: is a substance that prevents or arrests the growth or action of microorganisms, either by inhibiting their activity or by destroying them. The term is especially used for preparations applied topically to living tissue.

Sterilisation: is the act or process physical or chemical, that destroy or eliminates all forms of microorganisms including spores.

Asepsis: prevention from contamination with microorganisms. This includes sterile conditions in tissues, or materials, and in rooms, as obtained by excluding, removing or killing organisms.

Bactericide: An agent which kills bacteria both pathogenic and non pathogenic but not necessarily bacterial spores.

Bacteriostat: An agent usually chemical that prevents growth of bacteria but not necessarily kills them or their spores.

Bioburden: The microbiological load, that is, the number of contaminating organisms in the product before sterilization.

Biocide: A chemical or physical agent that kill all living organisms pathogenic and non pathogenic.

Decontamination: Disinfection or sterilization of infected articles to make them suitable for use, including microbial, chemical, radioactive and other hazards.

Preservative: An agent that inhibits the growth of microorganisms capable of causing biological deterioration of substances or materials.

Sporicide: product that destroys all forms of microbial life, including spores. (Sporicide and sterilizer are synonymous)

Antiseptics: are disinfectants that can be used on body surfaces, such as skin or vaginal tract, to reduce the number of flora and pathogenic contaminants.

Bactericidal agents or germicides can kill bacteria. Bacteriostatic agents only prevent multiplication of bacteria which may, however, remain alive.

SPAULDING CLASSIFICATION

Dr. Earle Spaulding in the year 1939 published a

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paper on disinfection of surgical instruments in a chemical solution. He divided the surgical items into 3 categories according to its use and the risk involved in usage: Critical, Semi critical and Noncritical. And he suggested a strategy for sterilizing / disinfecting each category in order to minimize the chance of introducing infection into the patients undergoing intervention.

Critical Items: Critical items are those instruments which enter sterile tissues or vascular system. The risk of contamination is high in these procedures and the items used must be sterile. This category includes surgical instruments, cardiac and urinary catheters, implants, and ultrasound probes in body cavities. Chemical agents used for sterilisation are ≥2.4% gluteraldehyde based formulations, 7.5% hydrogen peroxide, 7.35% hydrogen peroxide with 0.23% peracetic acid, 0.2% peracetic acid and 0.08% peracetic acid with 1.0% hydrogen peroxide. Items can be autoclaved and heat sensitive items can be sterilized with Ethylene oxide or hydrogen peroxide gas plasma.

Semi critical items: These are instruments / equipments that contact mucous membrane or non-intact skin. This category includes respiratory therapy and anaesthesia equipment, some endoscopes, laryngoscope blades, cystoscopes, colonoscopes, oesophageal and rectal manometry probes. Semi critical items require high level disinfection using chemical agents. Gluteraldehyde 2% for 20 minutes, hydrogen peroxide, orho-phthalaldehyde, and peracetic acid with hydrogen peroxide are recommended for high level disinfection.

Tonometer is a semi critical item. The manufacturer of the device would have given the disinfection protocol for the item supplied. Read the instruction carefully. In order to prevent transmission of viruses (herpes simplex, adenovirus, HIV) by tonometer tips, CDC recommends that the tonometer tips be wiped clean and disinfected for 5 – 10 minutes with either 5000 ppm chlorine, or 70% ethyl alcohol. After disinfection the tonometer should be thoroughly washed in tap water and dried.

Non- critical items: Those items which come into contact with intact skin alone are categorized under non-critical items. Intact skin provides an effective barrier to most of microorganisms. Thus the items which come into contact with intact skin are non-critical. These can be further divided into two: Non critical patient care items (bed pans, BP cuff, crutches and computers) Non critical reusable items (bed rails, bedside tables, patient furniture and floor) Non critical items are frequently touched by hand of the healthcare worker, so the contaminated hand can secondarily transmit microorganism to another patient. Hand hygiene of the health care provider is of utmost importance.

Mops and reusable cleaning clothes are used to attain low level disinfection. These items should be adequately cleaned, disinfected and dried. The low level chemical disinfectant should be frequently changed (after 3 or 4 rooms or after every 60 minutes)

LEVELS OF DISINFECTION

High level disinfection

Most complicated critical instruments and devices are not heat stable and are adversely affected by repeated sterilizing cycles in a steam autoclave or forced air-dry heat oven. These items must be processed by low temperature sterilization, such as ETO or hydrogen peroxide gas plasma systems or high-level disinfection using liquid chemical sterilants. Pre cleaning of devices to be sterilized is of vital importance. If cleaning is not adequate, disinfection and sterilization failures will occur and hence will not ensure patient safe instrument. The capability of killing bacterial spores is an assurance of the relative potency and activity spectrum of a germicide. It is important to recognize that contact time is the single important variable between sterilization and high level disinfection with chemical sterilants / disinfectants. The assurance of a sterilization process being effectively accomplished by a liquid chemical germicide is less than such a procedure done using a validated sterilization system such as steam autoclaving, dry heat, ETO, or hydrogen peroxide gas plasma. Liquid sterilization or disinfection procedures cannot easily or accurately be monitored biologically. Glutaraldehyde based germicides, are capable of sterilization, after extended contact time (6 - l0 hours) in the absence of extraneous organic material. Unfortunately some instruments are not able to withstand the immersion time.

Intermediate level disinfection

Intermediate level disinfectants are not necessarily

capable of killing bacterial spores, but they do inactivate M tuberculosis var. bovis, which are more resistant to aqueous germicides than are ordinary vegetative bacteria. When choosing a chemical agent for a particular situation it would be prudent for the user to examine the specific activity of brand name disinfectants and also to consult scientific literature for information about the virucidal spectra of generic chemicals, such as alcohols and halogens. A variety of intermediate to high level disinfectant chemicals (two commercial glutaraldehyde based products, 500mg/L free chlorine from sodium hypochlorite, an idophor product, 70% isopropanol, 80% ethanol and dilutions of glutaraldehyde as low as 0.1%) were shown to inactivate hepatitis virus effectively, in relatively short exposure times, and at low temperatures. Some germicides with good tuberculocidal activity can destroy small lipid viruses. Klein and Deforest (1963) showed that both 70% ethanol and 70% isopropanol are rapidly virucidal: alcohols are also known to be rapidly tuberculocidal. The germicidal resistance of fungi is probably about the same as that of gram-positive vegetative bacteria.

Low level disinfection

Low level disinfectants are those that cannot be relied on to destroy, within a practical period bacterial spores, mycobacteria, all fungi, or small or non lipid viruses. Examples of low level disinfectants are quartenary ammonium compounds and certain iodophores or phenolics.

FACTORS AFFECTING DISINFECTION

An ideal chemical for disinfection should have the following: It should have high efficiency with a broad range of activity. It should have a minimum contact time at room temperature with low concentration. It should be non toxic. The agent should act in the presence of organic and non organic material, it should be cost effective. The solution may be reused, non corrosive and non staining. The disinfectant should be easy to use and safe to dispose. No single disinfectant has all these qualities. To achieve maximum effect one should read the written instructions by the manufacturer.

There are many factors affecting the activity of a chemical disinfectant.

i) Number and location of microorganisms: the germicide requires more time to destroy if the microbial load is large and located at a difficult location for the disinfectant to access. To reduce the number of microorganisms meticulous cleaning and drying of items is mandatory prior to disinfection.

ii) Instruments with multiple parts, joints, cervices and channels are difficult to disinfect than flat surface simple instruments.

iii) Air pockets within the instruments with lumen will prevent contact of disinfectant; the items should be fully immersed without air pockets and remain fully immersed during the prescribed contact time.

iv) Innate resistance of microorganisms: spore coat and cortex of spores, waxy wall of mycobacteria, outer membrane of gram negative bacteria; all these are barriers to disinfectant.

v) Concentration and potency of disinfectant; the more concentrated the disinfectant the greater the efficiency and shorter the time (except for idophors)

vi)Physical and chemical factors: generally increase in temperature augment bactericidal activity, however, too great a temperature leads to degradation of disinfectant.

vii) Activity of gluteraldehyde and quarternary ammonium compounds increases at a higher pH, but activity of phenolic compound, hypochlorite and iodine decreases at higher pH.

viii) For gaseous disinfectants like ethylene oxide, chlorine dioxide and formaldehyde relative humidity affects the activity. Hardness of water used to dilute the disinfectant reduces the rate of kill.

ix) Organic and inorganic matter: Serum, blood, pus, faecal matter or lubricant material protects the microorganisms. Meticulous cleaning of the items prior to disinfection is a must for maximum bactericidal activity.

x) Biofilm: is a group of microorganisms which stick together and are frequently embedded in a matrix produced by the clump of cells. The biofilm is firmly attached to any surface and is difficult to remove. They are 1000 times more resistant to anti microbials than the same bacteria in suspension. Chlorine compounds can effectively inactivate biofilm.

Levels of disinfectant action according to type of microorganism

	Bacteria				Viruses	
Level of action	spores	Tubercle bacilli	Vegetative cells	fungi	Non lipid & small	Lipid & medium
High	+	+	+	+	+	+
Intermediate	-	+	+	+	+ / -	+
Low	-	-	+	+ / -	+ /-	+

Activity levels of selected liquid germicides

Sterilization	Aqueous concentration	Activity Level
Glutaraldehyde	Variable	
Hydrogen peroxide	6 – 30%	
Formaldehyde	6 – 8%	
Chlorine dioxide	Variable	

Disinfection	Aqueous concentration	Activity Level
Glutaraldehyde	Variable	High to intermediate
Ortho-phthalaldehyde	0.5%	High
Hydrogen peroxide	3 – 6	High to intermediate
Formaldehyde	1 – 8%	High to low
Chlorine dioxide	Variable	High
Peracetic acid	Variable	High
Chlorine compounds	500 – 5000 mg/L Free/available chlorine	Intermediate
Alcohols	(Ethyl, isopropyl) 70%	Intermediate
Phenolic compounds	0.5 – 3%	Intermediate to low
Idophore compounds	30 – 50 mg/L free iodine; upto 10000 mg/L available iodine	Intermediate to low
Quarterny ammonium compounds	0.1 – 0.2%	Low

Alcohol: ethyl, isopropopyl, trichlorobutanol

Isopropyl alcohol is preferred as it is a better fat solvent, more bactericidal and less volatile.

Optimum bactericidal strength is 60 – 90% solution in water (v/v). Presence of water is essential for antimicrobial activity.

Mode of action: Alcohols are bactericidal rather than bacteriostatic. They kill vegetative forms of bacteria rapidly. They are also tuberculocidal, fungicidal and virucidal. They have no action on bacterial spores. Alcohol acts by denaturing protein. Methyl alcohol (Methanol) has the weakest bactericidal action. Ethyl alcohol in concentration between 40% -95% in exposure periods of 10 seconds to 1 hour proved to be effective against most of the microorganisms. Isopropyl alcohol was found to be more effective than ethyl alcohol for E. coli and Staph aureus.

Ethyl alcohol at concentrations of 60 – 80% is a potent lipophylic virucidal agent (herpes, vaccinia, and influenza virus) and act against most hydrophilic viruses (adenovirus, enterovirus, rhinovirus and rotaviruses) but not against hepatitis A virus or poliovirus. Isopropyl alcohol is not active against the non lipid enteroviruses but is fully active against the lipid viruses.

Use: Thermometers, scissors are to be immersed. Wipe equipment surfaces (not optical lenses), BP hand cuff, hospital pagers, and stethoscopes. 70% alcohol is useful on items that cannot be immersed like electric and radiographic equipments and external monitors. It is used to flush the lumens of instruments since after evaporation the lumen will be dry.

WHO has designated alcohol "as the gold standard against which all other skin disinfectant should be measured"

Advantage : considerably effective against most viruses including HBV and HIV. Highly active against gram negative bacteria, fungi, and M. tuberculosis.

Disadvantage: inactive against spores and many viruses. It is inflammable. Alcohol evaporates rapidly and may not give adequate contact time. Not a high level disinfectant. Alcohol is readily inactivated by exposure to protinaceous material. It causes damage to optical lens incorporated instruments. Alcohol should not be used over the eye ball as it will cause corneal epithelial damage.

Aldehydes: formaldehyde

Optimum strength: 8% formaldehyde in water is 20% formalin solution.

Mode of action: formaldehyde is active against amino groups in the protein molecule.

Contact time: 8% formaldehyde plus 70% alcohol is a high level disinfectant; the time taken to inactivate spores is up to 18 hours. 4 – 8% formaldehyde in water is intermediate level disinfectant.

Method of application: 10% formalin containing 0.5% tetraborate is used to sterilise clean instruments. Formalin solution is boiled to produce gas for fumigation. Formalin tablets in formalin chambers are used to sterilise heat sensitive instruments. Formalin solution can preserve tissues.

Use: sterilising rooms, laboratories, furniture, books, clothing, woolen blankets, mattresses, respirators, heat sensitive instruments. In spite of the disadvantages mentioned below formalin is used to preserve tissues, embalming and preparation of viral vaccines. In the operating room, for each 1000 cubic feet of space (28.3m3), 500 ml of 40% formaldehyde in 1 litre of water is boiled to dry. The OR is closed for 8 – 10 hours.

If aeromax vapouriser is used 250cc of 40% formalin is dissolved in 5000 cc of tap water. 1 litre of this solution is used for 1000 cu.ft. of space.

Disadvantage: irritant and toxic when inhaled. Causes irritation to mucous membrane and eyes. Articles, surfaces may emit irritant vapour for sometime; this can be nullified by exposing to ammonia vapour. Less effective than gluteraldehyde in comparison to the effective time of exposure. Formaldehyde has an impending carcinogenic activity.

There are several formaldehyde-free chemical compounds available for fumigation / fogging.

Active agents in 100 g

- Glyoxal 8.8 g + Glutaral 4.5 g
- Glutaral 9.8 g + Benzalkonium chloride 5.0 g
  + Didecyldimethyl ammoniumchloride 5.0g
- Complex formulation of stabilized hydrogen peroxide11% w/v + 0.01% Silver nitrate solution

Each combination has its own dilution requirements.

This has to be strictly followed. Switch off the AC. Fogging is done for 5 minutes. Close the door of OR. The contact period for most of the disinfectants is 1 hour after fogging. You can switch on the AC after this.

Para formaldehyde tablets

Para formaldehyde tablets can be used for degerming measures. This is effective in reducing the number of microorganisms. Items to be disinfected should be kept in air tight containers. Items should be cleaned properly before loading. Effective disinfection requires 10 tablets/dm3 (dm3 – cubic decimeter volume unit equivalent to 1 litre) with an exposure time of 5 hours. For cold sterilisation 10 tablets/ dm3 with an exposure time of 15 – 24 hours is required. 80% of relative humidity is a must inside the chamber for the disinfection and cold sterilisation process. This method can be used only for items that are heat sensitive. Chemical indicators or any other methods of validation of the process are not available.

Gluteraldehyde

Gluteraldehyde is a saturated dialdehyde, chemically related to formaldehyde. Mode of action is similar to that of formaldehyde. It is a colourless oily liquid with pungent smell.

Contact time: 20 minutes of contact time at 20^0C is sufficient to achieve high level disinfection in 2.0% alkaline buffered solution, at a pH 8 – 9. Gluteraldehyde is slow in acting against many species of mycobacterium, hence a minimum exposure time of 45 minutes is recommended to achieve high level disinfection. Gluteraldehyde inactivates vegetative bacteria, fungi, viruses in less than 10 minutes. "Gluteraldehyde can be used as a sterilant. It has no deleterious effect on the cement or lenses of instruments such as cystoscopes and bronchoscopes.

Gluteraldehyde is effective in the presence of serum and protein. However, pre cleaning and drying of the instruments prior to immersion is recommended.

Disadvantage: can cause contact allergic dermatitis, throat, eye and respiratory irritation. Using knives without thorough washing to dislodge the chemical, will result in corneal de-compensation

Use: for high level disinfection/sterilisation of heat sensitive instruments like cystoscope, bronchoscope, endoscopes, sharp instruments, thermometers, corrugated rubber anaesthetic tubes, face masks, plastic endotracheal tubes, polythene tubing,

Shelf life of gluteraldehyde once activated is 14 days. Other formulations Gluteraldedyde – Phenate and stabilised gluteraldehyde have double the shelf life of 28 to 30 days.

Biguanides

Chlorhexidine

Chlorhexidine is a bisbiguanide disinfectant. It is less active against gram negative bacteria such as Pseudomonas and Proteus species. And in an aqueous solution it has limited virucidal, tuberculocidal, and negligible sporicidal activity. Hence it is often combined with compatible detergents or with alcohol as a hand rub. It is inactivated by organic matter, soap, anionic detergents and hard water.

Chlorhexidine is most effective in neutral or slightly acidic pH. It used as 4% chlorhexidine gluconate solution in presurgical hand scrub, health care worker hand wash and preoperative skin preparation of patients. Randomised design studies have shown that chlorhexidine is more effective immediately and residually (its action lasts up to 6 hrs) at reducing Colony Forming Units(CFU), when compared with povidone iodine.

Chlohexidine may cause contact dermatitis, vesicle formation, conjunctival inflammation, corneal epithelial oedema

Dyes

Dyes are low level disinfectants. Two groups of dyes are available. Aniline dyes (Brilliant green, malachite green, crystal violet) and Acridine dyes (Acriflavine, proflavine euflavine and aminacrine).

Mode of action: the bactericidal action is due to the reaction with acid groups in the cell. They impair the DNA complexes of the microorganisms and thus kill or destroy the reproductive capacity of the cell. Aniline dyes interfere with the synthesis of peptidoglycan component of cell wall. Acridine dyes interfere with the synthesis of nucleic acid and protein in both bacterial and mammalian cells.

Method of application: Aniline and Acridine dyes are extensively used as skin and wound antiseptics. When impregnated in gauze they are slowly released in a moist environment.

Advantage: presence of organic matter does not affect the action of both dyes. They have no activity against tubercle bacilli. The acridine dyes are more potent against gram positive than gram negative organisms.

Halogens

Chlorine compounds

Sodium and Calcium hypochlorite (household bleach), Chlorine dioxide and Chloramine T are chlorine compounds used for disinfection.

Optimum Strength: Sodium hypochlorite (50 ppm) exhibit rapid activity against vegetative bacteria, 100 ppm effective against most fungal agents. Viruses are inactivated at 200 ppm and HBV at 500 ppm of free chlorine. Concentration of 1000 ppm is required to inactivate M. tuberculosis. Concentrated solutions will have 50,000 ppm of free chlorine. The use of sodium hypochlorite at 1000 ppm is considered adequate to achieve high level disinfection. Sodium hypochlorite is available in 5 liter canister. 5 ml of sodium hypochlorite liquid is added to 495 ml of distilled water to make it 1% solution. Optimum pH 6-8 for sodium hypochlorite solution.

Mode of action: exact mode of inactivation is unclear. It is postulated that the free chlorine acts by inactivating enzymes, denaturing proteins and destruction of nucleic acid.

Chlorine dioxide retains chlorine for a longer time, and is sporicidal unlike hypochlorite.

Use: disinfection of counter tops, floor, decontamination of cardiopulmonary mannequins. Sodium hypochlorite 0.1% solution is used as a general disinfectant. Concentration should be increased to 0.5% in presence of organic matter.

Advantage: Sodium hypochlorite is fast acting, non staining, and effective in low concentrations and is inexpensive.

Disadvantage: higher concentrations are corrosive to certain metals (aluminum, copper, brass, stainless steel) and instruments on extended exposure. Hypochlorites are inactivated by organic matter. In higher concentrations solutions are unstable and are affected by light and heat. Therefore it is stored in opaque closed containers.

Iodine compounds

Tincture of iodine is a solution of 2% iodine in 50% alcohol and has been used as an antiseptic on skin and tissue for 150 years. Iodophors have largely replaced inorganic iodine. They are water soluble complexes of iodine and a solubilising agent or carrier that allows a slow but continuous release of free iodine for longer period of time. One of the most widely used idophor is iodine complexes with polyvinylpyrrolidone, referred to as povidone - iodine.

Optimum Strength: As the concentration of solution increases bactericidal activity decreases. Within defined limits, as the degree of dilution increases bactericidal activity increases. This is as a result of increased level of iodine present in the dilute solutions. Activity of povidone iodine solution is greater at an acidic than an alkaline pH; it should not be used in alkaline conditions or mixed with other disinfectants.

Contact time: 2 to 3 minutes

Method of application: solution10% to paint over the skin and leave it to dry.

Used as surgical scrub solution 7.5% to disinfect hands prior to surgical procedures

As a 5% solution it is used for preparing the conjunctival cul de sac before ocular surgery.

Disadvantage: They are not sporicidal and are not considered suitable for high level disinfection. Iodine solutions are unstable, stains skin and fabric, toxic, may cause skin irritation.

Reports of prolonged presence of pseudomonas aeruginosa in povidone – iodine solution have been attributed to presence of organic matter, inorganic material or biofilm formation on items being treated.

Association of Practitioners of Infection Control (APIC) do not advise iodophors as high level disinfectant because of their unproven efficiency against bacterial spores, M. tuberculosis and some fungi.

Phenols

It was Joseph Lister who noticed the antibacterial action of phenol (carbolic acid) and started using it as a dressing for wounds in surgery in 1867. Phenol is obtained from coal tar by destructive distillation, one among 50 other phenolic compounds.

Germicidal potency of coal tar and related disinfectants has been assessed by using Salmonella typhi phenol coefficient. The phenol coefficient compares the activity of different dilutions of phenolic disinfectant after contact time of 5 – 10 minutes, with that obtained from a standard dilution series of phenol.

Mode of action: It is the free hydroxyl group that determines the reactive entity of the phenol molecule. Alkyl substitutions affects such things as the ratio between aqueous and non aqueous (including bacterial) phases, the capacity for reducing surface tension, and in some instances species selectivity, all of which determine bactericidal action of phenol derivatives.

In higher concentrations phenol is bactericidal; however, in lower concentrations it remains bacteriostatic. Phenol acts optimally under acidic and neutral conditions. It is more effective when temperature is increased and presence of organic matter reduces its bactericidal activity.

At higher concentration it acts by penetrating and disrupting the cell wall and precipitating the cell protein. Gram positive bacteria are more sensitive than mycobacteria.

Disadvantage: phenolics are not sporicidal but are sporistatic inhibiting germination. Phenolics can cause skin depigmentation and hyperbilirubinemia in infants. So phenolics should not be used to wash infant bassinets and incubators.

Surface active disinfectants

Surface active substances include both hydrophobic (water repelling) and hydrophilic (water attracting) groups. On the basis of charge or the absence of ionization of hydrophilic group, these surfactants are classified into anionic, cationic, nonionic and amphoteric compounds. Nonionic surfactants do not have antimicrobial activity.

Quarternary Ammonium Compounds (QAC)

Cationic synthetic surface active agents or quarternary compounds are excellent disinfectants. The quarternary ammonium compounds are free of odour and colour, are highly stable and have little corrosive action on metals when used in recommended concentrations. They are basically bacteriostatic and more effective against gram-positive than gram-negative bacteria. The agent which enters the cell denatures protein.

They act on cell membrane and also enter the cell. They are more active in the presence of small amounts of organic matter than any other class of disinfectants, but are inactivated by soaps, anionic detergents and inorganic polyphosphates. They are more expensive than hypochlorites.

Commercially available preparations are cetrimide (cetavalon) and benzalkonium chloride. They are most active in alkaline pH.

Anionic surfactants (common soap) have strong detergent but weak antimicrobial activity. They are most active in acidic pH. These compounds cause disruption of lipoprotein frame work of the cell membrane. Soaps made from saturated fatty acids(such as coconut oil) are more effective against gram negative bacilli while those prepared from unsaturated fatty acids (oleic acid)have greater action against gram positive and Neisseria group of organisms.

Amphoteric agents (Tego compounds) have detergent properties of anionic and antimicrobial activity of cationic compounds. Their potency is reduced in presence of organic matter. They are effective over a wide range of pH.

Hydrogen Peroxide

Chemical agents containing hydrogen peroxide is a high level disinfectant. Hydrogen peroxide acts by producing hydroxyl free radicals that can attack membrane lipids, DNA and other essential cell components. Hydrogen peroxide was found to be active against bacteria, yeast, fungi, viruses and spores. A 7% stabilized hydrogen peroxide proved to be sporicidal (6 hours), mycobacterial (20 minutes), fungicidal (5 minutes) at full strength and bactericidal (3 minutes) at a 1:16 dilution when a quantitative carrier test was done. The marketed product is a premixed ready to use chemical that contains 7.5% hydrogen peroxide and 0.85% phosphoric acid (to maintain a low pH). When effectiveness of 7.5% hydrogen peroxide at 10 minutes was compared with 2% gluteraldehyde at 20 minutes in disinfection of endoscopes no significant difference was found in germicidal activity.

3% hydrogen peroxide is an effective disinfectant when used on inanimate surfaces. 3% - 6% hydrogen

peroxide is used to disinfect tonometer biprisms, ventilators, fabrics and endoscopes. Proper rinsing of tonometer is necessary to avoid corneal burn.

Dilution of hydrogen peroxide must be closely monitored to maintain the minimum effective concentration of 0.6 – 7.5%.

Ortho- phthalaldehyde (OPA)

OPA contains 0.55% 1,2-benzenedicarboxaldehyde. OPA is a clear solution of pale blue colour with a pH of 7.5. OPA interacts with amino acids, proteins and microorganisms. OPA seems to kill spores by blocking the spore germination process.

OPA has superior mycobactericidal activity than gluteraldehyde. It has excellent stability between pH 3- 9. It does not irritate eyes or nose. It does not require activation. OPA has only a barely perceptible odour. A potential disadvantage of OPA is that it stains proteins gray (including unprotected skin); therefore personal protective equipments should be worn while handling. Meticulous cleaning, using correct exposure time (12minutes) and copious rinsing with water should prevent staining.

Peracetic acid

Peracetic acid acts rapidly against all microorganisms. It enhances removal of organic material and is sporicidal even at low temperature and leaves no residue. Peracetic acid can corrode copper, brass, bronze, plain steel and galvanized iron.

OPA acts by denaturing protein and disrupting cell wall permeability. Peracetic acid inactivates gram positive and gram negative bacteria in ≤ 5 minutes at <100ppm; in the presence of organic matter 200-500 ppm is required. It is active against virus (12-2250 ppm), polio virus in 15 minutes (1500-2250 ppm), mycobacteria in 20-30 minutes (0.26%), and bacterial spores 15 seconds to 30 minutes at 500-1000 ppm (0.5%-1%).

It is used in an automated machine in USA to chemically sterilize endoscope, arthroscope etc, surgical and dental instruments. 35% peracetic acid is diluted to 0.2% with filtered water at 500C.

Radiation

Non ionizing radiation

Ultraviolet radiations (UV) in the in the range of 250 to 260 nm wave length are highly effective. Most vegetative bacteria are susceptible to UV radiations; however, spores are highly resistant. UV radiations induce thymine dimers in DNA and this interferes with DNA replication. Their use is restricted to disinfection of clean surfaces like inoculation hoods, laboratories, wards and operation theatres.

Infra red is considered as a form of hot air sterilization. Infra red radiation is used for rapid sterilization of pre packed syringes and catheters.

Ionising radiations

X-rays, gamma rays and cosmic rays are ionizing radiations. They damage DNA by various mechanisms. These have very high penetrating power, hence are lethal to all cells including bacteria. Gama radiations are used commercially to sterilize heat sensitive items like plastic syringes, transfusion sets, catheters, cannulas, culture plates etc.

Important Do's	&	Don'ts of Disinfection
Add the measured amount of disinfectant to precise amount of clean water to make an effective solution for use.		Add detergent to disinfectant; this may inactivate both.
Use a clean, dry container for the solution		Store instruments or cleaning tools immersed in a disinfectant
Wash and clean the surface, where possible, before using the disinfectant		Top up previous day's solution. Make fresh solution every day
Remember: Disinfectant used carelessly may promote microbial growth		Use two disinfectants together, unless one of them is alcohol
Check expiry date		Bring your own disinfectant to the hospital
Give adequate time for disinfectant to act		Disinfect only if cleaning is sufficient
Read manufacturer's instructions before preparing the solution		

Testing of disinfectants

The disinfectant solutions can become ineffective or contaminated. Surprise checks for its efficiency and sterility is advisable. The chances of contamination of the solution increases:

i) if the container is not cleaned and dried properly

ii) if refilling of the container is done with residual solution

iii) if the diluent is contaminated

iv) if the measuring cup is not cleaned and dried after use

v) if the process of dilution is done in dirty environment

vi) if the diluted solution is stored in unclean condition

vii) if strict precautions are not taken during preparation, handling and usage

Validation of Disinfection

Disinfection process validation is defined as "establishing documented evidence that a disinfection process will consistently remove or inactivate known or possible pathogens from inanimate objects"

It is essential to make sure that the chemical solutions used is effective in removing the mocroorganisms. Several methods of testing the potency and efficacy of disinfectants are available.

i) **The MIC test** measures lowest concentration of disinfectant that will inhibit the growth of a known strain of bacteria eg: Salmonella typhi

ii) **The Chick – Martin & Garrod test** determines the phenol coefficient of the disinfectant, on adding a standard amount of organic matter is incorporated in the test mixture

iii) Tests for disinfecting action on the surfaces

iv) **The capacity use dilution test** measures the effect fo repeated challenge by the addition of fresh bacteria on the anti bacterial effectiveness of the disinfectant.

v) **The stability test** measures the stability and long term effectiveness of the diluted disinfectant in clean and dirty situations. This supplements the capacity use dilution test.

vi) **The in use test** determines whether living bacteria are present in sample of liquid disinfectant taken from containers from different areas.

This test should be done in hospitals as surprise checks.

In Use Test

Take samples of disinfectants from any container in which it is being used; such as cleansing bucket, closed containers of diluted solutions ready for use.

The sample is removed with a pipette. 1 ml of the sample is diluted in 9 ml nutrient broth (1 in 10 dilutions). Take 2 nutrient agar plates. Inoculate the diluted disinfectant in 10 spots in each plate. One spot should contain 20 µml of 1/10 dilution disinfectant placed on the surface of the agar plate. One nutrient agar plate is incubated at 370 C for 3 days and the other at room temperature for 7 days.

Reading: Any growth (bacterial/fungal) in any one of the plates in 5 or more than 5 spots means failure in disinfectant activity (inefficient due to contamination of the disinfectant with microorganism)

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Other Chemical Disinfectants*

(*few products available in the market-list incomplete-author has no financial interest)

Bacillocid Special

1,6 dihydroxy, 2-5 dioxahexane 11.2 g, gluteraldehyde 5.0 g, benzalkonium chloride 5.0 g alkyl urea derivatives 3.0g

Gluteraldehyde combines with chemically bound formaldehyde (1,6 hydroxy, 2-5 dioxahexane) in hydrolisation with water is an excellent bacteriocide.

High risk areas: A 2% (100ml of solution in % L of water) solution is used weekly or 1 % (50 ml solution in 5 L of water) is used alternate days or 0.5% (25 ml of solution in 5 L water) daily.

Non critical areas 0.25% to 0.5% solution is used for mopping.

Fogging: 2% 20 ml in 1 L water is used for fogging.

Bacillocid Extra

Each 100gm contains (Ethylenedioxy) dimethanol - 14.1g, Glutaraldehyde - 5.0g, Specialized, Hi-Tech inbuilt Cleansors, Corrosion Inhibitors

0.25 to 1% solution for surface disinfection

Aldasan

100g solution contains 9.8g formaldehyde and 9.9g gluteraldehyde

Critical areas are wiped with 1% solution with a contact time of 15 minutes

Lysoformin Plus

100 g solution contains 8.9g Polyhexamethylene biguanide HCl, 23.2g Bis-(3-aminopropyl) dodecylamine, 5.0 g Didecyl dimethyl ammonium chloride

Critical areas are wiped with 1% solution with a contact time of 15 minutes

Lysoformin 2000

100g solution contain 13.0g Formaldehyde, 3.2g Glutaral and 3.6g Glyoxal

Critical areas are wiped with 2% solution with a contact time of 30 minutes

Lysoformin 3000

100g solution 7.5g contain Glyoxal, 9.5g Glutaral and 9.6g Didecyl Dimethyl Ammonium Chloride

1% solution can disinfect surfaces in 15 minutes

Incidur

It is a formaldehyde free surface disinfectant; active agents in 100 ml are 8.8 g Glyoxal and 4.5 g gluteral. It is a broad spectrum microbicidal, its reaction time is 1 hour, effect last long, non corrosive. The solution is non irritant and non carcinogenic. Recommended dilution is 1% in high risk areas and 0.5% in non critical areas.

Incidur Rapid

This disinfectant contains gluteraldehyde, Benzalkonium chloride and Didecyldimethyl ammonium chloride. It is a sporicide at 2% (20ml/ 1L water) and acts in 1 hours time, and a high level disinfectant 0.5% (5ml/ 1L water) 1 hour or 7.5% 7.5ml/ 1L water) in 30 minutes.

Incidin Plus

Active ingredient in 100g : 26 g Glucoprotamine

An aldehyde free compound. 1% solution is used for surface disinfection

Envodil (Complex formulation of stabilized hydrogen peroxide 11% w/v with 0.01% silver nitrate solution)

Surface cleaning 10% solution (100ml Envodil + 1 litre of water) for mopping walls, surfaces and OT floor. Fogging/ Fumigation: 20% solution (200 ml Envodil + 1 Litre water) fogging OT, ICU etc. For 1000cft 200 ml in 800 ml water contact time 20 minutes.

2.45% w/v

Alkaline Gluteraldehyde (Cidex, GlutraMiL, Tridex Plus)

High level disinfection: immerse for20 minutes at 200C. Sterilization: Immerse for 10 hours at 250C. Once activated it can be used for 14 days. Instruments should be cleaned properly and dried before immersion.

Tridex 28LL

Expiration date 28 days from the date of activation. High level disinfection: immerse for20 minutes at 200C. Sterilization: Immerse for 10 hours at 250C.

Cidex OPA

High level disinfectant

Active ingredient

Ortho- phthalaldehyde : 0. 55%

inert ingredients : 99.45%

No activation required, lasts for 14 days

Contact immersion time : 5 minutes at 20 C

Scrubbing and Gowning

***K. Girija MS & **Thomas Cherian MS**



A careful scrubbing and painting are essential procedures in any Ocular surgery. Meticulous scrubbing, painting and draping have helped to reduce the rate of endophthalmitis to around 0.05% to 0.3% all over the world. It has been proved that topical preoperative antibiotics also play a very important role in bringing down the rate of endophthalmitis.

Preoperative preparation of patient

Although it is impossible to sterilise the external eye completely, it is imperative to try and reduce colony counts on the lids and conjunctiva preoperatively, since the main source of infection is the patient's own ocular flora.

The first step in achieving this objective is to emphasise the importance of a hot scrub bath with a head wash on the day of surgery. Thorough facial washing with a medicated soap helps to clean the surgical area prior to disinfection with chemical agents.

Topical instillation of antibiotics in the conjunctival sac is a simple method of delivering drugs to the anterior segment. Topical antibiotics should be started 24 hours before surgery and used 6-8 times during the day. Antibiotics should not be started more than one day prior to surgery, since instillation of topical antibiotics for more than 24 hours may lead to replacement of the patient's own flora by more virulent microorganisms.

A single topical application of 5% Povidone-iodine solution reduces the incidence of endophthalmitis by a factor of three. Povidone-iodine is bactericidal and need not be irrigated out of the eye before surgery.

Although cilia-trimming was once considered helpful in reducing postoperative infection, the present trend is not to trim cilia for intraocular surgery. This has been replaced by the widespread practice of isolating lashes with sterile adhesive drapes. Cleaning the lids, lid margins and adjacent skin with Povidone-iodine 5% is an effective method of eliminating microbes.

Personal hygiene

This includes the surgeon, staff and the patient (already mentioned). Personal cleanliness is of extreme importance for operating theatre personnel. A daily shower, frequent hair washing and attention to hands and fingernails are most important. Finger nails should be kept short enough so that they are not visible over the tips of the fingers.

Short nails are easy to keep clean, will not puncture gloves and should be free of any form of nail treatments or polish. Staff should note and report to the person in charge, any infection, rash or open lesion on their hands, nails or arms. Those with infective lesions should not be allowed to enter the operation theatre. It is recommended that staff use the rest room facilities before scrubbing. Surgery should preferably be done prior to ward rounds.

Dress-code

All personnel entering the operation theatre should change into freshly laundered clothes provided in the changing room. All street clothes should be removed including socks, underskirts etc. Hair must be tied back and up off the collar and should be completely covered with a cap. Mask should be covering the nose and mouth and must fit snugly to the face to prevent passage of air around the sides and fogging of glasses if worn. The mask should be worn only once and should be changed after a break or if it becomes damp. Disposable masks are very efficient and achieve around 98% filtration of bacteria and aerosols.

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All personnel should keep a pair of designated footwear for use in the operating theatre only. All jewellery must be removed prior to scrubbing, as bacteria and dead skin cells accumulate beneath watches, bracelets and rings. All staff should adhere to "bare below the elbows" prior to any form of clinical contact with patients.

Surgical hand wash

Hand antisepsis remains a cornerstone of the overall aseptic technique in surgery, to eliminate transient micro-organisms and reduce resident skin flora. Despite significant advances in glove manufacturing techniques, glove perforation rates have been reported to be as high as 17%, reiterating the importance of good hand antisepsis. Traditional surgical hand antisepsis consists of an aqueous scrub with or without brush, using Povidone iodine (PVP-I) or Chlorhexidine based detergents or using alcohol-based hand rub as an alternative.

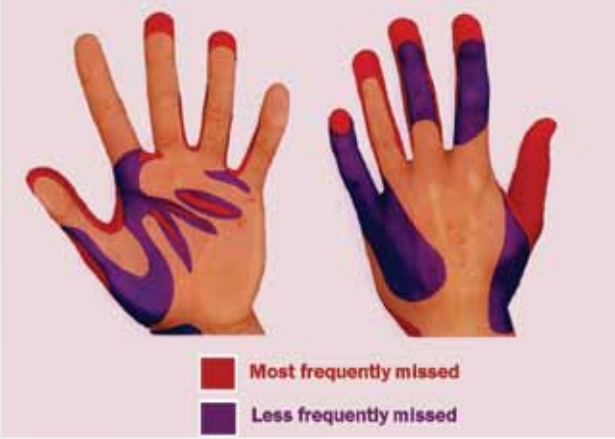
All persons should wash their hands with soap and water before entering the operation theatre. All sterile team members should perform the hand and arm scrub before entering the surgical suite. The basic principle of the scrub is to wash the hands thoroughly, and then to wash from a clean area (the hand) to a less clean area (the arm).

- Turn on the taps. Use your elbows to operate the tap. Alternatively, the tap could be operated with a foot switch, or automatic sensors could be provided for the water taps.
- Wet the hands and arms for an initial pre-scrub wash. Use several drops (5ml) of surgical detergent, work up lather, and then wash the hands and arms thoroughly to the elbows for one minute. Rinse hands and arms thoroughly, allowing the water to run from the hands to the elbows. Do not retrace or shake the hands and arms, let the water drip from them.
- Moisten the sterile brush and work up lather. Clean fingertips and spaces under the fingernails of both hands.
- Only nails should be brushed as brushing of other areas has been shown to be detrimental to the skin surface causing abrasions.
- One can miss several areas of the hand and fingers in a routine hand wash.
- Care should be taken to include all these areas in the surgical hand wash.
- The steps of surgical hand scrub should be meticulously followed
- Spread the antimicrobial scrub solution using Palm to palm to and fro motion.
- Right palm over dorsal surface of left hand, then left palm over dorsal surface of right hand with the fingers interlaced
- Palm to palm with the fingers interlaced
- Back of fingers to opposing palm with fingers interlocked
- Rotational rubbing of right thumb clasped in left palm and vice versa
- Rotational rubbing with clasped fingers of right hand over the palm of left hand and vice versa
- Rotational rubbing of left wrist with palm of right hand and vice versa
- Always rinse from fingertips to elbows. Repeat the process. The whole washing should last for 3-5 minutes.
- Take care not to soak yourself. Remember that wet theatre scrubs can contaminate a sterile gown.
- Once complete, dry both hands using the towels provided.

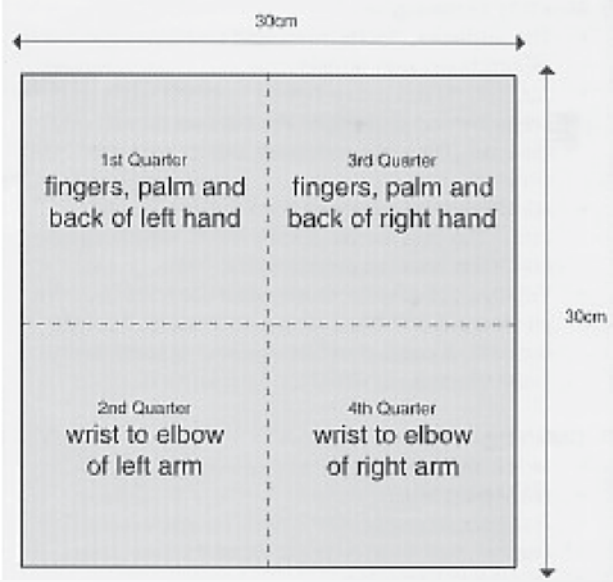
Dry with a Sterile towel employing "4 corner technique". The sterile towel should be at least 30 sq.cm. Use one quarter of the towel to dry the fingers, palm and back of left hand. The second quarter is used for the fingers, palm and back of right hand. Rotate the towel and use the 3rd quarter to dry the wrist to elbow of left arm and use the 4th quarter to dry the wrist to elbow of the right arm. An alcohol based disinfectant solution may be used to rub the hands and allowed to dry.

Certain principles should be followed while scrubbing:

- Rinsing time is not to be included in the total scrub time.







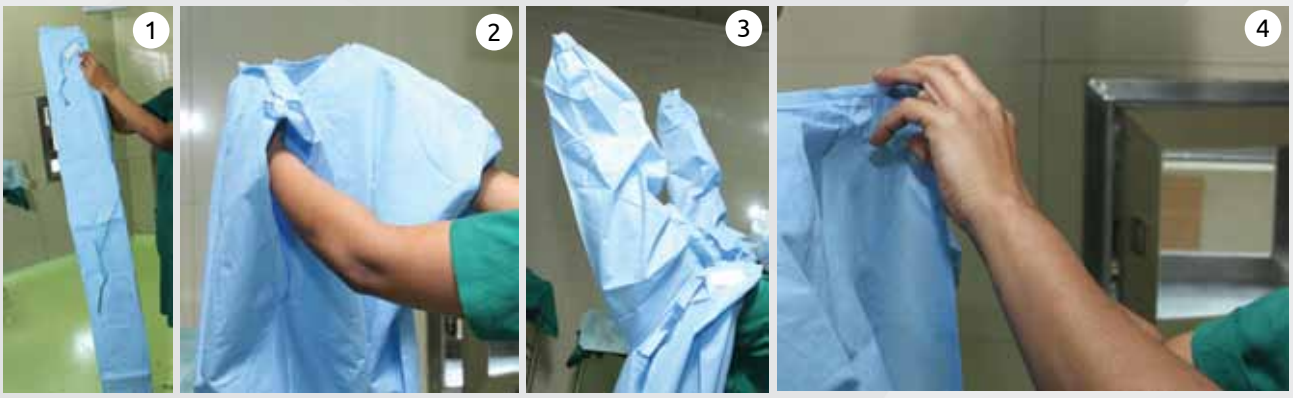
- Un-sterile objects should not be touched once the scrub procedure has begun. The entire scrub procedure must be repeated if an un-sterile object is touched.
- The same scrub procedure should be utilized every time whether it is the first or last one of the day.

Gowning

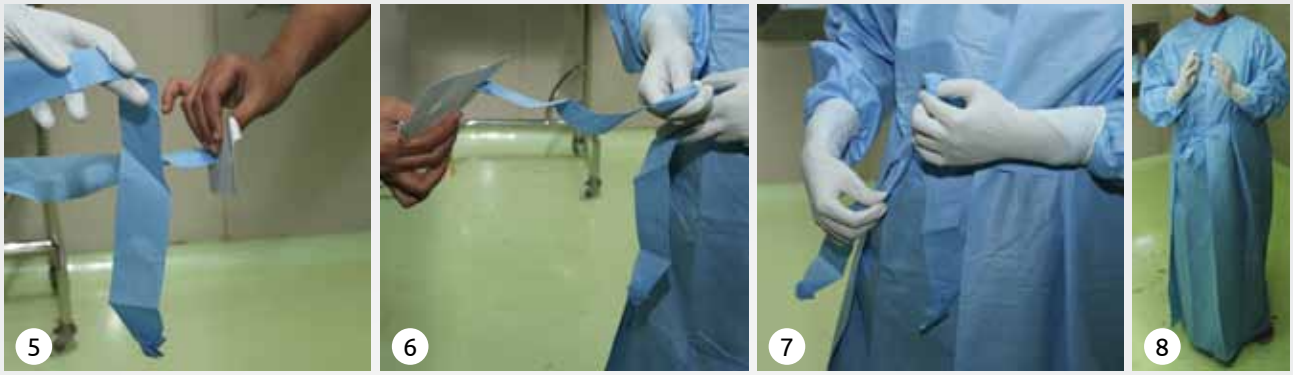
The principle of draping and gowning is that bare skin should not touch the surgical field.

Sterile area of gown extends from chest to the level of sterile field and sleeves from cuff to about 5 cm. above the elbow. Surgical gowns are folded with the inside facing the scrub person. This method of folding facilitates picking up and donning the gown without touching the outside surface. Only the inside of the gown should be touched while putting it on.

Gowning



Gowning (contd.)



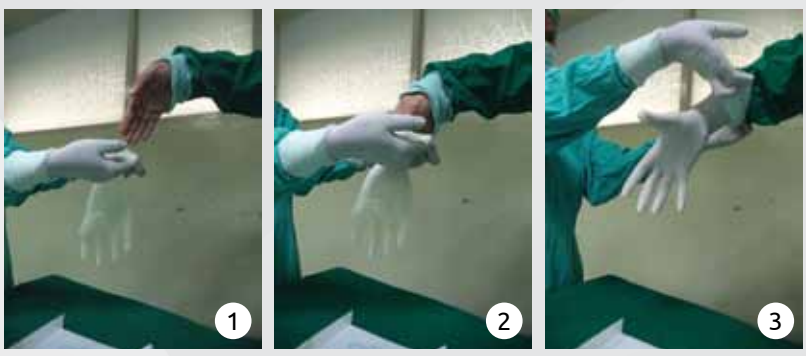
Open Gloving



Closed Gloving



Assisted Gloving



With one hand, pick up the entire folded gown from the wrapper by grasping the gown through all layers, being careful to touch only the inside top layer which is exposed. Step back from the trolley / shelf. Hold the gown near the neck and allow it to unfold being careful that it does not touch either the body or other un-sterile objects.

Grasp the inside shoulder seams and open the gown with the armholes facing. Slide arms part way into the sleeves of the gown keeping hands at shoulder level away from the body.

Slide arms further into the gown sleeves and when the fingertips are level with the proximal edge of the cuff, grasp the inside seam at the juncture of gown sleeve and cuff using thumb and index finger. Be careful that no part of the hand protrudes from the sleeve cuff.

The circulating person should assist at this point to position the gown over the shoulder by grasping the inside surface of the gown at the shoulder seams taking care that their hands are only in contact with the inside surface of the gown. They secure the gown with ties at the neck and waist.

Removal of gown: The circulating staff will unfasten the gown. The gown is carefully removed leaving the gloves on and then gloves are removed. Gown is folded with the inside out.

Gloving (open method)

1. Pick up a glove from the packet by touching only the insides of the 'cuff' of the glove (the gloves are packed 'folded back' upon themselves).

2. Advance your hand into the glove with the assistance of your other hand, making sure that you only touch the insides of the glove (this will keep the external surface as sterile as possible).

3. Once one hand has been gloved, using this 'already-gloved' hand, pick up the other glove, again by only touching the outside of the cuffed area of the glove.

4. Advance the ungloved hand into glove (with the help of the other hand).

5. Be careful when turning the cuff area downwards so that you don't accidentally contaminate the glove.

Gloving (Closed Method)

In this the tips of fingers are kept with in the edge of the sleeve. Glove is picked up with the fingers using the sleeve edge and inserted into the hand taking care not to touch the glow with bare fingers. The other hand can be gloved just as in open gloving.

Assisted Gloving

An assistant in sterile attire holds the glove open so that the surgeon can slide his hand easily into it.

Removal of glove

Grasp the inside of the cuff of right hand glove with left hand. Pull the glove down and discard to the red waste container.

Prepping (Painting)

Ensure that the correct eye is marked before prepping the patient. Use a cap or towel over the patient's head to keep hair tucked away. The hairline is considered a contaminated area.

Do not use Chlorhexidine or alcohol solutions. Povidone iodine paint (not scrub as it contains soap) is used after instilling local anesthetic into the eyes. With a swab soaked in Povidone iodine held on a swab holder, starting from medial to lateral canthus, paint operative eye, cheek, forehead and nose on correct side, using ½ circle motions above and below the eye. Instill 5% Povidone solution into the eye. The antimicrobial effect of Povidone-iodine occurs within one minute of irrigation; it kills 96.7% of bacteria and lasts for at least one hour.

Draping the patient

The purpose of draping is to prevent passage of organisms from unsterile to sterile areas. Draping material may be disposable or non-disposable. The head is draped with a towel exposing the eye to be operated. A large towel drapes the body up to the mouth. A third drape preferably disposable is stuck onto the open eye so that after splitting the adhesive part in the middle, the drape can be folded into the fornices with the speculum, covering the lid margins completely.

A frame may be used to keep the drape away from nose so as to avoid breathing difficulty. A nasal catheter may be used to deliver oxygen. A pulse-oxymeter may be used to monitor the patient.

Please Remember

- The most sterile area is the surgical field and the

area of eye drape extending up to the chest of the patient.

- The palm of the hand comes next (gloved area).
- The whole of forearm, anterior surface of upper arm and area of chest.
- Rest of the areas even though covered with gown or glove are not considered sterile.
- Do not touch tip of instruments even with the gloved hand.
- In between cases if you are changing only the gloves, do not touch any part of the gown with the glove.
- Always keep your hands at chest level; do not hang them loose below the waist.

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Universal Blood and Body Fluid Precautions



Rajiv Sukumaran MS, FRCS

Introduction

Universal Precautions: The practice of avoiding contact with bodily fluids by wearing nonporous gears such as gloves, goggles, and face shields was introduced way back in 1985–88. In 1996, this term was renamed as "Standard Precautions".

The Centre for Disease Control (CDC) defines Standard Precautions as: "A set of precautions intended to prevent transmission of HIV, Hepatitis B virus (HBV), and other blood borne pathogens when providing first aid or health care. Under standard precautions, blood and certain body fluids of all patients are considered potentially infectious for HIV, HBV and other bloodborne pathogens"

Standard infection control precautions

There are eight key elements of universal/standard infection control precautions:

- Hand hygiene,
- Personal protective equipment,
- Sharps disposal,
- Waste disposal,
- Linen handling and segregation,
- Blood and body fluid spillage procedure,
- Handling and transport of specimens,
- Decontamination of equipment and the environment.

1. Hand decontamination

Hand decontamination is the most effective means of preventing cross infection (Fraise& Bradley, 2009). All health workers must be trained appropriately on hand hygiene techniques right at the time of induction. Further, to reinforce the importance of Standard Precautions, an on-going assessment and training of the techniques should be made mandatory for all health workers at least once every two years.

It is important to embrace the 'Five Moments for Hand Hygiene' Appendix 2 (WHO 2009)- "Clean Care is Safer Care". It's a well-known fact that Bacteria and viruses cannot penetrate intact skin. It is therefore, extremely important to maintain healthy skin and prevent cracking, chapping and drying of the skin.

The following are typical situations when hands must be washed using detergent and water:

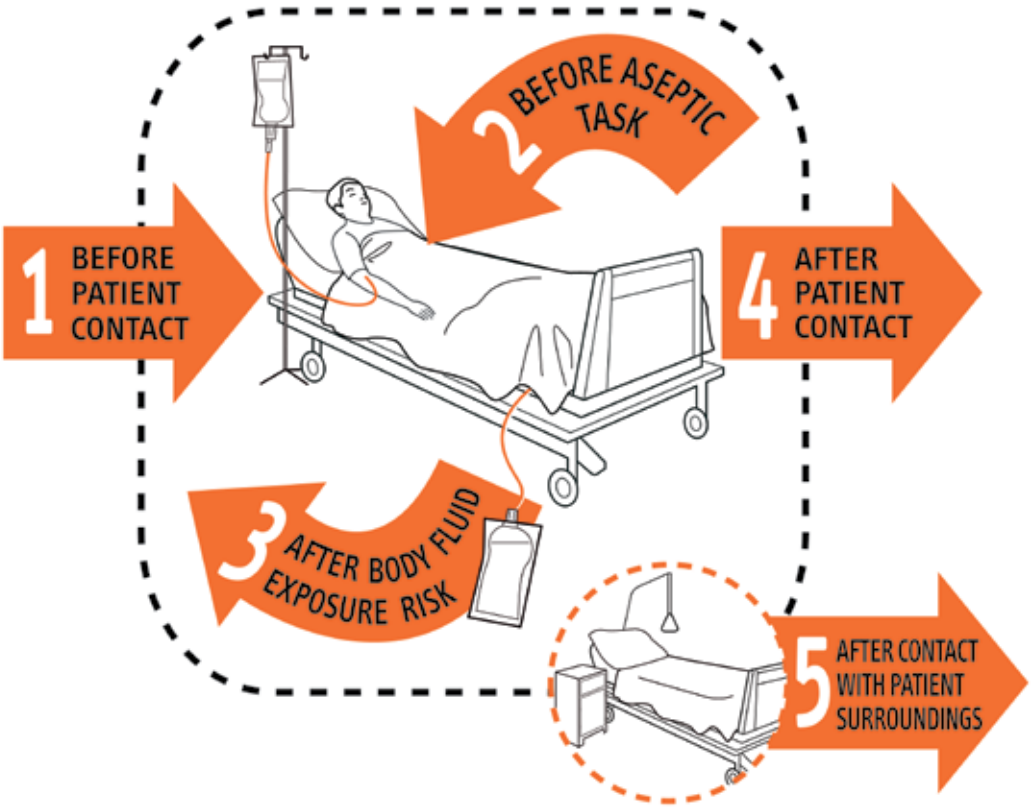
- Whenever hands are visibly dirty,
- After removal of gloves,
- Following any handling of blood or body fluids,
- After any microbial contamination (e.g. wound examination, wound dressing, sputum aspiration etc),
- Before performing an aseptic procedure,
- Before preparing, handling or eating food,
- After visiting the toilet,
- After patient toileting,
- After handling laundry,
- After dealing with patients symptomatic with diarrhoea and vomiting e.g. Rotavirus or Clostridium difficile.

Hand decontamination using alcohol based gel or solution.

In the following situations, alcohol based gel or solution can be used on socially clean hands:

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Your 5 moments for HAND HYGIENE



1 BEFORE PATIENT CONTACT	WHEN? Clean your hands before touching a patient when approaching him or her WHY? To protect the patient against harmful germs carried on your hands
2 BEFORE AN ASEPTIC TASK	WHEN? Clean your hands immediately before any aseptic task WHY? To protect the patient against harmful germs, including the patient's own germs, entering his or her body
3 AFTER BODY FLUID EXPOSURE RISK	WHEN? Clean your hands immediately after an exposure risk to body fluids (and after glove removal) WHY? To protect yourself and the health-care environment from harmful patient germs
4 AFTER PATIENT CONTACT	WHEN? Clean your hands after touching a patient and his or her immediate surroundings when leaving WHY? To protect yourself and the health-care environment from harmful patient germs
5 AFTER CONTACT WITH PATIENT SURROUNDINGS	WHEN? Clean your hands after touching any object or furniture in the patient's immediate surroundings, when leaving - even without touching the patient WHY? To protect yourself and the health-care environment from harmful patient germs

WORLD ALLIANCE FOR PATIENT SAFETY

WHO acknowledges the Hôpitaux Universitaires de Genève (HUG), in particular the members of the Infection Control Programme, for their active participation in developing this material.

World Health Organization

October 2006, version 1.

- Prior to and following examination of a patient,
- Prior to handling patient equipment,
- On entering and leaving the clinical environment,
- Between social patient contacts e.g. ward rounds,
- Before entering and leaving an isolation room or area,
- Before and after transfer of patients from / bed/ chair/ trolley,
- Venepuncture.

2. Personal Protective Equipment

'Personal Protective Equipment' (PPE) consists of aprons, gloves, masks and eye protection. These are primarily used to protect staff and health workers from the risks involved in transmission of micro-organisms. The selection of the PPE would differ depending on the risk of transmission of micro-organisms to the patient and the contamination of the Health Care Worker(HCW) clothing/skin by the patient's blood, body fluids, secretions and excretions.

Gloves

The use of gloves can reduce the risk of acquiring infections due to direct skin contact between HCW and patients. Gloves should not be worn unnecessarily or as a substitute for hand decontamination as prolonged and indiscriminate use may cause adverse reactions and skin sensitivity (WHO 2009).

- Gloves are a single use item.
- Gloves can reduce the likelihood of contact dermatitis in staff exposed to chemical agents.
- Gloves must be worn when direct contact with contact with blood, body fluids, non-intact skin or mucus membranes is anticipated.
- Gloves must be changed between patients and different procedures on the same patient.
- Gloves must be disposed of in a yellow clinical waste bin.
- Hands must be decontaminated with soap and water immediately on removal of gloves.

Indications for wearing gloves:

- Venepuncture,
- Wound inspection,
- Cannula insertion,
- Aseptic Non touch Technique,
- Emptying urinary catheter bags/stoma bags,
- Cleaning soiled equipment,
- IV drug administration,
- Invasive procedures,
- Dealing with body fluids,
- Surgical procedures – use sterile gloves.

Sterile gloves

Training on the correct procedure for donning and removing sterile gloves must be provided to all staff to prevent the contamination of the outer surface of the glove and the hands. Where a patient is known to be allergic to latex, staff must use non-latex gloves.



Non-latex glove

Disposable aprons and gowns

Plastic aprons must be worn to reduce the level of contamination of uniforms/clothing where direct patient care is given and there is potential for the dispersal of pathogens.

Such activities may include:

- Assisting patients with toileting,
- Bathing,
- Bed making,
- Procedures causing splashing of body fluids or blood.

Sterile gowns protect patients from infection where

they are undergoing procedures such as insertion of central venous catheters. The type of apron or gown to be worn depends on an assessment of risk of contact with body fluids.

Aprons:

- Must be worn where there is a risk of blood or body fluid contamination of the uniform,
- Must be changed between patients and different procedures on the same patient,
- Must be disposed off in a yellow clinical waste bin, as clinical waste,
- May be worn while on decontamination activities like cleaning and disinfecting.



Disposable plastic apron

Gowns:

- Full body gowns must be worn by operating theatre scrub staff. These should be either single use waterproof disposable or re-usable waterproof gowns,
- They must be worn where there is a risk of extensive contamination of uniform or clothing,
- Must be single use and replaced after each episode of care or task,
- If disposable, it has to be discarded in a yellow clinical waste bin.
- For general clinical procedures long sleeved non sterile gowns should fully cover the area to be protected,
- Gowns are not required for the routine care of patients with influenza unless aerosol generating procedures are being performed,
- Gowns may be required when nursing patients with Norwegian scabies,
- Gowns may be required when nursing a patient with possible/confirmed viral haemorrhagic fever.

Eye protection

Mucous membranes of the eyes and mouth must be protected when there is a risk of blood splashes. Eyes can be protected by using goggles, visors or spectacles with side cover. They must be comfortable to wear, fit correctly and allow for clear vision. Eye protection that is designed for multi-use, must be cleaned with detergent between each task and each patient. Eye protection must be available in all areas especially where splashesare more likely:

- Emergency Department,
- Endoscopy,
- Theatres,
- Central Delivery Suite,
- Critical Care Unit.

Eye protection should be worn

- Where Splash or spray of blood or body fluid is likely,
- When dealing with chemicals,
- During aerosol and sputum generating procedures.



Face and eye protection equipment

Masks and respirators

Masks are worn to protect the wearer from potential exposure to micro-organisms through splashes of blood or body fluid. The use of a mask must be based on an assessment of risk of body fluid exposure. Staff may select a face mask or respirator depending on the level of protection required. Masks are rarely worn in general ward environments.

Surgical face masks protect the wearer from expelling droplets (>0.5 microns) into the environment. If the mask is fluid resistant, the wearer will be protected

from splashes. Respirators are made to specific standards EN 149 2001, FFP2, FFP3. Respirators are worn to protect the healthcare worker from airborne particles (<0.5microns) such as viruses. Every staff must be trained in the correct application of these masks to ensure their efficacy.



Respirator

Guidance for the selection of masks

Choosing the appropriate mask is important to ensure protection is adequate,

- Where a mask is required it should be applied prior to entering the isolation room.
- Masks must be worn correctly and be close-fitting.
- Handled as little as possible.
- Changed between operations or patients.
- Changed if wet.
- Discarded immediately after removal, in a yellow clinical waste bin.
- Hands must be washed on removal of mask.

3. Blood /body fluid spillage

Protective clothing like gloves and apron must be worn when dealing with blood/body fluid spillage. The area must be made safe to prevent further contamination and protect staff and patients.

Blood/body fluid spillage can be divided into groups:

- Spillage on the floor or a large surface area,
- Soiling of equipment or where it is not practicable to use a hypochlorite powder.

Spillage on the floor or a large surface area

For spillages on the floor or a large surface area, a 10,000 ppm hypochlorite powder must be used.

- Use PPE, wear gloves and apron.
- Cover the spillage with chlorine releasing powder.
- Hypochlorite containing products must not be used on urine spillage as chlorine gas will be released.
- Use paper roll to remove the spillage and place in a yellow clinical waste bag.
- Wash area with detergent and water.
- Dispose of PPE in a yellow clinical waste bin.
- Decontaminate hands using soap and water.

Small blood spillage on equipment and in other areas where it is not practicable to use hypochlorite powder

- Use Personal Protective Equipments like gloves and apron.
- Clean the area with detergent and water.
- Surfaces or equipment contaminated with blood should be disinfected with a chlorine based disinfectant.
- Dispose of waste in a yellow clinical waste bin.
- Dispose of PPE as in a yellow clinical waste bin.
- Decontaminate hands using soap and water.

Body fluids e.g. vomit, urine, faeces

- Use Personal Protective Equipments like gloves and apron.
- Clear away spillage with paper roll.
- Wash area with detergent and water using paper roll.
- Dispose of used paper roll in a yellow clinical waste bin.
- Dispose of PPE in a yellow clinical waste bin.
- Decontaminate hands using soap and water.

4. Waste Disposal

- Waste bins/bags must be of the appropriate type, colour and size,
- Ensure adequate supplies of waste bags/bins to enable the right process of waste segregation
- Waste bag holders are fire-proof, leak-proof, foot pedal operated, secure, well-maintained and well-cleaned

- Signs and notices must be displayed to ensure that staff can quickly refer to correct information about segregation of waste and the correct container to be used,
- Waste bins and other containers must be kept clean.

Segregation of waste

All waste is to be segregated at the point of use.

5. Inoculation (Sharps) injury or Needle Stick Injury (NSI)

An inoculation injury occurs where a needle or other sharp contaminated with blood or other high risk body fluid penetrates percutaneously (through the skin). Such injuries also include cuts, pinches, scratches and bites which break the skin and splashes of body fluids to the eyes.

Accidents with needles are the most common, so injuries from sharps are often called needle stick injuries.

Preventing inoculation injury

The emphasis on preventing contaminated inoculation injury must focus on ensuring safe handling practices:

- Attend Infection Prevention and Control Induction and Infection Prevention and Control Clinical Update,
- Use appropriate PPE,
- Used sharps must be discarded into a sharps container at the point of use. Needles and syringes must not be disassembled by hand prior to disposal,
- Do not re-cap needles,
- Do not carry loose sharps in your own hands - use a plastic tray,
- Sharps must not be passed directly from hand to hand, use a tray so that the same sharp device is not touched by more than one person,
- Sharps containers must not be filled above the mark indicating they are full,
- Temporary closure mechanisms should be used when sharps boxes are not in use,
- Sharps containers should be located in a safe position,

• Report all incidents (including near misses) involving contaminated sharps at the time of occurrence, or as soon as possible afterwards, to the line manager/ Supervisor/Team Leader on duty and Occupational Health.

6. Linen Handling

Used linen is a potential source of infection as it is likely to be contaminated with potentially pathogenic organisms.

- Gloves and aprons must be worn when dealing with soiled, wet or blood stained linen.
- Linen should be bagged by the bedside, never carried through a clinical area by hand.
- Linen bags must be half full only. They must not be overfilled.
- Lined from infected patients or blood stained must be placed in an inner red alginate bag, and then placed into an outer red plastic bag.
- When removing soiled linen avoid the production of aerosols.
- If patient's clothing is being laundered at home, place soiled laundry in a water soluble clothing bag, inside an outer plastic bag. Inform visitors that laundry is awaiting collection in the patient's locker.

7. Pathology specimens

All specimens should be handled with care. PPE must be used when handling specimens.

- All specimens must be safely contained in a leak proof container which is additionally placed in a sealed polythene bag.
- The request form should be attached.
- Ensure that the outside of the container bag remain free from contamination with blood or body fluids, faeces or vomit

Bio-hazard specimens from known or clinically suspected infected patients

- The request form must be labelled with 'inoculation risk' (hand written on the request form or free text on ICE).
- If there is a risk of spillage of contents then the specimen should be placed inside a second polythene bag i.e. 'double bagging'.

Colour Coding	Type of Containers	Waste Category	Treatment Options as per Schedule 1
Yellow	Plastic bag	1,2,3,6	Incineration/deep burial
Red	Disinfected Container/ Plastic bag	3,6,7	Autoclaving/Micro waving/ Chemical Treatment
Blue/ White translucent	Plastic bag/puncture proof container	4,7	Autoclaving/Micro waving/ chemical treatment and destruction/ shredding
Black	Plastic bag	5,9,10 (Solid)	Disposal in secured landfill

The following bio-hazard specimens must not be sent via the vacuum tube system;

- Classic or variant Creutzfeldt-Jakob disease (CJD),
- Diphtheria,
- Hepatitis B or C,
- HIV,
- Rabies virus,
- Tuberculosis,
- Typhoid.

8. Decontamination of equipment

Any equipment that is used on several patients can be a potential source of infection if not appropriately decontaminated after each use. The selection of the appropriate decontamination method will ensure that the equipment is clean and risk-free. Cleaning is an essential stage in the decontamination process and must always precede disinfection and /or sterilization. Always check the manufacturer's instructions for use of suitable cleaning agents. The user of the device is responsible for ensuring that it is visibly clean and free from contamination with blood/body fluids after every procedure and prior to re-use or prior to sending the equipment for repair (internally/externally). The user must sign and date the appropriate labels to confirm that the equipment has been cleaned. During decontamination, the user must check clinical equipment for signs of damage and send for repair or disposal as required. Equipment sent for repair must be labelled with the user's name, signature and date. Suitable personal protective equipment must be worn during decontamination procedures to protect the healthcare worker from exposure to microorganisms or infectious agents, where the risk of splash is anticipated.

As far as an Ophthalmologist is concerned, cleaning of Slit lamp after examining every patient, especially if they have infective eye disease, should be made a routine. The tonometer, examination lens, etc. should also be decontaminated after every single use.

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Hospital Waste Management



C.V. Anthrayose Kakkanatt MS; DOMS; MPhil

Management of waste generated by health care institutions and hospitals has emerged as a prime area of concern in recent times. Safe and effective management of biomedical waste is not only a legal necessity but also a social responsibility.

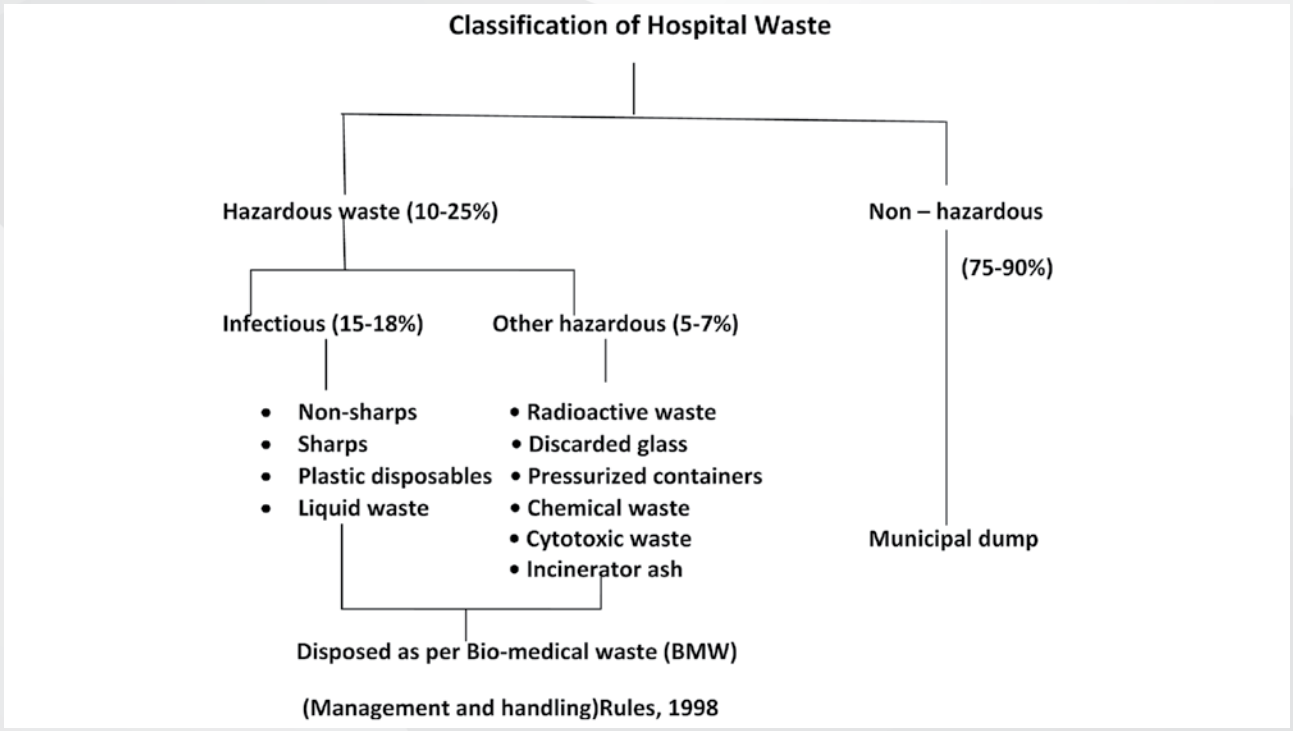
It has been established beyond doubt that improper management of hospital waste has been responsible for spread of infection and diseases. Improper disposal of waste is a health hazard for

1. Hospital employees
2. Patients
3. Society

Hospital employees comes in close contact with infected tissues, biological fluids and infected materials of patients. The risk of accidental infection is faced by doctors, nurses, labour staff, and technical staff working in laboratories. As far as patients are concerned the risk of cross infection and hospital acquired infection increases, if adequate precautions are not observed.

Biomedical Waste (BMW) Management Rules

Hospital waste management has been brought into focus recently, particularly with the ruling by Hon'ble Supreme Court of India and the notification of the Biomedical Waste (Management and Handling) Rules, 1998, which makes it mandatory for the health care establishments to segregate, disinfect and dispose their waste in an eco-friendly manner. No efforts need to be spared to ensure



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implementing strategies for safe and sound management of hospital waste. Rising to the need, National Guidelines for management of Hospital Waste, based on the Biomedical Waste (management and handling) Rules, 1998 were prepared by the Directorate General of Health Services/ Ministry of health and family Welfare.

Biomedical Waste

It is the waste generated by health care establishments, research facilities and laboratories. Waste may be generated during:

- Diagnosis, treatment of a disease and immunization for disease
- Associated biomedical research, and
- Production and testing of biologicals

Major sources of Biomedical Waste

Broadly, the biomedical waste is generated in the hospitals, nursing homes, clinics, pathology/ microbiology laboratories, blood banks, animal houses and veterinary institute

The hazardous hospital waste may further be classified into the following categories.

1. Infections
2. Injurious
3. Cytotoxic
4. Chemical

WHO has classified the biomedical waste into following categories:-

a) General Wastes: All nonhazardous, domestic wastes e.g., i) Peels of vegetables, fruits ii) papers iii) packing materials etc.

b) Pathological Wastes: Which include i)tissues ii) organs iii) body parts iv) human foetus v)products of conception –abortus vi) animal carcasses vii) blood viii) body fluids

c) Radio active wastes includes : i)solids ii) gases iii) liquids resulting from analysis, procedures, body organs imaging, tumour localization, treatment

d) Chemical Waste : This may be hazardous or non hazardous

Hazardous: material which is i) toxic ii) corrosive iii) flammable iv) reactive v) genotoxic(can alter genetic material) vi) teratogenic (can cause congenital malformations)

Non Hazardous: e. g antiseptics.

e) Infectious waste: This waste contains pathogenic organisms in sufficient quantity and therefore pose a threat of serious infection.

These items are i) culture from laboratories ii) waste from surgery- i.e. removal of infected tissue. iii) autopsy on patients with infected diseases iv) waste from patients in isolation wards v) waste from patients undergoing haemodialysis vi) waste associated with infected animals.

f) Sharps: the items which can cause a cut or puncture. i) needles ii) blades

iii) broken syringe iv) glass pieces

g) Pharmaceutical waste: Certain items in the drug industry or in hospitals can be harmful. i) degraded raw materials ii) by product iii) outdated drug iv) contaminated drug v) spilled drug or chemical.

h) Pressurized containers and aerosols

Simplified classification of hospital wastes for developing countries:

a) Non hazardous hospital waste – i.e. general waste

b) Sharps

c) Infectious waste (other than infected sharps)

d) Chemical and pharmaceutical waste

e) Other hazardous hospital or medical waste.

Routes of Transmission of Disease by Biomedical Waste

- Inhalation(Breathing)
- Ingestion
- Contamination of wounds
- Absorption from cutaneous and mucous membranes
- Injury causing breach in continuity of surface followed by infection.

Mode of infection

There are different ways by which the infection enters the body:

1. Injury on the job: e.g. accidental needle injury, cut

on finger coming in contact with infected patient or material.

2. Negligence: Not talking routine precautions while handling potentially infected or infected material. E.g. not using protective gloves while handling patients, during autopsy or transporting garbage.

3. Ignorance: Not talking about the consequences of handling infected material or patient. Handling patients without due precautions can cause infection e.g. not using gloves, while handling infected patient or material because the risk of infection is not known.

4. Drug addicts: drug addicts abusing injectable substances are likely to acquire used syringes directly from the garbage disposal site or may purchase the same from grey market. This behavior exposes them to higher risk of infection

5. Rag pickers: Almost all the garbage dumping sites are regularly visited by the rag pickers who try to scavenge the items which could be sold. E.g. gloves, needles, syringes, tubings, used oxigenators, polythene bags, boxes etc.

6. Reuse of disposable items: Inspite of manufacture's instructions like 'for single use only' or 'do not resterilize' many departments and hospitals reuse disposable items after sterilization. If the items like needles, syringes, fine catheters are not properly cleaned or properly sterilized, there is risk of infection.

Disease Associated with Biomedical Waste

- AIDS
- Hepatitis
- Gastroenteritis, typhoid fever
- Skin infections
- Sepicaemia
- Tuberculosis
- Tetanus
- Cancer
- Genetic / foetus abnormalities

Safety Measures

According to WHO (1999), with regard to life threatening virus infections such as HIV/ AIDS and Hepatitis B and C, health care workers, particularly nurses, are at greatest risk of infection through injuries from contaminated sharps (largely hypodermic needles)

Aims of Biomedical waste Management

1. To prevent the transmission of disease from patient to patient, from patient to health worker and vice versa,

2. To prevent injury to the health care workers and workers in support services, while handling biomedical waste, and

3. To prevent a general exposure to the harmful effects of the cytotoxic, genotoxic and chemical waste as much as possible.

Personal Protective Devices

Important protective devices are:

- Gloves
- Cap and mask/ face mask
- Gown /apron (and full sleeve shirts)
- Gumboots with thick sole
- Eye glasses/ protective goggles
- Shield

The law Regarding Biomedical waste Treatment

THE LAW: WHAT AND FOR WHOM?

Safe disposal of biomedical waste is now a legal requirement in our country. In this connection, the government of India, first, enacted the Environment (Protection) Act in 1986 and then notified the Rules of the Management and Handling of Biomedical Waste on 20th July, 1998. These rules apply to all those who generate, collect, receive, store, transport, treat, dispose or handle biomedical waste in any form.

Provisions of the Law

As per these notified rules, biomedical waste is not to be mixed with any other type of waste. It has to be segregated and disinfected into specified containers/ bags at the point of its generation. Each container has to be specially labeled also. Transportation of such waste has to be done in specified vehicles only. The untreated medical waste is not to be stored beyond a period of 48 hours. Specific methods of treatment and disposal of various categories of biomedical waste are also prescribed in these rules.

The Schedules

The Biomedical waste (Management and Handling) Rules have six schedules. A brief summary of the contents of each schedule is presented below:

Schedule	Contents
Schedule I	Classification of Biomedical waste into various categories.
Schedule II	Color coding and type of containers to be used for each category of biomedical waste.
Schedule III	Proforma of the label to be used on container/bag.
Schedule IV	Proforma of label for transport of waste container/ bag.
Schedule V	Standards for treatment and disposal of waste.
Schedule VI	Deadlines for the creation of waste treatment facilities.
Form I	Format of application for authorization
Form II	Format of annual report
Form III	Format of accident reporting

Categories of biomedical waste and methods of disposal

Category	Waste type	Treatment and disposal
Category 1	Human waste (Tissues, organs, body parts)	Incineration &/ deep burial
Category 2	Animal waste	Incineration &/ deep burial
Category 3	Microbiological and Biotechnology waste	Autoclave /microwave incineration
Category 4	Sharps	Disinfection (Chemical treatment)-Autoclave /micro waving and Mutilation /shredding.
Category 5	Discarded medicines and cytotoxic drugs	Incineration &/ Destruction and disposal in secured landfills
Category 6	Contaminated solid waste	Incineration &/ autoclaving/micro waving
Category 7	Solid waste(Disposable Items, other than waste Sharps)	Disinfection by chemical treatment autoclaving/ micro waving and mutilation / shredding
Category 8	Liquid waste(Generated from laboratory washing, cleaning, house keeping and disinfecting activity)	Disinfection by chemical treatment and discharge into drains
Category 9	Incineration ash	Disposal in municipal landfill
Category 10	Chemical waste	Chemical treatment and discharge into drain for liquids and secured landfill for solids

Standards for Incinerators

Operating Standards

1. Combustion efficiency (CE) shall be at least 99.00 percent

2. The temperature of the primary chamber shall be 800˚C ± 50˚C

3. The secondary chamber gas residence time shall be at least 1(one) second at 1050˚± 50˚C, with minimum 3 percent oxygen in the stack gas.

Emission Standards

Parameters	Concentration mg/Nm^3 at (12% CO_2 Correction)
Particulate matter	150
Nitrogen oxides	450
HCL	50
Minimum stack height shall be 30 meters above ground Volatile organic compounds in ash shall not be more that 0.01percent	

Standards for deep burial

A pit or trench should be dug about two meters deep. It should be half filled with waste, then covered with lime within 50cm of the surface, before filling the rest of pit with soil.

Authority of the Government

The government is empowered with certain authority to implement these rules as per provisions in various sections of Environment Protection ACT, 1986.

Disposal of hospital waste

For safe and effective disposal of waste generated in hospitals, following principles are followed:

1. Segregation
2. Disinfection
3. Storage
4. Transport
5. Final disposal

Waste collection and segregation

Waste should be collected and segregated at the site of generation itself. Segregation of waste denotes the separation of waste into various specified categories as per its nature. For this purpose, use of specially colored waste containers and plastic bags is mandatory.

Advantage of segregation:

a) General waste does not become infectious b) segregation reduces chances of infection of staff c) treatment cost comes down d) non infected waste to be recycled

Segregation is carried out at the site of waste generation

a) Wards b) operation theaters c) ICUs d) stores e) pharmacy f) laboratories g) autopsy room etc.

Color coding and Types of Containers for Disposal of Biomedical waste

Color Coding	Type of Container	Waste Category	Treatment Option
Yellow	Plastic Bag	Cat.1,2,3,6	Incineration/deep burial
Red	Disinfected Container/ Plastic Bag.	Cat.3,6,7	Autoclaving /micro waving/ chemical treatment
Blue/White	Plastic bag/Translucent Puncture proof Container.	Cat.4,7	Autoclaving /micro waving/ chemical treatment and destruction /shredding
Black	Plastic bag	Cat. 5,9,10	Disposal in secured landfill

Contents of Waste Bag

A brief description of the wastes to be segregated in to different colored bags is given below:

1. Yellow bag: Human tissues, organs and body parts. Waste generated from the animal houses. Microbiology cultures, stocks and vaccines, human and animal cell cultures, waste generated from production of biological, solid contaminated waste like cotton, dressing, plaster casts, linens, beddings and other such material contaminated with blood or body fluids.

2. Red bag: In case, incineration is not available for certain type of waste mentioned above for the yellow bag(microbiology/biotechnology waste, contaminated solid waste), then it may be collected in the red bag alone with solid disposal waste(e.g. syringes, IV sets, urobags, blood bags, gloves, catheters, etc). All these items can be sent to a landfill site only after autoclaving / micro waving or chemical disinfection.

3. Blue bag: This contains used and unused sharps. It may also contain solid disposal waste. All these items are sent to the landfill site after chemical disinfection/ autoclaving/ micro waving and shredding and mutilation.

4. Black bag: Discarded drugs, incinerator ash, food and paper waste are put in the black bags and sent to the municipal landfill.



Colour coded wastebins

Transport

Transportation of garbage can be within the hospital i.e. internal and from hospital to final disposal site i.e. external

Transportation to the Central Storage Area (Internal Transport)

While transporting the waste to the central storage area, certain rules must be followed as given below:

1. Check that the waste bags/ containers are properly and effectively sealed.

2. Waste bag is properly labeled.

3. Bags should always be picked up by the neck and placed. If it has to be moved for further handling, the bag should be picked up by its neck only. Hand should not be put under the bag. At a time only one bag should be lifted.

4. Manual handling of the waste should be minimized to reduce the risk of needle prick injury and infection. Avoid close contact between body and bag/container.

5. Waste bags or container should not be thrown or dropped.

6. Waste bags and containers should be removed daily from wards/OPDs or even more frequently as in operation theaters, intensive care units and labour rooms.

Central Storage

The central storage area in a hospital should be ideally situated on the ground floor and near the rear entrance. This will make the transportation of waste to the site of final disposal easier. As per rules, biomedical waste cannot be stored for more than 24 to 48 hours.

Transport to the Final Disposal Site (External Transport)

Transportation from the health care establishment to the site of final disposal (incinerator/ landfill area etc) should preferably be done in a motor vehicle, as these sites are likely to be situated at a distance from the hospital. Closed transportation in these motor vehicles (truck, tractor, trolly, etc) is desirable as it prevents the spillage on the way.

Disposal Techniques

Disposal of biomedical waste in to two steps:

1. Pretreatment: The infected waste that cannot be incinerated (e.g. plastic and rubber items, sharps, etc)

has to be disinfected first, before it is sent for the final disposal.

2. Final disposal: This involves deep burial, land filling or incineration. Both these forms are discussed below in detail.

Pretreatment- Disinfection

To render infectious items free from pathogenic organism disinfection is carried out before transporting and disposing them. Disinfection of non-incinerable items can be done in many ways as described below:

Chemical Disinfection

Plastic, rubber and metallic items (like IV sets, blood bags, gloves, catheters, urobags, syringes and needles, must be chemically disinfected before they are sent for final disposal (Landfill)

Chemical disinfection can be done in following steps:

1. Mutilate the syringe and needles with a needle destroyer. Cut all other plastic / rubber item with the help of scissors (so that they cannot be reused).

2. Make 1 per cent hypochlorite solution (fresh everyday) by dissolving 10 Gms of this powder (approx 2 spoonfuls) in 1 Litre of water in a plastic bucket.

3. Keep another, smaller bucket with perforations inside the main bucket(having the solution). Put all the items that are to be disinfected inside the perforated bucket and ensure that they are kept well dipped in the solution for 30 to 60 minutes.

4. After 30 to 60 minutes pull out the perforated bucket (while solution remains back in the main bucket), take out the disinfected items and put them in a proper waste bag. Sharps should be kept in a tough cardboard box and then in the plastic bag so as to avoid damage to the bags.

5. Change the solution every 12 hours.

Autoclave

This is an effective technique for sterilization of microbiology /biotechnology waste and also for the infected disposable plastic and rubber waste (e.g., gloves, blood bags, urobags, IV sets, syringes, etc)

There should be separate autoclave for the sterilization of biomedical waste.



Hydroclave

In this method shredded infectious waste is exposed to high temperature, high-pressure steam like an autoclave. This also inactivates most of the micro organisms if temperature and contact time are sufficient. This method has a relatively low investment and operating cost and its environmental impact is also less.

Microclave Irradiation

This technique is also effective (like autoclave / hydroclave) in sterilizing the infected, disposable waste. Most microorganisms are destroyed by the action of microwaves. The water contained within the waste is rapidly heated and the infectious components are destroyed by the heat conduction.

Shredder for Plastic Material

Shredder for plastic material (plastic bottles, IV sets, syringes etc.) cuts the plastic waste into small pieces of 1 cm size chips. It ensures that syringes and other plastic materials are rendered non-recyclable.

Final disposal

Final disposal of waste depends on its category. Noninfectious waste like papers can be recycled.

Biodegradable waste can be used for landfill, vermiculture, or just buried.

Infectious solid waste is incinerated. Infectious liquid waste is disinfected and flushed out or discharged in the drains.

The following techniques can dispose off the biomedical waste on a final basis.

Incineration

It is a high temperature, dry oxidation process that reduces organic and combustible waste to inorganic, incombustible matter. It also reduces the waste volume and weight. It is usually selected for the waste that cannot be reused, recycled or disposed off in a landfill site. Incineration requires no pretreatment provided certain waste types are not included.

Following waste types may be easily submitted for incineration:

1. Human waste(tissues, body parts. blood and body fluids)

2. Animal waste

3. Laboratory waste

4. Dressing material

Following waste should not be incinerated

1. Pressurized gas containers

2. Large amount of reactive chemical waste

3. Photographic /radiographic waste

4. Halogenated plastic such as polyvinyl chloride(PVC)

5. Waste with high mercury or cadmium content (such as thermometers, used batteries)

6. Sealed ampoules or ampoules containing heavy metals

Incinerators are of three types:

1. Single chamber furnaces: These may be the cheapest units

2. Double chamber pyrolytic incinerators: These are most reliable and commonly used for disposal of biomedical waste. They are also referred to as double chambered incinerators. This equipment may be somewhat expensive and requires trained personnel to handle it. Regular maintenance and operational care are also needed.

3. Rotary kilns: It comprises a rotating oven and a post combustion chamber. It may be specially used to burn chemical waste.

Safe pit for Sharps

Besides other methods of disposal for sharps, burial in safe pit is an effective and economical method. Sharps (needles and blades) are being used in day –to –day practice in all health care units.

Design and construction: It can be constructed by 5 feet circular concrete ring of 3' diameter or by using bricks (4'×3'×5' deep) which can be made circular or rectangular.

A slab is used on top in which GIC pipe with 5½ or 6½ diameter is used which is fitted with lock and key arrangements. Size will vary as per requirement, i.e. is quantum of sharp waste.

Landfill

It is another choice for final disposal of biomedical waste and it can be quite effective if practiced appropriately. While open dumping of biomedical waste cannot be recommended for the reasons of acute pollution problems, fires, higher risk of disease transmission and open access to scavengers and animals, a sanitary landfill observing certain rules can be an acceptable choice particularly in developing countries.

Alternative Techniques

Several other techniques have been developed for management of biomedical waste.

Plasma Arc Technology

Using a plasma converter, the system forces gas through an electrical field to ionize the gas into plasma state that conducts electricity and achieves high temperatures. The plasma converter is very well insulated and completely computer controlled.

The advantages are:

a. Can process any and all waste materials.

b. Recycles waste into valuable commodities

c. Provides safe and irreversible destruction of the most hazardous waste

d. Converts toxic substances into harmless material and does not require the waste to be sorted.

Type of container and color code for collection of biomedical waste

Sl.No.	Category	Type of container	Color coding
	Human anatomical waste	Plastic bag	Yellow
	Animal waste	Plastic bag	Yellow
	Microbiological and Biotechnology waste	Plastic bag	Yellow/Red
	Waste sharps	Plastic bag, Puncture proof Container	Blue/White/Translucent
	Discarded medicines and Cytotoxic waste	Plastic bag	Black
	Solid waste(Soiled)	Plastic bag, Puncture proof Container	Yellow/Red
	Solid waste(Plastic)	Plastic bag	Blue/White/Translucent
	Liquid Waste	Plastic bag	
	Incineration ash	Plastic bag	Black
	Chemical waste(solid)	Plastic bag	Black

e. As there is almost no residue, it eliminates the need for landfill and can be used in the countries, which lack landfill space.

Electro thermal Deactivation (ETD) Technology

It uses radioactive frequency (RF) waves for treatment of regulated waste. This is an alternative technology to incineration and similar to microwave. The advantage over microwave is that RF has a longer wave-length (9-12 feet) having deep penetration. Compared to incineration, this technology has no toxic air or water emissions. The waste is reduced by 85 percent volume and rendered unrecognizable.

Detoxification Technology

Under detoxification technology waste is simultaneously shredded and heated to 480-700˚C. Gases evolved raise temperature to 1540˚C, by which the organic compound is destroyed.

Other Emerging Technologies

Other emerging technologies include electrochemical oxidation, molten metal technology, solved electron process and superficial water oxidation.

Sharp Waste Disposal

The world health organization's (WHO) Safe Injection Global Network (SIGN) has delineated three primary components of behavior change, provision of safe injection supplies and implementation of sharp waste management systems to achieve injection safety.

WHO estimates that contaminated syringes and needles caused HBV, HCV and HIV infections which lead to significant morbidity and mortality and result in substantial cost of families, communities and nation.

The Risk and Challenges of Sharp Waste

The risk associated with sharp waste is particularly high in developing countries because few systems for the waste management have been established. Injuries from sharp of all type in the clinics, health centers and hospitals are an important hazard to all the categories of health personnel and waste handlers. The persons most at risk are doctors and nurses in clinics and other health providers in the hospital.

More attention need to be paid to the hazardous sharp waste generated at clinics and hospitals and must be secured and prevented from access by outsiders.

a. They can be achieved by bringing about awareness among health workers, community about potential hazards of sharp waste.

b. Minimizing, segregating, decontaminating (disinfecting) the hazardous waste at the site of generation.

c. Destroying (mutilating) used items to prevent their reuse.

Current Practice of Sharp Management

Sharp waste is frequently dumped along with the municipal garbage. Large hospitals are having incinerator for all sharps, some hospitals are segregating, disinfecting and mutilating and disposing off in pits whichever is appropriate. Some cities in India and state like Kerala (IMA-IMAGE) have common health care waste management facilities. These facilities collect health care waste from the hospitals/ nursing homes/ clinics on a charge based on per bed or per kg.

Biomedical Waste (BMW) Management Rules

Government of India under the provision of the Environmental Act, 1988 notified the BMW Rules in 1998, which regulates the disposal of all biomedical waste including sharp waste with an objective to ensure safety of health / environment.

Sharp Waste

As per the schedule I, Rule 5 of BMW Rules, sharp waste are classified in category 4, which says, sharp waste means needles, syringes, scalpel blades, blade, glass etc., that may cause puncture and cuts. This includes both used and unused sharps, which should be treated.

Color Coding

As per schedule II, color coding of container for disposal of sharps is a must. Blue/ White translucent colored puncture proof container has to be used and disposed as per schedule (as above). Please refer to the revised guidelines from the Central Pollution Control Board of India (CPCB).

BMW Management – CPCB Policy

Section 4 of the BMW rules act has given a policy statement.

The following steps should be followed:

1. Minimization
2. Segregation
3. Handling
4. Storage of hospital waste
5. Disposal

Minimization of Sharp Waste

As far as possible minimize the use of sharps. Emphasis the rational use of injections in the treatment of illness. The use of disposal syringes/needles has increased considerably generating potentially infectious waste with limited options for treatment and disposal. The use of plastic disposables should be limited as far as possible because plastic are not degradable, not necessarily legally produced and more likely to cause reuse.

Segregation of Sharps

Sharps should be segregated at source. The clinical staff is responsible for segregating the waste at source. Appropriate and different types of waste



containers have to be placed at different points as per the ACT e.g., in the ward, OT, ICUs, Clinics.

Blue/ White translucent puncture proof containers should be placed at strategic and easily accessible locations. Sharps include syringes and needles, scalpel blades, catheters, stylette, used slides and broken glasses. Needles should not be recapped, removed and transported by hand. Sharps should be disinfected. Hub cutters/ needle and syringe destroyer should be used at the site of generation to reduce the bulk, to disinfect, and to prevent reusing.

Handling of Sharps

Sharp containers should be picked up and carried by the handle provided. They should not be supported at the bottom.

Sharp containers should not be carried on back and

they should not be dropped/ thrown. Containers should be labeled. Vehicles used to transport sharps containers should be authorized and labeled with signage written boldly on the vehicle.

Storage (Containers)

Sharps Decontaminating Units (SDU) for syringes and needles are made of plastic and puncture proof materials and they can be foot- operated with an inner perforated container with secured handles.

- Should be filled 1/3 with 1% (10g bleaching powder mixed in one liter of water) hypochlorite solution.
- Sharps in inner containers after treatment with hypochlorite solution should be transferred to puncture proof containers for shredding. (Please refer to the recent guidelines about use of sodium hypochlorite – it was found to serve as an medium for organism to grow and hence the guidelines are being revised)
- Should be labeled as sharps only.
- Fiber board boxes, discarded plastic cans or metal tins can be used alternatively for transport in absence of proper containers.

Treatment and Disposal

It is necessary to treat certain wastes before disposal to prevent hazards to human health and environment. Onsite treatment is preferred than offsite. Chemical disinfectants like 1% Hypochlorite solution can be used to treat the sharp wastes. Immediately after use, syringe with needle should be dropped into SDU, so that both parts are completely immersed in Disinfectant. When SDU is 1/3 full- after contact time of 30 minutes the perforated container contents are drained into puncture – proof containers for shredding. Hub cutter / needle and syringe destroyer can be used. The separated/ destroyed needles are collected in puncture –proof containers where they are disinfected by immersing in 1% Hypochlorite or any other disinfectant.

Heat Disinfection

Sharps are collected in a heat resistant container, which when full, should be placed in autoclave / hot air oven. Autoclave is done for 30 minutes at 121˚c, dry heat for one hour or by boiling at 100˚c for 20 minutes in steam sterilizer.

Encapsulation

Sharp containers when full with sharp wastes are encapsulated by filling with cement clay and plastic foam. The container is sealed and buried in a landfill.

Smelting

This is suitable for metal sharps, scalpel and lancets. The metal sharps are collected in puncture proof containers which are sealed and smelted in a furnace to recycle.

Burial

Sharps can be buried in a landfill after encapsulation or in a special pit only for sharps.

Incineration

Used in the absence of safe land. Puncture proof containers with waste sharps are placed in incinerator. Metal sharps are incompletely destroyed and will be present in the incinerator ash. GOI Biomedical Waste Management Rules does not allow incineration of plastic waste which includes disposable syringes.

Implementation of BMW Rules

Human element is more important than technology. It requires well trained and well motivated staff to implement proper waste management than the sophisticated technology without motivated persons.

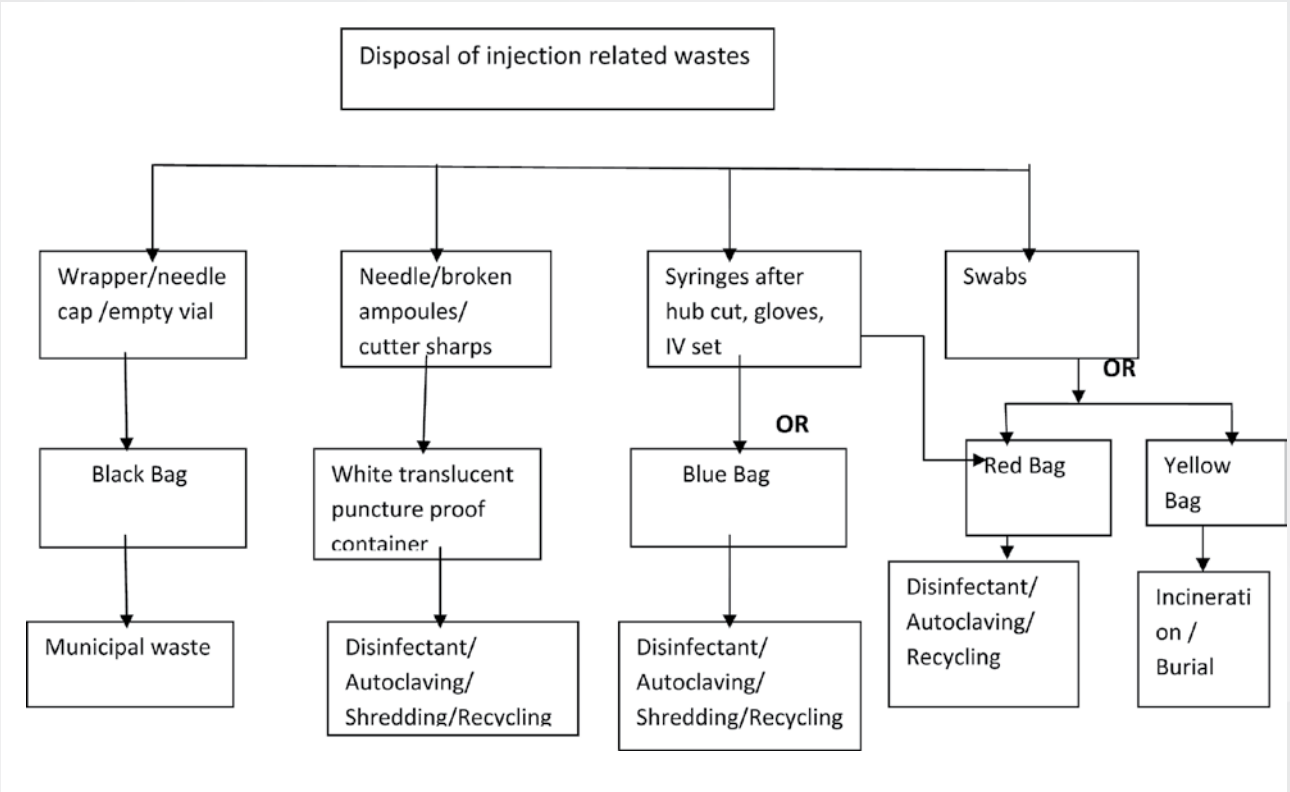
Do's of Sharp waste management

- Do segregate infectious sharps(e.g. hub cutter)
- Do collect in a Blue/White transparent color coded container.
- Do decontaminate all sharps and plastic waste.
- Do use shredder.
- Do use recyclable/ reusable consumables.
- Do immunize all Health Care Professions / Workers/ Wash Handlers.
- Do create awareness.
- Do monitor the health waste management activities.

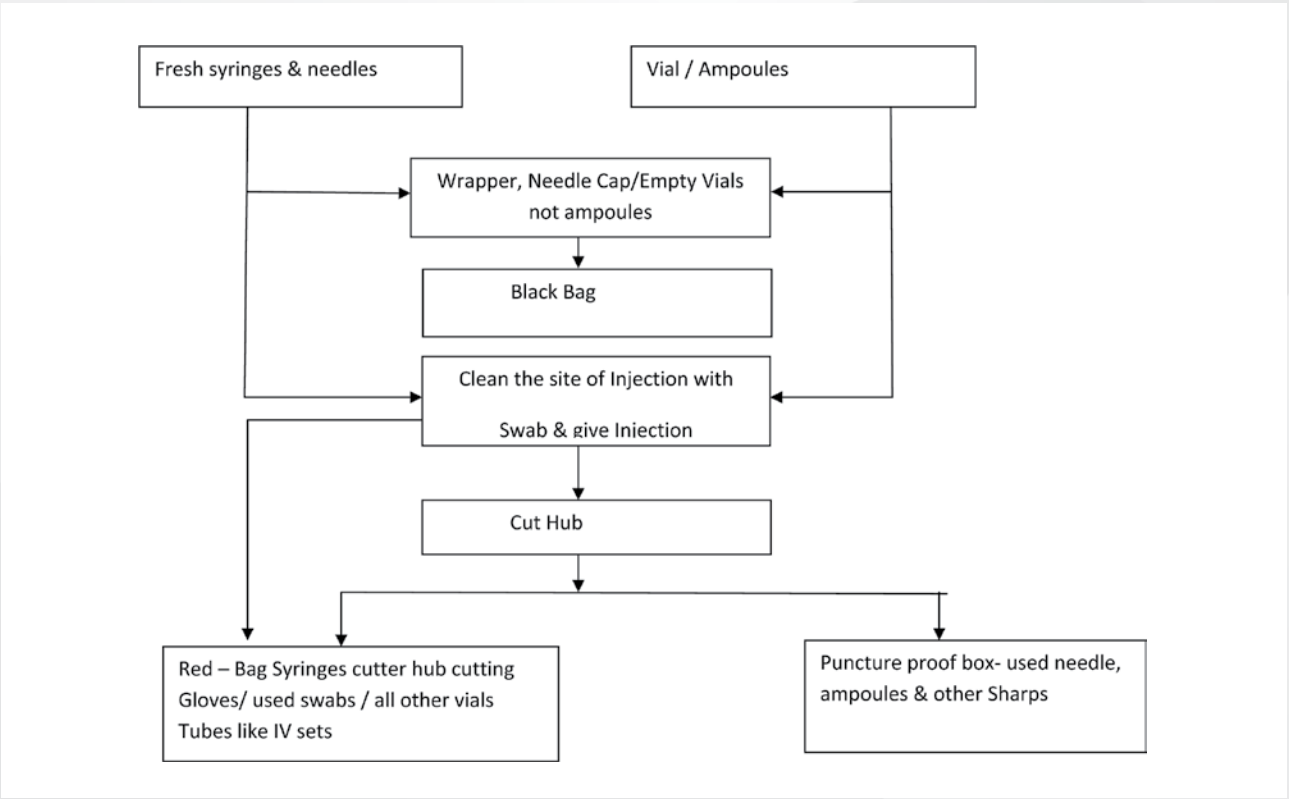
Don't of Sharp Waste Management

- Don't recap the needle
- Don't disconnect the needle from syringe by hand.
- Don't mix the infectious and non – infectious wastes.
- Don't throw the sharps in the trash / non- puncture proof containers.

Flow chart I Disposal of injection related wastes at the health facility



Flow chart-II Steps of Disposal Injection related waste



- Don't use open buckets for infectious waste / sharps.

Advice to Clinics

Hub cutter / needle and syringe destroyer can be used at clinics to segregate / destroy sharps / needles at source. They should be transported and disposed by an authorized agency like Kerala IMA – IMAGE who uses closed transport system and disposes as per health care waste management rules.

In small towns / cities all clinicians and consultants should organize themselves to have local medical waste management system for proper management of waste disposal for the safety of themselves as well as community.

Implementation of sharp waste management systems will ensure injection safety and practice it in letter and spirit.

Creation of awareness, behavior change and effective team building will give success.

Hospital Waste - Management Issues:

Almost any system of hospital waste disposal can be operated by well trained staff. Following measures are useful.

a) Attitudinal change: Management of hospital waste requires diligence and care from a chain of people starting with nurse, doctor, labour staff, and persons transporting waste, persons handling mechanical and technical aspect. If need for safe disposal is stressed, cooperation for segregation, storage, disinfection etc. will not be difficult.

b) Training and motivation: Those who handle garbage are often not aware of the risk and the hazard of the activity. They are also not aware of the importance of their contribution. Training of the staff is therefore necessary.

c) Responsibility: It is desirable to specify job responsibility. If there are failures or problems, proper communication will sort out the same and decide on better alternatives.

d) Occupational health: Health hazards due to improper handling of hospital waste, i.e., without taking precautions must be known by the employees. The hazards are not faced by the society alone; they are faced more by the staff.

e) Standardization and pricing: Steps required for the safe disposal of hospital waste require some expenditure. If proper system is evolved and implemented the cost of safe disposal works out to be 0.1% to 0.2% of the total running cost of the hospital. Saving on this activity is of little significance in proportion to total expenditure.

f) Surveillance: i) It is necessary to monitor the entire process. ii) Hospital infection control committee should actively carry out surveillance. iii) Monitoring of accidents, injuries and infections are necessary. iv) staff handling waste should have regular medical check up. v) rag pickers cannot be easily eliminated, at least in poor countries.

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Operating Room Etiquette:

"Few basic tips to help keep you out of trouble..."



K. Jithendranath MBBS, DA

History

Attention to hygiene can be traced back to the ancient civilization of Indus Valley - dating from 1000 BC - of Waste removal, steam baths and swimming pools. Susruta, in 600 BC, published an account of surgery, insisting on extreme cleanliness. Hippocrates (460 BC - 370 BC) advocated aseptic methods with attention to absolute cleanliness and advised surgeons to thoroughly cleanse their hands before operating.

The modern concept of asepsis evolved in the 19th century. Semmelweis showed that washing the hands prior to the delivery reduced puerperal fever. After the suggestion by Louis Pasteur, Lister introduced the use of carbolic acid as antiseptic and reduced surgical infection rates.

William Halstead of Johns Hopkins Hospital in Baltimore used Goodyear's technology to produce rubber gloves for his scrub nurses. However, in 1883 it Was Joseph Colt Bloodgooa' who equipped his whole team with surgical gloves and collected data to prove that their use reduced infections among patients.

Tait went from antisepsis to asepsis, introducing principles and practices that have remained valid till today. Von Bermann introduced the autoclave, a device used for sterilization of surgical instruments.

Operating Rooms

Operating rooms are sterile environments. The Operation Theatre Complex is environmentally controlled by a central air-condition with filters (HEPA) to prevent infection.

The operating room has special guidelines set up by each institution, which will enhance effectiveness, when the need for entering the operating room and working there arises. The person in the OR must also observe rules of etiquette to guard against interference with the established procedure routine.

If possible all the operating rooms should be made accessible only through Air Shower Passage, which ensures more safety and germ free atmosphere.

Preparation Of Medical Personnel For The Operating Room Environment

1. Posture

Maintaining-correct posture is extremely important to prevent chronic backache, sprain while lifting equipment/ gas cylinder from the floor etc. Surgeon should use a hydraulic or electrically operated chair with back and hand rests. Assistants and circulating personnel should be instructed in the correct method of moving equipments, especially heavy ones. The knee joint is stronger and they should be taught to bend down by flexing the knees than arching the back (just as a loading worker does). It spares the muscles and ligaments of the back.

2. Agility

Personnel should be alert all the time. They should be trained to react quickly and correctly in case of emergencies.

3. Salutation and mannerisms

It is always nice to greet your co-workers in the OR. Remember that you are an important part of surgical team. Each one's contribution is vital to the surgical outcome. Your mannerisms should win the confidence of the patient as he is wheeled in for surgery.

4. Use of sign language, phonation and language

All unnecessary talk should be curtailed. One should not make any noise that will distract the surgeon or

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the patient. Use polite language; the patient can hear you! All instructions should be specific, and in simple language. Try not to bring local slang when you speak.

Assistants should follow the procedure closely, and anticipate the surgeon`s requirements from time to time without him asking for instruments. Sign language with finger movements should convey the message to the assistant as the surgeon is looking down the operating microscope. Imagine the patient hearing you calling out for knife and scissors!

5. Administration – OR

All rules and regulations in the OR are to be strictly followed. These are to be displayed on the board, and a copy shall be given to all the fresh appointees and the visitors. Do not bend these rules for VIP visitors / patient's observers in the theatre. All are applicable to visitors and observers.

Surgical list posted should reach the OR in charge on the previous day before noon, so that the staff can sterilise the instruments, disinfect the OR, post necessary staff and alert the anaesthesiologist.

6. Preparation / sterilisation of OR Environment and Surgical instruments.

Operating theatre complex should be kept clean at all times. There should be procedures in writing to fit each area of the theatre complex. Do not allow dust in and dirt to accumulate at any area. Always use vacuum cleaner and do wet mopping of all surfaces - floor, wall, tables, trolley, equipment, light fixtures etc. Never store mops in a wet condition. This will increase proliferation of organisms. They should be disinfected and dried after cleaning. Once a week, usually on Saturdays, thorough cleaning is recommended. Operating rooms and scrub rooms should never be dry dusted.

Disinfectants used in operation theatre

- Floor & Wall cleaning: wet mopping with "disinfectant cleanser"
- Instruments: (Refer Chapter on Cleaning and packing).
- For biohazard instruments: Operating microscope, wipe with alcohol (other than optics)
- Commonly Used agents for Disinfection and Antisepsis: (Refer-Chapter on Disinfection)



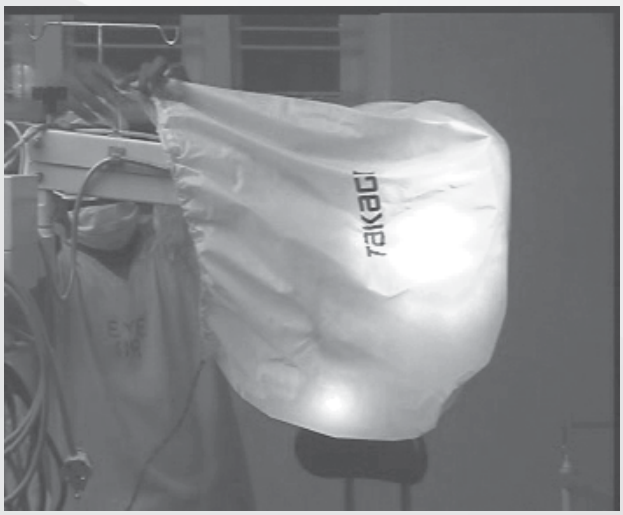
Microscope Cleaning

Microscope can be wiped with alcohol swabs. Never use alcohol spray directly on the microscope head. Never wipe the optics with alcohol.

Disinfect the OR by fumigation employing any of the following techniques (Refer chapter on Disinfection)

Formalin is not advocated these days due to its carcinogenicity. New method of fumigation has been evolved to obtain formaldehyde free surface and environmental disinfection.

Placing a lighted zero watt bulb or silica gel sachet in the microscope head before putting on the cover will reduce the chance of fungus accumulation in the optics.



7. Personal hygiene, Hair, Nails, Skin, ENT, Dental etc.

It is a good practice to have a bath in the morning of

your theatre day. Hair should be combed well. Nails should be manicured on the previous day. Staff with upper respiratory infections or broken areas of skin on the hands should not scrub. Since most of us wear open foot wears, it is advisable to wash our feet before you change into OR dress and wear OR footwear.

8. Stomach (FULL), Bowel (EMPTY) and Bladder (EMPTY) - for the OR Personnel

You should be comfortable when you operate. Please see that the entire team is in such a condition.

9. Disinfection and antisepsis

Asepsis means freedom from disease producing organisms.

The procedures used to accomplish this are:

A. Surgical asepsis: Refers to procedures used to keep objects or areas sterile or completely free from all microorganisms. These techniques are used in the operating room and in treatments where aseptic technique is to be followed.

B. Medical asepsis: Refers to all procedures used to protect the patient and his environment from the transmission of disease producing organisms that can travel from one patient to another. This involves strict sterilization of articles and methods of maintaining cleanliness of others. Correct hand washing is very important in carrying out medical asepsis.

Skin of the staff and the patient is an important source of contamination to the operating wound, that micro-organisms are being transferred to the wound via the air and via direct or indirect contact.

- Probability for transfer is higher under wet conditions than dry.

- Transfer of microorganisms to the surgical wound is influenced by the properties of the operation theatre textiles used.

There will always be microorganisms present on or in the human skin - even after the most strict hygiene procedures before an operation.

The purpose of surgical barrier devices such as protective apparel is to prevent the bacteria from entering the surgical wound. Surgical drapes with impermeable areas and adhesive edges around the incision area block the transfer of bacteria from the patient's skin to the air or to the surface of the drapes and from there onwards to the wound. Surgical gowns do the same with the bacteria from the skin of the surgical staff, provided they offer the right protective properties for the particular surgical procedure being performed.

Even if the proper drapes and gowns are used in most cases, one route is often left open for bacteria to pass from the skin of the surgical staff to the air in the operating theatre simply because skin particles carrying micro-organisms are shed from under the gown. From there they spread into the air, helped by the often-intensive turbulent ventilation.

Clean Air Suites

To date it has been proven that the use of clean air suites has an important impact on infection control during surgery. The reason is that the clean air suite is intended to be used under dry conditions and prevent passage of skin scales to the air and the gowns are intended to prevent contact transfer to the sterile field.

What is aseptic technique? Aseptic means "without microorganisms."

Aseptic technique refers to practices that help reduce the risk of post procedure infections in patients by decreasing the likelihood that microorganisms will enter the body during clinical or surgical procedures. Some of these practices are also designed to reduce service providers' risk of exposure to potentially infectious blood and tissue during clinical procedures.

Aseptic techniques are those that do some or all of the following:

- Remove or kill microorganisms from hands and objects.

- Employ sterile instruments and other items.

- Reduce patients' risk of exposure to microorganisms that cannot be removed.

Aseptic technique refers to the practices performed immediately before and during a clinical procedure to reduce postoperative infection.

These include:

- OR Dress
- Hand scrub
- Using barriers (sterile gown: colour green; and gloves - Adhesive drape)
- Preparing a patient for clinical/ surgical procedures
- Maintaining a sterile field
- Using safe operative technique (making small incisions, avoiding trauma to tissue and surrounding structures, and controlling bleeding)
- Maintaining a safer environment in the surgical/ procedure area

Every one of these practices is important and should be used during clinical procedures to reduce the risk of infection.

l0. Patient preparation

First and foremost be sure of the identity of the patient. Patient mix-ups are not uncommon. All patients shall have the procedure / operative site (eye) marked with a skin marker prior to entering the operating room. Patients should not wear cosmetics, hair pieces or removable dentures in the Operating Room. Hearing aids are permitted.

Consent

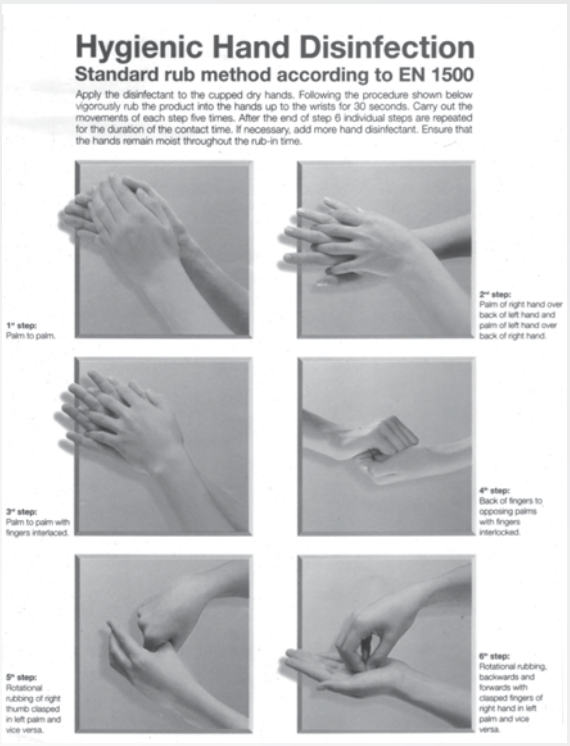
Written, signed, informed consent shall be obtained prior to the operative procedure for all surgery and shall include the signatures of the patient and his relatives/attendant. The consent should be signed after the physician has fully explained the risks, benefits and alternatives of the procedure to the patient.

When the patient's life is in jeopardy and appropriate signatures cannot be obtained because of the patient's condition, the surgeon shall document in the medical record a note fully explaining the circumstances and next of kin's signature should be obtained. A completed anaesthesia consent form shall also be in the medical Record.

Whenever anaesthesia is required, informed consent for anaesthesia has to be obtained.

ll. Changing of clothes and use of mask

12. Washing of hands (Refer Chapter on Scrubbing and Gowning)



l3. Gowns & Gloves Painting &Scrubbing (Refer chapter on Scrubbing and Gowning)

l4. Draping

A sterile field is an area created by placing sterile towels or surgical drapes (adhesive) around the procedure site and on the stand that will hold sterile instruments and other items needed during the procedure. When the team is properly dressed in sterile surgical attire, the personnel's sterile area is the only area that should come in contact with the sterile field.

Only sterile objects and personnel may be allowed within the sterile field.

- When a sterile field is created around a procedure site, items below the level of the drape are outside the field and are not sterile.
- A properly gowned and gloved provider's sterile area extends from the chest to the level of the sterile field. Sleeves are sterile from 5 cm above the elbow to the cuff
- For example, sterile objects become contaminated if you touch the object with your bare hand, if the object comes in contact with dust or other airborne particles, or if the object is held below the level of the

sterile field.

Trolley

Trolleys should be placed as near to the surgeon as possible to facilitate handing instruments to surgeon.

- If laminar airflow system is in use, trolleys should be placed within its confines to maintain the sterile field

- Do not place sterile items near open windows or doors.

- Place only sterile items within the sterile field.

- Do not contaminate sterile items when opening, dispensing, or transferring them.

- Consider items located below the level of the draped client to be unsterile.

- Do not allow sterile personnel to reach across unsterile areas or to touch unsterile items.

- Recognise and maintain the provider's sterile area.

- Recognise that the edges of a package containing a sterile item are considered unsterile.

- Recognize that a sterile or high-level disinfected (HLD) barrier that has been penetrated (wet, cut, or torn) is considered contaminated and unsterile.

- Be conscious of where your body is at all times, and move within or around the sterile or HLD field in a way that maintains sterility or HLD status.

15. Maintenance of Equipment / Anaesthesia:

Surgical instruments. (Refer chapter on Cleaning and Packing)

- All the equipment must be cleaned with soap and water and wiped dry. Decontaminate the equipment by soaking/washing with soap and water. Allow them to dry in an open condition so that the joints are clean and dry. Visually inspect the instruments after cleaning and if not satisfied do it under magnification. Soak them in disinfectant solution or subject to other process of sterilization. Sensitive equipments used for monitoring may be wiped or sprayed with chemical disinfectants like isopropyl alcohol.

- Equipments should be checked, cleaned / repaired once a week. Preventive maintenance should be done once every week, and major repair / maintenance work should be taken up once a year.

- Those that are needed for the operating field are then subject to sterilisation. Autoclaving / Hot air Ovens / ETO / Gas plasma are the methods of choice for sterilisation.

16. Electrical and plumbing

- Get the earthing certified by more than one agency. The entire suite should be properly earthed for safety.

- All Electrical outlets to be familiar with the staff and to be properly labelled for easy identification, especially UPS outlets so that unnecessary equipments are not plugged on to that.

- There will be several switches in the OR. All personnel should know the functioning of each switch, and plug points also. They should also know how to replace a fused bulb, especially that of the operating microscope. It is advisable to have an uninterrupted power supply to the essential equipments.

- All have to learn to switch over to alternate power supply in case of power failure. All personals have to know the location of the torches, replacement batteries and automatic power on lights.

- All plugs and sockets should be checked for loose contacts at least once in a week. Extension boards of 5-meter length to be provided.

- The AC unit should be cleaned including all filters at least every month. Filters to be immersed in a detergent solution for a specific time, washed with potable water and sundried.

- Antistatic mats to be provided near the high voltage equipment like sterilisers etc. All staff to wear insulated / rubber footwear at all times. First aid in case of electrical shock drill to be conducted.

- Plumbing lines are there in the Wash and the preparation areas. The outlets tend to get clogged with solid waste like human tissues. lt is advisable to have a separate water source, at least a separate storage tank for the OR use.

- In the hand wash area UV filtered water is preferred. All drains should have covers to prevent cockroaches and other pests.

l7. Personnel in the OR

These occupations require physical stamina, sensitivity, patience, understanding, emotional stability and dependability. Workers in these occupations should

be responsible and have good judgment. They should also have good communication and interpersonal skills and enjoy caring for people of all ages. They must be able to work as part of a team, follow direction and work under close supervision and must be willing to perform repetitive, routine tasks.

- Limit the number of people who enter the OR.
- Close doors during all procedures.
- All personnel who enter surgical areas wear clean clothes, a mask, a cap (should completely cover the scalp hair), and OR footwear.
- Air-condition the room, use HEPA filters and install laminar air flow systems.
- Before a new patient is brought into the room, clean and disinfect all horizontal surfaces that may have been contaminated during the last procedure-including and surgery table, instrument carts, trolleys etc.

Discipline:

As far as possible, talking should not be allowed inside the OR. There should be no noise or hurried actions that will distract the surgeon, assistants or patients.

Common Sense:

- Do only what you are confident and have been instructed to do.
- Think always one step ahead and be prepared for the next step.
- Be honest. Honesty is the best policy.
- If you do not know something - Accept and announce it straight away - Probably some one will teach you soon. Better than pretending that you know and getting caught at it.

Surgeon:

A surgeon should be calm and composed in the OR. Remember that he has to maintain high standards of discipline and lead the team. He has to have pleasant demeanour so as to impress and win the patient's confidence.

Check the operating microscope, surgeon's chair, vitrectomy / Phaco machine settings etc. before you scrub for surgery. Do not leave anything to chance. Question your assistants to clear finer points before scrubbing for surgery and prior to the patient's arrival.

During the surgical procedure surgeon has to be patient; and should have a clear surgical plan. It is advisable to mentally revise each step as he proceeds with the surgery. Anticipate problems, as they do occur. Do not loose your cool when catastrophes happen. Be always ready with an alternate plan or have a definite plan to handle difficult situations.

Surgeon should restrict all unnecessary movements. Every manipulation during surgery must be purposeful, accurate, and precise. Your assistant should be able to learn the technique by watching your hand and finger movements.

Assistants

A good teamwork is essential for a predictable surgical outcome. Individual contribution is of great importance. Assistants should have a sound knowledge of the technique. The assistant should always face the operative site so that they can observe the procedure closely and should be able to anticipate every step of the surgical procedure and hand over correct instruments. Instruments should be passed in front of the surgeon, not blocking the surgeon's field of vision. Instruments should be passed in an ergonomic manner, allowing their immediate use.

A good assistant should be able to relieve the anxiety of the surgeon.

Scrub Personnel

Scrub personnel should pass each other back to back. There should be no unnecessary change of assistant during an operation. There should be no noise or hurried actions that will distract the surgeon, assistants or patients.

Anaesthesiologist

- Looks after the Anaesthesiology service.
- Pre-anaesthetic checks of the patient and also of the machinery that he has to use.
- Check on the gas supplies and also of the emergency resuscitation equipment.
- Post op. status is assessed before transfer of the patient to the ward / room.
- Anaesthesiologist is responsible for patient safety during and after surgery.

- Has to be alert to avert complications and ensure Patient Safety.
- Coordinates between the Patient, Surgeon and the Nursing staff during the surgery like a ring master in a circus.
- Is a witness to the procedure and has to record his observations and records in the case sheet.

OT Matron / Scrub nurse

- Checks the identity and records of the patient.
- Sees that the instrument needed for the case / day are readied.
- Sets the instrument trays.
- Rechecks the instrument count at the end of the day.
- Oversees the sterilisation process.

Fleet nurse

- Assists in all the duties of the Scrub Nurse.

OT technician

Operating room technicians perform some or all of the following duties:

- Clean and sterilize the OR and instruments.
- Prepare patients for surgery by washing, and sterilizing the patients' operative areas;
- Assist in surgery by laying out instruments, setting up equipment, assisting surgical teams with gowns and gloves and passing instruments to surgeons.
- They may also operate Sterilisers, Operating microscopes, Lights, Electro Cautery machines, Suction machines and diagnostic equipment and special machines like Vitrectomy / Phaco machines etc. After operations they help transfer patients to the recovery rooms and clean and restock the operating room.

Sanitary staff

- Looks after the cleaning and segregation and disposal of the Biomedical wastes.
- Wash and reuse of the linen and the OT wear.

Bio Medical Wastes - Handling Rules: Mantra is Segregate at source. (Refer chapter on Waste Management)

OT Administrator

- Specific duties to each personnel is assigned by the OT administrator.
- Train staff to cover absentee's duties also.
- Ensures protocols to be followed in the OR.
- Ensures scientific and good biomedical waste management techniques.

Support for staff

Providing clean environment, getting the OR and instruments sterilized, assisting in surgeries, cleaning instruments and OR after use and prepare for another day of surgery; can lead to high level of stress within the team. The pressures upon them may be manifested as indifference towards work and even can lead to behavioural changes. If the issue is that of personal nature, counseling may be required. To reduce stress in the OR, good communication is necessary between the team members. The staff should be given a chance to discuss their feelings and emotion among co-workers. Occasional staff meeting is advisable to evaluate the performance and to plan improvements.

The staff should receive educational support. Regular orientation programmes are necessary. It may be required for some of them to observe other centers of excellence, especially when new equipment or new surgical procedure is introduced.

18. Proper use of multidose vials

Multidose vials of medication or other fluids can become vehicles for transmitting infections between clients. Before filling a syringe from a multidose vial:

- Check the vial to be sure there are no leaks or cracks.
- Check the solution to be sure it is not cloudy and that there is no particulate matter in the vial.
- Wipe the top of the vial with a fresh cotton swab soaked with 60-70% alcohol, and allow it to dry.

l9. Preventing transmission of HIV and the hepatitis B virus in the workplace

- Prevent injuries from sharps and other instruments contaminated with blood or body fluids.
- Prevent contact between blood or body fluids and the eye, or other mucous membranes, and broken skin or cuts.

- Universal precautions involve placing a barrier between staff and all blood and body fluids.
- Sharp instruments should not be passed between surgeons & assistants. Surgeons should be responsible for the safe placement of sharp instruments.
- Used needles and other disposable sharp instruments must be discarded into an approved sharps container as soon as possible.
- Disposable one-piece scalpels should be used where possible to avoid injuries that occur when removing scalpel blades from reusable handles.
- Needles must never be picked up nor the fingers used to expose and increase access for suturing. Heavy tissue forceps with grooved pads at the ends should be used instead to pick up used needles, and retractors used to expose the wound while suturing.
- Used surgical instruments should be washed in a sink of warm water with detergent, not under running water.

Documentation

Registers which will require to be maintained in the OT to satisfy the NABH

- Attendance Register
- Autoclave Register
- Birth Record Register
- C Arm Register
- Consent file
- Culture Record Register
- Biochemistry, Micro and Histopathology register
- Daily checking Record of OT Equipments
- Delivery Register
- Despatch and Receipt from CSSD
- Fumigation Register
- Health Talk Record
- Implant Register
- Injection Record book
- ISO Format File
- Major OT Paediatric Register
- Major OT Register
- Minor OT Paediatric Register
- Minor OT Register
- OT and Labour Room Demand Book
- OT Anaesthesia Fees register
- OT Culture Reports File
- OT Day Night report
- OT Instruments Register
- OT Inventory Linen Main equipment and Furniture
- OT Oxygen Nitrous Oxide Oxygenator Entonox Register
- OT Surgeons Fee Register
- Overtime Register
- Pharmacy medicine demand file
- Record of Collection of Surveillance Data from operation theatre.

This list is not complete and the inspecting authority will add on to it!!!

Last but not the Least is Patient Care.

Develop the art of communication.

Intra and post operative status of the patient should be informed in detail to his / her bystander: He is observing all that is happening around. They too need to be handled with extreme delicacy, caution and care.

Operating Theatre Environment is a highly disciplined fun learning experience, so if you have any questions - just ask.

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Disinfection Protocol - Ultraclean OT

Daily Procedures

Date of surgery - ..... No: of surgeries - .....

Before Surgery

1. Autoclave labels are checked and recorded on the previous day. ☐
2. Wipe OT surfaces with **chemical disinfectant of adequate conc.** - if not done on the previous day. (dilution as recommended by the manufacturer) ☐
3. Wipe OT table with alcohol based disinfectant (without aerosols). Exposure time - 5 minutes. ☐
4. Wipe Op. microscope head with same disinfectant and wipe. (Do not apply directly on the optics) ☐
5. All OT staff has done proper hand disinfection. (Wash hands with liquid soap, followed by rubbing of hands with alcohol-chlorhexidine hand rub for 3 minutes). ☐

Procedure 3 to be repeated after every surgery

After surgery

1. OT is terminally cleaned with **chemical disinfectant of adequate conc.** (dilution as recommended by the manufacturer) ☐
2. All cannulae are cleaned in ultrasonic cleaner and flushed with distilled water and air. ☐
3. All micro surgical instruments are cleaned in ultrasonic cleaner with mild detergent. ☐
4. Segregate all OT wastes in separate bags for proper disposal. ☐
5. Prepare **chemical disinfectant solution of adequate conc.** and dip cleaning towels in it for 1 hour. ☐
6. Operating Microscope head is covered, and silica gel kept inside. ☐
7. Wipe OT surfaces and common areas with the **chemical disinfectant solution of adequate conc.**
   - a. Walls upto 6 ft. (arm's reach) ☐
   - b. Entire floor area. ☐
   - c. OT table ☐
   - d. Mopping of floor is done backwards only ☐
   - e. **Ensure no entry.** (lock the OT) ☐
8. Remarks (explanation for not doing any of the above procedures)

Name & Signature of the OT in-charge :

Disinfection Protocol - Ultraclean OT

Weekly Procedures

Date - .....

1. Damp dusting of all the surfaces:

i. All horizontal surfaces and objects in the OT. ☐

ii. Common areas. ☐

iii. Floor, roof and entire extend of the walls. ☐

2. Chemical disinfection:

(Switch off the AC while disinfecting the OT surfaces and before using the fogger)

a. Prepare **chemical disinfectant of adequate conc.** using a measuring cup. (dilution as recommended by the manufacturer) ☐

b. Clean mops are kept in the above solution for 30 min. ☐

c. Areas covered in the OT complex.

i. OT table. ☐

ii. Roof. ☐

iii. Entire extent of the walls. ☐

iv. Common areas. ☐

3. Floor is mopped last, with the solution, and done backwards. ☐

4. Fogger is used in OT rooms with 500ml of chemical disinfectant solution of adequate conc. for 5 min. only. (Ensure AC is switched off and microscope is covered before fogging. Minimize water in the fogger, to reduce humidity) ☐

5. ENSURE NO ENTRY. (lock the OT) ☐

6. Culture taken. Yes No

7. Culture details: *(AC should be switched on for open plate cultures)*

a. Pre-disinfection blood agar plate kept open for 30 min at the head end of the table ☐

b. Post disinfection blood agar plate kept open for 30 min at the head end of the table ☐

c. Pre & post disinfection swabs from head end of OT table and microscope head ☐

d. Others (specify) ☐

8. Culture results

9. Remarks (explanation for not doing any of the above procedures)

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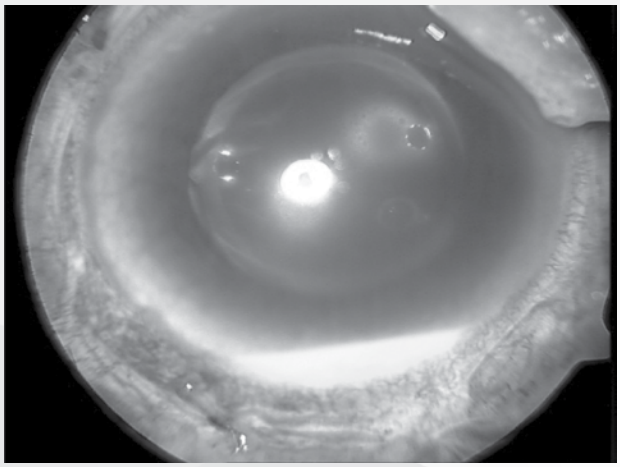
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Name & Signature of the OT in-charge :

Post-operative Endophthalmits – AIOS Guidelines



Lalit Verma MD & Arindam Chakrabarti MD



Worldwide, the reported incidence of post-operative endophthalmitis is 0.04-4%. Post cataract surgery incidence is 0.265% (more with clear corneal incision), post keratoplasty 0.382% and post vitrectomy 0.05%. The incidence of bleb associated infection is 0.2%-9.6%.

Though rare, it is potentially the most devastating complication of intraocular procedures and can lead to a permanent, complete loss of vision. Endophthalmitis has been associated with severe visual loss in 20% of patients.

Patient symptoms indicative of endophthalmitis include ocular pain, diminished vision and headache. Although pain is an important symptom, it is not universal.

It is important to differentiate infective endophthalmitis from sterile post-operative inflammation. Toxic Anterior Segment Syndrome (TASS) is an acute postoperative inflammatory reaction in which a noninfectious substance enters the anterior segment and induces toxic damage to the intraocular tissues. Almost all cases occurred after uneventful cataract surgery. Differentiation is important as the management and prognosis of TASS is significantly different.

In order to evolve guidelines to prevent or minimize post-operative infections, a workshop was held under the aegis of AIOS . The guidelines given below are a synopsis of the consensus arrived at that workshop.. The aim of these guidelines is to assist the ophthalmic surgeon in minimizing the occurrence of post operative infection. These, in any case, are not inclusive and are not a substitute for good surgery and pre/per/post operative care. These guidelines are mere suggestions and cannot be used in court of law to safe guard against or for any legal proceedings. AIOS has no financial or any other interest in formalisation of these guidelines. Any suggestion may please be forwarded to secretary AIOS at: lalitverma@yahoo.com

(Guidelines also available on AIOS website : http://aios.org/endophguidelines2011.pdf)

The guidelines have been classified as :

1. Pre-operative measures.
2. Intra-operative measures.
3. Post-operative measures.

PRE-OPERATIVE MEASURES:

Blood and Urine sugar

- Random blood sugar should be < 200 mg/dl
- Urine sugar if performed must be nil
- If urine sugar is positive, surgery to be done only after blood sugar results

Dr Lalit Verma , Hon. Gen. Secretary, All India Ophthalmological Society, Centre for Sight , New Delhi
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Table Showing Differences Between Tass And Infective Endophthalmitis

	TASS	ENDOPHTHALMITIS
Cause	Noninfectious reaction to toxic agent present in: BSS solution Antibiotic injection Endotoxin Residue	Bacterial, fungal, or viral infection
Onset	12-24 hours	4-7 days
Signs/ Symptoms *distinguishing feature	Blurry vision Pain: none, or mild to moderate Corneal edema: diffuse, limbus to limbus* Pupil: dilated, irregular, nonreactive* Increased IOP* Anterior chamber: mild to severe reaction with cells, flare, hypopyon, fibrin Signs and symptoms are limited to anterior chamber* Gram stain and culture negative	Decreased VA Pain (25% have no pain) Lid swelling with edema Conjunctival injection Hyperemia Anterior chamber: marked inflammatory response with hypopyon Vitreous involvement Inflammation in entire ocular cavity*
Treatment	Rule out infection. Culture anterior chamber. Intensive corticosteroids. Monitor IOP closely for signs of damage to trabecular meshwork and side effects of steroids. Watch closely over next few hours for signs of bacterial infection.	Culture anterior chamber and vitreous. Intravitreal and topical antibiotics. Vitrectomy.

Blood Pressure

- Adequately controlled
- Should be lesser than 150/90mm Hg

Ocular Examination

- No syringing
- If regurgitation is positive: No surgery – First get DCR / DCT done.
- If infection of Lids, Adnexa and surroundings present: Surgery should be postponed.

Pre Operative Topical antibiotics

- One day prior to surgery: 3-4 times a day
- Broad spectrum antibiotic drops to be used.

Physician Clearance

- For known Systemic Diseases
- To check for cardiac, neurologic, renal, respiratory, HIV, endocrine and hepatic disease
- Fitness from a physician (With PG degree)

In Mass Surgeries

- Fitness from a Physician (PG degree)
- Patients with multiple systemic problems: Surgery in Camps to be avoided.

- Combined Surgery: Not to be done
- High risk cases and topical surgeries to be done only by experienced surgeons with all due precautions.

OPERATIVE MEASURES

General

- Anaesthetist /Pulse oximeter desirable (Not a must)
- Emergency drugs are mandatory
- Microsope is a must
- Magnifying glasses not to be used for surgeries.
- Written informed consent in patient's language explaining the risks involved and benefits expected

Surgeon

- Sterilized gloves for every case
- Same gown for maximum of 5 cases
- Surgeon should not come out of OT in OT gown
- Mask should cover nose properly
- OT cap to be worn properly tucking in all hair
- Position of hands after scrubbing and gloving should be above waist and upright in front
- Shoe covers are not to be used
- Separate washable rubber OT slippers with different colour coding
- Separate bathroom slippers
- Doctors/Staff with URTI/Skin infection or any other obvious infection should not be allowed to enter the OT
- Gowning/Hand washing/Gloving as per standard protocol for all OT personnel with betadine/ chlorhexidine, running tap water and boiled-cooled water.
- Clean, washed OT dress
- No street clothes inside OT for staff / patient
- OT etiquette to be put on walls
- Important Do's and Don'ts to be put on walls
- No contact procedures like biometry/tonometry on day of surgery
- Document sequence of surgeries
- Avoid corneal incisions
- Prefer SICS for mass surgeries
- Avoid more than 25 cases per session/surgeon

Irrigating fluids

- Batch number should be noted.
- Glass/plastic bottles should be used.
- If glass bottles are used, vacuum test should be done (Appearance of bubbles on putting drip set)
- Physical inspection against light should be done.
- Preferably, one bottle should be used per patient.
- Double autoclaving should be avoided.
- Preferably, infusion bottle should be kept for 24 hours after use.
- Microbiological work up and approval for each batch should be done, wherever feasible.
- Ringer lactate and BSS are equally effective.
- Antibiotic in irrigating solution is not essential.

Wound security

- When in doubt, sutures to be applied
- Phaco probe tips and sleeve to be changed for each case.
- Tubing to be primed.

Sterility of patients

- Bath/facial wash with soap and water before surgery.
- Surgery should be cancelled if there is unusual congestion or discharge.
- Use of eye speculum is a must.
- Disposable adhesive drape to isolate lashes should be used.
- Patients to wear clean, washed OT dress with cap and gown (No street clothes)
- Povidone iodine 5% should be applied for 3 minutes on conjunctival sac, skin and perorbital area with a boundary including the hairline, tip of nose, nasolabial fold and ear.



At the end of surgery

- Combination of subconjunctival antibiotic and steroid is injected in the inferior fornix if surgery has been done under peribulbar block.
- If surgery performed under topical anaesthesia, topical application of broad spectrum antibiotic is enough.

Post Operative Measures

Post surgical care

- Patching is optional: Desirable to patch for 4-6 hours if surgery performed under peribulbar/retrobulbar block.
- Follow up on 1st, 3rd, 7th and 28th post operative days.
- Parameters to be checked during follow up:
  - Visual acuity with pinhole
  - Slit lamp examination preferable
  - To look for media opacity with direct ophthalmoscope
- Protective glasses/eye shade for one week
- Oral antibiotics prescribed only in high risk cases.
- Topical antibiotics with steroids prescribed for a minimum of 4 weeks
- Personal hygiene is to be emphasized
- Short acting cycloplegic prescribed at discretion of surgeon.
- All post operative findings to be documented.
- Surgeon/Assistant surgeon to be available at the venue for at least seven days.

OT Sterilization

Suggested OT Lay Out

- Outer zone: Reception
- Clean zone: Changing
- Room/Transfer zone
- Aseptic zone: Scrubbing, Gowning, Gloving, Operation room, Autoclave room
- Disposal zone: Equipment and supplies are processed

Fumigation

- When starting OT for first time, at least 3 fumigations required and preferable get three negative microbiological cultures of OT.
- In a running OT, single fumigation to be done.
- Standard protocol for fumigation as per government guidelines: 30 ml of 40%formalin dissolved in 90 ml of clean water for 1000 cft by aerosol spray. It is to be left for 6 hours followed by carbolization by 2% carbolic acid.
- If fumigator not available,35 ml of 40% formalin in 10 gms of potassium permanganate for 1000 cft to be left for 24 hours.

Important considerations in OT Sterilization

- Sterility of OT:
  - Personnel
  - Fumigation
  - Walls and Floor
  - Space: Minimum 180 sq ft.
- Personnel in OT: Maximum 5 personnel per 180 sq ft
- Sterility of OT through Aldekol: Formaldehyde 6%, Glutaraldehyde 6% and Benzalkonium chloride 5%.
- For 4000cft, 325 ml aldekol in 350 ml of water sprayed for 30 minutes followed by closure of OT for 2 hours. Air conditioner is then switched on and OT is ready for use after 3 hours.

- Air conditioner maintenance: Filters should be cleaned every week. Servicing and cleaning should be done every month.

Sterilization of Instruments

- Preferably ETO/Autoclave or Flash autoclave.
- 6-8 sets should be available.
- Autoclaving to be done in between cases.
- Chemical sterilization is not recommended.

Monitoring of Sterilization

- Chemical Indicators: 3 indicators

One on outside wrap, 2nd on inside wrap and 3rd inside the tray

- Microbiological Indicators
- Log book to be maintained
- Maximum use of disposable instruments

Training

- Periodic assessment and training of OT personnel through seminars and educational videos.

What To Do, In Case Of Infection?

- Dialogue with patient and relatives
- Clearly explain the possible causes and pathophysiology of infection and further management. Need for co-operation and referral should be emphasized.
- All findings should be documented.
- Review all sterility factors.
- Have a peer review.
- Referral to higher centre.
- Treat energetically with intravitreal antibiotics and supportive therapy.
- OT should be sealed and cultures for microbiological evaluation should be taken.
- Batch numbers of all solutions used should be noted and samples sent for culture.
- All solutions used should be sealed and kept in safe custody.
- Seek help from Legal Cell of AIOS.

Checklist for Elective Intraocular Surgery

1. Random Blood Sugar <= 200 mg %
2. BP < 150/90 mm Hg
3. Physician Clearance in cases with Systemic Disease
4. Pre-Op Broad Spectrum Topical Antibiotics for 1-3 days.
5. Written Informed Consent in Patient's Language
6. No Contact Procedures / Syringing on day of Surgery
7. Microscope Must
8. Sterilized Gloves for every Case
9. Disposal Adhesive Drape to isolate Lashes
10. Betadine on Skin & Periorbital Area for 3 minutes
11. Betadine in Conjunctival Sac for 3 minutes
12. Note Batch Number of Irrigating Fluids
13. Document all findings (Pre-Op, Operative, Post-Operative)
14. Use Autoclaved / ETO Instruments
15. `NO` chemical sterilization
16. Maximise Use of Disposables
17. In case of doubt of Infection :

Talk to Patient/ Relatives

Institute Prompt Appropriate Treatment

Seek Help from higher Authorities Seek Help from Legal Cell of AIOS

What To Do In Cluster Infections Or Outbreak

- Cluster infection is defined as occurrence of two or more infections at a time, or the occurrence of repeated post operative infection.
- Inform authorities (CMO, Medical Superintendent, Senior Authority)
- Institute Infection Control Committees
- Inform AIOS and seek help of Legal cell.
- Engage and seek help of lawyer.
- Press has to be handled carefully to prevent pandemonium from spreading.
- It is desirable that Medical Superintendent/Hospital Committee does press briefing.

Legal Issues Related To Endophthalmitis (courtesy: Dr Babu Rajendran, Past President, AIOS)

Legal Issues Related To Endophthalmitis

Legal Issues related to Endophthalmitis are Multifold and can be Patient related, Surgeon related, Institution related, Media related, or government related. While each of these have their own and peculiar problems associated with them, handling the Media is of particular importance and one must ensure that the surgeon involved never speaks to the Press. Whether Instituional head or some other representative of the institution, other than the surgeon, should handle the Press the Surgeon SHOULD be insulated from them since one wrong word quoted by him or her could be misquoted and made a huge issue of.

Who ever or what ever the cause, Courts will look upon the Surgeon as the "Captain of the Ship" and will hold the Surgeon responsible. The Supreme Court has in case after case and particularly in Indian Medical Association Vs. V.P. Shantha & Others (1995) had used the Bolam's case and was also discussed and adopted, in the now famous Jacob Matthew Vs. State of Punjab and another (2005). It held "That the guilty doctor should be shown to have done something or failed to do something which in the given facts and circumstances no medical professional in his ordinary senses and prudence would have done or failed to do"*.

Negligence is the breach of duty to care. it means carelessness in a manner in which the law mandates carefulness. A breach of this duty gives the patient the right to initiate action against negligence.

Suresh Gupta (Aug. 2004) said - "Negligence could be ascertained by literature and expert evidence - Standard of negligence should be "gross" and "reckless" but a larger bench overturned this ruling since "These words did not occur anywhere under Sec 304A IPC"

In the famous Jacob Mathews VS State of Punjab - the court directed the Central Govt to frame guidelines to avoid unnecessary harassment to doctors., and observed "A simple lack of care, an error of judgement or an accident, even fatal, will not constitute culpable medical negligence. If the doctor had followed a practice acceptable to the medical profession at the relevant time, he or she cannot be held liable for negligence merely because a better alternative course or method of treatment was also available, or simply because a more skilled doctor would not have chosen to follow or resort to that practice. They further and more importantly observed that "Doctors accused of rashness or negligence may not be arrested simply because charges have been leveled against them; this may be done only if it is necessary for furthering the investigation, or for collecting evidence, or if the investigating officer fears that the accused will abscond"

For a brief while, doctors had a respite from the ruling in Marin F. D'Souza - versus - Mohd. Ishfaq .. Respondent when In February 2009, Justice MarkandeyKatju and Justice R.M. Lodha of the Supreme Court ruled in favour of the doctor in Martin D'Souza vs Mohammed Isfaq. The court held that Dr Martin had not been negligent and said *consumer forums should refer medical negligence complaints to a committee of doctors.*

However, Justice Asok Kumar Ganguly, New Delhi, March 8, 2010 ruled that the earlier ruling directing consumer bodies to refer cases to experts is incorrect and this is where the matter stands to date.

Apart from the Bolam test, Courts in The United Kingdom now use the Bolitho Test and this may soon be applied in India as well.

The Bollitho test - "The decision in Bolitho suggests that the court should adopt a more interventionist stance in assessing expert evidence and in setting the standard of care. One such approach towards a more objective measure in determining the legal standard of *care could be through the use of clinical guidelines."*

That is where this printed guidelines authorised by the All India ophthalmological Society will come in

Frequently Asked Questions in OT Asepsis

Editors

1. Which is a better machine for Formalin fumigation, OT care or Fogger?

If you are so addicted to fogging both can be used. See that the particle size can be adjusted to minimum. That can be done only in a fogger. Ensure that the amount of water in the fogger is minimal and the machine is run not more than 5 minutes so that the humidity induced by the procedure is less.

2. Do you need separate cloth for cleaning different surfaces in the OT (eg: wall, floor, trolley, roof, etc.)?

Separate cloth is needed only if you expect more contamination in any area. Cleaning cloth should be kept in disinfectant solution at the end of the day for 30 min and preferably sun-dried. In between mopping, cloth should be cleaned in potable water and excess water should be squeezed off before dipping it again in the disinfectant solution.

3. After fumigation, can the OT floor be wet?

After fumigation OT floor can be wet but not excessively soaked. If OT is washed it has to be mopped dry to reduce humidity

4. Can we use broom in the OT?

Brooms are not advised, especially dry sweeping as it will spread the dust. Brooms if used during washing of floor will splash water on to the walls and other materials.

5. Which is better for cleaning OT, with stick or using hand?

Cleaning stick can be used for the floor and ceiling. Walls are best cleaned by hand by unidirectional mopping. Floor should be mopped backwards.

How do we dilute the solution for fumigation and cleaning?

Diluting the disinfectants should be done as prescribed by the manufactures, but always use a measuring cup.

6. Can we use alcohol spray daily in the A/c filters?

Alcohol will not give much antimicrobial coverage. AC filter is better treated with aldehyde compounds, which is effective against fungus that is rampant in our hot and humid climate. Ac filter should be taken out, cleaned, dipped in 2% Bacillocid special, Aldasan or similar compounds for 20 minutes, rinsed with distilled / RO water and dried in sun at least once a month.

7. What should be the exposure period for fogging?

If newer aldehyde compounds like Bacillocid special or Aldasan are used, one hour will be sufficient. During the contact period the door of the operating room should remain closed. No one should enter the OR during this period.

8. Do we need to clean OT just before any surgical procedure?

If the OT was disinfected the previous day no further cleaning procedure need be done on the day of Surgery.

9. Can we use disinfectant inside the Autoclave machine?

Autoclave sterilizes the articles. Then why use a disinfectant. It needs periodic servicing and calibration only. If at all you are cleaning it, use clean water.

10. Which is the best solution for instrument

cleaning and what should be the concentration?

Instruments need only be cleaned with distilled water and mild soap. They should be cleaned immediately after surgery to prevent formation of biofilms. Enzymatic cleaning is not needed in Ophthalmic OTs, as we don't have blood and other organic dirt in our instruments. There are very good instrument cleaning liquids (enzymes) in the market, but they are available in big containers (1gallon) which will last a life time for us.

11. Can we use soap solution for cleaning OT floor along with brush?

OT floor doesn't need scrubbing unless it is mosaic or other rough surface. If it is visibly contaminated soap solution can be used. If there is blood spillage, it has to be contained, disinfected with 1% freshly prepared sodium hypochlorite and then cleaned.

12. Is it necessary to disinfect Lasik head, if so what should be the concentration?

Lasik head has been reported to get damaged even with alcohol. So people are trying UV light and just cleaning with distilled water.

13. How to dry the A/c filter?

AC filter is best dried under the sun.

14. After surgery, is it good to wipe OT floor with plain water?

After every eye surgery OT floor need not be cleaned unless there is spillage of blood or other organic material. In case of spillage of irrigating fluid wet mopping with a clean cloth dipped in a disinfectant is sufficient.

15. How to clean the OT chappals? Is Fumigation needed for chappals?

Disinfection of every article is dependent on whether it is a critical item (that enters the body like needles), semicritical (that which comes in contact with mucosa like endoscopes) or non critical (that which comes in contact with intact skin). Chappal is a non critical item and it need be washed after every OT day with soap and water.

16. Is autoclaving compulsory for OT staff uniform?

OT dresses are better autoclaved. Autoclaving can be avoided if they are freshly laundered and sun dried or ironed in a clean environment.

17. Should we take culture swab from the wash basin?

Surfaces are not uniformly contaminated while air is. The chance of contamination from surfaces far from the surgical site is very low. Hence routine sampling of surfaces like corners, washbasin etc. is not of much value. It only shows how meticulous your cleaning is.

18. Is Daily fumigation needed?

Daily fumigation is not needed in Ophthalmic OTs. But the walls (upto arm's length) and floors should be wiped with disinfectants after every OT day.

19. How often do we have to take the OT cultures?

Once you have established an effective protocol of disinfection of your OT, cultures need be taken once in 2-3 months or if there is a suspicion.

20. Can ultra sound cleaner be used daily?

US cleaners should be used every day for cannulas, hinged and serrated instruments.

21. Is fumigation needed for all area in the OT complex or only for main OT?

Once a week fumigation can be used in the entire OT complex.

22. Can Lignocaine bottle be autoclaved?

Why should you autoclave the lignocaine bottles? In that case we have to autoclave the eye drops also. Further we do not know how autoclaving will affect the pH and potency of these drugs.

23. Can formalin chamber be used in OT?

Formalin chamber is best avoided. But in unavoidable circumstances it may be used but the tablets should be replaced periodically and it should not be used to disinfect instruments with lumen like vitrectomy probes.

24. Can the A/c be switched on during the OT cleaning time?

AC will circulate the OT air. While disinfecting the room we don't need any turbulence in the room and the chemical should remain in the room. It is therefore better to switch off the AC while disinfecting the

room.

25. Is A/c mandatory in OTs?

AC is a must for OT. The purpose of the AC is to provide clean air at controlled temperature and humidity and re-circulate it periodically. (20-22 degree, 45-55 RH and 25 air circulation per hour)

26. Which surface has to be wiped first, trolley, roof or wall?

Trolleys are movable (trolleys can be moved out of the OR) and can be done any time. But ceiling and walls should be mopped before the floor and as mentioned before, floor should always be mopped backwards.

27. Can the eye drops used in minor OT which has been already used in the main OT (if we keep it in the Fridge)?

Any eye drop once opened can be used within one month and need not be kept in the fridge. Povidone iodine 5% drops should be used on the same day itself.

28. Can we use the cardboard boxes in the OT store room for keeping the consumables?

Card board boxes should be kept in the outer zone of the OT (reception and recovery room). There are high chances of dust accumulation in these boxes and fungus growth in the rainy days.

29. Do we need separate solution (BSS, Appavisc, Auroblue etc) for each case?

In an ideal set up separate consumables are preferred for every case. It is not done usually. In case of Trypan blue, try to take required quantity from the vial each time under sterile precautions. In case of Viscoelastic drugs change the cannula after every case.

30. How often should the Phaco items (tip, sleeve, hand piece, tubing) be autoclaved when there are continuous cases in a day?

Ideally the hand piece, the tips, sleeve, chamber and I A cannulas are autoclaved after every case. (Anything that goes inside the eye should be autoclaved). In many hospitals hand piece is usually not changed every case but only wiped with alcohol, which is a compromise.

31. What should be the minimum size of an Ophthalmic OT?

Operating room - 150sq ft, Can have a good OT complex with 800-1000 Sq ft area.

32. What material should be used for the wall, floor and ceiling of OT?

For Walls and floor- non porous, glazed surface is better. (Large joint free Ceramic/ vitrified tiles with joints filled with epoxy. Epoxy paint, joint free metallic sheets are typically used in modular OT) Large vitrified tiles with minimum joints can be used. Epoxy is a good alternative. False ceiling may be needed if one opts for Vertical laminar flow. Otherwise conventional ceiling is enough with a good antifungal paint.

33. Which type of door is advised for OT, swing or sliding and why?

Sliding doors are preferred as Swing doors cause more air turbulence while opening and closing.

34. How many Operating tables can be used in one OT?

One table per OT. More than one will compromise aseptic principles

35. Can false ceiling be used in OT?

False ceiling is not mandatory. If opted, better to go for metallic one (like steel or similar) with air tight joints

36. Which is the best type of ventilation for OT?

Vertical laminar flow system. (VLF)

37. Is Air Conditioning a must for OT? If yes, which type?

AC is mandatory. Centralised AC with VLF is the best as it controls temperature, humidity, air exchange, positive pressure and provides (HEPA) filtered air.

38. Which is the safest and cheapest method of sterilisation?

Horizontal autoclave

39. What is the shelf life of autoclaved items?

Items packed in pouches remain sterile for 6 months. Linen packs with a thread count of 140 if packed and stored properly has a shelf life of 7 days. With medical grade crepe paper it is 30 days, non woven cloth 3 month and PVC paper pouch 1-2 year.

40. Can flash sterilizer be used routinely?

Not to replace Horizontal autoclave. New generation flash autoclave with dynamic air removal system may be used in between surgeries, however, the sterilised items are not to be stored.

41. Is Cidex safe for sterilizing instruments?

Can give high level disinfection if kept in freshly prepared Cidex solution for 10 hours. The items should be rinsed thoroughly in sterile water or saline to remove all traces of chemical. However it is not advised in ophthalmology as reports of corneal decompensation have been reported due to Cidex.

42. Which is the best hand disinfectant?

70% Isopropyl alcohol. Alcohol with Chlohexidine is even better due to residual action of chlorhexidine.

43. Which is the best Autoclave Indicator?

Biological indicator. Class 6 emulators are equally good

44. How frequently theatre culture should be taken and from where?

Open plate Blood agar culture kept open for 30 minutes at the head end of the OT table once a month. Moist swabs from the head end of the table and under surface of the operating microscope are taken and preferably streaked on to blood agar immediately.

45. How many persons can be there in the theatre during a procedure, safely?

According to AIOS Guidelines 5 people can remain in an area of 180 sqft

46. Is fumigation still a method of disinfection?

Not needed. Wiping of all surfaces with an appropriate chemical disinfectant of required concentration is good enough.

47. Is double autoclaving advisable for extra safety?

No.

48. Can cloth mask be used in OR?

2or 3 ply masks are preferred over cloth masks

49. What is HEPA filter?

High Efficiency Particulate Air filter which can filter particles of up to 0.3 microns which is used in air conditioning system.

50. How long should we do the surgical hand wash and why?

5 minutes if done properly.

51. Is it necessary to trim the lashes before eye surgeries?

No. But eye lashes should be kept away from the field by proper lid tapes and adhesive drapes

52. Which is the best antibacterial prophylaxis for ocular surgery?

5% Povidone Iodine drops retained for 2 minutes in the conjunctival sac

53. Is it necessary to Autoclave Ophthalmic Viscoelastic Drugs (OVD)?

No.

54. Can you give the ideal method of mopping the OT with disinfectant?

3 bucket system to reduce bacterial load in the OT: Take 3 clean buckets. 1st and 2nd bucket is to be filled with potable water. In the 3rd bucket prepare diluted disinfectant as per the manufacturer's instruction. To start with wet the mop in disinfectant. After wiping a portion of the floor, dip and rinse the mop in the 1st bucket, squeeze the mop, then dip and rinse the mop in the 2nd bucket containing potable water, squeeze and then dip the mop in the 3rd bucket with disinfectant. Continue this cycle until all area is covered.

55. Do you need an ultra clean OT for ophthalmology?

Ultra clean OT with Vertical Laminar Flow (VLF) and HEPA filter, alone will not make a good ophthalmic OT. Conventional OT with strict adherence to regular disinfection protocol is adequate for eye surgeries.

NOTES

NOTES



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