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NEWS LETTER

FROM THE DESK OF EDITORIAL BOARD

Dear Friends,

All of you would have come to know that National Programme for Control of Blindness has come out with a revised version of the protocol to be followed in the operation theatre. If anybody wants a copy of the same, do get in touch with us.

In the last issue, we have started talking about sterilization which is the most important activity in preventing cluster infections. And more importantly, this activity is done in our absence and also that most of us do not have a clear understanding of what is sterilization and how it occurs in a sterilizer.

This time, Dr. Lalitha from Aravind Eye Care System talks about the sterilization processes in the world's biggest eye care facility. It becomes all the more important to ensure proper sterilization in high volume activity. And in light of that, the protocol at Aravind becomes more relevant. Along with it, one more article, explaining the sterilization and its monitoring by Mr. Shaileshbhai Mehta from Medovation products is included in this issue. His article will encourage the reader to refer to more details on how sterilization occurs and how we can ensure that we monitor the process well. One needs to understand that using chemical indicator alone is not enough. Why? Please read the article. If you have any questions, ask Mr. Mehta.

We would like to stress once again that doing proper sterilization is an art and it needs to be mastered. At the same time, how to monitor the activities done in our absence need to be learnt and practiced. There is no alternative to constant vigil.

Proper training of our own staff members in doing the job of sterilization properly and our understanding of monitoring will go a long way in ensuring patient safety. Careful selection of the machine and its proper maintenance are often over looked-do not commit this grave mistake. One time investment in a good machine will pay you rich dividends in the long run.

Feedback from readers will encourage us to work harder. We are waiting to hear from you.

Dr. Lalitha Prajna.
Chief Microbiologist, Madurai

Dr. Lalitha Prajna heads the Ocular Microbiology Laboratory in one of the Eminent Eye hospitals at Madurai. She did her MBBS at Kilpauk Medical College, Chennai and MD in Microbiology at Madurai Medical College and also acquired DNB in Ophthalmology from the National Board of Examinations. Dr Lalitha Prajna's research focuses on the immunopathogenetic mechanisms of fungal and bacterial corneal ulcers. Her other areas of interest are to develop and apply molecular diagnostic techniques in the diagnosis of various ocular infections.

She has around 45 publications, including national and international to her credit and has authored a textbook on Ocular Microbiology. She has received the award for the best paper published in Bacteriology in the Indian Journal of Medical Microbiology for the year 2004-2005.

CLEANING OF INSTRUMENTS AND STERILIZATION PRACTICES IN THE OPERATION THEATRE: PRACTICES FOLLOWED BY ARAVIND EYE CARE SYSTEM, MADURAI

This article describes the protocols for cleaning instruments and sterilization practices that are followed in the operation theatre at Aravind Eye Hospital. It covers the main areas of instrument cleaning, packing and loading of the instruments and bins into the autoclave. It also describes the various sterilization measures, mainly steam and gas sterilization, the methods of storage and utilization of sterile items that will be used for cataract surgery.

The protocols and practices have evolved keeping in mind the high volume and low cost for performing cataract surgery, at the same time with no compromise on quality. It is very important that the operation theatre technicians are properly trained and have adequate knowledge and awareness of the various protocols that have to be followed.

Operation theatre personnel from the manager, supervisor and technician, involved in the day to day work, have to be responsible for all the activities equally. There must be a team involvement. Each person must understand their job requirements and perform to the best of their ability. Everybody must be equally vigilant to any lapse in the protocols.

1. CLEANING

PURPOSE:

Cleaning of the instruments before sterilization is a very important step. Thorough cleaning is required before sterilization because inorganic material like dust and organic materials like dried blood or viscoelastic that remain on the surfaces of instruments interfere with the effectiveness of sterilization. The instruments must not be allowed to dry and must be soaked in water soon after surgery to remove any dried debris. This is a very important step and the OT personnel doing the cleaning must never forget this and always ensure that good and proper cleaning is done for all the instruments each and every time.

CLEANING OF INSTRUMENTS IS DONE MANUALLY USING THE THREE BASINS METHOD.

- Cleaning is done both in-between surgeries and also at the end of the day.
- No detergent or disinfectant is used in the water.
- The quality of water used for cleaning instruments is very important. Reverse osmosis filtered water is used. The quality of this RO water is checked for chemical contents and sterility every month.
- After manual cleaning, the instruments are cleaned in the ultra-sonic cleaner everyday
- RO water is used in the ultrasonic cleaner also.
- Again, no disinfectants for detergents are used in the ultrasonic cleaner.
- The ultrasonic cleaner is dried thoroughly after the cleaning and no wet surface is left.
- Many ophthalmic instruments are very delicate and operation theatre personnel must be very careful in handling these instruments.

REQUISITES

PROCEDURE

- The bench where the cleaning is done is wiped thoroughly with RO water.
- After cleaning, the area is covered with a sterile cloth.
- That is again covered with a sterile blue coloured plastic drape to avoid contact with dust and other surface contamination.
- Hands are washed with soap and sterile gloves are worn for washing the instruments.
- The used sets that are received from the OT are segregated into the instruments for ultra-sonic cleaning and manual cleaning.
- Discipline should be maintained in the cleaning area and no unnecessary talking or walking in the cleaning area. This is also treated as an operation theatre.

CLEANING INSTRUMENTS MANUAL

Cleaning is done in three basins by pouring adequate amount of RO water:

- Each instrument is inspected for any dirt or broken tip.
- One basin for initial cleaning using tooth brush and others for final cleaning without tooth brush.
- All sharp instruments are immersed in the first basin and cleaned thoroughly but smoothly using soft tooth brush in order to remove all debris, tissues and blood stains.
- Hard instruments like, speculum, needle holder etc are cleaned properly two or three times.
- Needle holders, scissors and artery forceps are opened completely to clean inside the jaws.
- Cannulas are flushed thoroughly because lens matter and visco-elastic can block the cannulae permanently.
- Cotton wool must not be used to clean instruments as it damages the tips.
- All the cleaned instruments are shifted into the second basin, which is already filled with RO water for cleaning and rinsed well and repeated in a third basin
- After cleaning in the third basin, the cleaned instruments are shifted onto the clean dry cloth and arranged in order to air dry for about five minutes.

CLEANING OF PHACO HANDPIECE AND I/A HANDPIECE

- Cleaning must be done immediately after each surgical procedure. Otherwise, tissue debris and salts from the saline irrigating solution may collect and cause permanent damage.
- The irrigation and aspiration ports are both flushed ten times with a 20cc syringe filled with warm water. This is again repeated with the syringe filled with air ten times.
- Simco cannula, phaco tips and sleeves and I/A tips etc. are segregated for removal of all blood stains, tissue, cortex, etc.

DRYING OF CLEANED INSTRUMENTS

- All instruments are air dried after they are cleaned .
- The excess water on the surface of the instruments are wiped using clean dry cloth.
- Instruments are placed in the open in dismantled position on a clean absorbent cloth.
- Before storing, the instruments are dried thoroughly to prevent rusting.
- A hair brush is used to dry the instruments in AC room.
- After drying, the instruments with tips are covered with the plastic tube.

Preparing the set tray for autoclave.

- The instruments are arranged in an orderly fashion according to the type of surgery.
- The required instruments are placed in an orderly fashion in each tray.
- In each tray, a 3 line label indicator is placed inside.

PACKING INSTRUMENTS

THIS IS A VERY IMPORTANT STEP AND MUST BE DONE VERY CAREFULLY.

- The bins in which the cleaned instruments will be placed are cleaned and dried.
- The instrument trays with perforated bottom are placed and covered with a towel to allow the steam to penetrate around the instruments during autoclaving and to prevent air trapping in the tray.
- Sharp or pointed instruments are kept in separate trays to prevent contact with other instruments that could damage their surface at the top.
- Hinged instruments are kept opened with box unlocked to permit steam contact on all surfaces.
- The instrument trays are placed perpendicular to another to enable better steam penetration.
- An indicator strip is placed in each tray and also in center, bottom and top of each bin and Steri Gage strip in the middle .
- The autoclave should not be overloaded as the steam can not penetrate easily.
- Instruments, syringes and needles are kept covered at all times.
- The bins are closed with the holes open so that the steam can penetrate into the bin.

PACKING DRESSINGS AND LINEN

The bins are cleaned with a dry towel. A sterile eye towel is kept at the bottom. The dressing and linen packs should not be packed too tight. About 20 pads can be kept together and tied with the bandage cloth to make a bundle. Other items like eye shields can also be kept in the same bin. Linen like eye towels, table towels, coats etc. are also packed in separate bins and are loaded in the same autoclave. All linen must be checked every day for any damage in the linen to be sterilized.

PACKING FOR STERILIZATION

Bundle the linen as per the specifications given below

Eye and table towels	15 per bundle
Small towels	20 per bundle
Coats	6 per bundle

One indicator is placed at the bottom, one at the middle and one at the top to check for the completion of sterilization. Paste the stickers and the indicators on the outside.

Send the bundles to the autoclave room.

STERILIZATION

STEAM STERILIZATION: AUTOCLAVE

- To sterilize all instruments, linen and bottles used in OT, OP and ward
- To kill microorganisms including the bacterial and fungal spores present on the surfaces of all items.

PREPARING FOR STERILIZATION

- Clean the autoclave with separate towel.
- Change the RO - water (daily).
- Check that the raw water valve and RO water valve are open.
- Switch on the autoclave (main switch).
- Switch on the power.
- The program is selected according to the manufacturers' instructions.
- Everybody operating the autoclave must be aware of the different settings and follow accordingly.

STERILIZING THE ITEMS

The autoclave parameters must be set and followed closely and monitored. If any deviation, like temperature or time or pressure is not reached, then the cycle must be repeated. Keep the bins one or two minutes in vacuum dryer. Check the indicator sticker for colour change from blue to black indicating adequate sterilization process. Take out the items using clean linen to prevent burning of the hands. Check the chemical indicator (Steri Gage) colour change from white to black indicating adequate sterilization process. If there is no colour change in the indicator tape, then follow the recall procedure. If the bin is closed properly, then follow the recall procedure for that bin alone. After sterilization, store the properly sterilized items in the sterile room. Make sure sterilized instruments and other items are made available on time in OT whenever necessary.

RECALL PROCEDURE

The OT personnel must be aware of the recall policy and procedures. If any complaints come from any theatre about the indicator not changing colour or any patient has developed infection, then all the instrument sets must be recalled from all the areas where ever it was distributed, cleaned once again and autoclaved. This must be informed to the chief doctor. Further episodes like this must be prevented.

A PACK IS CONSIDERED TO BE NON-STERILE WHEN IT

- Is damaged or open.
- Comes out of the steam sterilizer wet or is placed on a wet surface.
- Is dropped or placed on a dirty surface.

DISADVANTAGES OF STEAM STERILIZATION

- Microsurgical instruments get damaged by repeated exposure.
- May leave instruments wet, causing them to rust.

EXPLANATIONS OF THE INDICATORS (METERS) IN THE AUTOCLAVE:

The operating of the autoclave must be taught to all the staff and the steps must be followed correctly all the time. Depending on the model and manufacturer, the operating instructions vary. So training is very important. The time, temperature and pressure must be accurately maintained and documented in the appropriate registers.

HIGH SPEED AUTOCLAVE.

PURPOSE:

Allows for immediate use of instruments for surgery especially in-between surgeries. Instruments are cleaned in the same manner as described above.

Used unsterile instruments are also cleaned before putting in the high speed autoclave. Adequate time must be taken for cleaning. There should be no hurrying up. Enough surgical sets must be available to allow adequate time for cleaning and sterilization.

STERILIZATION OF CLEANED INSTRUMENTS IN THE HIGH SPEED AUTOCLAVE.

- The autoclave is cleaned with a towel and RO water should be changed daily.
- The instruments are placed in trays with sharp or pointed instruments at the top of the tray to prevent contact with other instruments that could damage their surface.
- Indicator sticker is placed in each tray and packed small bins
- The lids are closed tightly and the holes kept opened to allow the instruments to be sterilized.
- The autoclave is operated according to the instructions.

MICROBIOLOGICAL SURVEILLANCE OF THE OPERATION THEATRE

Controlling air-borne pathogens is important for the safety of the patients and prevention of post-operative infections. Environmental monitoring by microbiological testing of surfaces and equipment is useful to detect the load of microbial flora in the operation theatre and prevent post-operative infections. Microbiological surveillance ensures that the aseptic and sterilization procedures are adequate and are working well. Microbiological surveillance gives us confidence that the environment, consumables and instruments that are being used are sterile.

The protocol and responsibilities for doing this lies both with the theatre personnel and the microbiology staff. They are responsible for ensuring monitoring of the sterility of air samples, water and sterility of the consumables used in the theatre every month and also ensuring proper documentation. They should also check whether effective sterilization has taken place by using various indicators including the biological indicators and proper documentation of the same.

MONITORING THE CONSUMABLES BEING USED : RINGER LACTATE AND VISCOELASTIC

One bottle from every new batch of ringer lactate bottle is tested for sterility and pH.

Normal pH should be 6-7 and culture should be negative with no growth of any organism.

Similarly, sample of new viscoelastic solution is also tested for sterility.

WATER FOR TESTING

Reverse osmosis is used in the operation theatre for cleaning instruments, autoclave and hand washing. The quality of water is checked every month for both the chemical contents and sterility. Adequate quantities of water are tested from all areas of the operation theatre.

Acceptable range for the microbial load in the water is

Raw water	less than 500 colonies. (Microbial colony)
RO water	less than 100 colonies
RO water with capsule filter	less than 1 colony.

The results are maintained in the water analysis register and monitored periodically.

MONITORING OF AIR: AIR SAMPLING BY SETTLE PLATE METHOD

Sampling of air for the microbial load is done once a month. The culture plates are kept one near the door, one near the operating table and one near the back of the room. The plates are kept open for about 20 minutes. Swabs are also taken from the microscope handle, instrument trolley and operation table.

AIR SAMPLING - USING SWABS

Done to check the presence of bacteria and fungus. Done once in a month, during the first week, early in the morning before OT has started. Areas to be swabbed are Operation table, Microscope handles, Instrument trolley and AC duct.

OT CULTURE REPORTING : AIR EXPOSURE PLATE

Number of bacterial colonies < 20	Acceptable
Number of bacterial colonies > 20	Not Acceptable
Fungal Colony = 1	Not Acceptable

USE OF BIOLOGICAL INDICATORS

Biological indicators are used to the check the effectiveness of the autoclaves, ETOs and high speed autoclaves once a week. Separate indicators for autoclave and gas sterilizer must be used. The biological indicator, after taking it out from the sterilizer is sent to the microbiology dept. This is incubated in a heating block at 56 °C for two days.

Nature of Culture	Frequency	Growth (Acceptable range)
AC culture	Monthly	<20
OT Culture	Monthly	<20
Biological Indicator	Weekly	No growth
RO water	Every 15 days	Normal -100; 0.45 micron filter -<1
Raw Water in OT	Every 15 days	<500 cfu
RL / Visco Culture	For Every Batch	No growth

REGISTERS MAINTAINED IN CSSD AND OPERATION THEATRE

1. Steam Sterilization Indicator File
2. Steam Autoclave receiving & issued record
3. High Speed Autoclave indicator File
4. Chemical Integrator File
5. Bowie Dick Test File
6. ETO Things Receiving & Issued Record
7. Temperature & Humidity Register
8. Bio Medical Waste management Record
9. Fumigation Record
10. Autoclave maintenance Record
11. Linen stock Register
12. OP & Ward things receiving & issued register
13. OT work completion Check List file
14. CSSD meeting register
15. OT cleaning register.
16. Complaints Register.
17. Microbiology reports of RL, VISCO, AC, air in OT
18. Biological indicator file
19. RO / RAW Water Culture file
20. Linen loading Register.

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Medovation Products (Specialized in monitoring validation and documentation for sterilization dialysis and cleaning process.)

Other Activities

- Worked with major hospitals, pharmaceuticals, biotech, and agro industries related to sterilization process.
- Succeeded to pass the process challenge device on over pressure cycle.
- Set up a process for phaco tubes on steam sterilization related to ophthalmology.
- Jointly working with sterilizer manufacturer to set up the process as per the EN Standard.
- Validation of sterilization process in industry and health care system.
- Scientific seminar activities in major cities of India for penetration and kill kinetics.

STEAM STERILIZATION

For processing surgical instrument with cavities, example: narrow channels, it is important that steam penetration in surgical instruments is sufficient to ensure sterilization conditions on inner surface. Recent studies demonstrates that measuring only temperature & pressure is insufficient. For Steam sterilization which is an essential step in processing of surgical instruments, we must attain the steam conditions as specified in the literature. These conditions are saturated steam at the specific temperature for a given time, example: saturated steam at 134° for 3 minutes or 121° for 15 minutes. If air is not removed from the sterilizing chamber before the sterilization stages commenses, particularly in processes designed to sterilize porous loads or instruments with lumens, the steam will not come in contact with the surface which needs to be sterilized. Each sterilization process is a unique event, so every load that is processed is to be monitored. It can be monitored by Temperature logger, Air Detector or a Process Challenge Device.

PROCESS CHALLENGE DEVICE (PCDs)

PCDs are devices which presents defined challenge to a sterilization process and should be used with every load that is sterilized. PCD should have a definite capability to detect process failure arising from chamber leaks, inadequate air removal and presence of non-condensable phases in steam supply due to inappropriate water quality.

The validation of sterilization process is a procedure generating a test report which guarantees that all goods being sterilized have achieved a Sterility Assurance Level (SAL) 10-6 CFU.

Steam Sterilizers are of 3 types :

(1) Flash sterilizer
(2) Gravity or over pressure sterilizer
(3) Pre-vacuum sterilizer.

Any sterilizers above 54 liters is treated as a big sterilizer and below as table top sterilizer.

Table top sterilizers are of 3 types :

(1) Class-N : This process is Flash sterilizer
(2) Class-S : This process is a Gravity Displacement sterilizer
(3) Class-B : This process is a pre-vacuum sterilizer

NOTE : All the above sterilizers have the same sterilization phase

121° C - 15 minutes
134° C - 3 minutes

(1) **Class – N sterilizer (Flash wet process) :** This sterilization process is ideal for solid instruments - unwrapped - mainly used for dropped instruments in operation theatre during surgery. The bigger disadvantages in this process is that it a wet process so that instruments cannot be wrapped, due to this, the materials cannot be stored, it is for immediate use only. Implants, porous materials like cotton, Gauze cannot be sterilized in this process.

(2) **Class – S sterilizer- Gravity displacement sterilizer (over pressure cycle) :** This process is a wrapped process, good for solid & porous materials and not recommended for hollow or complex instruments for example : Phaco tubes. In this process, there is no air removal so steam penetration is minimal, due to this there are uneven heating patterns. Implants are not recommended in this process. Gravity processing includes following stages of sterilization.

a. **Pre-sterilization :** Build up phase to achieve a pressure co-related to the temperature required, for example :

Pressure BAR	Temperature
1	121° C
2	134° C

b. **Sterilization Phase**
   a. 121° C - 15 Minutes
   b. 134° C - 3 Minutes

c. **Post-sterilization**
   Exhaust of steam and air inflow to the chamber for drying the products which are sterilized.

NOTE : In gravity process there is no air removal.

(3) **Class –B Process (Pre Vacuum sterilizer) :** This sterilization process is ideal for solid, porous & hollow instruments. As mentioned above, air removal is very important in the steam sterilization process, without air removal there is no steam penetration - with no steam penetration, you cannot achieve sterility assurance level. In a pre-vacuum sterilizer the following sterilization phases take place:

a. **Pre-sterilization:** There is a negative pressure created to remove air and replace it with steam. More the air removal, deeper the steam penetration. This helps the sterilant (water) to kill the micro organics in the sterilization phase

b. **Sterilization Phase :**
   121° C - 15 Minutes
   134° C - 3 Minutes

c. **Post-sterilization:** In this phase the steam is removed in a negative phase and air is introduced into the chamber to make the load dry.
   NOTE: This process is ideal for hollow & complex instruments.

Monitoring of Pre-vacuum sterilizers (Class-B)

BOWIE DICK TEST (PCD)

Bowie Dick test is not a sterility test, it is an empty load test to be performed every day before starting of the day. This test is performed to monitor air removal process. This can be monitored with a defined length & diameter of a PCD.

There are 2 kinds of Bowie Dicks
(1) 7 Kg Bowie Dick Test, as per European standards.
(2) 4 Kg Bowie Dick Test, as per American standards.

Process monitoring system is very important to monitor every load that is reprocessed. Sterilization process can be monitored with Chemical & Biological indicators. Usually Chemical indicators are used for routine monitoring & Biological indicators are used for validation once in 15 days.
Chemical indicators are of different types:

Type 1 Indicators (Process Indicators):
Autoclave Tapes & Documentation labels are process indicators. These indicators are used only to know that the product underwent a sterilization process.

Type 2 Indicators:
Bowie Dick Test & Process Challenge Device are called Type 2 Indicators. They monitor Air removal, Steam penetration and also monitor NCG.

Type 4 Indicators:
This indicator monitors any 2 parameters like temperature, time or pressurised steam, steam temperature. These type of indicators are called as Packaging Indicators. They are used inside the pack.

Type 6 Indicators:
This Indicator monitors time, steam & temperature. They are used in the packs. They can be used for Flash & Gravity Process.

PCD (Process Challenging Device)
PCD's are of different kinds depending on the speciality in health care.

Ophthalmic PCD: Ophthalmic PCD is used by Ophthalmic Surgeons.

Dental PCD : Dental PCD is used by Dental Surgeons .

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