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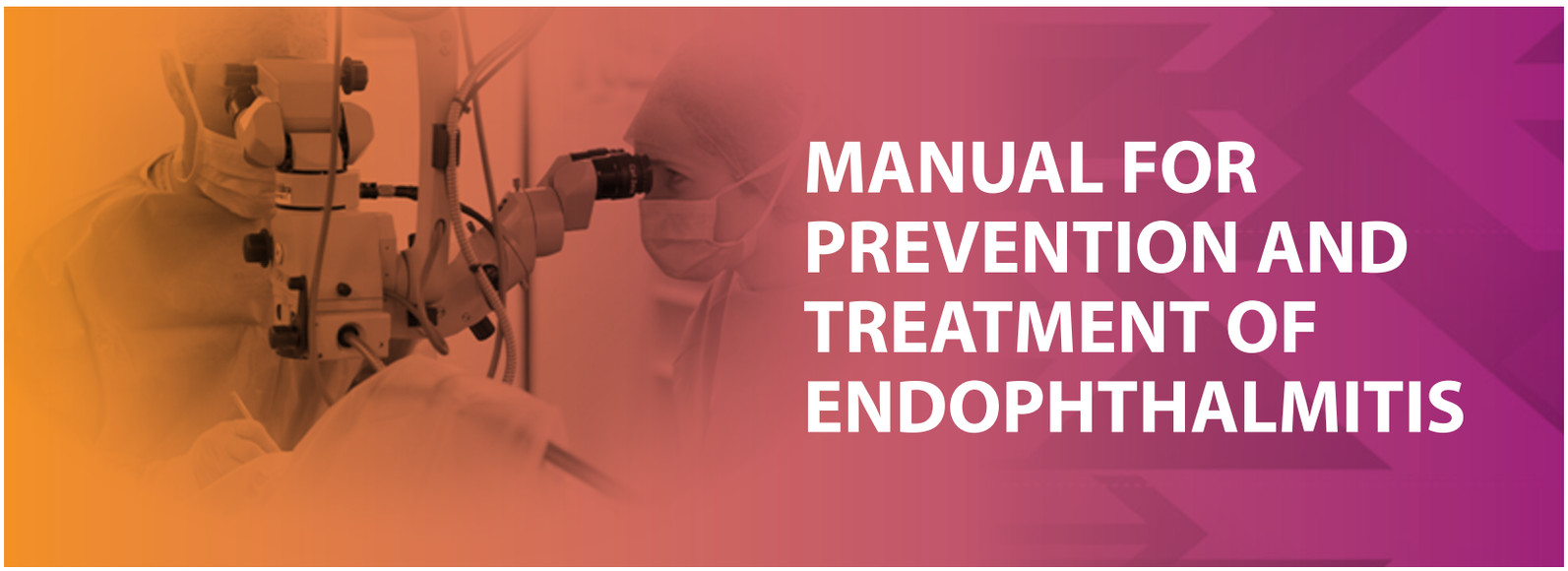
Livewire

OPERATION THEATRE MANUAL



MANUAL FOR PREVENTION AND TREATMENT OF ENDOPHTHALMITIS

HIPPOCRATIC OATH, MODERN VERSION

I swear to fulfill, to the best of my ability and judgment, this covenant:

I will respect the hard-won scientific gains of those physicians in whose steps I walk, and gladly share such knowledge as is mine with those who are to follow.

I will apply, for the benefit of the sick, all measures which are required, avoiding those twin traps of over treatment and therapeutic nihilism.

I will remember that there is art to medicine as well as science, and that warmth, sympathy, and understanding may outweigh the surgeon's knife or the chemist's drug.

I will not be ashamed to say "I know not," nor will I fail to call in my colleagues when the skills of another are needed for a patient's recovery.

I will respect the privacy of my patients, for their problems are not disclosed to me that the world may know. Most especially must I tread with care in matters of life and death. If it is given me to save a life, all thanks. But it may also be within my power to take a life; this awesome responsibility must be faced with great humbleness and awareness of my own frailty. Above all, I must not play at God.

I will remember that I do not treat a fever chart, a cancerous growth, but a sick human being, whose illness may affect the person's family and economic stability. My responsibility includes these related problems, if I am to care adequately for the sick.

I will prevent disease whenever I can, for prevention is preferable to cure.

I will remember that I remain a member of society, with special obligations to all my fellow human beings, those sound of mind and body as well as the infirm.
If I do not violate this oath, may I enjoy life and art, respected while I live and remembered with affection thereafter. May I always act so as to preserve the finest traditions of my calling and may I long experience the joy of healing those who seek my help.

FOREWORD

Endophthalmitis, which is an inflammatory reaction of the intraocular fluids and tissues to an exogenous organism, with poor functional results and the possibility of phthisis, is the most serious complication of cataract surgery. It is a very embarrassing situation for a surgeon, especially when it is a cluster infection. Hence, proper measures to effect foolproof sterilization of everything that may be used during surgery should be undertaken.

Dr. Uday Gajiwala needs to be congratulated for creating a manual that will help enable total sterilization measures in an eye surgery theatre. It is a culmination of the efforts he has made in going around the country to teach the sterilization measures. In my opinion, this manual is a complete reference for both colleagues and students.

Congratulations again and my best wishes to him.

Dr. Pran Nagpal
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Ahmedabad

AUTHORS

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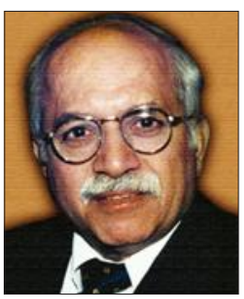
Dr. Uday Gajiwala is working as a Superintendent in the Tejas Eye Hospital run by the Divyajyoti Trust, Mandvi, District Surat, Gujarat & is also the Founder and Vice-President of the Trust. He is also a Trustee of Drashti Nethralaya, Dahod, Gujarat. He is the President - Vision 2020: Right to Sight Gujarat Chapter and of the IMA Mandvi chapter. He has many publications to his name. He is an expert in infection control activities and conducts clinical audits of hospitals on a regular basis. He has authored a manual on operation theatre protocol and also prepared a video demonstrating the protocol. Working in the rural tribal area of Surat district, he has devoted his life to the service of the poor people. He was instrumental in developing a comprehensive eye care programme at SEWA Rural, Jhagadia, and has now done the same in the Divyajyoti Trust, which includes tertiary eye care activities, training programmes and rehabilitation of incurable blinds and integrated education activities for blind children. He has received many awards, including the ACOIN Award and Dr. G. Venkatswamy Memorial Award given by the Community Ophthalmology Society of India for outstanding work in community ophthalmology.



Dr. P. N. Nagpal
MS Ophthalmology

Dr. Professor P. N. Nagpal was born in a small township in what is now Pakistan and shifted to India in 1947 after Independence. After initial schooling at Ajmer, Lucknow and Delhi, he joined medicine at Jaipur in 1957. After clearing the under- and post-graduation courses in 1965, he joined as a member of the teaching faculty in the Gujarat Medical Services. He went for training in the field of retina surgery to Germany in 1970. He decided to start his own Retina Foundation in 1976 and continued to involve himself in teaching the art of retina surgery. The Government of Gujarat also invited him to join as Professor Emeritus at B. J. Medical College, Ahmedabad. His contributions brought him national recognition with the President of India bestowing on him the prestigious Dr. B. C. Roy Award. He has been a member of the International Council of Ophthalmology & the prestigious Academia Ophthalmologica International is where he was elected the first Vice-President. He is also the President of the Afro-Asian Council of Ophthalmology.

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MS Ophthalmology

Dr. Rajesh Patel, an ophthalmologist, is practising as an Anterior Segment and Advanced Phaco Surgeon at Sai Drashti Eye Hospital, Bharuch. He has done his MBBS and MS (Ophthal) from the Baroda Medical College. He has worked as Senior Ophthalmologist at Sewa Rural, Jhagadia. Has also worked abroad at Acha Hospital, Cameroon, Central Africa and was involved in the Standard Chartered Bank and IAPB's joint venture "Seeing Is Believing Project" from 2009 to 2014. During this 12 years of experience, he has performed 15,000+ varieties of eye surgeries. He has made several presentations at various conferences at the national and local level. He has authored and co-authored a few articles in peer-reviewed journals. He has many photographs published in the online atlas of ophthalmology to his name. He is also an excellent teacher.

Dr. Amish Patel
MS Ophthalmology

Dr. Amish Patel has done his MS (Ophthal), FRF. He is a Consultant Ophthalmologist and Vitreo-Retinal Surgeon in private practice in Ahmedabad, Gujarat. He has a keen interest in diabetic retinopathy and is a visiting Diabetic Eye Disease Specialist at Dia Care, a comprehensive diabetes care clinic. His subject of interest and expertise is infection control in the eye OT and he conducts workshops and seminars on different topics pertaining to the same.

Dr. Madhvi Sheth
MS Ophthalmology

MS DNB Retina Vitreous Fellow from AEH 1992. Private practice since 20 years. Done MS (Ophthal) from Vadodara. Has pursued law also –a rare combination. She is one of the leading retina practitioners of Vadodara. Known for high-quality output. A good orator. She has given many presentations and lectures at local and state-level conferences and workshops.

INTRODUCTION

We had an unfortunate episode of cluster infection in the year 2004 while I was working in SEWA Rural. Following the painful episode, we did an extensive literature search and interacted with many experts in the field. This manual, "Protocol for the Eye Operation Theatre" was the outcome of all that hard work and it was published in 2008.

We still keep hearing about episodes of cluster infection every now and then. These episodes have serious adverse effects on the work that we are doing.

Often, they do not come to light for one reason or the other. Unfortunately, the topic of infection control measures is overlooked during the medical education and, hence, most of us do not know the exact details. The science of asepsis and antisepsis has advanced rapidly in the last couple of decades and, today, the rate of infection in cataract surgery in the developed countries has come down to less than 0.01%. However, it is bound to remain somewhat on the higher side considering the given limitations in India, particularly in rural areas and public hospitals, such as dust, heat, humidity and poor hygiene, etc., in addition to lack of trained manpower.

Among the various causes of blindness, post-operative complications are a major issue. That does not speak good about the work that we are doing. We must make sure that we bring down the rate of post-operative complications. One solution could be to prevent post-operative infection by taking appropriate but systematic and stringent steps.

Patients and the staff working in the hospitals or clinics are at a risk of acquiring an infection unless proper preventive measures are taken. Nosocomial infections are a major concern for any hospital in the world and are on the rise, more so in the developing countries. It is stated that about 25% of the patients getting admitted in the hospitals in developed countries and 50% in developing countries develop nosocomial infections. Everybody is fighting hard to bring down these figures.

Most of the infections can be prevented by strictly adhering to safe practices such as hand hygiene, use of gloves, effective practices of decontamination of instruments and other soiled items and also by improving the safety systems in critical areas where chances of infection are high, e.g. the operation theatre (OT).

Sterilization is the complete destruction of all pathogenic microorganisms, i.e. bacteria, viruses, fungi and spores. The word 'sterile' means free from, or the absence of, all living organisms. All that cannot be sterilized has to be handled by taking aseptic precautions. Sterilization and aseptic conditions are vital to any hospital and more so for ophthalmic work. The maintenance of sterile

conditions in a hospital is very essential and is not difficult. Trained manpower in combination with systematic planning, scheduling of duties and regular monitoring will achieve the desirable results. Priority should be given to communicating as well as internalizing the importance of these practices. Policies and procedures should be put in place and strict adherence to these should be enforced.

There are several guidelines and protocols available nationally and internationally. One can refer to the details. However, for us in India, the guideline given by the National Programme for Control of Blindness (NPCB) will be the final reference.

This manual has been updated to include the latest information available following recent developments in the field and also contains information about the common practices to be followed in maintaining the sterility of the ophthalmic OT complex. The central sterile supplies department is responsible for the sterilization of equipment, instruments, surgical supplies, etc. The manual is aimed at all who are involved in maintaining the sterile conditions in an ophthalmic OT. It lists down the basic and acceptable practices followed.

We have added chapters on the diagnosis and treatment of endophthalmitis and management of a cluster infection so as to make the manual a one-stop place for advice regarding endophthalmitis. We hope that the readers will appreciate the details given herein. Feedback from the readers will certainly help us in improving this manual further. However, this manual is only a guideline. There is room for minor modifications without deviating from the scientific facts. One can do the modifications as per the resources and space available. More importantly, all the staff working in the OT must be well aware of the protocols existing in their own hospital or clinic and should practice the same religiously. We hope it will help all those involved in eye care to bring down the post-operative infection rate in times to come.

I am very thankful to Dr. Pran Nagpal who has kindly given his expert inputs so as to make the section on endophthalmitis treatment complete and comprehensive. My sincere thanks also go to Dr Madhviben Sheth for reviewing the section on endophthalmitis treatment. I am indebted to my colleague, Dr. Rajesh Patel (ophthalmologist) and Dr. Amish Patel for their valuable contribution in making this manual possible, everyone on the OT team for pre-testing the manual and giving important feedback, and to the computer room staff for their support in DTP work. My thanks to Dr. Tanuja Rakhe also for helping me with proof reading. Thanks to the authors of "Ophthalmic Operating Theatre Practice - A Manual for Developing countries" who have kindly consented to allow us to reprint the OT layout and a couple of tables from the manual. Also, thanks to the NPCB - we have taken some details from the NPCB guidelines directly.

Dr. Uday Gajiwala
Divyajyoti Trust, Mandvi, Surat

CONTENTS

I. PROTOCOL IN THE OPERATION THEATRE TO PREVENT POST-OPERATIVE INFECTION

Uday Gajiwala, Rajesh Patel, Amish Patel, Pran Nagpal

A. OPERATION THEATRE (OT) LAYOUT[1-8]

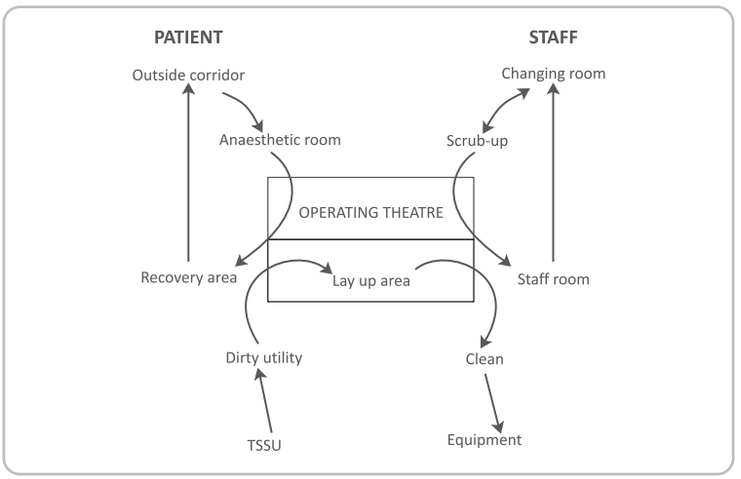
- Zoning inside the OT:
  - Outer zone -reception, footwear removal area. Dress protocols should be displayed here, e.g. street clothes may be allowed here.
  - Clean zone -changing room/transfer zone, cleaning area, temporary waste holding area.
  - Aseptic zone -scrubbing/gowning/gloving/OT/autoclave room.
  - Disposal zone-where equipment and supplies are processed.
- Only a dedicated eye OT should be used. (Makeshift OTs to be used only under extenuating circumstances with prior permission from Govt. officers.)
- Septic OT should be separate and away from the main OT.
- Space - minimum 180 sq. ft. for one OT table.
- Have a maximum of five personnel per 180 sq. ft. (separate OT with single operating table for each surgeon is the highest ideal). The microbial level in the OT is directly proportional to the number of people moving about in the OT.
- Separate entry for both scrubbed staff and unscrubbed staff/patients is necessary. Scrubbed staff should enter towards the head end of the patients. More space should be given towards the head end.
- Segregation of sterile and unsterile areas is necessary. Floor lines, etc., should be used to delineate them.
- Circular passage to ease removal of dirty items around the OT is preferable.
- There should be strict restriction of circulating staff/observers in the sterile area.
- All doors should be air-tight - rubber sealing can be used for the purpose.
- Air-lock should be created by providing an enclosed space before the main OT.
- Air should move from clean to less clean areas.
- Air changes should be at least 20 per hour- minimum requirement is a split air conditioner. A window air conditioner is not considered good, as it circulates outside air into the OT.
- A HEPA filter, which can filter out the smallest organisms (0.3 micron size), should be considered.
- Laminar flow above the surgical field also is a good option to provide clean air continuously atop the surgical field.
- If an air handling unit (AHU) with central air conditioning and pressure control with a manometric system can

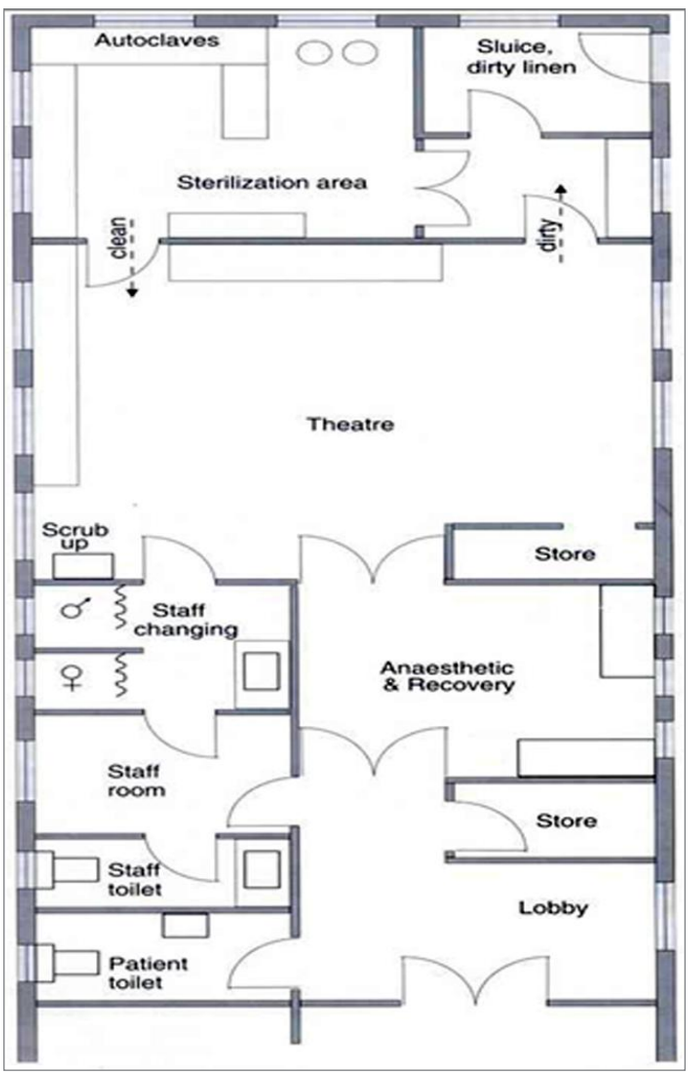
be used, that would be most ideal.

- Ultraviolet light can help clean the environment by killing the organisms due to its bactericidal property.
- Humidity should be controlled and maintained between 30 and 60%.
- Temperature should be maintained between 20 and 23°C.
- No fans, coolers or exhaust fans should be permitted inside the OT.
- Flooring should not contain marble as it is a porous material. Kota stone, granite or large-sized vitrified tiles are useful.
- There should be full wall tiling of large sized tiles.
- False ceiling of gypsum is allowed.
- All the corners should be rounded so as to avoid dust accumulation.
- No platform should be allowed above the height of the table, which is called the sterile level.
- No openable windows, cupboards or wooden furniture are allowed inside the OT.
- No direct exposure to the exterior.
- No toilets within the OT complex.
- Empty OT should have <35 colony-forming units of bacteria/M^3 of air.
- During an operation,there should be <180 CFU/M^3 of air.
- In the infective OT, all the facilities should be separate and dedicated, including sterilization facility, microscopes, vitrectomy machine and linen, etc., with negative pressure ventilation.

Parameter	Desired range
Temperature	20–23^{0}c
Relative humidity	30–60%
Air movement	From clean to less clean areas
Pressure	Positive air pressure by manometric control
Air changes	Minimum 20 total air changes per hour

SCHEMATIC DRAWING OF OT
(Taken from textbook on infection control by Dr. Shaheen Mehtar)





Taken from: **Ophthalmic Operating Theatre Practice:**
A Manual for Developing Countries by **Ingrid Cox & Sue Stevens,** INTERNATIONAL CENTRE FOR EYE HEALTH

Air cleaner

Air curtain

Dehumidifier

Ultraviolet light

B. PREOPERATIVE PREPARATION

(a) PATIENT PREPARATION

All patients should preferably be admitted a day prior to surgery to ensure that pre-op testing and preparation is adequately done and antibiotic drops started. History of dental caries, septic foci in the body and systemic diseases like asthma, hypertension, heart diseases, diabetes, rheumatoid arthritis, etc., should be elicited. Only exception could be day-care patients who can be allowed to go home after all the preoperative work-up is completed.

- The patient is allowed inside the block room, preferably after taking a bath, BUT minimum requirement is a facewash with soap and water.[9,10]
- Washed or disposable (preferred) cap, gown and shoes/leggies are worn.
- The eyebrows and eyelids are cleaned thoroughly with 10% povidone iodine or with chlorhexidine before block and in the wards also.[9,10]
- One drop of a NSAID eye drops & tropicamide/cyclopentolate with phenylephrine eye drops (for hypertensive patients, phenylephrine should be avoided) are instilled.
- After block, one drop of 5% povidone iodine is instilled.[11,12]
- Just before the surgery, the conjunctival sac is again washed with diluted povidone iodine and one drop of 5% povidone iodine is instilled and allowed to stay for a minimum of 2 - 3 minutes.
- Random blood sugar should be <200mg %.
- Urine sugar
  - If checked, must be NIL.
  - If positive, surgery should be done only after fresh blood sugar results.
- BP adequately controlled should be 150/90 mmHg.
- Internist's clearance -if patient has any systemic disease.
- High-risk surgery cases should be handled only by experienced surgeons with all due precautions.

- Preoperatively, use broad-spectrum topical antibiotics (levofloxacin, ofloxacin, ciprofloxacin or tobramycin newer ones should be reserved for frank infections) 1-hourly on previous day or four times a day for about 3 days may be used to reduce the conjunctival bacterial flora.[13-15]

- Sac syringing should not be done. Do ROPLAS[16] (Regurgitation On Pressure over Lacrimal Sac). If at all sac syringing is to be done, it should not be performed on the previous day or on the day of the surgery, as by doing it, even more bacteria are washed from the lacrimal sac into the conjunctival sac. If regurgitation is positive, postpone the surgery.

- If there is infection of the eyelids, adnexa and surroundings, postpone the surgery. Evidence of any current infection in any part of the body, including eyelids and surrounding area and dental infection, should prompt a postponement.

- No contact procedures (such as biometry/tonometry) should be done on the day of surgery. A scan and refraction should be done for both eyes. An average of minimum six readings for biometry is suggested; if a difference of >1D is observed between two eyes, the biometry should be repeated by another person.

- Adequate facial wash should be given with soap and water, and the periocular skin should be painted with povidone iodine solution on the previous night and on the morning of the surgery.

- Use of a plastic drape or other similar adhesive [specific attention to ensure its tight adherence at the medial canthus, nasal bridge and naso-labial fold] to isolate the surgical field is a must. It should cover the eyelid margin and lashes properly. There is no need to trim the eye lashes.[17, 18]

- While dealing with patients with HIV-, Hbs Ag- or HCV- positive reports, surgery should be done using universal precautions and that particular surgery should be done as the last case for the day. The OT should be cleaned immediately after the surgery, the linen washed with sodium hypochlorite solution (immerse everything in the hypochlorite solution for 2 hours before washing), and instruments should be cleaned and sent for sterilization.

- For patient identification, there are several methods in use -wrist band, identification badge for the patient, etc. For the identification of the eye to be operated, marking the eye with a marker pen, putting a strip of adhesive on the eye, wrist band, etc., are in use.

Patient identity and the eye to be operated on should be verified by the nursing staff at the time of sending the patient to the OT, by the staff present at the time of giving block, and by the surgeon and assistant just before beginning with the operation.

(b) PERSONNEL PREPARATION: ATTIRE, SCRUBBING, GOWNING AND GLOVING

ATTIRE

- No street clothes inside the OT (both staff and patients).

- Mask should cover the nose properly
  - Preferably high-filtration,triple-layered disposable type if affordable cost-wise.
  - To be changed after one session OR if one comes out of the OT for any reason.

- OT cap should be worn properly, tucking in all the hair.

- No shoe covers are allowed inside the OT- change to OT slippers.

- Clean, washed OT dress- dress code has to be strictly enforced.

- OT staff should not come out of OT in OT gown/dress.

- OT staff should wear scrub apparel with long sleeves and tight cuffs at the wrist.

SCRUBBING[10]

- Principle: To scrub from a clean area (hand) to less clean area (forearm).

- Aim: To minimize transient flora on the skin.

- Effective scrubbing is mandatory to protect the patient and the medical team from infection before and after performing surgery. The purpose of the surgical hand scrub is to reduce transient skin flora (bacteria) to a minimum. Because resident bacteria are firmly attached to the skin, they are difficult to remove. However, their growth is inhibited by the antiseptic action of the scrub detergent used. Transient bacteria are usually acquired by direct contact and are loosely attached to the skin. These bacteria are easily removed by soap and by the friction created by the scrubbing procedure. Proper hand scrubbing and the wearing of sterile gloves and a sterile gown provide the patient with the best possible barrier against pathogenic bacteria from the surgical team. It is followed prior to any surgical intervention

Material to be used for scrubbing

- Use purified water from water purifier. If distilled water can be used, it is the best. If this is not possible, one can boil the water the previous evening & allow it to cool and use it next day. Minimum is to chlorinate the tank water daily and use it.

- Liquid soap is considered better.

- Must use surgical hand scrub solution, either povidone iodine 7.5% or chlorhexidine 4%

- No machine or brushes are recommended any more for scrubbing.

- The tap should be either foot-operated or elbow-operated.

Auto dispenser – povidone iodine

Scrub area with water purifiers

Scrub area with water purifiers

Adapted from Taylor L(1978).An evaluation of hand washing techniques- I. Nursing Times,12 January, pg 54-55

Methods

Step 1 (3 Minutes)

- Prior to hand washing, all the jewellery on the hand and wrist watches should be removed. The nails should be short and should not be painted.
- The tap should be turned on using the elbow or an unsterile person should do it. The flow of water should always be from fingertips to the elbow.
- Clean under the fingernails for the first scrub of the day. This step need not be repeated for subsequent scrubs in the same session.
- Scrub the hands with a liquid soap and then with a hand scrub like povidone iodine or chlorhexidine. Lather is worked up to 3 cm above the elbow. Scrub each hand with the other. Scrub all surfaces in a circular motion, starting from nails, forearm and up to approximately 3 cm above the elbow. Special attention should be paid to web space, nails and subungual area.

- Hands should be rinsed thoroughly under running filtered water after scrubbing. If filtered water not available, boiled and cooled water can be used. In such a case, the nurse will pour water from a jug. The hands are held up and elbows below.
- Repeated thrice-take 1 minute each time.

Step 2 (4 Minutes)

- The next step is scrubbing of the hands with a hand scrub like povidone iodine (7.5%) or chlorhexidine (2.5%). Scrub each hand with the other. Using a circular motion, scrub all surfaces, starting from nails, forearm and up to approximately 3 cm above the elbow. Special attention should be paid to web space, nails and subungual area (Annexure 3).
- Hands should be rinsed thoroughly under running filtered water after scrubbing. If filtered water is not available, boiled and cooled water can be used. In such a case, the nurse will pour water from a jug. The direction of water flow must be from the fingertips to the elbow. The hands are held up and elbows below.
- Repeated twice - take 2 minutes each time.

Step 3

- After rinsing, the hands should be kept away from the body; hold the arms bent with the hands held up-upright in front, with the elbows away from the body.
- The tap should be closed with the elbow or a nurse turns it off.
- The hands should be dried with a sterile towel. Begin with the hand, wrists and then forearms. The same section of the towel is not reused. If required, a second towel can be used. Drying is not done all the way up to the elbows to prevent contamination.
- A minimum 5 minutes of scrubbing is considered the shortest acceptable duration for hand washing prior to surgery however, we suggest seven minutes for first scrubbing of the session.
- Re-scrub after every 2–5 surgeries for 3 minutes if we do not touch elsewhere and circulating staff should remove the scrubbed person's gown. (The highest ideal is to rescrub after each surgery.)

GOWNING AND GLOVING

- In order to minimize the risk of contaminating the sterile operative setup, during the process of gowning and gloving, a separate table should be used.
- The staff and surgeons are all required to use surgical gloves, which, after being worn, are cleaned by using sterile autoclaved water or cotton balls soaked in sterile water prior to the procedure to remove the powder used in the gloves, so as to prevent sterile uveitis the next day.
- Only the scrub nurse should gown and glove herself; the rest should avoid self-gowning and gloving. This minimizes the risk of contamination from dripping water on the sterile table in the process of picking up the hand towel and self-gowning.
- Apply 2.5% chlorhexidine hand rub on the gloves after cleaning with water.
- Members of the operating team should be gowned and gloved as soon as they enter the room. Once gowned and gloved, they should remain in the sterile area of the room until the patient is draped and the sterile setup is moved

into place.

- During any waiting period, the sterile gowned and gloved members of the team must keep their hands above waist level in front of them clasped together or place them on the sterile trolley. They should never sit, place their hands on lap or fold their hands. Hand movement in the air should be minimized.
- Change the gown if it becomes wet due to any reason.
- Application of a hand rub solution containing chlorhexidine 2.5% or alcohol further enhances sterility of the gloves.
- Minimum requirement is to change gloves after each surgery.
- Position of hands after scrubbing and gloving should be above waist level and held upright in front of the body.
- If any tear is found in the gloves, they should be changed immediately.

(c) INSTRUMENTS AND EQUIPMENT PREPARATION: CLEANING AND STERILIZATION[19-21]

1. INSTRUMENTS

Preparation of instruments for sterilization

FLOW CHART: INSTRUMENTS PREPARATION

Clean all the instruments immediately after use

↓

Separate sharp and blunt instruments

↓

An ultrasonic cleaner can be used once a WEEK
- Specially for cannulated instruments and for instruments with joints.
- An enzyme solution is added to facilitate the cleaning process.
- The ideal cycle time is 30 minutes.

↓

Four bowls cleaning technique
- The instruments are first brushed with a soft toothbrush in the first bowl containing mineral water with disinfectant and then rinsed in three bowls containing mineral water.

↓

- Flush lumened instruments with distilled water three times and then flush with air three times.
- Instruments should be dried with a towel and/or a hot air oven.

↓

They should be tipped with a plastic sleeve on the tip and packed in individual trays.

Bin packing and autoclaving

- Instruments should be cleaned as soon as possible after use, especially the simcoe cannula.
- Instruments should be placed in a tray with a perforated bottom to allow steam penetration around the instruments during autoclaving. Keep the instruments with joints opened out. Working surface of the instruments should be exposed to steam. Separate medium-sized drum for each surgery set is preferable, so that all the items that are required for one surgery are kept in this drum.
- Size of instruments pack and their placement in the tray should allow space for steam penetration in the drum.
- Place the tray inside a bin after spreading a towel inside.
- Must wear gloves for handling instruments to avoid contact with infective material.
- All the instruments should be cleaned with ultrasonic cleaner once a week. Cannulated instruments should be cleaned daily. Cycle time should be 30 minutes. To add enzyme solutions, use mineral water. However, use of an ultrasonic cleaner is not essential.
- Single-use of disposable tubing and other disposable items that become wet during the operative procedure is always preferable, if cost allows. (Tubing is not easy to effectively sterilize unless a class B autoclave or an ethylene oxide gas sterilizer is available.)
- Minimum 6–8 sets should be available per surgeon depending on the workload, particularly in high-volume settings.
- Chemical sterilization should not be done.
- An autoclaving log book should be maintained, including cycle time, temperature and pressure attained, etc.
- After autoclaving, the indicator strips from inside the drums should be pasted into the register, which should be signed by the OT in-charge and the ophthalmologist before the session begins.

Blunt instruments

Method of choice: General autoclave

This is a safe method of sterilization, as it kills bacteria, spores, viruses, fungus. Indicator tapes should be used in every cycle. Normally three tapes (bottom, middle and at the top, within the drums) are placed. One more tape is placed onto the external surface of the drum. Holding time of 20 minutes is required after attaining required temperature and pressure.

Note:

- Autoclaved instruments should be used within 48 hours.
- The water should be drained out fortnightly from the machine to avoid settling of salt on the instruments and in the chamber.
- Clean the autoclave machine's outer and inner surfaces regularly.
- Once in 6 months, the autoclave should be serviced. Calibrate and validate pressure and other gauges regularly and maintain a record.
- See Annexure 4 for method of sterilization by vertical autoclave.

Mode of sterilization during surgery (in between cases)

- Autoclave for 5 minutes (holding time) in a high-speed autoclave at a temperature of 134°C and 30 lb pressure OR in a regular autoclave with a holding time of 20 minutes after attaining the required temperature and pressure.
- The instruments are cleaned in clean sterile water or distilled water, using the four bowls technique mentioned previously.
- The cleaning water should be changed after cleaning 4–5 sets, or earlier if it appears soiled.

TABLE 1: STERILIZATION METHODS OF CHOICE FOR ARTICLES DURING EYE SURGERY

Articles to be sterilized	Sterilizing method
Linen (gowns, caps, masks, drapes)	Autoclaving
Glassware (syringes)	Dry heat sterilization/Autoclaving
Metal instruments - heat-labile	Autoclaving/Dry heat/Ethylene oxide sterilization
Metal instruments - heat-resistant	Autoclaving
Plastic instruments/Components	Ethylene oxide sterilization
Sharp-edged instruments (e.g. Vannas scissors, keratome)	Ethylene oxide sterilization/Hot air oven/Autoclaving
Intraocular lenses	Ethylene oxide sterilization
Sutures (including monofilament nylon)	Autoclaving/Ethylene oxide sterilization
Diathermy, cautery electrodes	Autoclaving/Ethylene oxide sterilization
Endoilluminators/probes	Ethylene oxide sterilization
Silicone oil/buckles/sponges	Autoclaving/Hot air oven

Sharp instruments

As for blunt instruments, sterilize prior to surgery as well as in between surgeries.
ETO can be used as an alternative method for sterilization of sharp instruments.

However, it is not essential to have the facility for all the methods. Autoclaving in regular vertical autoclave machine is the standard technique used to sterilize everything used for surgeries (the only exception being cannulated items, which can not be sterilized in vertical machines; cannulated items will need a horizontal machine with a vacuum cycle).

A European standard for benchtop steam sterilizers is currently being prepared.* It classifies benchtop steam sterilizer cycles according to the types of load they are intended to process, which are summarized in Table 2.

TABLE 2 – TYPE OF AUTOCLAVES

CYCLE TYPE	AIR REMOVAL	LOAD TYPE	ADVANTAGES	DISADVANTAGES
N	Passive (gravity displacement)	Non-wrapped solid items	Simplest type. Least expensive to purchase, operate and maintain.	Not be used for hollow devices or those with lumens wrapped loads (e.g. items in pouch).
B	Active (forced) air removal	Wrapped or non-wrapped solid items (e.g. forceps, dental probes). Wrapped or non-wrapped hollow items (e.g. cannulae within dimensions specified by sterilizer manufacturer). Porous loads (e.g. fabrics, swabs, dressings)	Widest range of applications.	Expensive to purchase and maintain. Additional periodic testing required. Post-sterilization drying stage essential for wrapped items increases total cycle times.
S	Active (forced) air removal	Only suitable for types of loads specified by the sterilizer manufacturer	Wider range of applications than Type N.	Expensive to purchase and maintain. Additional periodic testing required. Post-sterilization drying stage essential for wrapped items increases total cycle times

Note: Ideally, only the highest specification cycle should be available to the operator. Other cycles should be disabled, until specifically needed.

Traditional (gravity displacement) benchtop steam sterilizers displace air passively from the chamber and load by steam generated within the sterilizer chamber or in a separate boiler within the sterilizer's casing. This is known as a 'Type N' cycle.

Vacuum benchtop sterilizers have a pump or some other active method to remove air from the chamber and load. This type of air removal is found in 'Type B' cycles and some 'Type S' cycles.

They are described variously as vacuum benchtop sterilizers, benchtop porous load sterilizers, Type B sterilizers or sometimes Type S sterilizers.

Note: Type S sterilizers should be used to process only the types of loads specified by the sterilizer manufacturer.

Vacuum benchtop steam sterilizers have a forced air removal stage prior to the sterilizing stage; a post-sterilization drying stage.

Alternative air removal systems

Some sterilizers remove air by using a succession of steam pulses, in which the chamber is alternately pressurized and then depressurized to near atmospheric pressure (or to below atmospheric pressure where this process is augmented by a vacuum pump). Air can also be removed from tubular devices by injecting steam through the lumens.

Type N cycles are intended to be used to sterilize solid devices that are not wrapped. Devices that are wrapped (the term 'wrapped' includes sterilization pouches) and devices that are hollow or have lumens cannot be sterilized in this type of sterilizer. These types of loads should ideally be sterilized in a Sterile Supply Department (SSD) but, alternatively, may be sterilized in a properly functioning vacuum steam sterilizer that has been validated for the intended load.

Type B cycles are intended for wrapped solid items (e.g. forceps, dental probes), hollow items (e.g. cannulae, tubing), whether or not they are wrapped and for porous loads (e.g. fabrics, swabs and dressings). They are necessary for items that cannot be processed using a Type N cycle (or a Type S cycle, unless it is intended specifically for these load types). Type B cycles must have a drying stage to ensure that the load is dry before the door is opened, which can increase the total cycle time considerably.

Type S cycles are intended for types of loads specified by the manufacturer of the sterilizer. They have a forced air removal system. (Forced air removal can be achieved using a vacuum pump or super-atmospheric pulsing or steam injection through the lumens of devices.)

The effectiveness of the air removal stage determines the types of load they are designed to process. Some models have a drying stage, which will prolong the cycle time.

Special instruments

Vitrectomy cutter, cautery wires

- Vitrectomy cutter and cautery wires should only be autoclaved.
- Alternate method a ethylene oxide (gas sterilization)
- Remove all lubricants from the instruments and they should be absolutely dry.
- Pack them in polythene bags with indicator tapes inside the bags.

Sutures

- Should be reused after autoclaving/ethylene oxide sterilization only.

Linen

- All OT clothing should be washed with detergent.
- Caps and masks are not autoclaved.
- Gowns and drape sheets should be washed with detergent, dried and autoclaved in a loosely packed, separate drum with indicator strips pasted.

Irrigation solutions

- Check clarity of the solution. Look for suspended particles, colour change or turbidity-preferably, do it against a light source.
- Check for leakage and quantity of the solution.
- Note batch number.
- Glass bottle is preferred-while using glass bottle, do vacuum test (bubbles on putting drip set). Do a physical inspection against the light.
- Irrigating fluid to be sterilized before use in the OT .
- Use one bottle for one patient. Bottles of solution containing irrigating fluid etc. should never be kept or used for more than one operating session.

- Keep the infusion bottle for 24 hours (not for reuse). This is to confirm that the irrigating fluid is not the origin of the infection in case infections occur.

Viscoelastics

- Viscoelastics should be autoclaved before surgery.
- Leftover items should be neither re-autoclaved nor reused in the OT.

2. EQUIPMENT

- Fans, light, clocks, etc., inside the OT should be wiped once a week with diluted 1% sodium hypochlorite or Savlon. Ordinary soap water can also be used.
- Microscopes (except the lenses)should be cleaned separately with 15% cetrimide and 3% chlorhexidine gluconate daily. Microscope knob should be autoclaved and changed after each surgery or at least cleaned with alcohol hand rub between cases.
- A 0.1% ethanol, 0.1% 2-propanol and 0.06% l-propanol mixture (Bacillol 25 spray) is used to clean the head of the microscope daily.
- Microscope lens should be cleaned once a week with lens cleaning solutions.

FURNITURE

- Tables, saline stands, revolving chairs (surgeon's chair) should be cleaned daily with 1% sodium hypochlorite or antiseptic liquid concentrate (10 ml of chlorhexidine gluconate 7.5% - should be diluted with 500 ml of water or 10% benzalkonium chloride).
- Do not keep wooden furniture inside the OT as it can harbour bacterial organisms.
- The furniture on which the sterile packs are to be placed should be placed in the sterile area of the room. These should be clean and dry.
- The top part of all furniture should be approximately the same height as the OT table. This level is known as the level of sterility.

AIR CONDITIONING UNIT AND WATER TANK

- Split air conditioner is recommended.
- Air conditioner filter must be cleaned once a week with detergent and sun-dried.
- Water tank should be cleaned with bleaching powder once a month.
- Servicing and cleaning of both should be done every month.

(d) OT ENVIRONMENT PREPARATION: CLEANING AND FUMIGATION[22-25]

OT AND CORRIDORS

- No sweeping or dry dusting should be done in the OT itself.
- Daily, the OT floor should be wet- mopped with 1% sodium hypochlorite solution using a two/three buckets technique. One bucket contains plain water and the other 1% sodium hypochlorite solution. The mop is rinsed in the bucket containing plain water and then soaked in 1% sodium hypochlorite solution and then mopping is done. Procedure is repeated until the whole OT is mopped (hypochlorite solution should be prepared fresh just before use).
- A record chart of the cleaning, containing the name of the person doing it and date and time of doing the work, should be maintained, which is to be verified and signed by the OT in-charge.
- After washing, formalin fumigation should be done once a week and the OT should be closed for 24 hours. After formalin fumigation on a Saturday, the OT should be opened on Monday only.
- Alternatively, a glutaraldehyde + formaldehyde combination and 1% hydrogen peroxide with silver nitrate can be used at regular intervals. Corridors should be fumigated with formalin.
- Formalin 30 ml of 40% formalin dissolved in 90 ml of clean water can be used as an aerosol spray for 1,000 cft. Keep the OT closed for 24 hours. Then, clean with disinfectant before use.
- If a fumigator is not available, use 35 ml of 40% formalin in 10 gm potassium permanganate for 1,000 cft. Keep the OT closed for 24 hours. A 10–15 ml liquid solution of ammonia can be used next morning to remove the formalin fumes from the OT.
- Many other non-aldehyde products are available in the market. They are costly BUT less irritating and fast-acting. Claims of higher efficacy are also made by the manufacturers.
- However, formalin is the cheapest chemical available for the purpose and is certainly not toxic at the levels of exposure that we use in the eye OT. Non-aldehyde products should be used as per the specifications given by the manufacturers. It may be a good idea to change the agent once in a while. Hydrogen peroxide 2% with silver nitrate can enable the OT to be ready in 1 hour and since it is totally odourless even when being sprayed, one can stay inside the OT.
- Sterile quality of air in the OT is better achieved and maintained by employing an air cleaner, air curtain and ultraviolet lights, and by improving the overall cleanliness in and around the OT.

DAILY CLEANING

WEEKLY CLEANING

FOGGER MACHINE

TABLE 3 : REGIMEN FOR CLEANING, DISINFECTION AND STERILIZATION OF THE OT

PROCEDURE AND AGENTS	ROUTINE	EFFICACY
Disinfection of OT floor, walls, tables, trolleys with Lysol, Clearsol, Stericol or 1% sodium hypochlorite	Every day	Reasonably effective against wide range of Gram-positive and Gram- negative bacteria, but little activity against endospores, viruses and hepatitis virus
Washing of OT walls, floor, tables, trolleys, etc., with detergent	Once a week	Enhances the effect of daily cleaning and disinfection
Fumigation of the operating room with formaldehyde or other agent	Weekly or after surgery on the infected cases	Efficacy is uncertain in temperature below 20°C andrelative humidity below 70%
Maintenance, repair of any breach, cleaning of the ventilation system	Once in a 6-month period. Repairs to be done immediately	Enhances and improves the effect of cleaning and disinfection

- Air cleaners should be turned on while the surgical session is going on.
- After the surgical session is over, the ultraviolet lights should be turned on overnight when the last person leaves the OT. Switch them off before the first person enters the OT the next morning'. This will continuously clean the inside air while you are not working.
- Humidity should be maintained between 30 and 60% by employing dehumidifiers, if necessary.
- Complete cleaning of the OT, including walls, doors and floors should be done daily with diluted 1% sodium hypochlorite, up to a height of 6 ft
- Block room, changing room, and the doctor's room must be cleaned three times daily with 1% sodium hypochlorite.
- If starting the OT for the first time, fumigation should be done at least three times on 3 consecutive days and, preferably, three negative cultures should be obtained inside the OT.
- If it's a running OT, fumigation once a week is enough.
- A record chart of the fumigation with the name of the person doing it and the date and time of doing it must be maintained. OT in-charge should check and countersign it.
- Aldekol (formaldehyde 6% glutaraldehyde 6% and benzalkonium chloride 5%) also can be used as an alternative to formalin fumigation. For 4,000 cft, 325 ml aldekol in 350 ml of water should be sprayed for 30 minutes. Then close the OT for 2 hours with the air conditioner switched on; the OT will be ready in 3 hours.
- The sink area should be cleaned several times daily and kept as dry as possible. No storage should be provided below the sink.
- The outside of autoclaves should be cleaned daily while the inside surface is to be cleaned weekly. The inside cleaning requires the use of trisodium phosphate to remove the chemical residue.
- Before removing her gloves, the scrub nurse should place all soiled linen inside the laundry bin. No one should handle soiled linen inside with bare hands. Soiled linen should also never be left on the floor or transported on a trolley used for other purposes.
- The laundry bin should be removed immediately after it fills up.

- Liquid waste material (e.g. the contents of the suction bottle) should never be disposed off in a scrub/utility sink but only into a container meant for the purpose. It can be disposed off in the drain after disinfection.
- Ideally however, disposable suction bottles should be used. Glass suction bottles when used should be cleaned with a disinfectant and cleaned with disinfectant between cases.
- Waste management as per the standard practices suggested should be followed.
- Overhead tank must be cleaned monthly. After cleaning, 1% sodium hypochlorite solution should be applied on the inner surface and allowed to dry. Tank should be covered and all the pipes should be checked for leakages.

C. DURING SURGERY

On the table

- The trolley should not be burnt but should be cleaned with spirit,using unidirectional strokes. Common trolley should not be used.
- Paint with povidone iodine 10% for 3 minutes on skin and periorbital area, boundary of hairline, tip of nose, nasolabial fold and ear on the side of the eye to be operated. The iodine-soaked swab should be held with a swab holder or artery forceps, not by hand.
- Application direction should be from medial canthus to lateral canthus in a semi-circular motion, inside out.
- If povidone iodine 10% is contraindicated (allergy or hyperthyroidism), an aqueous solution of chlorhexidine (2%) should be used instead.
- Use a disposable adhesive drape (big-sized plastic disposable drape) to isolate the eyelashes. If possible, avoid using a linen drape as it is a porous material, which can transmit organisms, more so if it becomes wet.
- For antisepsis of the conjunctiva and cornea, 5% povidone iodine solution to be instilled in the conjunctival cul-de-sac just before beginning with the actual surgery is the chemical preparation of choice; it should be left in place for a minimum of 3 minutes.
- Keep sharp instruments on the towel such that their tip/edge is facing up.
- Do not poke the instruments into the towel.
- Do not touch the sutures/intraocular lens or any instruments to the eyelid margins.
- Keep used and unused instruments separate.

Between cases

- Apply 2.5% chlorhexidine hand rub on bare hands after removing the gloves and also on the surface of the gloves after cleaning them with sterile water.
- Change the gloves after each case or when they come in contact with unsterile surfaces. Re scrubbing after 2–5 surgeries
- Remove everything from the trolley and re-do the whole trolley.

At the end of surgery

- Post-operatively, a significant reduction in bacterial count in the conjunctival sac can also be achieved by

antisepsis with a 5% povidone iodine solution in the conjunctival sac.

- Sub-conjunctival antibiotic+ steroid in the inferior fornix —preferably use cefazoline with dexamethasone (avoid using a higher class of antibiotics –should be reserved for actual infection).
- If no sub-conjunctival injection is used (topical anaesthesia), topical application of a broad-spectrum antibiotic should be done.

D. OT ETIQUETTE

While observing the surgery

- One should keep one's hands behind one's back, thereby decreasing the temptation to reach out and contaminate the sterile supplies or area.
- Never touch or reach out with the hands over the sterile field.
- Maintain at least a 1-foot clearance from the sterile field.
- Avoid passing between two sterile fields.
- One should not lean over the sterile field and also do not allow any part of one's clothing to touch the sterile field.
- Excessive sneezing and coughing should be avoided.
- Talking, singing should also be avoided.
- Observers should not stand behind the surgeon but should stand in front and away from the operating table.

While circulating for surgery

- A sterile package should not be used if the sterility is doubtful. Check for holes or any breach in the packaging.
- Always check the expiry date before opening the package.
- When opening a sterile package, it should be held away from oneself, keeping one's fingers on the outside of the wrapper.
- When pouring sterile water, hold the container approximately 6 inches above the sterile field.
- Do not pass any item over the sterile field.
- Do not pierce the instruments in to the towel.
- If there is any doubt about the sterility of anything, consider it to be unsterile.
- Never touch or reach out with the hands over the sterile field
- Maintain at least a one-foot clearance from the sterile field.
- Avoid passing between two sterile fields.
- One should not lean over the sterile field and also do not allow any part of one's clothing to touch the sterile field.

- Excessive sneezing and coughing should be avoided.

While scrubbed for the surgery

- When donning the gown and gloves, it is to be ensured that the bare hands touch only the inside of the gown and gloves.
- The back of the gown and area from the waist below is not considered sterile; hence, one has to always remain facing the sterile area. The area around neck and the armpits are also considered unsterile.
- When changing places with another scrubbed person, one should do so back to back.
- The sterile instruments should be kept above the waist level.
- Keep gloved hands above the waist level and below the chin level or keep them on the topside of the sterile field. If one's hands are idle, clasp them together in the front or place them on the sterile trolley. One should not fold one's hands under the armpits or put them into the gown pocket.
- When a cough or sneeze is inevitable, step back from the sterile field and turn the head away.
- The surgeon should not touch the unsterile portion of the microscope.
- Sharp instruments should be kept on a clean towel, with the edge facing up.
- Don't let the face mask hang loose around the neck and reuse the same.
- Don't prepare all trolleys beforehand.
- Moisture is a potential source of contamination—don't use moisture-soaked linen packages.

GENERAL

- Nails should be trimmed regularly.
- All dresses should be washed with detergent.
- Gown, bed sheet and OT slippers should be washed with detergent daily and dried.
- OT staff should be instructed to change dress and slippers before leaving the OT.
- Mobile phones are strictly not allowed inside the OT.
- Stretcher and wheel chair for use inside the OT and outside the OT should be separate.
- Periodic assessment and training of OT personnel should be done.
- Slippers for toilet use and OT should be kept strictly separate (colour coding).
- Always keep the doors of the OT closed.
- Garbage should be disposed off after each session.
- General health and personal hygiene of doctors/staff working in the OT needs close monitoring. Anyone with upper respiratory infections, draining skin and lesions or infections of the eyes, ears or mouth should not be permitted to work in the OT until the lesions have healed in case of skin and at least 2 days of antibiotic therapy in

case of respiratory infection.

- Restriction of surgeries up to 25 surgeries per surgeon per OT in a day to give sufficient time to the staff for OT preparation for the next day.
- Restriction of the surgeries up to 15 cases on Saturday to give sufficient time for weekly cleaning and OT staff meetings.
- OT to be closed on the last Saturday of every month for OT washing after shifting all the movable items outside the OT.
- Tables are sterile only at table-top level.
- Keep non-sterile personnel or visitors to a minimum.

E. MONITORING[20,21]

- Periodic culture is done once in a month from areas such as hand washing area, saline, cannula, and distilled water, and swabs are taken from the surgeon's and assistant's hands, floors, walls and air conditioner for culture once in 15 days. Interpretation is important. Swabs from non-sterile items will indicate only the level of cleanliness.
- The bacteria-carrying particle (BCP) load in the OT is checked by open-dish sedimentation plating technique every fortnight. If the number of bacterial colonies is less than ten, it is considered okay. However, no fungal colony should grow on the plate.
- Also, the swabs from sterile areas should not have any growth at all.

Mechanical monitoring

An autoclaving log book should be maintained where the time, temperature and pressure are recorded along with the time and duration of the cycle.

Chemical monitoring

The change of colour of the indicator strips at the end of the cycle indicates attainment of the desired temperature during the cycle. The colour of the strip at the end of the cycle should be jet black; otherwise, the cycle should be repeated once a week, if affordable cost-wise, a Bowie Dick test pack or a vapour line indicator can also be used.

Failure of the chemical indicator test should prompt thinking about possible causes and another type of chemical indicator/other company’s product should be tried and a biological indicator should be used to confirm proper functioning of the machine.

Biological monitoring

- Bacillus stearothermophilus spores is used for steam sterilization and Bacillus subtilis for dry heat and ethylene oxide sterilization cycles.
- The biological indicator ampoule should be put in the load along with other items.

Chemical indicator strips

Biological indicator ampoules

Bowie Dick test pack and vapor line indicator

- Monitoring is generally done once in a month.
- It is supposed to be a surprise check.
- Failure of the biological indicator test should be taken seriously and a detailed check of the functioning of the autoclave machine should be done.

A basic summary of the monitoring requirements for steam sterilizers is listed below:

Process recorder∋	Temperature measurement	Chemical monitoring	Other	Optional monitoring
Every cycle	Only during calibration and performance qualification of sterilizerσ	Every load and, if required, every item	• Pre-vacuum sterilisers -weekly leak rate if sterilizer fitted with an automatic air detector; otherwise daily • Biological indicator for emergency non-validated loads	• Biological indicators Σ • Process challenge devices • Electronic data loggers • Internal chemical indicators

∋ The condition here is that the record is generated automatically by the sterilizer controller system and crucial details of every cycle are recorded in a permanent form.

Σ Any of the three types of biological indicators for steam sterilization available in the Indian marketplace may be used, subject to sterilizer operators demonstrating the value of their contribution to sterilizer monitoring.

σ This involves use of an independent means of temperature measurement and the introduction of electronic temperature measurement leads (thermocouples) into the sterilizer chamber. The aim is to measure during the sterilizing stage, the chamber temperature and the inside temperature of a test pack/packs.
Note: The placement of thermocouples within packs should be done considering the complexity of the contents, e.g. insert thermocouples into cannulas and places where steam penetration is likely to be impeded.

Different classes of indicators

- Class 1: Process indicators
  - Used to show exposure to a process. No information about the success or failure of the process.
- Class 2: Specific test indicators (e.g. Bowie Dick Test pack)
- Class 3: Single-variable indicators
  - Respond to a single variable in the process, e.g. temperature.
- Class 4: Multi variable indicators
  - Respond to two or more variables in the process.

- Class 5: Integrating indicators
  - Respond in a way that mimics the response of a Biological Indicator if used in the same process.
- Class 6: Emulating indicators
  - Respond to all defined critical variables of the process at levels associated with acceptable sterilizing conditions, e.g. 134°C for 5 minutes.

Important: Classification is non-hierarchical!

F. COMMON SUGGESTIONS TO PREVENT INFECTION

- Don't use the same irrigation line, irrigating solution, viscoelastics, surgical instruments set, cannula, cautery wire etc. for several surgeries.[26,27]
- Preferably, avoid corneal incisions.[28-31]
- Prefer SICS for mass surgeries.
- When in doubt, apply sutures. Improper valve, gaping wound to be avoided-wound must be water-tight at the end of the surgery and not air-tight.
- Phaco - tips, sleeve, tubings and cassette to be changed for each case.
- Not more than 25 cases/surgeon/day should be undertaken. Surgical session should allow enough time for cleaning activity (as per the AIOS guideline).
- Document sequence of surgeries.

G. PATHWAYS TO SEPSIS AND ASTERILITY : GENERAL

- Preparing all trolleys beforehand.
- Relying on unconventional methods (boiling).
- Unsterile person completing a trolley using a chittle forceps.
- Throwing around soiled linen and covers, etc.
- Discarding swabs used for skin preparation onto the floor.
- Sterile persons leaning over an unsterile area.
- Non-sterile persons reaching over a sterile area.
- Sterility of items being used is doubtful, but decides to use the same.
- Linen is soaked with moisture and still using it.
- Heavy traffic.
- Excess people inside the OT.

H. PATHWAYS TO SEPSIS AND ASTERILITY: PATIENT PREPARATION

- Not specifically ruling out adnexal (e.g. dacryocystistis) and ocular surface infections and dental infections.
- Operating in the presence of active septic foci.
- Performing repeated contact procedures (e.g. applanation, biometry) on the day of surgery.
- Unclean patient attire and exposed scalp hair.
- Improper surgical painting.
- Uncovered nostrils and eyelashes (linen + plastic drape)
- Not washing away meibomian secretions.
- Not washing conjunctival sac with povidone iodine.
- Uncontrolled diabetes.

I. PATHWAYS TO SEPSIS AND ASTERILITY : SURGEON FACTORS

- Exposed scalp hair and nostrils.
- Operating in spite of an open wound.
- Improperly scrubbed hands-hand washing is not equal to surgical scrubbing
- Un gloved hands or torn gloves.
- Gowns are not sterile below waist, in the back, region of armpits and neck.
- Cap and mask not fully covering scalp hair and nostrils.
- Letting the face mask hang loose around the neck and reusing the same.
- Wearing the same footwear from unrestricted to restricted area.
- Moving around with hands folded (under armpits) or in gown pocket.
- Getting irrigation fluid all over: trolley surface, gown, drape etc.
- Not checking indicator tapes (autoclave, ethylene oxide sterilisation etc.).
- Not checking irrigating fluid for particulate matter/presence and concentration of antibiotic.
- Inadvertently touching an unsterile area but not changing gloves.
- Same irrigation line used for several surgeries.
- Re-using instruments from trolley of another patient directly.
- Reusing dropped instruments without adequate re sterilization.
- Inserting a dropped intraocular lens after washing it!

- Leaving eye pre disposed: improper valve, wound gape, exposed suture knots, vitreous wick.

J. PATHWAYS TO SEPSIS AND ASTERLITY: INSTRUMENTS FACTORS

Pay special attention to the following:

- Tubular instruments (e.g. cannula).
- Devices with anti-peristaltic pumps and reflux mechanism (e.g. phaco/vitrectomy machines): Ensure suction bottle is empty and sterile.
- Perform the cleaning cycle of the phaco machine as per the company recommendations and document the same.

K. POST-OPERATIVE FOLLOW-UP

- Patch preferable for at least 6 hours — avoid rubbing the eye.
- Follow up on days 1, 4,14 and 45 (30^{th} for phaco) (variable among surgeons).
- Check visual acuity with pinhole examination during each visit- if it is <6/60, find the cause.
- Slit-lamp examination is a must.
- Look for media opacity with direct ophthalmoscope.
- Wearing of protective glasses/eye shades for 1 week.
- Oral antibiotics only in high-risk cases.
- Topical antibiotics with steroids for a minimum of 4 weeks.
- Hand hygiene is important and should be emphasized to the patients and relatives.
- Personal hygiene to be emphasized.
- Diabetes Mellitus control to be emphasized.
- Short-acting cycloplegic, at discretion of surgeon when required.
- Document all post-op findings, including complications.
- Surgeon/assistant to be available at the venue for at least 4 days.
- Must report excessive redness/pain, watering, discharge, sudden blurring of vision, floaters/flashes, excessive photophobia.
- Refraction (final) and prescription of glasses at the end of 45 days for SICS and at the end of 30 days for phaco cases.

L. OPD

- Instrument tray should be autoclaved daily.
- Instruments once used in OPD must be autoclaved.

- Instruments used on infective cases are to be autoclaved twice before use.
- Disposable products should be strictly disposed off following strict disposal procedures / guidelines
- Slit lamp should be cleaned with spirit after an infective case is seen and this should be done routinely every day.
- Floors should be swept thoroughly and then mopped with a disinfectant cleaning solution such as phenyl mixed with detergent at least three times a day.
- Eye drops and ointments should not be kept uncapped.
- Trays in which medications are kept should be cleaned daily.
- Do not share hydro needles between patients.

M. WARD

- Floor mopping daily with phenyl mixed with detergent (disinfectant cleaning solution).
- Instrument trolley to be cleaned everyday. A separate trolley for dressing infective cases.
- The eye drop bottle should be kept in a clean place and the tip of the dropper should not be touched. Dropper should not be left uncapped.
- The hands should be washed before and after applying or administering any medication.
- The slit lamp should be cleaned everyday.

N. DEBATABLE ISSUES IN THE PROTOCOL SUGGESTED HERE

1. Use of Ringer lactate (RL) versus Balanced Salt Solution (BSS)

The results of a prospective randomized masked trial demonstrated that eyes receiving BSS had significantly lesser corneal thickness and inflammation on the first post-operative day as compared to eyes that received Ringer lactate however, there was no significant difference at 1 and 3 months post-operatively.

BUT we cannot go by such single or small studies. We have been using Ringer lactate for decades in our country without any problem. Considering the cost factor, Ringer lactate appears to be a preferred agent for irrigation in the Indian scenario.

The argument that use of Ringer lactate for irrigating the eyes is an off-label use - we are using many drugs off-label for years together now. The latest example is Inj Avastin. It is used even in the Western world. We, as doctors, have a right to use any drug off-label that we find to be beneficial to the patient.

2. Autoclaving of Ringer lactate and viscoelastic before use

Several reports of cluster post-operative endophthalmitis have been reported, implicating contaminated intraocular solutions. The fluids for intraocular and intravenous use such as BSS, Ringer's lactate, etc., should be inspected for intact packing and for any obvious bacterial or fungal contamination. Any visible particulate matter should render a bottle unsafe for use even if its sterile packing seems undisturbed. A similar evaluation of containers of viscoelastic material such as methylcellulose 2% or sodium hyaluronate is mandatory before use.

The question is that even if the company has supplied the bottle totally sterile, meaning that the production was

upto the mark using the latest and best available technology, who will take the responsibility of anything going wrong during storage or transit? The manufacturers have written an instruction on the bottle: "If any solids are found in the bottle, do not use it and send it for replacement." We must bear in our mind that during storage or transport, if more than seven packs of fluids are stacked on top of each other, the lowest ones have so much pressure from the top that they develop micro-cracks. We keep coming across fungus in fluids frequently. As the end user, it is our responsibility to make sure that the products that we used were sterile. The company will not take any responsibility. Under the given situation, even when we inspect the bottle visually, if the micro-cracks have developed recently, the number of organisms or fungus may not be enough to develop visible particles and, yet, it will be there, which can be disastrous. So we strongly advocate autoclaving of the irrigating fluids and viscoelastics, both- in the hospital before use.

3. Frequency of scrubbing and change of gloves after each surgery

The principle of surgery says that we should scrub after each surgery. That is what we do in general surgery. In eye surgery, apparently, the gloves or linen used does not get soiled, so we feel that it is safe to continue without scrubbing or changing the gown and gloves. However, as we all know, organisms are not visible to the naked eye. If at all, during the process of one surgery, the gown or gloves have become contaminated, it will have a disastrous outcome. It is true that we have the highest backlog of cataract surgery in the world BUT we cannot compromise on quality at any cost. We have seen the adverse effects of cluster infections being reported from various regions in India.

Though some reports showed that applying chlorhexidine after surgery can be effective and an alternative to changing the gloves, glove changing should be done. It seems this requires a very strict discipline to be followed and that is difficult in our conditions, particularly with locally trained staff being employed in the majority of the hospitals.

Weighing the overall benefits and risks, it is suggested that the gloves must be changed after each surgery. Rescrubbing should be done minimum after five surgeries; it would be preferable if there is a higher frequency of scrubbing. One must understand fully that when we do not scrub after each surgery, we are compromising a lot and many patients are at risk if anything goes wrong.

4. Operating on both eyes simultaneously

This issue is a very hot topic debated in the Western world. However, there the cost of hospitalization is very high and to save on this cost, some people are advocating bilateral simultaneous surgery. However, a totally separate set of instruments and all the disposables is considered a must. It is done in a separate OT. Bilateral cataract surgery is not an appropriate choice for all surgeons. It is best suited for confident, experienced surgeons who are aware of their complication rates and biometric accuracy.

However, in the Indian context, it is not encouraged at all. The hygiene of our patients is poor and they cannot always be relied upon to take care of post-operative requirements at home. In fact, in many situations, they don't even use the eye drops regularly. As such, the cost of cataract surgery is not very high; more over, the hot, humid conditions prevailing in our country make it difficult for the patient to follow all the post-operative instructions. With several cluster infections being reported across the country every now and then, nobody should take a risk of bilateral endophthalmitis in our country.

5. Use of systemic gatifloxacin/moxifloxacin

Endophthalmitis Vitrectomy Study (EVS) very clearly indicated that systemic antibiotics have no role whatsoever in treatment of intraocular disorders. However, after the introduction of gatifloxacin and moxifloxacin, pharmaceutical companies have started making tall claims about the penetration of these drugs into the intact blood ocular barrier. However, talking to the ocular pharmacologists, the penetration is doubtful and the role of these drugs by the systemic route is still debatable. We will have to wait until it is established

beyond doubt that the drugs penetrate to such an extent as to reach desired MIC levels. Until such time, the systemic use of antibiotics, whether prophylactic or for treatment, will be considered doubtful.

6. Number of surgeries/surgeon/day

If we consider 5 minutes as actual surgical time in the most experienced hands also, the preparation time and the post-surgical tasks that we need to perform take away another 5 minutes each. That means, overall, we need about 15 minutes for each surgery and so, we can perform, at the most, four surgeries in 1 hour. Considering 5–6 hours of surgical time, we can do twenty-five surgeries within the comfort zone. The chances of compromise will start increasing after we get fatigued. This holds true more so for our assistants who have to remain standing for long hours and assist in somewhat uncomfortable positions. Fatigue starts telling on them much ahead of us and we must be mindful of this fact.

7. Length of OT session in a day

We must make allowance for the cleaning activity before and after the operating session. It takes about an hour before the operating session begins and approximately 2 hours after the session is completed. Total operating time should not exceed 5–6 hours. The chances of compromise definitely increase after we get fatigued.

The amount of work required to be done in India is so much that stretching ourselves for a few more surgeries does not make sense. At the same time, if we end up with a disaster, it has such a great deleterious effect on our work that it is not worth taking any risk of a disaster.

8. Number of tables in one OT

The ideal is only one table in one OT. That is what we generally do in general surgery. In ophthalmology, we have a huge backlog of cataract surgery cases and the number of ophthalmologists available to take care of this work is limited. In addition, it takes only about 10–20 minutes for one cataract surgery, so in order to increase the output per surgeon, most of us use two tables in one OT. However, no scientific studies are done to prove that using two tables in one OT does not increase the chance of endophthalmitis.

9. Use of topical antibiotic preoperatively

Some recent studies have shown that topical use of 5% povidone iodine as eye drops just before the surgery and allowing it to act for a minimum of 2 to 3 minutes is equal to or better than topical antibiotic for 24 hours preoperatively. However, until we get conclusive evidence to this effect, it appears to be safer to use both topical antibiotic and 5% povidone iodine.
It is conclusively proved that the use of topical antibiotic for longer periods is not helpful or, rather, it can have adverse effect on the flora of the conjunctival sac.

10. Need for trimming of the eyelashes

The trimming of the eyelashes[1] and flushing of the lacrimal drainage system[2] are no longer considered necessary before cataract surgery. The eyelashes should be properly covered by the sterile drape. Studies have proved that by trimming the lashes, we release more bacterial organisms into the conjunctival sac. Some lashes may even fall into the sac and come in the way of the surgery. Instead, we have plastic adhesive drapes that can cover the lashes well so that they are kept away from the sterile field. By doing this, we avoid the irritation to the patient of growing lashes and then waiting for them to grow back.

11. Need of doing sac syringing

Today, modern drapings exclude the lashes from the surgical field. Schmitz et al. reported that flushing the lacrimal drainage system, using eye shields and trimming the eyelashes had no demonstrable effect in preventing endophthalmitis. We can do a ROPLAS (Regurgitation On Pressure over Lacrimal Sac) test instead.

12. Subconjunctival antibiotic/intracameral antibiotic at the end of surgery

Prophylactic subconjunctival antibiotic injections at the conclusion of cataract surgery decreases the incidence of post-operative endophthalmitis. This is because the very high concentrations of antibiotics achieved in the anterior chamber from such injections, destroy any bacteria that may have been introduced during surgery. Wallin et al. recommended that the topical antibiotic should be started from the same day of operation and not from the next day. Subconjunctival injection of antibiotics at the end of surgery helps to reduce post-operative infection, particularly in the setting of the developing world.

Subconjunctival injection can cause congestion and chemosis and does not aid topical anaesthesia surgery; so, intracameral or intrabag can be considered.

Distilled water should be avoided for dilutions and irrigation because it is toxic to the corneal endothelium.

ANNEXURE-1: STERILIZATION PROTOCOL AT A GLANCE

AREA	PROCEDURES	ACCEPTED PRACTICE
No. of Standard Surgical Sets	One surgeon with one OT table: 4 sets One surgeon with two OT tables: 7 sets One junior surgeon with one OT tables: 2 sets	
Cleaning Procedures	Manual cleaning	Use four bowls technique. First wash with disinfectant and clean with a soft toothbrush. Then followed by three washes with distilled water
Blunt Instruments	Prior to surgery	Steam sterilization
	Between cases	High-speed sterilizer
Sharp Instruments	Prior to surgery	Autoclaving/Ethylene oxide sterilization
	Between cases	High-speed sterilizer
Heat-labile Instruments	Cryo-probe	Formalin chamber/Ethylene oxide sterilization
	Vitrectomy cutter and cautery probes	Ethylene oxide sterilization/Autoclaving
Linen	Surgeon's dress	Washed with detergent
	Gowns	Steam sterilization
	Drape sheets	Steam sterilization/Disposables
Hand Washing	Prior to surgery	Hand scrubbing with povidone iodine scrub or chlorhexidine for 7 minutes

	Between cases	Rescrub after every two to five surgeries for 3 minutes if you don't touch anywhere after removing the gloves. Change gloves after each surgery
Surgical Supplies	Irrigation solution/Ringer lactate (glass bottles)	Steam sterilization before opening the seal
	Viscoelastics	Steam sterilization
Theatre Sterilization/ Disinfections	Floor	1% sodium hypochlorite, chlorhexidine, Lysol
	Fumigation of OT	Formaldehyde alternated with formalin + glutaraldehyde or hydrogen peroxide or Aldekol
	Air conditioners	Filters to be removed and washed with soap and water weekly and sun-dried
	Walls	Washed with water and disinfectant weekly
	Theatre trolleys	Disinfectant
Patient	Dress for OT	Washed gown, cap and leggies
	Disinfection of conjunctival sac	5% povidone iodine + antibiotic eye drops on the previous day - every 1 hour
Sutures	Prior to surgery	Ethylene oxide sterilization (if the pack has been opened but only once)
	Between cases	Used only after autoclaving

ANNEXURE-2: SUMMARY- INFECTION CONTROL PROTOCOL

A. OT LAYOUT

- Segregation of sterile and unsterile areas should be ensured in OT layout.
- Have a dedicated eye OT, which should be away from septic OT.
- Separate entry for both scrubbed staff and unscrubbed staff/patients.
- Air changes should be at least 15–20 per hour (split air conditioner), which should be passed through a series of dust filters and then enters the room through a HEPA filter.
- Humidity should be controlled and maintained between 30 and 60% with a de-humidifier.
- Temperature should be controlled and maintained between 20 and 23°C.
- Space - minimum 180 sq. ft. for one OT table, with a maximum of five personnel per 180 sq. ft.

B. PREOPERATIVE PREPARATION

(a) Patient preparation

- Preoperatively, use broad-spectrum topical antibiotics on the previous day.
- No need for sac syringing; ROPLAS is sufficient.
- No contact procedures (such as biometry/tonometry) to be done on the day of surgery.
- Eyebrows and lids should be cleaned with 10% povidone iodine before block and in the ward also.
- Allow the patient into the OT after taking a bath and wearing washed cap, gown and leggies.
- After block, one drop of 5% povidone iodine is instilled in the conjunctival sac
- If infection of eyelids, adnexa and surrounding area or unusual congestion or discharge is seen, then no surgery.
- Use plastic adhesive drape.
- Patient with systemic illness should get a clearance from physician. Rule out dental infection.
- Blood sugar and blood pressure to be adequately controlled.
- High-risk cases, one-eyed patients and combined surgeries should be done by a senior consultant.
- Blocks to be given by trained personnel using sterile items, ensuring a no-touch technique after doing a hygienic hand wash. Pulse oximeter should be used to monitor patients and emergency drugs should be present at the site.

(b) Personnel Preparation: Attire, Scrubbing, Gowning And Gloving

1. Attire

- Mask should cover the nose properly and OT cap should cover the head completely.
- Clean, washed OT dress should be worn. No shoe covers allowed - change to OT slippers.

2. Scrubbing

- Scrubbing direction must be from a clean area (hand) to a less clean area (arm).
- Hands should be washed with ordinary purified water + liquid soap and surgical scrub solution (povidone iodine 7.5% liquid scrub or 4% chlorhexidine) for 7 minutes.
- Re-scrub after 2–5 surgeries for 3 minutes, if no other item or area has been touched and an OT staff member removes the scrubbed person's gown (ideally, it would be best to re scrub after each surgery).
- Nobody should come out of the OT in OT dress.

3. Gowning and Gloving

- Members of the OT team should be gowned and gloved as soon as they enter the room.
- When donning the gown and gloves, ensure that the bare hands touch only the inside of the gown and gloves.
- After wearing sterile gloves, wash hands with irrigating fluid to remove talc from the gloves.
- Apply 2.5% chlorhexidine hand rub onto the surface of the gloves.
- During any waiting period, one should keep hands above waist level and upright in front and never sit, place the

hands on the lap or fold the hands.

(c) Instruments and equipment preparation: cleaning and sterilization

1. Instruments

- Instruments should be cleaned as soon as possible after their use.
- Instruments should be thoroughly cleaned by washing in distilled water/mineral water. Surfactant cleaner can be used for effective cleaning.
- After removing the instruments from the ultrasonic cleaner, they should be washed in mineral water, using the four bowls technique, then dried, and tipped with plastic sleeves and packed in individual trays.
- It would be ideal if everything required for one surgery is autoclaved in a separate drum.

Blunt instruments

- Normally three indicator tapes (bottom, middle and on top, within the drums) are placed. One more tape is placed on to the external surface of the drum.
- Autoclaved instruments should be used within 48 hours.

Vitrectomy cutter, cautery wire, sutures

- Vitrectomy cutter, cautery wires and sutures are autoclaved/ethylene oxide-sterilized.

Irrigation solutions

- Look for suspended particles against the light, note the batch number and use one bottle for one patient. Sterilize the irrigating fluid before use (use glass bottles only).

Viscoelastics

- Viscoelastics are autoclaved before surgery; anything leftover is neither re-autoclaved nor reused.

2. Equipment

- Fans, lights, clocks etc. inside the OT should be wiped weekly with 1% sodium hypochlorite.
- Equipment such as microscopes (excluding the lenses) should be cleaned separately with 15% cetrimide and 3% chlorhexidine gluconate daily.
- A 0.1% ethanol, 0.1% 2-propanol and 0.06% i-propanol mixture (Bacillol 25 spray) should be used to clean the head of the microscope daily.
- Microscope lens should be cleaned once a week with a lens cleaning solution.

Furniture

- Tables, saline stands, revolving chairs (surgeon's chair) should be cleaned daily with antiseptic liquid.
- Do not keep wooden furniture inside the OT as it can harbour bacterial organisms.

- The top part of all furniture should be at the same height as the operating table (the level of sterility).

Air conditioning unit and water tank

- Air conditioner filter must be cleaned once a week.
- Water tank should be cleaned with bleaching powder once a month.

(d) OT environment preparation: cleaning and fumigation

Operating room and corridors

- Daily, OT floor should be wet-mopped with 1% sodium hypochlorite solution.
- After washing, formalin fumigation should be done once a week. Then, OT should be closed for 24 hours.
- Alternatively, glutaraldehyde + formaldehyde combination, 1% hydrogen peroxide with silver nitrate or Aldekol used every 15 days/month.
- Sterile quality of air in the OT is better achieved and maintained by employing an air cleaner, air curtain and ultraviolet lights and through improving the overall cleanliness in and around the OT.
- Complete cleaning of the OT, including walls, doors and floors should be done daily, up to a height of 6 ft, with 1% sodium hypochlorite solution.
- Block room, changing room, doctor's room should be cleaned thrice daily with 1% sodium hypochlorite solution.
- When starting OT for the first time, do fumigations daily for three days and preferably, get three negative cultures of the OT
- The sink area should be cleaned several times daily and kept as dry as possible.
- The outside of the autoclaves should be cleaned daily while the inside surface should be cleaned weekly.

C. DURING SURGERY

On the table

- The trolley should not be burnt but cleaned with spirit in unidirectional strokes.
- Paint the eye lids and periorbital area with povidone iodine 10% and leave it for 3 minutes.
- Direction of application – from medial to lateral canthus, in semi-circular motion, inside out.
- Alternatively, chlorhexidine (2%) should be used.
- Disposable adhesive drape should be used to isolate the eyelashes.
- A drop of 5% povidone iodine solution should be put in conjunctival cul-de-sac and allowed to act for 2-3 minutes.
- Sharp instruments should be kept on the towel such that their tip/edge facing up.

Between surgeries

- Apply 2.5% chlorhexidine hand rub.
- Change the gloves after each case or when it comes in contact with unsterile surfaces. Rescrub after 2–5 surgeries.
- Remove everything from the trolley and re-do the whole trolley.
- Use high-speed autoclave to sterilize instruments in between the surgeries.

At the end of the surgery

- Inject subconjunctival antibiotic + steroid
- Instill 5% povidone iodine eye drops.

D. OT ETIQUETTE

When observing the surgery

- Keep hands behind the back and do not stand behind the surgeon.
- Never touch or reach out with hand(s) over the sterile field.
- Maintain at least a 1-foot clearance from the sterile field.
- Avoid passing between two sterile fields and leaning over the sterile field.

When circulating for surgery

- A sterile package should not be used if the sterility is doubtful. Check for holes or any breach in the packaging and the expiry date before opening the package.
- When opening a sterile package, it should be held away from oneself, keeping one's fingers on the outside of the wrapper.
- When pouring sterile water, hold the container approximately 6 inches above the sterile field.

After having scrubbed for the surgery

- The back of the gown and from the waist below is not considered sterile; hence, one should remain facing the sterile area.
- When changing places with another scrubbed person, one should do so back to back.
- The sterile instruments should be kept above the waist level.
- Gloved hands are to be kept above the waist level and below the chin level.
- If not doing anything, one should keep one's hands clasped together in front or place them on the sterile trolley.
- When a cough or sneeze is inevitable, step back from the sterile field and turn the head away.

- Do not let the face mask hang loose around the neck and reuse the same.
- Don't prepare all the trolleys beforehand.
- Moisture is a potential source of contamination; don't use moisture-soaked linen packages.

General

- Nails should be trimmed regularly.
- All OT clothing and OT slippers should be washed with detergent daily and dried.
- Stretcher and wheelchair for use inside the OT and outside the OT should be separate.
- Periodic assessment and training of OT personnel should be done.
- Slippers for toilet use and OT should be kept strictly separate (colour coding).
- Keep the doors of the OT always closed.
- Garbage should be disposed off after each session.
- Anyone with upper respiratory infections, draining skin lesions or infections of the eyes, ears or mouth should not be permitted to work in the OT.
- Restrict number of surgeries per surgeon to 25 per surgeon per day per OT to give sufficient time to the staff for OT preparation for the next day.
- Prefer small incision cataract surgery (SICS) for mass surgeries and avoid corneal incisions.
- OT should be closed on the last Saturday of every month for OT washing after shifting all the movable items outside the OT.
- Restrict surgeries to 15 cases on Saturday to allow time for weekly cleaning and OT meetings.

E. MONITORING

- Periodic culture should be done once a month from sterile and unsterile areas of the OT.
- The bacteria-carrying particle load in the OT should be checked by the sedimentation plating technique every fortnight.
- An autoclaving log book should be maintained where the time, temperature and pressure are entered with the time and duration of the cycle is also recorded – counter signed by OT In-charge.
- The colour of the indicator strip at the end of the cycle should be jet black; else, repeat the cycle.
- Once a week, if affordable cost-wise, a Bowie Dick test pack/vapourline indicator can also be used.
- Biological indicator ampoules of Bacillus stearothermophilus spores for steam sterilization and Bacillus subtilis for dry heat and ethylene oxide sterilization cycles should be put in the load once a month.

F. SURGEON FACTORS

- Don't use the same irrigation line for several surgeries.
- Preferably, avoid corneal incisions.
- When in doubt, apply sutures (improper valve, wound gaps) – wound should be watertight.
- Phaco-tips and sleeve should be changed for each case.
- Not more than 25 cases/surgeon/day over 8 hours should be undertaken.

G. POST-OPERATIVE FOLLOW-UP

- Follow-up should be done on days 1, 4, 14 and 45 with checking of visual acuity with pinhole, slit-lamp examination and documenting all post-op findings (at the end of 30 days for phaco cases).
- Topical antibiotics with steroids for a minimum of 4–6 weeks.
- Must report excessive redness/pain, watering, discharge, sudden blurring of vision.

H. OPD

- Instruments, once used in the OPD, must be autoclaved.
- Instruments used on infective cases should be autoclaved twice before use.
- Slit lamp should be cleaned with spirit after an infective case is seen and to be done every day.
- Floors should be swept thoroughly and then mopped with phenyl mixed with detergents (disinfectant cleaning solution) at least three times a day.
- Hands should be washed before instilling eye drops and the bottle should not be kept uncapped.

I. WARD

- Floor swabbing should be done daily with a disinfectant solution of phenyl mixed with detergent.
- The eye drop bottle should be kept in a clean place and the tip of the dropper should not be touched.

ANNEXURE-3: SCRUBBING TECHNIQUE – STEPS TO BE FOLLOWED

1. Palm to palm

2. Left dorsum over right palm

3. Right dorsum over left palm

4. Palm to palm with fingers interlaced

5. Back of fingers of each hand onto opposite palm with fingers interlocked

6. Rotational rubbing of each thumb with the opposite hand

7. Rotational rubbing of the tips of the fingers and thumb of right hand in left hand palm and vice versa

ANNEXURE 4: METHOD OF STERILIZATION BY VERTICAL AUTOCLAVE

- First, open the valve of the glass tube of the autoclave.
- Fill the distilled water up to the mark in the glass tube and close the valve.
- Open the window of the drum and put it in the autoclave machine.
- Close the pressure valve. Air valve to be closed when steam starts coming out.
- Insert the pin in the plug and switch on.
- Once pressure builds up to 20 PSI and the temperature reaches 121°C, it should be maintained for 30 minutes before switching off.

- Immediately open the lower air valve and after 5 minutes, open all the pressure valves.
- Allow air to leak and then open the door of the autoclave.
- After hand washing, remove the drum from the autoclave machine. Immediately close the window of the drum.

ANNEXURE 5 : ENVIRONMENTAL DISINFECTANTS

Name	Contents	Contact time	Stability after dilution	Dose/ 1,000 cft	Remarks
Formalin	Formaldehyde 40%	24 hours		75 ml in 1 litre water	Toxic, irritant to eyes, poor against spores, carcinogenic
Insidur	Glutaraldehyde Glyoxal	1 hour		10 ml in 1 litre water	
Bacillocid 2%	Formaldehyde Chemically bound Glutaraldehyde	1 hour	1 Day	20 ml in 1 litre water	
Ecoshield	Stabilized Dihydrogen peroxide Silver nitrate	1 hour	1 hour	200 ml in 1 litre water	Non-irritant/ non-toxic, corrosive
Envodil 20%	Hydrogen peroxide Diluted silver nitrate	1 hour	1 hour	200 ml in 1 litre water	Non-irritant/ non-toxic, corrosive
D-125	Alkyl Dimethyl BAC 2.37% Alkyl Dimethyl BAC 2.37%	40 minutes	64 days	15 ml in 1 litre water	
Vicron	Oxone (potassium peroxy-monosulphate) Sodium dodecyl benzene sulphonate Sulphamic acid Inorganic buffers		7 Days		Less effective against fungi and spores; costly
Aldekol	Formaldehyde 6%, Glutaraldehyde 6% and Benzalkonium chloride 5%	3 hour		325 ml + 350 ml water for 4,000 cft	

ANNEXURE 6 : CARE OF OPHTHALMIC SURGICAL INSTRUMENTS (ICEH GUIDELINE)

Care of ophthalmic surgical instruments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Handling and safety

Sharps

Protect the tips of all sharp instruments with silicone or rubber tubing.

Intravenous infusion tubing or tubing from 'butterfly' intravenous needles may be used.

Remember!

- Never re-sheath a disposable needle
- Always use artery forceps to remove a blade from a Bard Parker handle
- Provide a gallipot on the theatre trolley to collect used needles and blades
- Do not touch the tips of any instrument
- Never throw an instrument down

Needles

Discard used needles immediately after use.

Place in a receptacle used only for this purpose.

Do not over-fill.

Preferably use small receptacles and dispose of them daily.

Seal and incinerate the receptacle when almost full.

Maintenance

Remember! All of these maintenance tasks must be done before you sterilise the instruments.

Cleaning

Ideally, instruments must be cleaned immediately after surgery (within 20 minutes). If this is not possible, place them in a pH neutral enzymatic solution or at the very least cover them with a moistened towel to prevent blood, tissue, and saline from drying and caking on the instruments.

Use a soft toothbrush and warm soapy water to thoroughly clean each instrument individually and in its **open** position.

Water should be warm, not hot. Hot water causes blood to clot (coagulate) faster, making it harder to remove.

Distilled water is preferable since regular water can leave mineral deposits.

Lubricating hinged instruments after cleaning

Use a lubricant immediately after cleaning hinged instruments to prevent rust and stiff joints.

Ideally, use water-based synthetic lubricants as these are designed to be compatible with sterilisation. Oil-based lubricants (mineral or silicone) can coat micro-organisms and prevent penetration of steam, preventing adequate sterilisation.

If water-based lubricants are not available, ordinary sewing machine oil is acceptable.

If you are using water-based lubricants, dip instruments and allow the lubricant to drain off (pictured). **Do not leave to soak, and never put cannulae in lubricant.**

If you are using sewing-machine oil, use a 2 ml syringe and a 21-gauge needle to draw up the oil and a 25-gauge needle to apply oil to the joints. Use a piece of gauze to carefully wipe away any surplus oil.

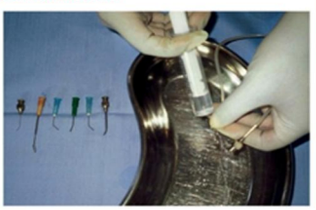
If any hinged instruments are stored, you must lubricate them at least once a week.

Drying

Thoroughly dry instruments before storing or sterilising them. Dry gauze (used cautiously) or a hairdryer may be used.

Inspecting instruments

Inspect instruments for alignment and sharpness under a good light and magnification.



Inspect cannulae to ensure they are not obstructed by flushing through with clean, warm water.

Storage, transport, and security

Remember! Silicone or rubber protectors must be used on sharp instruments when in storage or transit.

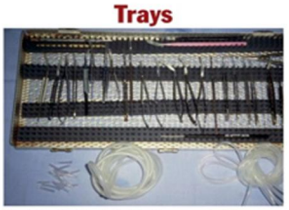
Shelves

Glass shelves in a lockable cupboard provide for secure storage and easy checking.

Never pile instruments on top of each other.

A well-ventilated room is recommended.

Trays



Each individual slot in the tray holds a single instrument.

Instruments must not touch each other.

The tray can be used for storage, transportation, and during some sterilisation procedures.

Cases

Cases may be of metal or plastic and contain a protective silicone mat.

Cases can be used for storage, transportation, and during some sterilisation procedures.

Rolls

Rolls, made of strong fabric, are inexpensive. Each pocket holds a single instrument.

Secure the roll with ribbon or cord, not elastic, as elastic can degrade in heat.

Use rolls only for storage and transportation of instruments, not for any other purpose.

ANNEXURE 7 : STRERILIZATION AND DISINFECTION
A REFERENCE FOR OPHTHALMIC PRACTICE IN DEVELOPING COUNTRIES

Method	Achieves	Timing	Destroys	Advantages	Limitations	Power source	Suitable for	Minimum Temperature
General autoclave	Sterilization	Approximately 45 minutes Follow manufacturer's instructions	Bacteria Spores Viruses Fungi	Low running cost Minimal maintenance Suitable for busy unit Drying cycle	Difficult to obtain spare parts in developing countries	Electric (single or 3-phase) Kerosene/ paraffin	All metal instruments, drapes, gowns, dressings, toughened plastic, glass	121°C
Bench top autoclave	Sterilization	20-minute cycle	Bacteria Spores Viruses Fungi	Quick and efficient. Small, bench-top size Suitable for busy unit	High running cost Difficult to obtain spare parts in developing countries No drying cycle Sensitive to voltage fluctuations	Electric (single- phase)	All metal instruments, toughened plastic, glass	134°C
Portable autoclave Domestic pressure cooker	Sterilization	Minimum of 15 minutes Follow manufacturer's instructions	Bacteria Spores Viruses Fungi	Low running cost. Quick and efficient. Suitable for mobile units. Spare parts usually readily available. Minimal maintenance.	Drying cycle unreliable Sensitive to voltage fluctuations Relatively small Various manufacturers whose instructions must be followed	Electric (single- phase) Gas Kerosene/ Paraffin Charcoal Wood	All metal instruments Drapes Gowns Dressings Toughened plastic Glass	121°C
Hot air oven	Sterilization	2-hour cycle	Bacteria Spores Viruses Fungi	Minimal maintenance Drying cycle	Expensive, slow. Instruments get extremely hot and cannot be used immediately Must not be used in a confined space	Electric (single-phase)	All metal instruments Toughened plastic Glass	180°C
Ethylene oxide C_2H_4O	Sterilization	Follow manufacturer's instructions	Bacteria Spores Viruses Fungi	Bulk quantities Suitable for delicate items and items that must be kept dry	Very expensive Dangerous, explosive Carcinogenic. Only suitable for large tertiary centres with appropriate facilities	Electric with C_2H_4O gas cartridges	Plastic eye shields Ophthalmic instruments and probes Delicate tubing	Varies with type of equipment used
Formalin	Sterilization	12 hours	Bacteria Spores Viruses Fungi	Low running costs Suitable for delicate items that are susceptible to rust Cabinet can hold a large quantity of instruments. Usually readily available	Airtight containers required. Irritant to skin, to eyes and if inhaled Gloves and eye protection advisable Items must be rinsed in sterile water before use	Electricity for heat source if a large cabinet is used (e.g. an adapted refrigerator not used for cooling)	All metal instruments Toughened plastic Glass Delicate tubing	Room Temperature 20°C Well ventilated
Ionizing irradiation	Sterilization	Follow manufacturer's instructions	Bacteria Spores Viruses Fungi	Bulk quantities Suitable for delicate items and items which must be kept dry	Usually only available commercially and used by large manufacturing companies	Gamma rays	Needles, syringes Sutures Toughened plastic	

Continue Next Page...

Boiling	High level disinfection	Minimum of 10 minutes	Bacteria Spores Viruses Fungi	Low running cost Quick and efficient Easy to teach Suitable for all situations Minimal maintenance Readily available	Does not kill spores. Blunts scissors and knives Causes rusting of instruments	Electric (single-phase) GasKerosene /Paraffin Charcoal, wood	Heavy metal instruments Plastic, glass Needles Sutures	100°C

Method	Achieves	Timing	Destroys	Advantages	Limitations	Suitable for
Glutaral -dehyde 2%	Sterilization Disinfection	Sterilization in 10hours Disinfection in 10 minutes Follow manufacturer's instructions	Bacteria Spores Viruses Fungi		(With drawn from sale in May 2002) Irritant to skin, eyes and if inhaled Gloves and eye protection advisable. May leave greasy residue Items must be rinsed and lumens irrigated thoroughly before use	All metal instruments Airways, endo tracheal tubes and face masks Plastic, Glass
Perasafe (recommended alternative to Glutaraldehyde)	Sterilization	10 minutes	Bacteria Spores Viruses Fungi	Non-corrosive No toxic vapour No requirement for ventilation, air extraction or protective clothing Environmentally safer	Not yet fully available in all developing countries Equipment must be well rinsed and flushed through with sterile water Not suitable for indirect ophthalmoscopy lenses or applanation prisms	All metal instruments, including heat-sensitive endotracheal airways, endotracheal tubes and anaesthetic face masks A more dilute version can be used as a disinfectant cleaning solution and for soaking contaminated linen Follow manufacturer's instructions
Isopropyl alcohol 70% (methylated spirit)	Disinfection	10 minutes The quantity used for soaking must be changed daily	Bacteria Spores Viruses (but not entero or adeno viruses)	Low cost Readily available Good for use on indirect ophthalmoscope enses	Highly flammable Corrosive (do not leave metal instruments soaking longer than 10 minutes) Tonometry items must be rinsed and wiped before use. Evaporates Does not kill entero or adeno viruses	All metal instruments Mechanism of Schiötz tonometer and applanation prism tip Indirect ophthalmos copy lenses
Sodium hypochlorite	Disinfection	10 minutes The quantity used for soaking must be changed daily	Bacteria Spores Viruses	Becoming more readily available Reasonable cost	Highly volatile and corrosive (do not use metal container to soak items) Bleach	Indirect ophthalmoscopy lenses Applanation prisms: only the tip. The applanation prism should sit in solution, and must be rinsed and wiped dry before use on the eye
Chlorhexidine	Disinfection	10 minutes The quantity used for soaking must be changed daily	Bacteria Spores Fungi	Low cost Readily available	Evaporates. Does not kill viruses. Blunts scissors and knives	Metal instruments Plastic, Rubber, Mechanism of Schiötz tonometer and applanation prism tip
Povidone iodine	Disinfection	10 minutes The quantity used for soaking must be changed daily	Bacteria Spores Viruses (but not entero or adeno viruses) Fungi	Low cost Readily available Versatile	Stains fabrics and surfaces Discolours instruments Solution is dark; so, difficult to see items .in soak. Irritant to skin. Does not kill entero or adeno viruses	All metal instruments Sutures Blades

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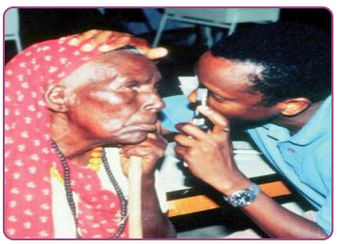
This poster highlights the main principles discussed in a full article in Community Eye Health Journal, Vol 9, Issue No 19, 36-42, 1996, and in Ophthalmic Operating Theatre Practice – A Manual for Developing Countries, ICEH, 2002. Supported by Sight savers International, Christian Blind Mission International, and Dark & Light Blind Care.

ANNEXURE 8: CONTROL OF INFECTION IN OPHTHALMIC PRACTICE (ICEH GUIDELINES)

RISK REDUCTION PRINCIPLES



PEOPLE

PEOPLE

Consider all patients and staff as a potential infection risk. Staff and patients should wash hands with soap before commencing any examination. Wash hands with soap before and after every clinical procedure, even if gloves are worn. Staff and patients with any broken skin, however small, must wear an occlusive dressing. Staff with any known or suspected infection should not have direct patient contact.

STAFF

STAFF

Wet hands with clean, preferably running water. Apply soap or cleanser. Rub palm to palm. Rub back of left hand over right palm. Rub back of right hand over left palm. Rub palm to palm with fingers interlaced. Rub backs of fingers on opposing palms with fingers interlocked. Rub around right thumb with left palm. Rub around left thumb with right palm. Rub around fingers of right hand with palm of left hand. Rub around fingers of left hand with palm of right hand. Rinse off soap with clean, preferably running water and dry well.

SURGICAL INSTRUMENTS AND DECONTAMINATION PROCEDURES

SURGICAL INSTRUMENTS AND DECONTAMINATION PROCEDURES

Loaded needle holders: Lay point down on trolley and table tops. Pass sharp instruments to colleagues with verbal warning and eye contact communication. Sharp instruments should not project beyond the surface edge. Ensure surgical instruments are thoroughly cleaned before being passed for sterilization or disinfection. Choose the appropriate sterilization or disinfection method for the specific instrument. Emphasize care of instruments and sterilization and disinfection procedures in training programmes.

CLINICAL PRACTICE AND SAFETY ISSUES

CLINICAL PRACTICE AND SAFETY ISSUES

Critically review work practices regularly. Include control of infection policies in training programmes. Implement and emphasize the need for strict adherence to universal infection control policies. Teach the correct hand-washing technique and display a written procedure in all relevant areas.

- **Eye drops and ointments:** Provide individual containers for each patient.
- **Eye dressings:** Following removal, dispose of immediately by burning.
- **Eye shields:** If removed from a patient who has a known infection, never re-use.
- **Pathological specimens:** Dispose of needles and blades that are used to obtain corneal and conjunctival material in to sharps container.

OT precautions: Wear rubber boots to protect the feet in the OT. Wear a plastic or rubber apron under the sterile gown if large amounts of blood spillage are expected. Wear eye protection and face masks in the OT. Wear gloves on both hands for all invasive procedures and when in contact with broken skin, mucous membranes, blood and body fluids.

Wear heavy duty gloves for all cleaning procedures. Clear up any spillages of blood or other body fluids immediately and then do the following:

- Cover with bleach and leave for 15minutes.
- Wipe with disposable paper tissue or cloth.
- Wash the surface with a clean cloth, detergent and water.
- Burn all cleaning tissues and cloths.
- Burn or bury soiled materials and other waste.

ENVIRONMENT

Soiled linen: soak first, dispose of the water carefully and boil the linen before (gloved) hand- washing.

EQUIPMENT

EQUIPMENT

Used needles and other sharps: Dispose of immediately in to a puncture-resistant container. Make sure plenty are available in all areas where needles are used. Never re-sheath a disposable needle. One-third of needle stick injuries are reported to occur during re-sheathing. If a needle stick injury occurs, remove the glove and instrument from the surgical field (see below for procedure following a needle stick injury). Applanation tonometer prisms (tips only), diagnostic contact lenses, A-scan probes, occluders and pin-holes should be wiped with disposable paper tissue after each use. Store in sodium hypochlorite 1% solution in a non-metallic pot for 10 minutes, rinse in sterile water and dry before re-use.

Slit lamp: Chinrest, headrim, hand grips and table top should be wiped with spirit between each patient examination.

IN THE EVENT OF A NEEDLE STICK INJURY

- Allow the wound to bleed for a few minutes.
- Wash with soap and water.
- Cover with a sterile dressing.
- Note the details, if known, of the person on whom the needle was used and, if possible, check their HIV status.
- Report the incident to the person incharge.

The injured person should be examined by a medical practitioner and referred for treatment if HIV transmission is a confirmed risk

Remember!

Control of infection principles must be applied in each and every situation and not only when the infection hosts are known or suspected.

The risk of HIV transmission after a single needle stick injury is small; the over all risk is about 3 per 1,000 injuries. HIV remains the least likely occupational infection to be transmitted, but still causes the most anxiety. Health care workers may become complacent about other serious and more likely risks.

The prion diseases, e.g. Creutzfeldt- Jakob disease (CJD), also give genuine cause for concern. CJD is resistant to most sterilization methods. The only guaranteed measure to prevent CJD cross-infection is the use of sterile, single-use disposable instruments.

(Tables and information given in this section for care of ophthalmic surgical instruments, sterilization and disinfection, and control of infection in ophthalmic practice are taken from the International Centre for Eye Health (ICEH) website with their kind consent and are presented without modification)

ANNEXURE 9: EYE OT CHECKLISTS AND REPORTS

These checklists are just examples. Organizations may design their own checklists as per their specific requirements

(1) Next Day Planning Report

Date: .....

1. No. of eye operations:.....

2. OT staff present: Note if anybody is on leave or break.

3. No. of nursing staff:.....

4. No. of OT boys:.....

5. No. of ayahs:.....

6. In case of OT boy and ayah being either on leave or break, who will be available from outside to fill such vacancies?.....

7. Arrangements in eye OT? At what time will the OT start?.....

8. Table 1 :.....

9. Table 2 :.....

10. Table 3 :.....

11. Notes :.....

.....

In-charge Sister:.....

HOD:.....

(2) Preoperative Checklist

Name of Patient:..... Indoor No:.....

1. Investigation: Hb and weight (if General Anaesthesia (GA) to be given):.....

   Urine sugar:.....

   Other:.....

2. Eye examination

   Vision:..... Sac:..... Xylocaine Sensitivity:.....

   Tension:..... A-Scan:.....

3. Obtained written consent?.....Attached Guarded Visual Prognosis (GVP) consent form?.....

4. Does the patient suffer from diabetes, BP?.....Medicine given?.....

5. Povidone iodine 5% drops instilled in the eye?.....

6. Eyebrows and eyelashes painted with povidone iodine 10%?.....

7. Eye dilated for operation?.....Dilated adequately?.....

8. It is cataract (intraocular lens) surgery:.....Intraocular lens brought as per A-scan:.....

9. Did medical officer examine?

10. Examination by anesthetist: Weight:

11. Did patient have bath/wash face?

Suggestion of Doctor: Date:

Signature of Ward Nurse:

Signature of OT Nurse:

(3) Logbook of Autoclaving Cycles

Date	Particular	On time	Pre- vacuum	Steam Pressure	Sterilization	Steam Release Time	off Time	Total Time	Remark

4) Preparation and Concentration of Disinfectants

Formaldehyde and glutaraldehyde

- For surface cleaning: 200 ml in 10 litres (2%)
- For fogging: 2% hydrogen peroxide and silver nitrate
- For surface cleaning, make a 5% solution (add 250 ml in 5 litres of water)
- For fogging: make 20% concentration of the solution (200 ml in 1,000 ml)
- Sodium hypochlorite 75 ml in 12 litres of water (1%)

(5) Daily Cleaning Checklist

Date:

1. Who checked the preoperative checklist?
2. Who put 5% povidone iodine eye drops before giving block?
3. Who checked autoclave strip register?
4. Who filled drum of gowns/gloves? Who checked it?
5. Who checked clarity of Inj. RL?
6. Who did preparation before arrival of surgeon? (cautery and microscope in order?)
7. Who did fumigation? With what? (formalin, 1% hydrogen peroxide, formaldehyde and glutaraldehyde combination)
8. Who did cleaning before leaving in evening? (doors should be cleaned every day)
9. Who checked operation and emergency medicines stock?
10. Who put on the U.V. light at night? Who put it off in the morning?
11. Was the chlorination of water tank done yesterday? Who did it?
12. Who checked anaesthesia trolley?
13. Who replaced bedsheet on OT table in the evening?
14. Who cleaned the equipment/instruments (cautery, suction machine and OT table) with 1% sodium hypochlorite?
15. Notes:

Signature of O.T. In-charge: **Signature of HOD:**

(6) Weekly Cleaning Checklist

Date:

1. List of medicines checked? Who did it? (daily use + emergency medicines)
2. Who checked eye OT checklist? (except medicines)
3. Did in-charge prepare the list of OT staff posting?
4. Who submitted autoclave report? Who checked it?
5. In-charge checked the list of Sunday work done?
6. Cleaning done on Saturday by shifting things? (microscope, OT table)
7. Who did sodium hypochlorite cleaning of sink?
8. Who cleaned walls and floor of OT with sodium hypochlorite?
9. Who fumigated the autoclave room on Saturday after cleaning?

10. Who cleaned A/C filters?
11. Who cleaned instruments? (check blade and change it if necessary)
    (check two-way cannuala)
12. Who checked staff's nails?
13. Who checked chlorination?
14. Who changed the water in the autoclave machine? (change every fortnight)
15. Who cleaned and autoclaved the bottle of surgical scrub and bottle of liquid soap?
16. Who checked the expiry dates of medicines?
17. Who cleaned the operating microscope lenses?
18. Notes:

Signature of O.T. In-charge: **Signature of HOD:**

(7) Monthly Cleaning Checklist

Date:
1. Over book of change of OT boy posting checked?
2. Swab sample culture done on second Saturday?
3. Air conditioner cleaned by air blower on last Saturday?
4. Did the OT in-charge check the washing of the OT on last Saturday?
5. Intraocular lens report prepared?
6. CME lecture delivered and exam conducted for OT staff?
7. Who cleaned the water tank? On which day?
8. Who cleaned the drums? Checked for any holes?
9. Cobwebs outside windows removed?
10. Notes:

Signature of O.T. In-charge: **Signature of verifying person:**

(8) Quarterly Checklist

Date:
1. Water tap filters of scrub area changed? Yes/No
2. Stock-taking done? Yes/No
3. Stock statement prepared? Copy sent to store? Yes/No
4. Acid cleaning of water pump of autoclave machine done? Yes/No
5. Notes:

Signature of O.T. In-charge: **Verified by ---------** **(Signature)**

(9) Weekly Nails Checklist

Date:

No.	Name of person	Nails cut	Nail bed clean?	Both O.K.

Notes:
Prepared by:
Signature of Incharge:
Signature of HOD:

(10) Preparation for operation and checklist of materials in the operation

Date:

Particulars	Eye OT
No. of operations done	
Time of start of operation	
Time of end of operation	
How many doctors attended the OT	
No. of nurses + field staff	
No. of OT tables + assistants	1.
	2.
No. of OT boys	
No. of ayahs	
Note:	

Particulars	Autoclaved	Used
No. of gowns		
No. of sheets		
No. of instruments sets		
No. of RL		
No. of gloves		
Inj. Viscomet Vial		
Phaco Probe (No.)		
Needle (No.)		

1 to 5 operations	1 drum for gowns	Total no. of gowns: 8	6 to 10 operations	2 drums for gowns	Total no. of gowns: 16
	1 drum for sheets	No. of sheets: 20		1 drum for sheets	No. of Sheets: 40
	1 drum for instrument sets	6 sets		1 drum for instrument sets	12 sets
	1 drum for Inj. RL	6 bottles		1 drum for Inj. RL	12 bottles
	Inj. Viscomet	7		Inj. Viscomet	13

Report prepared by:	Note
Signature of I/C:	
Signature of HOD:	

References

1. *Ram J, Kaushik S, Brar GS, Taneja N, Gupta A. Prevention of post-operative infections in ophthalmic surgery. Indian J Ophthalmol 2001;49:59-69*
2. *Standardization manual. Guidelines for: quality cataract management in secondary level eye centers. Sight savers international publication.New Delhi;2007.Available online:*

   http://www.sightsavers.net/in_depth/quality_and_learning/learning/13172_Guidelines%20for%20quality%20cataract%20management.pdf
3. *Ingrid Cox, Sue Stevens. Ophthalmic operating theatre practice: a manual for developing countries. International Centre for Eye Health: London; 2002*
4. *Guidelines for pre-operative, operative and post-operative precautions for eye surgery. National Programme for Control of Blindness in India. Directorate General of Health Services, Ministry of Health & Family Welfare, Govt. of India: New Delhi. Available online:*

   http://npcb.nic.in/writereaddata/mainlinkfile/File128.pdf
5. *AIOS Guidelines to Prevent Intraocular Infection.2009.Available online .http://aios.org/guidelinesendoph.pdf*
6. *Guidelines for the management of cataract in India. A Vision 2020:The Right to Sight INDIA Publication: New Delhi ;2011.p.29-49.Available online:*

   http://www.vision2020india.org/pdfs/cataract-manual-vision2020.pdf
7. *Barry P, Behrens - Baumann W, Pleyer U, Seal D. ESCRS Guidelines on prevention, investigation and management of post-operative endophthalmitis. Version 2 August 2007;8-14.Available online: http://www.escrs.org/vienna2011/ programme /handouts/ic-100/ic-100_barry_handout.pdf*
8. *Infection Prevention in Eye Care Services and Operating Areas and Operating Rooms - AAO Quality of Care Secretariat, Ho skins Center for Quality Eye Care 2012.Available online:*

   http://one.aao.org/clinical-statement/infection-prevention-in-eye-care-services-operatin
9. *Speaker MG, Milch FA, Shah MK, Eisner W, KreiswirthBN.Role of external bacterial flora in the pathogenesis of acute post-operative endophthalmitis. Ophthalmology. 1991;98(5):639-49; discussion 650.*
10. *Centers for Disease Control and Prevention. Guideline for hand hygiene in health-care settings. MMWR 2002;51(RR-16):1-45.Available online: http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf*
11. *Speaker MG and Menik off JA.: Prophylaxis of endophthalmitis with topical povidone iodine. Ophthalmology.1991; 98:1769-1775*
12. *Wu PC, Li M, Chang SJ, Teng MC, Yow SG, ShinS J, Kuo HK et al. Risk of endophthalmitis after cataract surgery using different protocols for povidone iodine preoperative disinfection. J Ocul Pharmacol Ther. 2006; 22:54-61.*
13. *Brusaferro S, Rinaldi O, Pea F, Faruzzo A, Barbone F. Protocol implementation in hospital infection control practice: An Italian experience of pre-operativeantibiotic prophylaxis. Journal of Hospital Infection 2001 ; 47:288-93.*
14. *Ta CN, Egbert P R, Singh K, Shriver E M, Blumenkranz M S, and Mino De Kaspar H.: Prospective randomized comparison of 3-day versus 1-hour preoperative ofloxacin prophylaxis for cataract surgery.Ophthalmology.2002; 109:2036-2040;discussion 2040-2041.*
15. *Donnenfeld ED, Schrier A, Perry HD, Aulicino T, Gombert ME, Snyder R. Penetration of topically applied ciprofloxacin, norfloxacin and ofloxacin into the aqueous humour. Ophthalmology 1994;101:902-05.*
16. *Thomas R, Thomas S, Braganza A, Muliyil J. Evaluation of the role of syringing prior to cataract surgery. Indian J Ophthalmol 1997;45:211-4.*
17. *Schmitz S, Dick HB, Krummenauer F, Pfeiffer N. Endophthalmitis in cataract surgery: results of a German survey.Ophthalmology. 1999;106(10):1869-77.*
18. *Niyadurupola N. and Astbury N. Endophthalmitis : controlling infection before and after cataract surgery. Community Eye Health. 2008 Mar; 21(65): 9–10.*
19. *Disinfection and sterilization. In: Hospital Infection Control Manual, 3rd edition. Vellore: Christian Medical College;2003.p.61-7*
20. *Prajna L, Chavali A. Sterilization and aseptic practices in an ophthalmic operation theatre. Madurai Aravind eye hospitals*
21. *Rutala W, Weber D, the Healthcare Infection Control Practices Advisory Committee (HICPAC) Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008.Avialble online: http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf*
22. *Kelkar U, Kelkar S, Bal AM, Kulkarni S, Kulkarni S. Microbiological evaluation of various parameters in an ophthalmic operating rooms. The need to establish guidelines. Indian J of Ophthalmol2003; 51(2):171-6.*
23. *Kelkar A, Kelkar J, Amuaku W, Kelkar U, ShaikhA.How to prevent endophthalm it is in cataract surgeries? Indian J Ophthalmol. 2008;56(5):403-7.*
24. *Laufman H. The Operating Room. In: Benett JV, Brachman PS, editors. Hospital Infections. Boston: Little Brown & Co; 1986;315-24.*
25. *Rutala WA. Guidelines for infection control practice. In APIC guideline for selection and use of disinfectants. Am J Inf Control 18:99-117, 1990.*
26. *Mistlberger A, Ruckhofer J, Raithel E, Müller M, Alzner E, Egger SF, Grabner G et al.Anterior chamber contamination during cataract surgery with intraocular lens implantation. J Cataract Refract Surg. 1997;23(7):1064-9.*
27. *Ariyasu RG, Nakamura T, Trousdale MD, Smith RE.Intra-operative bacterial contamination of the aqueous humour. Ophthalmic Surg. 1993;24(6):367-73; discussion 373-4.*
28. *Cooper BA, Holekamp NM, Bohigian G, Thompson PA. Case-control study of endophthalmitis after cataract surgery comparing scleral tunnel and clear corneal wounds. Am J Ophthalmol. 2003 Aug;136(2):300-5.*
29. *Nichamin LD, Chang DF, Johnson SH et al. ASCRS White Paper: what is the association between clear corneal cataract incisions and Post-operative endophthalmitis? J Cataract Refract Surg 2006; 32:1556–1559*
30. *Lundström M, Wejde G, Stenevi U et al. Endophthalmitis after cataract surgery; a nationwide prospective study evaluating incidence in relation to incision type and location. Ophthalmology 2007; 114:866–870*
31. *Berdahl JP, DeStafeno JJ, Kim T. Corneal wound architecture and integrity after phacoemulsification; valuation of coaxial, microincision coaxial, and micro incision bimanual techniques. J Cataract Refract Surg 2007; 33:510–515*

II. PRACTICAL MANUAL FOR THE MANAGEMENT OF POST-OPERATIVE ENDOPHTHALMITIS: AN OPHTHALMOLOGIST'S PERSPECTIVE

Pran Nagpal, Uday Gajiwala, Amish Patel, Madhvi Sheth

A. Definition

Endophthalmitis is an inflammatory reaction of the intraocular tissues and fluids to an infecting organism.

B. Introduction

Endophthalmitis is the most unfortunate and serious complication of cataract surgery, with social and legal implications.

It results in poor functional results. It can lead to total blindness and phthisis bulbi.

That is why prevention, early diagnosis and quick management are very important in this disaster.

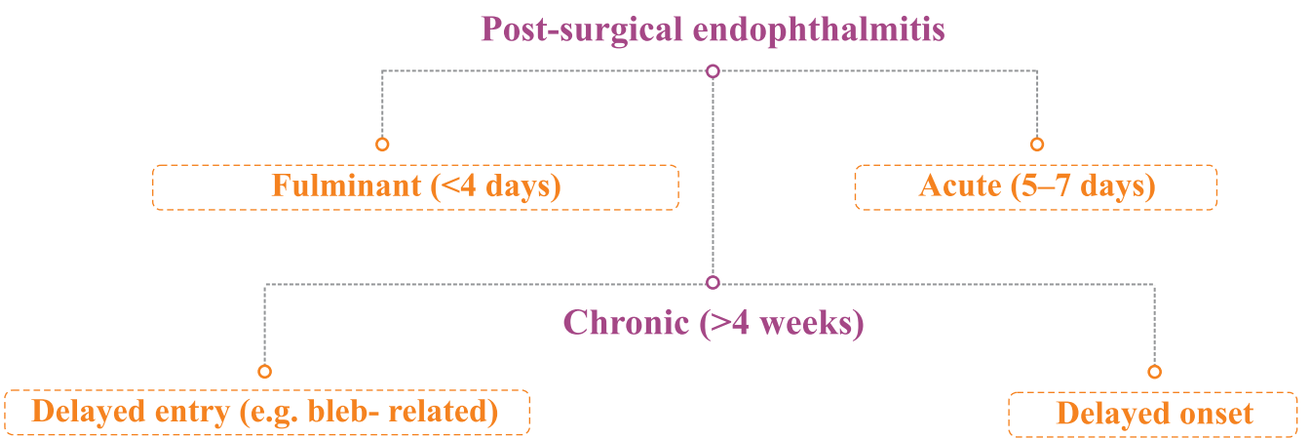
C. Epidemiology

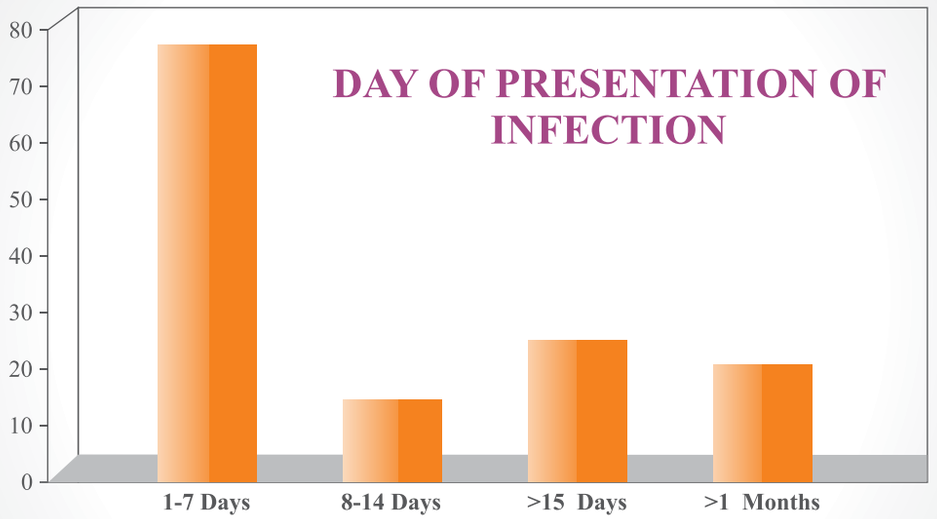
The incidence of infectious endophthalmitis following cataract surgery has decreased steadily over the past century because of the advances in the science of asepsis and antisepsis. Published data indicate that the incidence varies from 0.005- 4%.[1-3] In the developed world, the incidence has come down drastically. But, recently, with the increased use of clear corneal temporal incision for phaco surgery, the rate has again climbed to 0.3%. Unfortunately, there is no published data available from our country. The guesstimates put it at 0.1%–0.4%. The incidence is definitely higher with intra capsular surgeries compared to extra-capsular surgeries & higher with conventional extra-capsular surgeries with sutures compared to small incision suture less surgeries or phacoemulsification surgeries. It is directly related to the length of the incision.

D. Clinical Presentation

Three forms of endophthalmitis are recognized, based on the clinical profile.

Table 1

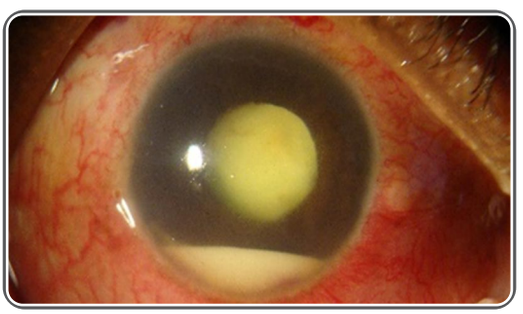




IN MOST CASES, INFECTION OCCURS IN IMMEDIATE POST-OP PERIOD

E. Signs and Symptoms of Endophthalmitis

- Blurring or loss of visual acuity
- Severe pain
- Increased watering /swollen lids
- Congested, oedematous conjunctiva with discharge
- Post-operative endophthalmitis
- Corneal oedema sometimes with an infiltrate forming a ring abscess
- Cloudy anterior chamber with cells, hypopyon or fibrin clot, lens precipitates
- Vitreous clouding (vitritis) from inflammation, precluding view of fundus
- Disappearing/reducing fundal glow



Post-operative endophthalmitis

Table 2 : Signs and symptoms of different forms of endophthalmitis

Particulars	Fulminant	Acute	Chronic
Presents in	<4 days	5–7 days	>4 weeks
Pain	Severe	Moderate	Mild
Visual loss	Profound & sudden	Severe and quick	Slow and less severe
Conjunctival congestion	Maximum	Intense	Variable
Corneal oedema	Severe	Less	Uncommon
Pupillary Fundal glow	Mostly absent	Quickly disappears	Mostly present
Prognosis	Generally poor	May be good if patient presents early and treatment is instituted quickly	Bacterial origin – good Fungal origin – bad

ENDOPHTHALMITIS: NON-INFECTIVE or STERILE-TYPE

It can occur in response to the following:

1. Chemical response - toxic anterior segment syndrome (TASS). Can be related to viscoelastic, intraocular lens material and coating, inadequate wiping of surgical instruments before resterilization
2. Complicated surgery (excessive/prolonged manipulation)
3. Dislocated cortical matter/lens/nucleus
4. Flared pars planitis (uveitis)
5. Phaco anaphylaxis

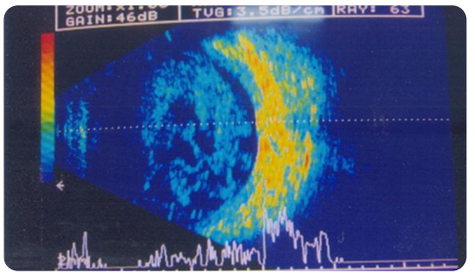
It can resemble the infective endophthalmitis and needs to be distinguished **(see Table 3 below).**

Table 3[4]

Infective endophthalmitis	TASS
Pain and photophobia severe	Pain mild
Presentation very early	Presents after 48–72 hours
Lid oedema	No lid oedema
Profound visual loss	Vision loss is less
Involvement of posterior vitreous and thickening of choroids	No involvement of posterior vitreous usually
Cultures are frequently positive	Cultures always negative

F. Role of USG in endophthalmitis

1. Choroidal thickening and posterior vitreous involvement are diagnostic of infective origin
2. Dislocated lens matter/nucleus indicates sterile-type
3. Choroidal detachment
4. Retinal detachment
5. Melting membrane instead of capsulotomy being done. It should arouse suspicion of low-grade chronic endophthalmitis.



USG B-Scan

G. Important Dictums and Features

- **A high degree of suspicion is required for early diagnosis, especially when risk factors exist.**
- **Be on the look-out for signs and symptoms of endophthalmitis in each post-operative case next morning.**
- **Any post-operative inflammation, particularly in the first 6 hours post-operatively, should be considered as endophthalmitis until proved otherwise.**
- **Increasing pain or reappearance of pain should arouse suspicion.**
- **Diagnosis of aetiology with the help of cultures must be done, but note the following:**

I. No need to wait for the culture report to start treatment.

II. The Endophthalmitis Vitrectomy Study (EVS)[5] found that 69% of patients with endophthalmitis had positive cultures for bacteria. Of these,

1. 70% were coagulase-negative microorganisms, mostly Staphylococcus epidermidis;
2. 10% Staphylococcus aureus;
3. 9% Streptococcus species;
4. 2% Enterococcus species;
5. 3% other Gram-positive species; and,
6. 6% Gram-negative species

H. Spectrum of Cultured Organisms from Cases in India

	Gram-positive		Gram-negative	
–	S. epidermidis	: 12.9%	P. aeruginosa	: 7.1%
–	S. aureus	: 7.6%	Pseudomonas spp.	: 8.8%

–	P. acnes	: 5.9%	Non-Fermenters	: 10.6%
–	Enterococcus spp.	: 2.3%	Others	: 5.8%
–	Streptococcus spp.	: 4.1%		
–	Others	: 4.8%		

1. Negativity of culture does not rule out the infective nature of endophthalmitis. Positivity helps in treating with antibiotics showing maximum sensitivity.
2. Up to 80% of the cultured organisms are from the commensals in the conjunctival sac.
3. Of interest is the study that showed 43% of the aqueous sample taken immediately after cataract surgery is positive for culture.
4. Hospital-based infections are showing MRSA too.

- **Beware of delaying diagnosis with a trial of corticosteroids drops only.**
- **Never underestimate symptoms.**
- **This is an ocular emergency.**
- **Institution of rapid treatment gives better outcome even when it is an odd hour when you are informed.**

I. Risk Factors for Endophthalmitis

Systemic factors

- Diabetic
- HIV-positive
- Post-uveitis cataract surgery
- Patient on steroids or immunosuppressive drugs
- Rheumatoid arthritis
- Undernourished state

Local factors

Ocular surface and adnexa are considered primary source of bacteria in culture-positive cases of endophthalmitis.

Organisms from patient's periocular skin flora are found to play a significant role in causing endophthalmitis.

- Nasolacrimal duct occlusion
- Blepharitis/Meibomitis
- Conjunctivitis

- Canaliculitis
- Contact lens wear/prosthesis wear in fellow enucleated eye

Peri-operative factors

- Duration of surgery more than 60 minutes. Prolonged surgery and manipulations.
- Clear corneal temporal incision.
- Suture dehiscence.
- Persistence of lens matter.
- Traumatic cataract.
- Vitreous loss during surgery/vitreous wick. Prolonged surgery and manipulations.
- Inadvertent bleb formation.
- Wound leak.
- Inadequate draping.
- High number of instruments passing in and out of the Anterior Chamber. Prolonged surgery and manipulations.
- Polypropylene haptic of intraocular lens.

J. Preventive Measures

- Risk factors managed
- Topical antibiotics started a day before surgery (preferably)
- Betadine usage
- Intracameral or intrabag antibiotics after surgery
- Use of disposable plastic drapes
- Covering the eyelashes with a drape
- Frequent instillation of antibiotic and steroid drops
- Extreme cleanliness required
- Don't raise expectations in early ambulation

K. Management [6-7]

- Confirm the diagnosis.
- Inform the patient about the diagnosis and the necessity of immediate management.

- Inform about the guarded visual prognosis.
- Can be managed as a day care also. Make sure the patient understands the importance of frequent evaluation and is willing to come back as required. Extreme cleanliness required.
- No bandage required. Protective goggles with sides closed preferred. Avoid smoke and dust. Use sterile cotton swabs without welling to clean the eye.
- Grade the severity of endophthalmitis: Severe when vision of inaccurate light projection, afferent pupillary defect, no fundus glow, limbal ring infiltrates (abscess) and cases not responding to appropriate intravitreal therapy

L. Objectives of Endophthalmitis Treatment

Primary objective is to save structure and vision while trying to make the patient symptom-free.

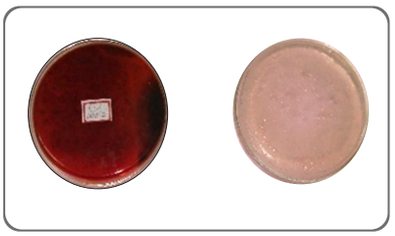
- The mainstay of treatment is in intravitreal administration of **broad-spectrum** antibiotics. Use steroids along with an antibiotic unless proved to be fungal origin. It reduces final ocular morbidity.
- Can plan to rupture the bag with needle and put some antibiotic in the bag also.
- **Vitrectomy** is indicated in a highly selective category of patients and is discussed in detail later on.
- **For fungal endophthalmitis,** early vitrectomy, intraocular lens removal and antifungal drugs are started.
- NSAIDs: Systemically given, reduce the pain and the collateral inflammation.
- Supportive therapy: Cycloplegics in the form of atropine 1% drops once or twice a day and vitamins, etc., to improve the resistance.

M. Microbiological Examination

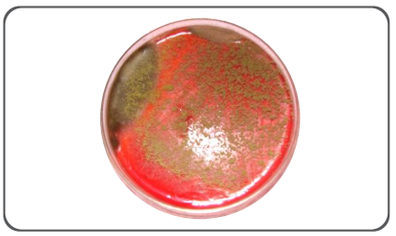
Conjunctival swab, aqueous tap and vitreous tap and technique

- Take a conjunctival swab.
- Take a sample of aqueous with a 27G/30G (preferred) needle. If sample is not adequate, needle can be sent for culture.
- Vitreous sample should be obtained via the pars plana route only.
- Using a syringe with a 20/24G needle, enter from the pars plana and take a sample. Use the same needle to give intravitreal injection without removing it.
- **OR** if vitrectomy is performed, take the aspirate from the cutter into the syringe and send it.
- Take a vitreous sample every time you enter the eye.
- Send the whole syringe under aseptic precautions to the laboratory immediately if the technician cannot come to the OT. Ask the laboratory staff to obtain a sample from the syringe under all aseptic precautions.
- Send the sample immediately to the laboratory or keep it in the refrigerator/an ice pack to prevent from drying.
- Take an aqueous sample first to create hypotony and space to inject the antibiotic.

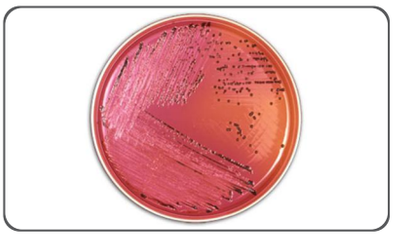
- At least a Gram stain and KOH preparation should be done (must for each case whether culture is done or not). This an be done if facilities are not available for culture in remote areas. The smear should neither be too thin nor too thick.



Agar plates and slides



Fungal colonies



Bacterial colonies

N) Intravitreal Antibiotics in Post-Surgical Endophthalmitis (Visual Acuity ≥ Hand Movement)

- Once the report of the Gram stain and KOH preparation is available, select the antibiotics to be administered; generally, antibiotics covering a wide spectrum are used.

- When the culture report becomes available after 48 hours, the antibiotic can be changed according to the reported sensitivity if there is no clinical response by this time.

- For this reason, it is suggested that the latest antibiotics should be reserved for use in case of endophthalmitis instead of using them for preoperative prophylaxis. It helps prevent creation of antibiotic resistance of the organisms.

The presently recommended combination therapy of choice in post-surgical bacterial endophthalmitis is as follows:

First choice

Injection Vancomycin : 1 mg in 0.1 ml +

Injection Ceftazidime : 2.25 mg in 0.1 ml

Second choice*

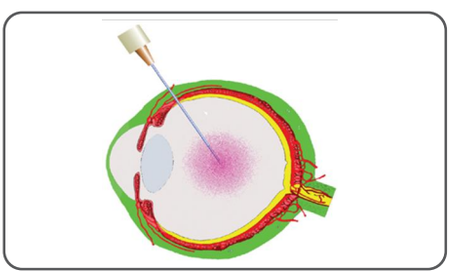
Injection Vancomycin : 1 mg in 0.1 ml +

Injection Amikacin : 400 ug in 0.1 ml

Third choice

Injection Vancomycin : 1,000 ug (1 mg) in 0.1 ml +

Injection Gentamicin : 200 ug in 0.1 ml



Schematic drawing showing intravitreal injection

* This was the preferred antibiotic combination in the EVS study

When Pseudomonas infection is suspected

Injection Vancomycin : 1 mg in 0.1 ml +

Injection Piperacillin + : 225 mcg in 0.1 ml

Injection Tazobactam

Preparation of the most frequently and less commonly used intra ocular drugs in the management of post-surgical endophthalmitis is shown in Appendix 2.

Ready kits for intravitreal injection are available in India now.

Checklist before intravitreal injection

a. Informed consent.

b. USG B-scan results -to rule out pre-existing retinal or choroidal detachment (if available, can be done and can help).

c. Wound integrity -suture if doubts of wound opening up.

d. Check for suture abscess - remove suture.

e. Check lens status for position and infected bag, etc.

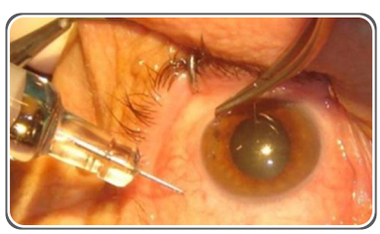
f. Check intraocular pressure-gently done digital tonometry or non-contact tonometry only.

Materials for intravitreal injection

1. Tuberculin syringes
2. 26G ½-inch and 23G needles
3. Antibiotic vials (vancomycin/amikacin/ceftazidime)
4. Surgical tray (lid speculum, sterile cotton-tipped applicators, callipers, fixation forceps)
5. Topical xylocaine 4% or 0.5% proparacaine eye drops

Tray for intravitreal injection

Site of injection: Should be 3.5 mm from limbus



Insert needle 3.5 mm away from limbus

Type of anaesthesia

Topical/Topical with facial/peribulbar in uncooperative patient/Under GA for children

TECHNIQUE

1. An intravitreal injection should be given with all aseptic and antiseptic precautions. Can be given as an office procedure.
2. Paint and drape the eye.

3. Mark the required distance from the limbus.

4. Fix the globe with fixation forceps.

5. Insert a 24G needle, bevel facing upwards and direction towards the mid-vitreous. Make a valvular opening.

6. Preferably with the tip of the needle visualized, take a vitreous tap before injecting the drug.

7. Change the syringe to the one with the drug without withdrawing the needle from the vitreous cavity and inject the medicine slowly in a drop by drop manner (achieved by rotating the plunger) and avoiding jet formation. (In case nothing comes from the vitreous cavity, the needle should be withdrawn and sent for culture.)

8. Withdraw the needle after administering the intravitreal injection and press the sclera at the injection site with the cotton bud.

9. Take an anterior chamber (AC) tap before giving the intravitreal injection. It helps to lower the intraocular pressure needed to accommodate the I.V. antibiotics.

10. Check intraocular pressure (using non-contact tonometry or digitally) after the injection and patch the eye.

Remember:

1. Do not mix different drugs in the same syringe.

2. Do not withdraw the needle each time from the vitreous cavity for injecting multiple drugs (in the same sitting).

3. Fix the syringe loosely on the needle and only change the syringes for different drugs, keeping the needle stabilized in the vitreous cavity.

4. Take 0.2 ml antibiotic into the syringe for injecting 0.1 ml (making sure to inject only 0.1 ml).

When to give second intravitreal injection

1. When first injection is effective, repeat it after 48 hours to assure knocking out the infections totally.

2. When culture shows sensitivity to other antibiotics then the one given intravitreally. Use the antibiotic to which the organisms are susceptible.

Post-intravitreal injection advice

- There is no need for a prolonged bandaging.
- Administration of topical drugs may be begun as early as 1 hour after the procedure.
- It has been suggested by some that making the patient head up immediately after the procedure may decrease the risk of the drug settling on the macula and thereby, preventing toxic damage to it.

O. Systemic Antibiotics in Post-Surgical Bacterial Endophthalmitis

Newer antibiotic like gatifloxacin and moxifloxacin[8] can penetrate the blood retinal barrier and achieve significant concentration in the vitreous cavity. The role of systemic antibiotics can be reconsidered in light of this fact. Apart from the points mentioned, their role is doubtful.

P. Topical Antibiotics in Post-Surgical Bacterial Endophthalmitis

For topical medication in endophthalmitis, a combination of two drugs is preferred, one having a predominant effect on the Gram-positive organisms and the other against Gram-negative organisms. The frequency of administration is every hour (with each drug used alternately) in the initial phases of treatment. This is modified depending on the response to overall measures. Fortified eye drops are recommended. The antibiotic drugs used in the EVS study were vancomycin (50 mg/ml) and amikacin (20 mg/ml). The method of preparing fortified eye drops is given in Appendix 3c.

Topical gatifloxacin and moxifloxacin are said to achieve bacteriostatic levels in the vitreous cavity.

Q. Antifungal Therapy

Systemic Antifungal Therapy

Discovery of certain antifungal drugs causing fewer systemic adverse effects and having a better intraocular penetration have improved the scenario, making it possible to give systemic antifungal drugs. Dose of various antifungal agents for systemic administration is shown in Appendix 5. One should consider early vitrectomy and intraocular lens removal.

Intravitreal Antifungal Therapy

- Intravitreal antifungal drugs act only as an adjunct to systemic medication, because fungi, unlike bacteria, multiply less rapidly and correspondingly, treatment of fungal endophthalmitis requires a prolonged duration (in weeks and not days) of adequate concentrations of the antifungal agent within the vitreous cavity.
- The method and the precautions while administering an intravitreal injection is the same as those described for post-operative bacterial end ophthalmitis.
- Steroids are absolutely contraindicated.
- Antifungal agents used as intravitreal drugs clinically include amphotericin B (5–10 ug/0.1 ml, depending upon the load of fungi) and fluconazole (25 ug/0.1 ml). Reports on use of fluconazole are few but encouraging. Use of voriconazole 50–100 mcg/0.1 ml has also been reported. Drugs other than amphotericin B are not freely available in the country at present.

Preparation of amphotericin B and voriconazole for intravitreal injection is given in Appendix 2.

R. Anti-Inflammatory Therapy: Role of Corticosteroids

- Timing of giving steroids in a case of endophthalmitis is crucial. Must be given under antibiotic cover.
- Start immediately only if you are sure that the inflammation is not fungal. May give it after 48 hours in fungal cases under effective antifungal cover.

The recommended dose of corticosteroids in bacterial endophthalmitis for intravitreal and systemic injections is given in Appendix 4.

S. Supportive Therapy

Cycloplegics like atropine 1% drops, 8-hourly, should be given initially; then change to either homatropine 2% drops or cyclopentolate 1%, 4- to 8-hourly.

Anti-glaucoma drugs: In patients with elevated intraocular pressure, drugs such as oral acetazolamide and timolol may be prescribed. An AC or vitreous tap before giving an intravitreal injection may also help lower the intraocular pressure, at least transiently, in some patients.

T. Role of Vitrectomy in Post-Surgical Endophthalmitis (VA ≤ PL)

- Vitrectomy is the second line of approach in the management of endophthalmitis with specific and definite indications, i.e. progressing inspite of I.V. injection.
- However, if vitrectomy is indicated, it must be done quickly.
- It is technically more demanding, needs experience and has a potential to lead to complications, particularly retinal detachment.
- It may not always be rewarding in terms of the functional outcome.
- Vitrectomy in the later stage is less demanding and less likely to cause complications in comparison to vitrectomy during the primary, acute stage of endophthalmitis.
- Role of USG before vitrectomy (if available) is to rule out choroidal detachment. If present, use a long infusion cannula (6 mm) and visually confirm the tip in vitreous before beginning with vitrectomy.

Indications for vitrectomy

- Primary in fulminant/acute phase-if Visual Acuity is Hand Movement-go for vitrectomy immediately. If there is no response to the intravitreal antibiotics and there is worsening of symptoms and failing light perception, go for vitrectomy.
- Secondary for vitreous opacities or membranes (can wait upto 3 months but if visual demands are more, can be done earlier also).

Vitrectomy takes away the bulk of the bacteria, reduces toxins secreted by them, permits better perfusion of antibiotics and gives a higher chance of vitreous culture-growing organisms as it yields good volume. Should be done by a vitreo- retina surgeon. When vitrectomy is done, use one-tenth of the dose of intravitreal antibiotic post-vitrectomy as compared to the usually recommended dose.

Bandaging or not following vitrectomy is left to the surgeon but if there is a corneal involvement, it is better to keep it open. However, the patient should be encouraged to use side-covered goggles.

Option of injecting silicone oil

Post-operatively, can be considered. It works as a conformer and is an inert substance. It maintains visibility of the fundus, recurrence of infection is less and confines the retina and prevents retinal detachment
In opaque corneas, an open-sky vitrectomy with a corneal transplant can be done with extremely guarded prognosis.

U. Causes of Treatment Failure in Endophthalmitis

1. Delayed diagnosis and late institution of treatment
2. Highly virulent organisms
3. Resistant infecting organisms

4. Inadequate drug concentrations (faulty dilutions during preparations)
5. Complications (e.g. retinal detachment)
6. Poor visibility during PPV (corneal oedema/abscess)
7. Macular infarcts related to aminoglycoside toxicity
8. Presence of risk factors perpetuating infection
9. Highly toxic organism, i.e. MRSA strain
10. Fungal infection

V. Monitoring during Follow-up

- The axiom, "if it isn't worse, it's better" may apply because medial clarity and visual acuity may not improve initially.
- Glow changes first so it is the best indicator.
- Hypopyon increasing or decreasing is the next important indicator.
- Symptoms of ocular pain.
- Visual acuity.
- Slit Lamp Examination-signs of inflammation-flare, cells, congestion, etc.
- USG B-scan-to monitor clinical response and to detect earliest RD, particularly in the presence of corneal involvement.

W. Medico-Legal Aspects

- Stray case of endophthalmitis does not mean neglect.
- Diagnosis was made and treatment started immediately.
- Tap for culture was done from aqueous and vitreous.
- Risk factors were taken care of to the best of one's ability.
- An informed consent exists.
- A second opinion was taken.
- Treatment was not delayed for the reason of affordability, etc.
- Every treatment given must be recorded
- Also inspect the records of the OT - if sterilization records exist, it is good enough.
- Any laxity in following the guidelines should be avoided at all costs.

X. Ethics and Endophthalmitis

- Sacred dimension to what we can do. We have been given the awesome power to heal. Must use it for the benefit of the patient. Religious leaders can be called.
- Follow internal conscious voice and external capacity to heal.
- Follow the dictum - don't harm if can't help.
- Try to serve competently and compassionately.
- Patient's interest must reign supreme.
- Patient operated elsewhere must be counselled more carefully without speaking ill of our colleague.
- Give extra time and undivided attention while talking to these patients. Break the news slowly and diplomatically. Give prognosis in detail to relatives.
- Don't talk about the cost of Rx.
- Don't insist while talking about cataract surgical options, viz. type of intraocular lens, type of surgery etc. Instead assist the patient to come to some conclusion.
- Cluster infection (occurrence of more than one case from a day or a series) is a serious lapse.

Y. Summary of Protocol for Treating Endophthalmitis

- Admit the patient. Prepare for the OT.
- Take conjunctival swab, aqueous/vitreous tap as appropriate under sterile precautions. Proper informed written consent is mandatory.
- Give an intravitreal injection of vancomycin 1mg and cefuroxime 1 mg or ceftazidime 2.25 mg or 0.4 mg amikacin if the patient is allergic to penicillin.
- Can start oral gatifloxacin 400 mg OR moxifloxacin 400 mg daily for 5 days.
- Send conjunctival swab and aqueous/vitreous sample for microscopy (Gram stain and KOH) and culture.
- Give a sub-conjunctival injection of vancomycin 50 mg and cefuroxime (or ceftazidime) 125 mg or 50 mg amikacin if the patient is allergic to penicillin.
- Monitor the pain experienced by the patient. Reduction in pain experienced by the patient suggests bacterial kill.
- Start vancomycin 5% and ceftazidime 5% eye drops hourly.
- Add a steroid to the intravitreal injection if you are sure that this is not fungal in origin.
- Give atropine topically and anti-inflammatory as supportive therapy.
- If you cannot see the posterior segment, do a B-scan ultrasonography if it is available.
- If there is no improvement in 24 hours, consider repeating vitreous culture and intravitreal injection. You may

have to change the antibiotic as per the culture report.

- Consider systemic or topical steroids, if you are confident that the infection is under control (i.e. pain is diminishing, fibrin is contracting and hypopyon is decreasing).
- Taper the drugs as per the patient's response and culture results.
- If there is no response even after repeat intravitreal injection OR there is worsening OR vision is only Perception of Light+ Projection of light+ at the time of presentation, a vitrectomy can be considered. Should be done earlier in fungal infections.
- Keep the patient informed of the progress.

APPENDIX 1

PREPARATION OF INTRAVITREAL DRUGS — READY RECKONER

Sr. No1	Antibiotic	Vial size	Amount of initial diluent	Initial concentration	Amount taken in tuberculin syringe	Volume of diluent added	Final concentration	Dose injected
1.	Vancomycin or Cefuroxime	500 mg powder	5 ml	100 mg/ml	0.1 ml	0.9 ml	10 mg/ml	1mg/0.1 ml
2.	Amikacin	100 mg/2 ml 250 mg/2ml		50 mg/ml 125 mg/ml	0.1 ml, 0.1 ml + 0.9 ml D/W	0.9 ml 0.7 ml	5 mg/ml 3.75 mg/ml	0.4 mg/0.08 ml 0.4 mg/0.1 ml
3.	Gentamycin and Tobramycin	80 mg/2 ml		40 mg/ml	0.05 ml	0.95 ml	2mg/ml	0.2 mg/0.1 ml
4.	Cefazolin and Ceftazidime	500 mg powder	2.2 ml	225 mg/ml	0.1 ml	0.9 ml	225 mg/ml	2.25 mg/0.1 ml
5.	Piperacillin+ Tazobactam	2.25 gm powder	10 ml	225 mg/ml	0.1 ml	9.9 ml	2.25 mg/ml	0.225 mg/0.1 ml
6.	Ciprofloxacin	200 mg/ 100 ml bottle		2 mg/ml	0.15 ml	0.05 ml of RL	1.5 mg/ml	150 ug/0.1 ml
7.	Dexamethasone			4 mg/ml	0.05 ml			0.4 mg/0.1 ml
8.	Triamcinolone	40 mg/ml			0.05 ml			4 mg/0.1 ml
9.	Amphotericin B	50 mg powder	10 ml 5% Dextrose	5 mg/ml –	0.1 ml	9.9 ml 5% Dextrose	500 ug/10 ml	5 ug/0.1 ml (50 ug/1 ml)
10.	Voriconazole	200 mg powder	20 ml D/W	10 mg/ml	1 ml	9.0 ml of D/W	1.0 mg/1.0 ml	0.05 ml – 50 mcg 0.1 ml – 100 mcg
	Less Commonly Used Antibiotics							
11.	Chloramphenicol	1,000 mg powder	10 ml	100 mg/ml	0.1ml	0.4 ml	10 mg/0.5 ml	2 mg/0.1 ml
12.	Clindamycin D/W : Distilled water	300 mg/2ml		150 mg/ml	0.1 ml	1.4 ml	15 mg/1.5 ml	1 mg/0.1 ml

APPENDIX 2

RECOMMENDED DOSE OF COMMONLY USED SYSTEMIC ANTIBIOTICS IN THE SUPPORTIVE MANAGEMENT OF POST-SURGICAL ENDOPHTHALMITIS

1.	Gatifloxacin	Oral 400 mg daily.		
2.	Moxifloxacin	Oral 400 mg q12-hourly on day 1, thereafter 400mg/day, 400mg/250ml I.V. infusion per day.		
3.	Vancomycin	1g I. V. q 12 hours		
4.	Ciprofloxacin*	750 mg PO q 12 hours		
5.	Ceftazidime	2g I. V. q 8 hours		
6.	Ceftrioxone	2 g I. V. q 8 hours		
7.	Cefazolin	1.5 g I. V. q 6 hours		
8.	Imipenem	1 g I. V. q 12 hours		(500 mg PO q 8 hours)
9.	Cephalothin	1 g I. V. q 4 hours	(30 mg/kg/day)	(100 mg/kg/day)
10.	Chloramphenicol	1 g I. V. q 8 hours	(400 mg I. V. q 12 hours)	(50 mg/kg/day)
11.	Amikacin	240 mg q 8 hours	(100 mg/kg/day)	(15 mg/kg/day)
12.	Tobramycin	80 mg q 8 hours	(100 mg/kg/day)	(5 mg/kg/day)
13.	Gentamycin	80 mg q 8hours	(75 mg/kg/day)	(5 mg/kg/day)
14.	Ofloxacin	200 mg PO q 12 hours		

* Avoid in children aged below 12 years and in pregnant and lactating mothers.

APPENDIX 3

PREPARATION OF COMMONLY USED FORTIFIED EYE DROPS*

Shake solution well before instilling into the eye!!

1. **Ceftazidime (50 mg/ml):** An injection vial of 500 mg powder and dissolve with 10 ml of artificial tear drops or 0.9% NaCl.

2. **Vancomycin (50 mg/ml):** Dissolve an injection vial of 500 mg vancomycin in 10 ml of artificial eye drops and store in the fridge.

3. **Cefuroxime (50 mg /ml):** An injection vial of 1,000 mg cefuroxime is diluted with 2.5 ml sterile water. Of this dilution, 2.5 ml is then added to 12.5 ml of artificial tears. This is stable at room temperature for 24 hours and in the refrigerator for 96 hours.

4. **Tobramycin (15 mg/ml):** Add 2 ml of parenteral tobramycin containing 80 mg of the drug into a commercially available 5 ml vial of tobramycin eye drops (0.3%).

5. **Gentamicin (15 mg/ml):** Add 2 ml of parenteral Gentamycin containing 80 mg of the drug into a commercially available 5 ml vial of gentamycin eye drops (0.3%).

* Fortified eye drops in endophthalmitis are not recommended routinely but only if there is a concurrent corneal ulcer or suture abscess and in bleb-associated endophthalmitis.

APPENDIX 4

RECOMMENDED DOSAGE OF CORTICOSTEROIDS IN BACTERIAL ENDOPHTHALMITIS

A. Intravitreal dexamethasone (400ug in 0.1ml): The drug is available as a solution in a strength of 8mg in a 2ml vial (4mg in 1ml); hence, use 0.4mg (400ug) in 0.1ml.

A 0.1 ml dose of the drug may be withdrawn directly into a tuberculin syringe without any further dilution.

B. Systemic corticosteroids

1. Prednisolone	1-2 mg/kg/day PO
2. Betamethasone	0.5-5 mg/day PO
3. Dexamethasone	0.5-5mg/day PO
4. Deflazacort	0.5–1 mg/kg/day PO

APPENDIX 5

RECOMMENDED DOSAGE OF SYSTEMIC ANTIFUNGAL AGENTS FOR FUNGAL ENDOPHTHALMITIS

1. Amphotericin B	0.7–1.0 mg/kg/day (given by slow I. V. over 2–6 hours after a test dose)
2. Fluconazole	200 mg/day PO in single or two divided doses
3. Ketoconazole	400 mg/day in single or two divided doses
4. Itraconazole	200 mg/day in single or two divided doses
5. Fluocytosine	50–100 mg/kg/day

References

1. Ravindran RD, Venkatesh R, Chang DF, Sengupta S, Gyatsho J, Talwar B. Incidence of post-cataract endophthalmitis at Aravind Eye Hospital: outcomes of more than 42,000 consecutive cases using standardized sterilization and prophylaxis protocols. J Cataract Refract Surg. 2009 Apr;35(4):629-36.
2. Friling E, Lundström M, Stenevi U, Montan P. Six-year incidence of endophthalmitis after cataract surgery: Swedish national study. J Cataract Refract Surg 2013; 39: 15-21
3. ESCRS Endophthalmitis Study Group. Prophylaxis of post-operative endophthalmitis following cataract surgery: results of the ESCRS multicenter study and identification of risk factors.J Cataract Refract Surg 2007; 33:978–98
4. Zachary B,Sue C,Nick M. Toxic anterior segment syndrome:Update on the most common causes. J Cataract Refract Surg 2012; 38:1902–1910
5. Results of the Endophthalmitis Vitrectomy Study. A randomized trial of immediate vitrectomy and of intravenous antibiotics for the treatment of Post-operative bacterial endophthalmitis. Endophthalmitis Vitrectomy Study Group. Arch Ophthalmol. 1995 Dec;113(12):1479-96.
6. Barry P, Behrens-Baumann W, Pleyer U, Seal D.ESCRS Guidelines on prevention, investigation and management of post-operative endophthalmitisVersion 2 August 2007;8-14.Available online:http://www.escrs.org/vienna2011/programme/handouts/ic-100/ic-100_barry_handout.pdf
7. Albert DM, Jakobiec FA. Post-operative endophthalmitis. In: Principles and Practice of Ophthalmology. W B Saunders Co; 2000:2441-2462.
8. Hariprasad SM, Shah GK, Mieler WF et al. Vitreous and aqueous penetration of orally administered moxifloxacin in humans. Arch Ophthalmol 2006;124:178–82

III. OUTBREAK POLICY POST-OPERATIVE ENDOPHTHALMITIS

Uday Gajiwala, Rajesh Patel

A. Introduction

This section contains the measures to be taken when suspecting an outbreak of post-operative infection. As soon as cases suspected to be post-operative endophthalmitis are seen (this will happen when the staff are very vigilant toward signs of endophthalmitis), it is important to pose the question early as to whether a cluster of cases constitutes an outbreak that might have a potential underlying cause or simply consists of a random series of events occurring by chance. Although our aim is definitely zero infection, this is not possible in real life -so we do have case of post-operative infection.

B. Definition and Grading

It is better to have a definition of outbreak so that there will not be any unnecessary panic among the staff.
An increase in the isolation rate of an organism or clustering of clinical cases in the same time frame suggests an outbreak.

Cluster cases ((Post-operative endophthalmitis- POE cases) occurring in relatively short succession in a single department), may be five or more within a month's period. The reason it is important to identify these is the fact that many clusters tend to originate from a distinct infective source and occur over a relatively short time period of days to weeks. And when a readily identifiable source of infection is present, we can prevent further episodes simply by eradicating that source.

How many cases of POE should be allowed to occur before suspecting something may be seriously wrong? After how many cases should one consider investigating? When should one close the OT?

INTERNATIONAL GUIDELINES

Factors suggesting an outbreak

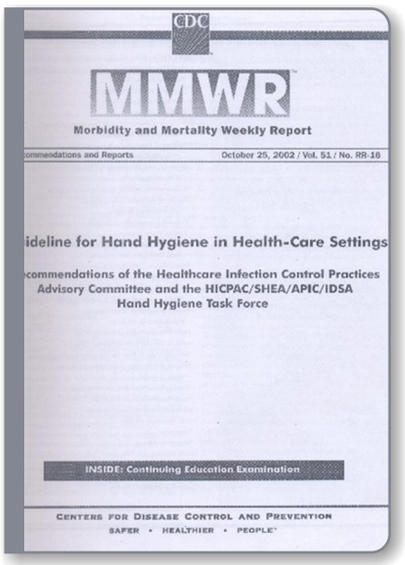
- A laboratory report of bacteriology specimen grows an alerting organism.
- Two or more patients are found to have an infection attributed to a species but previously documented, particularly if it has occurred after a surgical procedure.
- The clinicians or the ward staff report multiple infections of a similar nature.
  Allardice *et al.*[2] used Poisson distribution to determine whether the number of cases is higher than can be expected by chance.

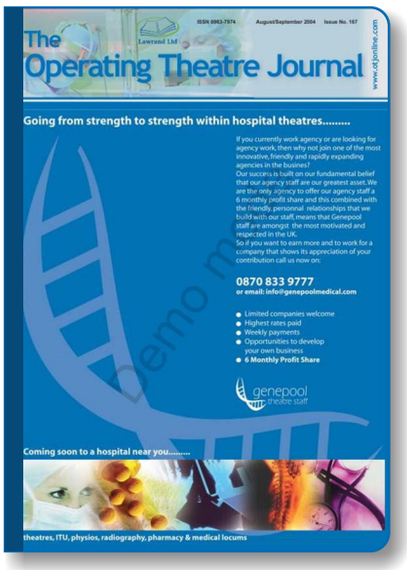
On this basis, they proposed a **'traffic light model':**

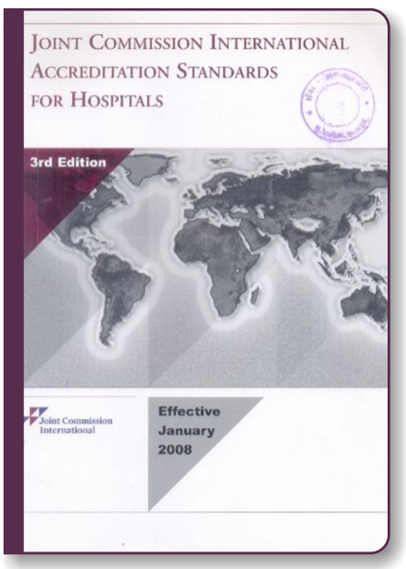
- Whether to continue surgery (green)
- When to continue surgery but also commence an investigation (amber)
- When to stop surgery and investigate (red)

A p-value is given depending on how many cases of POE have occurred per number of operations since the first cluster case.

- It assumes a rate of 0.1% to be normal.
- It is, therefore, important to consider the local rate.







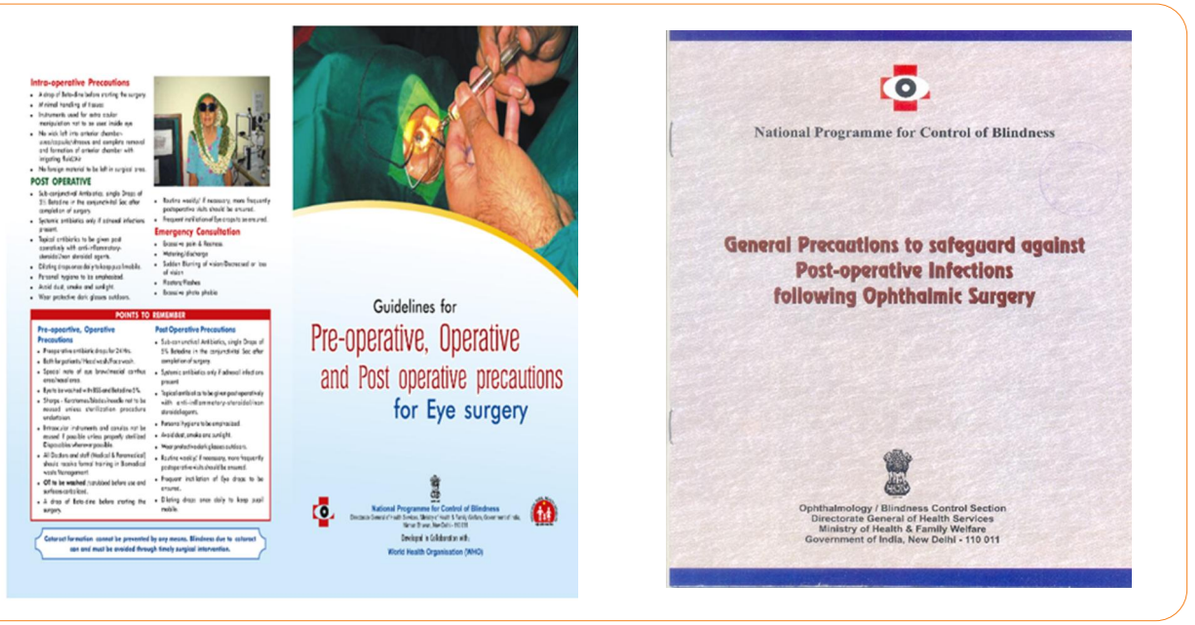
INTERNATIONAL GUIDELINES TO PREVENT HOSPITAL-RELATED INFECTION

C. Constitution of an Outbreak Control Team

An investigative team can be brought together that comprises the following staff:

- Microbiologist
- Ophthalmologist
- Theatre nursing staff
- Clinical risk manager
- Hospital manager

The team should meet regularly. Areas of concern should be scrutinized carefully. Each aspect should be assessed for the potential risk and procedures put into place to minimize that risk.

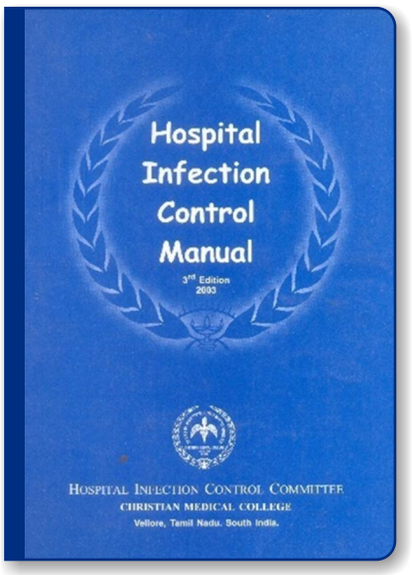


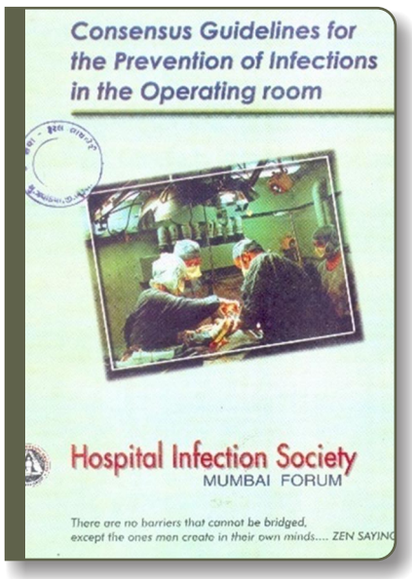
NPCB GUIDELINES TO PREVENT INFECTION

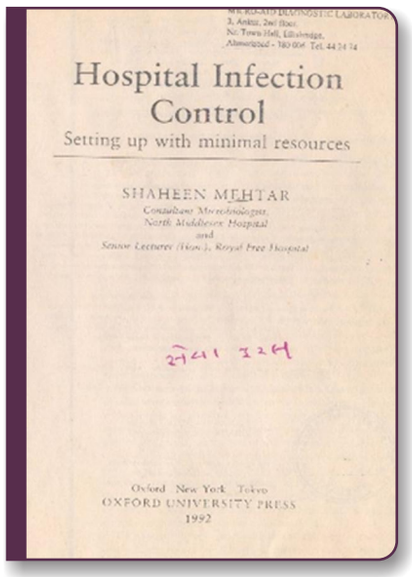
D. Investigation of an Outbreak

General

- An outbreak is an infection control emergency; measures should be taken as soon as an outbreak is suspected.
- Begin preliminary evaluation and determine a background rate of infection.
- Confirm the existence of an outbreak.
- Confirm the diagnosis using the microbiological methods.
- Create a case definition that may include laboratory and clinical data. Start with a broad case definition that can be redefined at a later date.
- Develop line listings by identifying and counting cases or exposures. Describe the data in terms of time, place and person. Remember that cases may have been discharged from the healthcare facilities.
- Take immediate control measures. Determine who is at risk of becoming ill. Look at changes that may have affected the rate of infection, e.g. new staff, new procedures, new laboratory tests and healthcare workers to patient ratio etc.
- Communicate information to relevant personnel.
- Screen personnel and the environment as indicated.
- Write a coherent report (preliminary and final).
- Summarize investigations and recommendations to the appropriate authorities.
- Implement long-term infection control measures for prevention of similar outbreaks.







MATERIALS TO PREVENT HOSPITAL INFECTION

E. Investigation and Management

Areas of investigation[1]

1. **Environment around the OT**
2. **Pre, intra and post-operative practices**
3. **Cleaning and sterilization practices**
4. **Microbiological screening**

1. Environment around the OT

External environment assessment highlighted ongoing building construction next to the OT. In some cases, reports have suggested a link between building construction and fungal infections, especially Aspergillus. In other cases, internal environmental assessment highlighted the use of one of the eye OTs for other surgical work.

- Ongoing building works next to the theatre suite.
- Use of one of the eye theatres for other practices

2. Pre, intra and post-operative practices

Preoperative practices

- Eyelids and conjunctival sac prepared with 5% povidone iodine.
- Proper application of the surgical drape to cover the eyelashes and eyebrows.

Intraoperative practices

- Movement and access to OTs.

- Everybody properly attired - use OT dress, cap, mask and shoes. It has been shown that face masks reduce bacterial eye contamination of the perioperative area.
- Routine practices e.g. saline cup, instruments exposed for long periods, etc.

Information such as the patient records, names of surgeons/assisting staff, date and OR number, type of surgery, intraocular lens batch number, saline batch number etc.
Log books: duty roster, autoclave, infection cases.

Post-operative practices

Wound leak, re-surgery, recording of intraocular tension, change of dressing, application of medicine.

3. Cleaning and sterilization practices

Proper washing and drying of instruments

- Special care for cannulated instruments
- Autoclave maintenance and servicing
- Storage of sterilized instruments
- Method of packing bins and loading autoclave
- Date of purchase
- Proper functioning of the equipment
- E.g. phacoemulsification, irrigation/aspiration hand piece

4. Microbiological screening

This is done by taking culture. Culture should be taken in all the appropriate places, such as the tables, doors, water, and saline. Each organism identified must be evaluated to decide whether it is significant or not. And finally, the cost must be worked out; accordingly, culture can be restricted.

OT surveillance must be carried out according to predetermined protocols. Interpretation of results and action taken are critical factors for meaningful surveillance. Five important criteria to be remembered are that such surveillances must be planned, purposeful, scientifically accurate, properly documented/analysed and finally, effectively communicated to all levels of the staff for the desired results.

NGO INITIATIVES TO PREVENT HOSPITAL INFECTION

F. A Model of Investigation[1]

1. Assembling an investigative team

It is important to act quickly and decisively and assemble a multidisciplinary team of all the staff involved from both clinical and managerial disciplines, i.e. ophthalmologists, microbiologists, theatre nursing staff, clinical risk and hospital management. The team should meet frequently to assess the incoming evidence and decide on a response.

2. Determining the cause of the outbreak

Determining the cause of an outbreak involves identification of factors in common between each case. Most cases of POE are due to bacteria entering the eye at the time of surgery by means of surgical instruments, the irrigation fluid or by contamination of the intraocular lens implant (IOL).[3-6] The incidence of positive cultures has been reported as 56% in the BOSU survey.[7] In many cases, the organisms involved are thought to originate from the periocular flora.[4,9]

A recent study isolated haemolytic Streptococci (Strept. viridans) in only 10% of preoperative conjunctival swabs, whereas coagulase-negative Staphylococcus and Staph. aureus were isolated in 56% and 13% of swabs, respectively.[10] Strept. viridans, isolated in three out of four culture-positive cases, could have been present in the throats of any of the theatre staff. Further analysis showed this to be of at least two different strains.

A prospective study by Nagaki et al.[11]compared POE rates following superior corneoscleral incisions versus temporal corneal incisions. Temporal incisions were shown to pose a higher risk. Corneal incisions have been reported to pose a higher risk when compared to corneoscleral incisions.[8,12] Cooper et al.[12]suggested reduced post-operative wound integrity to be a possible factor.

A recent review of prophylactic measures by Ciulla et al.[13]showed the evidence supporting the benefit of post-operative sub-conjunctival antibiotics to be inconclusive.

Ciulla et al.[13] found stronger evidence supporting povidone iodine as an effective form of endophthalmitis prophylaxis. It has been reported to be effective in reducing conjunctival flora and, in one prospective study, was shown to be effective in reducing the rate of POE.[14]

The incidence of culture-positive bacterial contamination in the anterior chamber at the end of cataract surgery ranged widely from 0%[15] to 46%[16] of cases found in previous studies. Given this wide variation, it is not clear why POE occurs in only a small number of patients in most eye units. This is often attributed to the intrinsic ocular immunity being overwhelmed when a critical bacterial load is reached, or when there is impairment of the ocular defences, such as in cases of vitreous loss, thereby establishing a communication between the aqueous and vitreous chambers. Bacteria may also enter the eye in the post-operative period because of cataract wound abnormalities, vitreous wicks, sutures and inadvertent filtering blebs.

3. Drafting of new protocol and recommendations

We recommend five main areas of investigation: (1) OT environment; (2) pre, peri and post-operative practices; (3) instrument cleaning and sterilization; (4) equipment maintenance, and (5) documentation. New protocols should be aimed at overcoming risks detected in each of the above areas. The importance of documentation cannot be overemphasized and is extremely useful in determining if any of the endophthalmitis cases contain factors in common. For example, if all the cases occurred in one of two OTs, then that would point to a focus of contamination in that OT. Unfortunately, it may only be following an outbreak that the absence of valuable documentation comes to light.

4. Re-auditing and ongoing microbiological surveillance

Maintaining ongoing microbiological surveillance after the introduction of new protocols is essential to monitor their effectiveness. The microbiology department must conduct ongoing sampling of instruments to ensure a safe environment. Routinely educate patients, clinical and nursing staff to be highly alert to symptoms of endophthalmitis. It is necessary to exercise constant vigilance in detection, compliance with the protocols and scrupulous monitoring in the hope that further outbreaks could be averted.

Methods

1. Is the number of cases higher than expected?

There are three stages involved in answering this question:

(a) A systematic literature review should be carried out by members of the Outbreak Control Team to establish the background rate of endophthalmitis following cataract surgery.

(b) The hospital patient record system (HPRS) should be accessed to establish some baseline statistics, in particular, the number of cataract operations. At this stage, a check should be made that the reported cases meet the case definition and that no case has been missed.

(c) The number of cases observed should be compared with the number expected using a method involving the ratio of a Poisson variable to its expectation. The analysis should be carried out for the whole time period.

2. Could the available statistics shed any light on the possible cause of the cases?

A case control study should be set up to investigate differences between the cases and controls, based on the routinely available data. The cases are the people who met the case definition. The controls were the rest of the

routine admissions for cataract surgery. The controls should include patients who had both eyes operated upon during the study period. They should be left in the database as each operation could have led to a case of endophthalmitis. The variables studied included the following: age, gender, first part postcode, date of admission, date of discharge, patient type (inpatient/outpatient), place on surgery list, type of anaesthetics, operation type, consultant, surgeon, anaesthetist, type of lens implant, history of diabetes, immunosuppression, rupture of the posterior capsule, uveitis, older age and instrument nurse. Possible associations between endophthalmitis and each variable were examined using Fisher's Exact Test.

A series of univariate analyses need to be carried out using Fisher's Exact Test 3. This should be followed by stepwise logistic regression 10, using both forward and backward conditional methods to examine the independent effect of each variable on endophthalmitis.

3. Is there a statistical method to identify when interventions (e.g. stopping surgery) are needed?

The question to be answered is "How many cases of a rare condition should be allowed to occur before suspecting that a significant problem exists?" Typically, the answer, from a statistical perspective, would be that post-cataract endophthalmitis depends on the number of events, e.g. operations being carried out and on the expected rate of cases.

These numbers are unlikely to be intuitively obvious but can be easily calculated in advance of the operations. Accordingly, a 'traffic light system' has been developed to formalize the decision process about when to intervene. The 'traffic light system' is based on standard statistical theory, which states that if an event is occurring randomly at a specified rate, then the probability of observing a given number of cases is defined by the Poisson distribution. One practical implication is that for a given rate, it is possible to construct a table showing the probability of observing a particular number of cases out of any given number of operations.

Table I was produced to show the probabilities of observing X or more cases of endophthalmitis following N cataract operations. The probabilities are derived from the Poisson distribution with a rate of one per 1,000. The columns represent the number of observed cases of endophthalmitis (X) and the rows represent the number of cataract operations carried out (N), rounded for convenience to the nearest round figure. The value in each cell is the probability associated with observing that number of cases, or more, from that number of operations.

Once the individual cell probabilities had been calculated, the table was overlaid by an action plan based on three types of action, analogous to a traffic light system of green, amber and red; namely, continue operating, continue operating but consult colleagues and stop operating. The table was set such that if the probability observing X cases (or more) from N operation was >0.05, then operations should continue; if $p<0.01$ then operations should stop; and if P was between 0.01 and 0.05, then a consultation phase was desirable. When surgery restarts, both the number of cases and the operation count should be reset to zero as it is assumed that surgery takes place under different (improved) conditions. The table was presented to the Outbreak Control Team with the probabilities printed in colour; red if operating should stop, amber if the consultation phase was recommended and green if no action was required.

Table I

Table of probabilities of observing X cases (or more) of endophthalmitis during N cataract operations, where cases are expected to occur with Poisson frequency and at a rate of 1 per 1,000 operations

No. of operations (N)	Cases observed (X or more)			
	X>1	X>2	X>3	X>4
50	0.049	0.001	0.000	0.000
100	0.095	0.005	0.000	0.000
150	0.139	0.010	0.001	0.000
200	0.181	0.018	0.001	0.000.
250	0.221	0.026	0.002	0.000
300	0.259	0.037	0.004	0.000
350	0.295	0.049	0.006	0.000
400	0.330	0.062	0.008	0.001
450	0.362	0.075	0.011	0.001
500	0.393	0.090	0.014	0.002
550	0.423	0.106	0.018	0.002
600	0.451	0.122	0.023	0.003

References

1. Anderson OA , Lee V , Shafi S , Keegan D , Vafidis G .A model for the management of an atypical endophthalmitis outbreak. Eye (2005) 19, 972–980
2. Allardice GM, Wright EM, Peterson M, Miller JM. A statistical approach to an outbreak of endophthalmitis following cataract surgery at a hospital in the West of Scotland. J Hosp Infect. 2001 Sep;49(1):23-9
3. Beigi B, Westlake W, Mangelschots E, Chang B, Rich W & Riordan T. Peroperative microbial contamination of anterior chamber aspirates during extracapsular cataract extraction and phacoemulsification. Br J Ophthalmol 1997; 81: 953–955.
4. Samad A, Solomon LD, Miller MA & Mendelson J. Anterior chamber contamination after uncomplicated phacoemulsification and intraocular lens implantation. Am J Ophthalmol 1995; 120: 143–150.
5. Doyle A, Beigi B, Early A, Blake A, Eustace P & Hone R. Adherence of bacteria to intraocular lenses: a prospective study. Br J Ophthalmol 1995; 79: 347–349.
6. Assia EI, Jubran RZ, Solberg Y & Keller N. The role of intraocular lenses in anterior chamber contamination during cataract surgery. Graefes Arch Clin Exp Ophthalmol 1998; 236: 721–724.
7. Kamalarajah S, Silvestri G, Sharma N, Khan A, Foot B & Ling R et al. Surveillance of endophthalmitis following cataract surgery in the UK. Eye 2004; 18: 580–587.
8. Schmitz S, Dick HB, Krummenauer F & Pfeiffer N. Endophthalmitis in cataract surgery: results of a German survey. Ophthalmology 1999; 106: 1869–1877. | Article | PubMed | ChemPort |
9. Harris MJ. Visual outcome after intravitreal steroid use for Post-operative endophthalmitis. Ophthalmology 2001; 108 (2): 240–241.
10. Johnson MW, Doft BH, Kelsey SF, Barza M, Wilson LA & Barr CC et al. The Endophthalmitis Vitrectomy Study: relationship between clinical presentation and microbiologic spectrum. Ophthalmology 1997; 104: 261–272.
11. Nagaki Y, Hayasaka S, Kadoi C, Matsumoto M & Yanagisawa S et al. Bacterial endophthalmitis after small incision cataract surgery. Effect of incision placement and intraocular lens type. J Cataract Refract Surg 2003; 29: 20–26.
12. Cooper BA, Holekamp NM, Bohigian G & Thompson PA. Case–control study of endophthalmitis after cataract surgery comparing scleral tunnel and clear corneal wounds. Am J Ophthalmol 2003; 136: 300–305.
13. Ciulla TA, Starr MB & Masket S. Bacterial endophthalmitis prophylaxis for cataract surgery: an evidence-based update. Ophthalmology 2002; 109: 13–24.
14. Dereklis DL, Bufidis TA, Tsiakiri EP & Palassopoulos SI. Preoperative ocular disinfection by the use of povidone iodine 5%. Acta Ophthalmol (Copenh) 1994; 72: 627–630.
15. Leong JK, Shah R, McCluskey PJ, Benn RA & Taylor RF. Bacterial contamination of the anterior chamber during phacoemulsification cataract surgery. J Cataract Refract Surg 2002; 28: 826–833.
16. Srinivasan R, Tiroumal S, Kanungo R & Natarajan MK. Microbial contamination of the anterior chamber during phacoemulsification. J Cataract Refract Surg 2002; 28: 2173–2176.
17. Bailor JC,Ederer F.Significance factors for the ratio of a poison variable to its expectations.Biometrics 1964;20:339-343
18. Fisher RA.Statistical methods for research workers,5th edition,Edinburgh:Oliver and Boyd,1934

NOTES

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