All India Ophthalmological Society (AIOS) Task Force guidelines to prevent intraocular infections and cluster outbreaks after cataract surgery

Lalit Verma, Aniruddha Agarwal¹, Vivek Pravin Dave², Santosh G Honavar³, and members of the Task Force, Ajit Babu Majji³, Ashish Lall⁴, Ashish Mahobia⁵, Ashok Kumar Grover⁶, Avnindra Gupta, Cyrus Shroff⁷, Dinesh Talwar, M S Ravindra⁸, Mallika Goyal⁹, Namrata Sharma¹⁰, Paritosh A Kamdar¹¹, Pramod Bhende¹², Preetam Samant¹³, Pukhraj Rishi¹⁴, R D Ravindran¹⁵, Raja Narayanan², Rajesh Sinha¹⁰, Rajiv Reddy Pappuru², S Sasi Kumar¹⁶, Saravanan V R¹⁵, Tatyarao P Lahane¹⁷, Uday Gajiwala¹⁸, Venkatesh Pradeep¹⁰

Infectious endophthalmitis is a serious and vision-threatening complication of commonly performed intraocular surgeries such as cataract surgery. The occurrence of endophthalmitis can result in severe damage to the uveal and other ocular tissues even among patients undergoing an uncomplicated surgical procedure. If the infections result from common factors such as surgical supplies, operative or operation theater-related risks, there can be a cluster outbreak of toxic anterior segment syndrome (TASS) or infectious endophthalmitis, leading to several patients having an undesirable outcome. Since prevention of intraocular infections is of paramount importance to ophthalmic surgeons, the All India Ophthalmological Society (AIOS) has taken the lead in the formation of a National Task Force to help ophthalmic surgeons apply certain universal precautions in their clinical practice. The Task Force has prepared a handy checklist and evidence-based guidelines to minimize the risk of infectious endophthalmitis following cataract surgery.



Key words: Cataract Surgery, cluster infection, endophthalmitis, guidelines, infection, prevention

Infectious endophthalmitis is a catastrophic complication following intraocular procedures such as phacoemulsification. While cataract surgery is one of the most commonly performed surgical interventions worldwide, it is a safe procedure with infections reported in 0.04%–0.2% cases.^[1-4] However, the

Centre for Sight, New Delhi, India, 1Department of Ophthalmology, Eye Institute, Cleveland Clinic Abu Dhabi, Abu Dhabi, United Arab Emirates, ²Smt. Kanuri Santhamma Center for Vitreoretinal Diseases, Kallam Anji Reddy Campus, L. V. Prasad Eye Institute, Hyderabad, Telangana, India, ³Centre for Sight, Hyderabad, Telangana, India, ⁴Lall Hospitals, Gurgaon, Haryana, India, ⁵Sai Baba Eye Hospital, Raipur, Chhattisgarh, India, 'Department of Ophthalmology, Sir Ganga Ram Hospital, New Delhi, India, 7Shroff Eye Care, New Delhi, India, 8Karthik Netralaya Eye Hospital, Bengaluru, Karnataka, India, 9Department of Ophthalmology, Apollo Eye Hospital, Apollo Health City, Hyderabad, India, ¹⁰Dr. Rajendra Prasad Centre for Ophthalmic Sciences, All India Institute of Medical Sciences, New Delhi, India, ¹¹Jashem Eye Institute, Mumbai, Maharashtra, India, 12Director, Sri Bhagwan Mahavir Department of Vitreoretinal Surgery, Sankara Nethralaya, Chennai, Tamil Nadu, India, 13P. D. Hinduja Hospital, Mahim, Mumbai, Maharashtra, India, 14Truhlsen Eye Institute, University of Nebraska Medical Center, Omaha, Nebraska, USA, ¹⁵Department of Ophthalmology, Aravind Eye Hospital, Chennai, Tamil Nadu, India, ¹⁶Kochi Eye Care Center, India, ¹⁷Department of Ophthalmology, Sir JJ Group of Hospitals, Mumbai, Maharashtra, India, 18 Divyajyoti trust, Mandvi, Dist. Surat, Gujarat, India

Correspondence to: Dr. Lalit Verma, Consultant Ophthalmologist, Vitreoretinal Services, Centre for Sight, B-5/24, Safdarjung Enclave, New Delhi – 110 029, India. E-mail: lalitverma@yahoo.com

Received: 12-Jan-2022 Accepted: 13-Jan-2022 Revision: 13-Jan-2022 Published: 27-Jan-2022 occurrence of infectious endophthalmitis can lead to permanent and severe visual loss and has serious implications for future interventions in the fellow eye. Since there is a multitude of causes that can result in infectious endophthalmitis, it is relevant to understand all the risk factors, microbiological profile, antibiotic sensitivities, pharmacokinetics/pharmacodynamics, and preventive measures, so that the risks are mitigated and damage can be minimized.^[1,2,5-7]

Infectious endophthalmitis can occur sporadically affecting an isolated random patient or as cluster outbreaks affecting several patients. Such outbreaks have been reported from across the globe, including several reports from India.^[8–12] To reduce such undesirable outcomes, several international societies including the American Society of Cataract and Refractive Surgery (ASCRS)^[13] and the European Society of Cataract and Refractive Surgery (ESCRS)^[5] have formulated guidelines to spread awareness and education in this regard. The All India Ophthalmological Society (AIOS) has also formed

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a national task force, which first convened in November 2008.^[7] Due to rapidly evolving changes in cataract surgery and advancement of systems in India, there was a felt need for a thorough revision of these guidelines. Hence, the revision was conducted by the AIOS Task Force in 2018.^[7] As per the ESCRS and AIOS guidelines, two or more cases operated on the same day in the same operation theater (OT) constitute a "cluster endophthalmitis."

The AIOS Task Force has used scientific principles and evidence from published literature considering the Indian context and has proposed several guidelines that can help to prevent infectious endophthalmitis and have successful outcomes. These guidelines also provide suggestions in case there is an infectious outbreak. Finally, the guidelines also provide a ready-to-use checklist for ophthalmic surgeons that can be applied in their practices before initiating surgery in their patients.

In the guide below, section A pertains to the preoperative measures that should be considered when taking up a patient for cataract surgery. Section B provides intraoperative steps that must be taken to minimize the risk of infections. Section C provides postoperative measures, whereas section D provides general information on aspects such as OT sterilization and disinfection. Section E provides important information applicable to situations such as cluster endophthalmitis or outbreaks. A concise checklist is shown in Table 1. It is imperative for every surgeon in individual practice or for groups in group practice or hospitals to have their standard operating procedures (SOP) incorporating standard guidelines, customized to their prevailing situations.

Preoperative Measures

Among the preoperative measures that can help in minimizing infectious endophthalmitis, the metabolic profile of patients is an important consideration. Patients with diabetes mellitus and hypertension can have reduced systemic immunity, making them prone to infections.^[14–18] Due to the ever-increasing burden of diabetes in India, it is important that basic screening for metabolic profile be performed at least 3 months within a planned surgical procedure such as cataract surgery. Fasting blood sugar and blood pressure should be monitored closer to the surgery.

Blood Sugar

- The blood sugar values should be recent, within 1 week before surgery.
- The fasting blood sugar should be $\leq 140 \text{ mg/dl}$.
- The random blood sugar or postprandial blood sugar should be ≤200 mg/dl.

Blood Pressure

- The blood pressure should be adequately controlled as per the physician.
- The blood pressure should be ≤160/95 mmHg before surgery.

Ocular Examination

Ocular examination during a preoperative visit must take into consideration several aspects of the patient factors that can be responsible for infectious endophthalmitis. The eyelids and adnexa form an important part of the patient factor leading to

Table 1: Checklist for elective intraocular surgery

- Comprehensive ophthalmic evaluation preoperatively to exclude potential risk factors for infection
- RBS ≤200 or FBS ≤140 mandatory
- BP ≤ 160/95 mmHg
- Physician or anesthetist clearance in cases with systemic comorbidities
- Preoperative topical antibiotics are preferable (not mandatory)
- Written informed consent and postoperative instructions in patient's language
- Avoid contact procedures or lacrimal procedures on the day of surgery
- · The use of an operating microscope is a must
- · Change sterilized gloves for every case
- Disposable adhesive drape to isolate eyelid margins and eyelashes
- Povidone iodine 5% prophylaxis on periocular skin for 3 min or until dry
- · Povidone iodine 5% in conjunctival sac for 3 min
- Note and document the batch number of irrigating fluids and all the drugs and viscoelastics that are used intraocularly
- Document all the findings (preoperative, operative, postoperative)
- Instruments are to be autoclaved or ETO sterilized (a fresh set of sterile instruments for each case)
- Avoid chemical sterilization
- Maximize the use of disposables
- In case of an infection, take the patient and relatives into confidence, rule out cluster infections and investigate the source, review OT protocols, initiate prompt and appropriate management and triage to higher centers as necessary, and most importantly, seek help from professional colleagues and societies, manage information flow and the media, and inform the authorities

BP=Blood pressure, ETO=Ethylene oxide, OT=Operation theater, RBS= Random blood sugar; FBS=Fasting blood sugar

infections with agents such as gram-positive bacteria.^[19-21] In addition, the eyelids and adnexa can harbor other organisms including gram-negative bacteria, leading to mixed infections which may be difficult to treat.^[1,2] Eyelids should be examined for meibomian gland dysfunction, entropion, ectropion, trichiasis, distichiasis, and lagophthalmos. The lacrimal system must be examined, preferably by regurgitation on pressure over the lacrimal sac (ROPLAS), micro-ROPLAS (minimal ROPLAS observed under a slit lamp), or lacrimal syringing, where appropriate.^[4,22-25] Lacrimal syringing would be ideal if a patient has prior history of lacrimal surgery, symptomatic or evident epiphora, discharge, or is ROPLAS positive. Lacrimal tests are ideally done in the outpatient department (OPD) preoperatively and are best avoided on the day of surgery. It is important to have a healthy ocular surface before initiating cataract surgery.

- If there is an infection of the eyelids, adnexa, and surroundings, it is best to postpone surgery, manage the infection, and then reschedule.
- Contact procedures such as biometry or tonometry should be avoided on the day of surgery.

Preoperative Topical Antibiotics and Povidone Iodine Prophylaxis

There are no universal guidelines on the use of preoperative topical antibiotics in preventing postoperative infectious endophthalmitis.^[5,26,27] The literature falls short on evaluating the role of routine preoperative antibiotics in preventing

infectious endophthalmitis. Thus, it depends on the surgeon preference and practice pattern, and, if available, on published reports of microbiological and antimicrobial sensitivity of common isolates from wounds and fomites in that region, hospital, or department.

The use of povidone iodine 5% is considered to be essential for minimizing the risk of intraocular infection.^[57,26,28–32] The use of povidone iodine 5% is recommended by all the guidelines globally. It should be carefully applied to the ocular surface including the conjunctiva, cornea, and the fornix in the form of instilled drops (after blotting the eye of excess fluid using a dry gauze over closed eyelids), allowing for a 3-min contact time, and painted over the eyelid and periocular skin (bounded by the hairline, tip of the nose, nasolabial fold, and external ear), allowing a minimum of 3-min contact time or until it becomes dry.

- The use of preoperative topical antibiotics is preferable, though not mandatory. Use broad-spectrum antibiotics if necessary.
- Povidone iodine 5% prophylaxis is to be used. Use before surgery and allow a contact time of 3 min. Wait for periocular povidone iodine to dry before draping.

Physician Clearance

• Fitness from a qualified physician (MBBS or higher) or an anesthesiologist, where required.

For Mass Surgeries

- There should not be more than 25 eyes operated per surgeon in a session of 4 h.
- If a patient has multiple systemic problems, then the surgery should preferably be avoided (however, emergency surgery for phacomorphic or phacolytic glaucoma may be an exception).
- High-risk cases and topical anesthesia surgeries are to be done only by experienced surgeons with all due precautions.
- Mono-ocular patients (with one functional eye) should not be operated on under the setting of mass surgery unless necessary. If they are to be operated on, then these cases can be prioritized early on the operative list with an experienced surgeon. All due precautions must be taken.
- Emergency services should be available for 1 week following mass surgeries.
- Surgeries should be done in a dedicated eye OT; no makeshift OT should be created.

Operative Measures

General Measures

- Written informed consent in patient's language explaining the risks involved and benefits expected to be signed by the patient, his/her relative, and/or interpreter (wherever an interpreter is required).
- An anesthesiologist is not mandatory, but a basic life support (BLS)-trained technician should be available.
- A pulse oximeter is preferable for all cases under topical or local anesthesia since all the comorbidities may not be known.
- For high-risk patients (with three or more comorbidities), an anesthesiologist or a doctor (other than the surgeon) should be there to monitor these cases. An intravenous line should be maintained.
- Emergency drugs are mandatory.
- The use of an operating microscope is a must.

• Standard practice should be followed for identification of the patient and the eye and cleaning and draping the eye.

Hygiene of Patients

Since patient factors form an important aspect of intraocular infections, patient education is important before any intraocular procedure and must not be overlooked. The patients must be educated regarding general hygiene (including preparation on the day of the surgery) and postoperative care for the eyes, face, and hair.

- Head, face, and feet need to be washed with soap and water before surgery.
- Reschedule the surgery when there is unusual congestion or discharge.
- Patients should wear fresh, clean, washed non-street clothes or OT dress with cap and gown.
- Apply povidone iodine 5% in the conjunctival sac and on the skin of the eyelid and periocular area (bounded by the hairline, tip of the nose, nasolabial fold, and external ear) for 3 min or till it becomes dry before draping.
- Disposable adhesive drape (to isolate eyelid margins and lashes) must be used in each intraocular surgery.
- Use of sterile eye speculum is a must.

Measures for the Surgeon and Scrubbed Surgical Assistants

- Anyone (including doctors or staff) with fever or any obvious systemic or local infection should not be allowed to enter the OT.
- Allow the presence of only a limited number of personnel (staff/fellows/observers). Viewing monitors need to be placed outside the OT.
- Shoe covers over the street or external use footwear are not recommended. External footwear should be removed outside the OT, and clean OT-specific footwear should be used within the OT.
- Separate washable rubber OT footwear with OT-specific color coding is desirable.
- Separate footwear should be used for toilets; meticulous toilet and personal hygiene must be maintained by all.
- A clean, washed OT dress should be used.
- No street clothes should be used inside the OT by anyone (including patients/doctors/staff).
- Washing, gowning, and gloving as per standard protocol should be practiced by the OT personnel.
- Hand scrubbing should be done with betadine or chlorhexidine scrub for 3 min (if liquid soaps, for 5 min; no bar soaps to be used).
- Potable or purified water is to be used for scrubbing.
- OT etiquette and important dos and don'ts have to be listed and posted in the OT area.
- A fresh new pair of sterilized gloves are to be used for every case.
- May use chemical disinfectant (70% isopropyl alcohol with or without chlorhexidine, e.g., Sterillium, Microshield, or Bactorub) between cases.
- A sterilized gown is mandatory.
- The surgeon should not come out of the OT in a gown. If the surgeon comes out, then he/she must scrub and change the gown for the next case.
- Mask should cover the nose and mouth properly.
- OT cap should be worn properly tucking in all hair.

- The position of hands after scrubbing and gloving should be above the waist and upright in front.
- Document the sequence of surgeries.

Intraocular Irrigating Fluids

Irrigating intraocular fluids form a constant source of fluid supply to the intraocular chambers during the surgery. Contamination of irrigating fluids and outbreaks of endophthalmitis related to such contamination are known. Hence, there must be utmost care taken in the procurement, storage, utilization, and disposal of intraocular irrigating solutions. Some of the measures listed below can be used to minimize such untoward incidences:

- Note the batch number of all the consumables.
- Use a glass or flexible pouch pack or a transparent plastic bottle.
- Ringer lactate and balanced salt solution (BSS) are equally effective (BSS is preferred as Ringer lactate is off-label for intraocular use).
- Resterilization of sealed bottles is not required.
- If glass bottle is used, do vacuum test (bubbles on putting drip set).
- Physical inspection of each fluid bottle against the light first in the unshaken state and thereafter, after shaking – hold it against light and look for any visible floating or moving impurities.
- Thump test: Thrust the palm of your hand against the bottom of the glass bottle to look for possible sediments.
- Microbiological workup is performed and approval taken for each batch, wherever feasible.
- Antibiotic infusion into intraocular irrigation fluid may not play an important role.
- As a routine practice, preserve the bottles of irrigating solutions for 24 h (to look for possible microbiological growth) before discarding them.

Wound Security

- When in doubt about wound security, sutures are to be applied.
- It may be preferable to use sutures in high-risk patients (poor cooperation, mental subnormality, diabetics, resurgery, and complicated procedures such as vitreous loss, nucleus drop, or intraocular lens drop).
- Sutures, when used, must be buried appropriately.
- Any instrument employed for intraocular use (including phaco tip, sleeve, cannula, vitrectomy cutter) must be changed for each case.

At the End of the Surgery

One of the important steps at the end of cataract surgery is the use of prophylactic antibiotics. In the literature, there is no clear evidence to support the routine use of intracameral antibiotics following all cataract surgeries, even though many surgeons use them in their practice.^[25,33] The use of intracameral antibiotics is, therefore, left to the surgeon's discretion. There is no role of subconjunctival antibiotics to prevent infectious endophthalmitis.

In case intracameral antibiotics are being used, either preservative-free moxifloxacin or cefuroxime must be preferred.^[25,33-37] Currently, the intracameral doses described for moxifloxacin range from approximately 100 to 500 µg. The dose of intracameral cefuroxime shown to be safe and effective is 1 mg.^[25,34-37]

- · Subconjunctival antibiotics: not necessary
- Topical broad-spectrum antibiotic drops can be instilled.
- Intracameral antibiotic use is at the discretion of surgeon.

Postoperative Measures

After-Surgery Care

- For cases under topical anesthesia, eye patching is not required, but protective glasses are recommended.
- For cases operated under a peribulbar or retrobulbar block, patching of the operated eye is preferab le for at least 4–6 h.
- Avoid eye rubbing.
- The first postoperative follow-up is to be done within 24 h by an ophthalmologist and slit-lamp examination is mandatory.
- Subsequent follow-up between days 3 and 7 is optional, followed by an examination 25–30 days after surgery.
- Topical antibiotics for 7–10 days are optional.
- Topical steroids or nonsteroidal anti-inflammatory drugs are given for 4–6 weeks.
- Personal hygiene, aseptic precautions while instilling eye drops, and continued control of diabetes are to be emphasized.
- The patient is encouraged to report early in case of unusual pain, watering, redness, diminution of vision, or other symptoms.
- Document all postoperative findings and the same needs to be preserved by the surgeon.
- Emergency services (in case of pain, discharge, photophobia, a decrease of vision, flashes, and floaters) by a qualified ophthalmologist should be made available, at least for 1 week.

OT Sterilization/Disinfection

Suggested OT Area Layout

- Outer zone or protective zone reception
- Mid zone or clean zone/common area changing room and transfer zone
- Aseptic zone or sterile zone scrubbing, gowning, gloving, OT, autoclave room
- Disposal zone where equipment and supplies are processed

Fumigation

- Starting OT for the first time or after a long time (>3 weeks) or after any civil work: At least three OT washings followed by fumigations and three consecutive negative cultures of OT are mandatory.
- Fumigation is not required if there is positive pressure ventilation in the OT.
- For a regularly running OT, single fumigation, disinfection mopping, and fogging weekly are sufficient.
- Use of fogger machine is preferable (not mandatory).

Newer Agents for Disinfection

- a. Bacillocid Special/DesNet
 - Its active ingredients are Glutaral 100 mg/g, benzyl-C12-18-alkyldimethyl ammonium chloride 60 mg/g, and didecyldimethylammonium chloride 60 mg/g.
 - It provides complete asepsis within 30 to 60 min.
 - Cleaning with detergent or carbolic acid is not required.
 - Bacillocid fumigation can be done using 2% Bacillocid (100 ml in 5 l of water). The room must be kept closed for 6 h before use by housekeeping personnel.

- b. Bacillol
- It contains ethanol, 2-propanol, and 1-propanol; it can be used as a spray for instant surface disinfection and is particularly useful before and after an emergency surgery with actual or suspected soiling or contamination. But it does not act on spores.
- c. Virkon
 - It is a surface disinfectant (Virkon 1%).
 - It contains triple salt potassium monopersulfate, an oxidizing agent; sodium dodecylbenzenesulfonate, a cleaning agent; sulfamic acid, a detergent; and inorganic buffers.
 - It is a virucidal, bactericidal, and fungicidal agent.
 - Mop the floor, walls, microscope, and all horizontal surfaces with 1% solution and allow it to dry.
 - Fogging with Virkon 0.25% can be performed weekly once.
- d. Ultraviolet radiation (preferable, not mandatory)
 - It is used daily for 12–16 h and switched off 2 h before entering the OT.

Airflow in the OT

- Maintain temperature at about 21°C (18°C–25°C).
- Maintain humidity at 20-60% (55% is ideal)
- Maintain positive pressure.
- Studies show no consensus on the benefit of high-efficiency particulate absorbing (HEPA) filters.
- The central air-conditioning unit is an individual choice.
- Split air-conditioning is acceptable (window air-conditioning is not acceptable).
- Clean the air-conditioning filters every week.
- Servicing and cleaning of the air-conditioning equipment to be performed every month and documented.
- The use of air-handling units is an individual choice.

Operation Room Cleaning Protocol

- Floor, microscope, surfaces, sinks and drains, and horizontal surfaces must be cleaned daily.
- The floor may be washed or wet mopped at the end of OT with 2% Bacillocid Special (100 ml in 5 l of water) or 1% Virkon. Walls (if tiled) should be washed or wet mopped up to a minimum of 4 ft in height.

OT Size

- 130–160 sq. ft for four persons (400 sq. ft as desired by the National Accreditation Board for Hospitals and Healthcare Providers ([NABH] is not practical)
- Can reduce proportionately to the number of people

Sterilization of Instruments

- Adequate reserve sets should be available.
- Sterilization should be preferably with ethylene oxide (ETO) or autoclave or flash autoclave or plasma sterilizer.
- Autoclaving is recommended for the resterilization of long tubings.
- Sterilization in between cases should be by autoclave.
- Sterilization records are to be documented.
- Chemical sterilization, formalin boxes, and Cidex are not recommended.

Monitoring of Sterilization

• Chemical indicators: Three indicators, first one on the outside wrap, second one on the inside wrap, and the third one inside the tray (Class 6 indicator or integrator for each load or batch)

- After opening the instrument tray in OT, please look for the condensation or moisture in the tray. If moisture is present in the tray or if instruments are wet, consider the tray as unsterile and discard it, even though chemical indicators show change in color.
- Biological indicator testing once in every 1–3 months
- Maximum use of disposable instruments
- Periodic routine and surprise checks of the sterilization areas and protocols are to be performed.

Periodic Cultures (Pre- and Post-disinfection)

- To be taken at least 1–3 months
- 10-cm blood agar plates kept open at the head end of the table for 30 min (colony count of < 10 with not even a single gram-negative bacillus or fungal colony is acceptable)

Use

- Autoclaved or ETO-sterilized instruments
- Standard quality irrigating fluids, dyes, viscoelastic materials, eye drops

Training

• Periodic training of all OT personnel through counseling, seminars, and educational videos and assessment is important.

Documentation

• Documentation using various standard checklists, records, and registers is mandatory.

What to Do in Case of a Presumed Sporadic Infection

- Rule out the possibility of cluster infection (recall patients operated in the same session on the same day for review).
- Interact and discuss with the patients and family and explain the mechanisms of infection despite full precautions; reassure that it is still treatable and request for cooperation and explain the possible need for referral.
- Treat promptly with intravitreal antibiotics and supportive therapy.
- Document all the findings.
- Refer to a higher center (such as a tertiary center with vitreoretinal facilities) after initiating treatment, if necessary.
- Review all OT practices and sterility parameters.
- Review all the sterilization protocols.

What to Do in Cluster Infection

- A cluster infection is defined as the occurrence of two or more than two infections in a single day from one theater or the occurrence of repeated postoperative infection [Fig. 1].
- Confirm an outbreak and determine the level:^[38-40]
 - a. Green alert: One case of endophthalmitis; one in ≥ 100 cases or two in ≥ 600 cases perform a review and check and ensure that the standard theater procedures and preventive measures are in place.
 - b. Amber alert: One case in 75 cases, two cases in 300– 500 cases, three cases in 700–800 cases – urgent review of relevant factors. Get complete microbiological workup including subtypes and antibiotic sensitivity.
 - c. Red alert: Two cases in ≤200 cases, three cases in ≤600 cases, four cases in ≤800 cases call for a detailed investigation.
- If possible, form an expert team including an ophthalmologist,

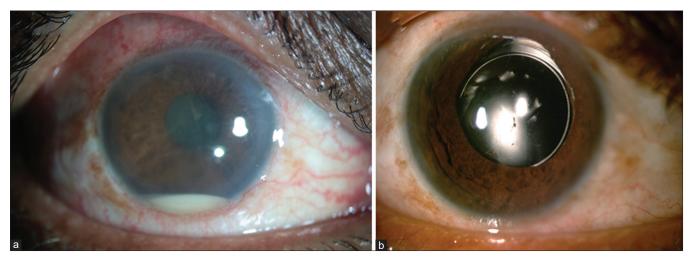


Figure 1: Cluster outbreak of infectious endophthalmitis after cataract surgery. (a) Hypopyon due to infectious endophthalmitis in a patient after uncomplicated phacoemulsification and intraocular lens implantation. (b) Resolution after pars plana vitrectomy with intravitreal antibiotics

hospital management, microbiologist, epidemiologist, and OT nursing staff.

- Distinguishing toxic anterior segment syndrome (TASS) from endophthalmitis could provide a clue to the source of the outbreak.
- Stop surgeries temporarily and review all protocols.
- The following steps could help in identifying the source of the outbreak:
 - Take cultures from OT.
 - Note the batch numbers of all solutions used and send samples for culture.
 - Keep all the solutions used in safe custody.
 - Review the surgical log and individual surgical notes.
- Institute appropriate treatment and refer to a higher center if required. Timely intervention, appropriate triage, and referral as required may help provide better outcomes. Fig. 1 shows a successfully managed case of cluster endophthalmitis.
- Inform the authorities: Notify the hospital authority and hospital infection control committee in writing. (For National Programme for Control of Blindness [NPCB]- related surgeries, inform the government authorities, Indian Medical Association local chapter, State Ophthalmic Society, Deputy Director, or Civil Surgeon.)
- Inform the AIOS and State Ophthalmological Society to seek help.
- Engage and seek the help of a lawyer/legal cell of AIOS.
- Alert colleagues and ensure identification and reporting of further cases.
- Handle the media carefully. The peer group or the hospital committee should handle the media.
- Interact with press and media if such an interaction is sought or is felt necessary and inform them the truth; give a formal press release in writing if necessary.

Conclusion

The AIOS National Task Force aims to provide general guidelines to ophthalmologists to prevent intraocular infections including endophthalmitis in commonly performed procedures such as cataract surgery. These guidelines are likely to change and evolve from time to time as new information becomes available or evidence is published in the literature. The guidelines are intended to serve as a reminder to all ophthalmic surgeons to maintain safe surgical practices, so that catastrophic complications including infectious endophthalmitis can be minimized and patient outcomes can be improved. Clinical suspicion should prompt early recognition of cluster infection, prompting identification and rectification of the cause of the outbreak and appropriate handling of the situation.

Note: These guidelines have been made keeping in mind the wide disparity of health infrastructure across India, so that majority of eye surgeons may adhere to them.

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Conflicts of interest

There are no conflicts of interest.

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