

GUIDELINES FOR MANAGING

POST-OPERATIVE CLUSTER ENDOPHTHALMITIS



Guidelines for Managing Post-operative Cluster Endophthalmitis

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VISION 2020: The Right to Sight – INDIA

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FOREWORD

Population-based surveys have identified cataract as the leading cause of blindness and visual impairment in India. Therefore, the most frequently performed eye operation is cataract surgery and it is normally highly successful in restoring vision. With the expansion of eye care across the country, India has registered a record of 8.34 million cataract surgeries in 2022-23.

With this figure in hand, if we consider all 365 days as cataract operating days, then the average cataract surgery per day stands approximately at 23,000. However, in a very small proportion of post-operative cases it is complicated by infection (endophthalmitis).

Prevention and elimination of postoperative endophthalmitis, has been a constant goal of every ophthalmic surgeon. Endophthalmitis being a serious complication of cataract surgery is something that every ophthalmic surgeon - and patient - strives to avoid. The visual loss and debilitation that occur in a large proportion of postoperative endophthalmitis cases can be severe and irreversible.

Those most in need of the operation are often the ones at greatest risk, such as the elderly, person with disability or the bilaterally blind. Without knowing exactly how, when or why to intervene with effective prophylactic measures, virtually every surgeon today follows a standard of care that involves antisepsis and antibiotics.

Given the high patient awareness and low threshold for tolerance, there is increasing number of medico-legal cases, lawsuits against eye hospitals and doctors. Most clinicians are hardly aware of legal aspects of ophthalmic practice or the laws with which he/she is concerned in his/her practice.

On many occasions, due to these incidents entire sector often gets tarnished and all year of goodwill earned by the hospitals is put to severe risk and criticism. Therefore, there is increasing need to develop awareness among clinicians, eye hospitals, eye care practitioners on the management of endophthalmitis or cluster infection right from preventive measures to post- infection scenarios.

I am extremely glad that VISION 2020 : The Right to Sight- INDIA has taken this much needed initiative of developing guideline on “Managing Post-operative Cluster Endophthalmitis”. The eminent members of the technical committee team are deeply acknowledged for their sheer dedication and hard work in bringing their expertise in the formulation of this guideline for the wider usage of eye care fraternity. I understand that Dr Uday Gajiwala led the earlier similar exercise in 2010 and, this time around, shared all resources and worked with the team that the guidelines evolved into its current format. We are thankful to all the Reviewers for providing the useful inputs which further helped us making the guidelines more accurate.

The guideline development has been widely consultative, incorporating recent advances in endophthalmitis management and emerging clinical challenges in eye healthcare of the 21st century.

The detailed guideline with evidence-based examples, will provide adequate understanding to eye care practitioners and clinicians regarding the risk factors, infection control measures and preventive strategies to mitigate the occurrence of cluster endophthalmitis.

I am quite hopeful that this guideline will be widely used and referred by eye care institutions and eye health professionals for the effective management of post-operative endophthalmitis.

With deep appreciation to everyone who is involved and contributed in the making of this guideline.

RN Mohanty
President, VISION 2020: The Right to Sight-India
CEO, Sightsavers India



PREFACE

Cluster Endophthalmitis that is post-operative is a nightmare for all of us involved in community eye care. In the beginning of our tenure as a scientific committee, we looked at this as a theme for our VISION 2020 India session at the Annual Conference of the All India Ophthalmological Society (AIOS). The feedback from the invited speakers and the audience, made us embark on this ambitious journey of collating a guideline that could be useful in the eventuality of a cluster.

VISION 2020 India & AIOS have in the past have introduced guidelines on various topics including Cataract Surgery and a task force report on endophthalmitis management. These guidelines have been referenced by ophthalmologists, administrators and those associated with the National Programme for Control of Blindness across India.

Many presentations and publications have been written on various aspects of managing a cluster outbreak of endophthalmitis. We have looked through this document to bridge this gap with it divided into chapter that could be relevant at different stages of managing a cluster outbreak.

Cluster and outbreak have been used interchangeably in the Royal Society of Ophthalmologists UK 2022 document. VISION 2020 India (2010) document differentiates between the two. As there are no clear definitions at this point in time, the two terms in this guideline document have been used interchangeably.

We are grateful to the Board of VISION 2020 India for allowing us to work on this document. Dr. Phanindra, as the CEO of VISION 2020 India, has been a shoulder to lean on and also been keeping us on track towards completing this guideline in time. A number of our colleagues in our institutions have been working on various aspects of this guideline at different stages.

We do recognise that this guideline would become a dynamic document being updated and made more relevant as new knowledge emerges about various aspects of managing cluster outbreaks.

We would recommend hospitals using this guideline to ensure their practices are in line with above guidelines. This adherence and documentation would be very useful in any adverse event especially in an enquiry. Also ensure that you inculcate the culture of surveillance & analysis, whenever any presumed infection occurs as part of your routine protocol.

While we wish that this guideline remains only an academic exercise and is not needed by those reading to actually implement in real life, however in that eventuality we certainly hope this does help.

Technical Committee 2022-23
VISION 2020: The Right to Sight-India



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INTRODUCTION, SCOPE & OBJECTIVE

1.1 INTRODUCTION

Post-operative endophthalmitis is a serious vision-threatening complication of intraocular procedures and can have devastating consequences for the patient and the eye healthcare provider. The severity and clinical course of endophthalmitis is related to the virulence and inoculum of infecting microorganism.

Worldwide, the most common organism implicated in acute endophthalmitis is *Staphylococcus epidermidis*, accounting for 60%–80% of the cases, followed by Gram-negative bacteria responsible for 6%–29% of the cases.⁽¹⁾ In India, Gram-negative organisms like *Pseudomonas* form up to 43% of the culture-proven cases.^(2,3)

With the advancement in surgical techniques and the adoption of standardized sterilization protocols, the incidence of post-operative endophthalmitis has significantly decreased over the past two decades.

Cataract surgery, one of the most commonly performed surgical interventions worldwide, is now considered a relatively safe procedure with an infection rate of 0.04%–0.2%.^(2–5) Infectious endophthalmitis, however, can occur sporadically affecting an isolated patient or as cluster outbreaks affecting several patients operated in an eye care facility.

Cluster endophthalmitis outbreaks are relatively rare but can have devastating consequences. By broad definition, cluster endophthalmitis refers to the occurrence of two or more infections in a single day from one theatre or repeated post-operative infection under similar circumstances— with the same surgeon, staff or operating room.⁽⁶⁾ The visual loss and debilitation for patients affected can be severe and irreversible and an outbreak also has grave medico-legal implications for the eye care organization.

Outbreaks of Cluster endophthalmitis have been reported from across the globe, including several reports from India.^(7–14) Most reported outbreaks occurred after cataract surgery was carried out in outreach camp settings, although few incidences of cluster infections have also been reported in routine elective surgeries done in a controlled environment. Potential sources of these outbreaks usually include bacterial contamination from the surgical instruments, contaminated ophthalmic solutions like balanced salt solution, trypan blue dye, viscoelastic, intracameral injections and IOLs, phacoemulsification tubing, and probe.^(9,13,15–17)

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Outbreaks of cluster endophthalmitis have also been reported after intravitreal anti-VEGF therapy.⁽¹⁸⁻²⁰⁾ Over the past few years, intra-vitreous injections have become the most common procedure in ophthalmology, having revolutionised the management of several retinal conditions, such as diabetic retinopathy, age-related macular degeneration (AMD) and retinal vein occlusions.⁽¹⁸⁾ Complications associated with these procedures, although rare, are visually significant. Post-injection endophthalmitis is the most common complication after anti-VEGF injections, with an estimated risk of 0.008% to 0.06%.⁽²¹⁾ Most of these outbreaks occurred after Inj. Bevacizumab, the most commonly used 'off-label' agent for AMD, diabetic macular oedema, and retinal vein occlusions due to its affordability. Bevacizumab (Avastin) is commercially available in vials of 4ml, from which aliquots of the required dose are prepared to reduce the injection cost.⁽²²⁾ However, the risk of contamination while preparing the aliquots of bevacizumab is a cause of great concern as causative microorganisms can be introduced during the compounding process, leading to catastrophic complications like cluster endophthalmitis.

Prevention and elimination of post-operative endophthalmitis is a constant goal of every ophthalmic surgeon. Occurrence of an outbreak requires prompt and coordinated management to prevent vision loss and mitigate its impact on affected individuals and the eye care organization. Management of cluster endophthalmitis doesn't stop at aggressive clinical therapy to salvage the best possible vision for the affected patients. It calls for many interlinked actions and responsibilities on the service provider, including identifying the source of infection to prevent another outbreak and building psychosocial confidence in both the caregivers and care seekers.⁽²³⁾ Medico-legal issues related to an outbreak can seriously affect the healthcare provider. Hence a deeper understanding of the legal implications and media management are imperative to minimize the impact on the reputation of the organization.

1.2 SCOPE & OBJECTIVE

The primary objective of this guideline is to provide evidence-based recommendations for managing cluster endophthalmitis outbreaks effectively. It aims to enhance the understanding of risk factors, infection control measures and preventive strategies to mitigate the occurrence of cluster endophthalmitis. Additionally, it emphasizes effective measures to be adopted after an outbreak, including patient management, surveillance protocols and hospital image damage control.

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DEFINITION & IDENTIFICATION OF AN OUTBREAK

2.1 DEFINITION OF CLUSTER ENDOPHTHALMITIS

There is no exact commonly accepted definition of cluster endophthalmitis.

A broad definition is –“Suspect a cluster endophthalmitis when the incidence rate is significantly over that expected.”^[1] Several other guidelines have been provided for suspecting an outbreak. These are listed below.

AIOS /ESCRS guidelines definition^[2] -Two or more cases operated on the same day in the same operation theatre constitute a cluster endophthalmitis.

Suspect outbreak when analysis of the cases^[3] demonstrates a common organism, especially an unusual organism, or the same apparent underlying cause or concern

- Demonstrates the cases related clearly to only one team member, a particular instrument, theatre or consumables batch number
- Two or more cases have arisen during the same theatre list
- Cluster occurring over a very short period, e.g. days to weeks

Identification when a case of endophthalmitis occurs

- It needs to be determined whether it is a case of endophthalmitis.
- Whether it is a sporadic case or part of a cluster

Endophthalmitis or not?

Increased post-operative inflammation could be because of endophthalmitis, Toxic Anterior Segment Syndrome(TASS), or increased post-operative reaction. The hallmark of infectious endophthalmitis is severe and progressive vitritis associated with decreased vision, pain, lid edema, circum-corneal congestion, hazy cornea, diffusely distributed keratic precipitates and severe anterior chamber reaction.

TASS presents within the first 24 hours after surgery with a fibrinous reaction and a diffuse limbus to limbus corneal edema, there is less severe congestion, pain and anterior chamber reaction with little or no vitritis.^[4]

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Increased post-operative reaction may be expected in patients with prolonged or complicated surgery, children and those with previous uveitis or retained lens material. All cases of increased response, especially those with no explanation, should be treated as suspicious and followed up closely.

Each case of suspected endophthalmitis must be reviewed and documented for patient / environment / surgery-related risk factors and recommended management guidelines must be followed. Even if the diagnosis is TASS, an investigation similar to endophthalmitis should be initiated to pinpoint the offending cause.

Sporadic	Cluster
Incidence – endemic rates	Incidence- Significantly higher than the normal for region/ institution
Affects isolated random patient	Affects more than one patient, cluster
Gram positive cocci (<i>Staphylococcus sp.</i> , <i>Streptococcus sp.</i>)	Gram-negative organisms, (<i>Pseudomonas</i>), fungal
Usually commensals, Patient-related factors	More likely to arise from a common source of contamination

Table 2.1 Sporadic or Cluster Distinguishing features^[1,3,5]

2.2 IDENTIFICATION OF CLUSTER

Broadly, cluster endophthalmitis is defined as a rate significantly more than expected in the modern era. The expected rate is the incidence of sporadic endophthalmitis – institutional rates can be used if available or the country rate can be used. Currently, for India, the country rate is 0.08%-0.16%^[5], which is 1 in 1250 to 1 in 625.

It is important to note that clusters can occur over months and appear as random or sporadic cases.^[6] Hence it is important to be vigilant, actively monitor and keep count of all cases of endophthalmitis.

How much is significantly over?

Statistical methods or charts can help determine the statistically significant rate over the sporadic rate to ensure a sensible balance between complacency and overkill.

Statistical methods

The most commonly used and quoted statistical method^[7] from which were derived the 2007 Royal College guidelines and the famous green, amber and red response. This has also been adapted by the AIOS Taskforce Guidelines.^[1] It is based on the table of **probabilities** (see below). The value in each cell is the probability of observing X (or more) cases of endophthalmitis during N cataract operations, where cases are expected to occur with Poisson frequency and at a rate of 1 per 1000 operations (a rate of 1 per 1000 is assumed & accepted). Therefore, higher the probability, numerically more likely that this number of cases is within the range expected for the number of surgeries performed. Similarly, the lower the probability, higher the chance it is a cluster.

DEFINITION & IDENTIFICATION OF AN OUTBREAK

Number 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

Table 2.2 Probabilities of observing cases of endophthalmitis during cataract operations with Poisson frequency

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. A heightened vigilance should be in place

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. This may need to stop all surgeries except emergencies and where possible, close the operating room until cause identified.

Red alert: Two cases in ≤ 200 cases, three cases in ≤ 600 cases, four cases in ≤ 800 cases – call for a detailed investigation. This may necessitate the closure of operating rooms to investigate for the cause of the outbreak

Other statistical methods that have been considered include;

- Control Charts^[8], Regularly monitor the number of non-infected cases – when the number starts falling below 2, SD (Standard Deviation) declare an outbreak
- Binomial distribution, Bayesian statistics^[6]
- Monte Carlo Simulation^[9] Computer-generated simulation software

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PATIENT CARE IN CLUSTER ENDOPHTHALMITIS

3.1 APPROACH TO PATIENT CARE AFTER CLUSTER ENDOPHTHALMITIS

Post-operative endophthalmitis is a rare but vision-threatening complication after any intraocular procedure. Various bodies have defined cluster endophthalmitis; however, it would be prudent to follow the guideline of the All India Ophthalmological Society, which refers to the occurrence of two or more cases operated on the same day in the same operation theatre.^[1]

Worldwide the incidence of postoperative endophthalmitis ranges from 0.02% to 0.8%.^[2,3,4,5] In India, the prevalence ranges from 0.04% to 0.15%,^[6] and culture-positive endophthalmitis accounts for 0.02% to 0.09%.^[7] Causative factors could be from the external origin, including contaminated irrigating solution, povidone-iodine, IOL, viscoelastic, dyes, intraocular solutions, operative room environment, surgical instruments, IOL and Phacoemulsification machine, topical anaesthetics, cotton swabs and sterilisation failure or defective autoclaving.^[8]

Surveillance of such cases is integral to evaluating the cause and its prevention. When a red alert has been issued, the State Government Health Authorities will appoint a team of ophthalmologists and microbiologists to evaluate the cause and provide recommendations for further prevention.^[9]

There were no specific guidelines to date for patient care in cluster endophthalmitis; hence this guideline is intended to address the same. Care of patients begins as the patient walks in through the outpatient department.

3.2 STEPS TO BE FOLLOWED FOR EVALUATION OF PATIENTS

Patients' examination is prioritized in the OPD/ Emergency. You can consider admitting the patient if endophthalmitis is fulminant.

Patients are treated empathetically and patient attenders are also counseled.

A detailed history should be taken about the onset of symptoms and duration, prior medications, frequency and compliance. Case sheets of these patients are needed for the investigation and could be called for later by investigating agencies and these must be kept aside for safe keeping.

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Complete details of the patient, including name, age, sex, address, contact number etc. are collected. The preoperative work-up sheet is examined for the history of systemic infection, comorbidities etc.

1. The patient's general systemic condition and hygiene are documented.
2. Symptoms to suspect endophthalmitis include rapidly progressive symptoms, including pain, red eye, ocular discharge and worsening vision. Suspect in any eye with inflammation greater than the usual post-op course.
3. Presenting visual acuity is recorded meticulously as it helps in prognostication.
4. The ocular examination must include identifying any infective foci like lid infection; lacrimal sac syringing details etc.
5. Associations to be considered include,
 - a) Wound leak or dehiscence- especially a leaking small incision cataract surgery (SICS)
 - b) Suture abscess
 - c) Vitreous incarceration in the wound
 - d) Wound infiltration.
6. Common signs include; decreased visual acuity, lid swelling, conjunctival congestion, corneal edema, anterior chamber cells + fibrin, hypopyon, vitreous inflammation, retinitis, retinal hemorrhages and blunting of red reflex.
7. Ultrasound evaluation should be performed if significant vitritis or media opacity prevents an adequate fundus view. The findings consistent with endophthalmitis include-
 - a) Dispersed vitreous opacities with vitritis
 - b) Chorioretinal thickening
 - c) Assess for the presence of retinal or choroidal detachment, retained lens material, retained foreign bodies
 - d) Retinal or choroidal detachment is poor prognostic factors.
8. Toxic anterior segment syndrome (TASS) must be differentiated from cluster endophthalmitis-
 - a) Rapid onset (within 12-24 hours, often with limbus to limbus corneal edema)
 - b) Increased intraocular pressure
 - c) Absent vitreous inflammation
 - d) Response to steroid

3.3 OBTAINING SPECIMENS FOR MICROBIOLOGICAL STUDIES

- In Endophthalmitis Vitrectomy Study (EVS), vitreous samples yielded positive cultures more often than aqueous samples
- Aqueous samples yielded positive culture only in a small minority (4.2%) of eyes.

Vitreous Specimen

- Needle aspiration
- A 22 to 25G needle attached to a syringe is inserted into the vitreous cavity through the pars plana (pull the plunger back first to break the vacuum before inserting it into the eye).

- Slowly aspirate. If no fluid vitreous can be obtained with a needle tap, an anterior chamber (AC) tap or vitreous biopsy must be performed instead, to avoid aspirating formed vitreous
- This procedure can cause undue vitreous traction on the retina, increasing the risk of retinal breaks. Needle aspiration is thus avoided where there is access to a skilled ophthalmologist who can complete vitrectomy.
- Vitrectomy probe attached to a syringe is inserted into the vitreous cavity through a sclerotomy placed 3-4 mm posterior to the limbus
- Approximately 0.3-0.5 mL of vitreous is removed from the anterior vitreous cavity by using the automated cutting mechanism of the probe and slow, manual aspiration. Using the cutter reduces the risk of traction.

Anterior Chamber Specimen

- A 27 to 30G needle is inserted near the limbus into the AC
- 0.3 to 0.5 ml of fluid is withdrawn.
- AC should not be flattened. Do not aspirate the hypopyon as it is congealed and may not go through the needle.

Specimen Handling

- Immediate culture inoculation by the surgeon or laboratory is ideal for the recovery of organisms
- Inject the specimen deeply into liquid media to ensure the sample is within the media
- Antibiotic sensitivities are to be performed (in the EVS, vancomycin and amikacin empirically covered 99.4% of all infecting organisms).
- More recently, polymerase chain reaction (PCR) testing has been increasingly used to identify suspected pathogens in the sample. PCR testing requires the physician to specify the suspected organisms when requesting the test.

3.4. OPHTHALMIC MANAGEMENT OF CLUSTER ENDOPHTHALMITIS.

Based on the AIOS Task Force defined levels,^[10] stop surgeries whenever there are Two cases in ≤ 200 cases, three cases in ≤ 600 cases, four cases in ≤ 800 cases & investigate the cause for the outbreak.

When One case in 75 cases, two in 300–500 cases, three in 700–800 cases – urgent review of relevant factors. Get a complete microbiological work-up including subtypes and antibiotic sensitivity. Limit the cases operated to emergencies.

Treatment

Time is very crucial in diagnosing and treatment of endophthalmitis. Even with the slightest suspicion, treatment should be initiated as early as possible without waiting for microbiological results.

The Endophthalmitis vitrectomy study group (EVS)^[11] showed that immediate vitrectomy is not necessary for patients with the presenting vision better than Hand Movements (HM), measured as recognising moving the hand at 60 cm but is substantially beneficial for those with light perception-only vision.

Immediate Pars Plana Vitrectomy (PPV) vs Tap & Inject

- In the EVS, patients who presented with HM only visual acuity had a significant, threefold improved chance of obtaining 20/40 vision after immediate vitrectomy (33%) compared to tap and inject (11%)
- 56% of eyes achieved 20/100 or better after immediate PPV compared to only 30% after Tap
- HM or better vision demonstrated no significant difference between the treatment groups in final visual acuity (consider earlier PPV for diabetics).
- Early vitrectomy is preferable in eyes with no fundus view or where there is no improvement after 2 or more intravitreal injections.

Pars plana vitrectomy (PPV) in endophthalmitis

- Advantages: reduction of infecting organisms, toxins, inflammatory materials and opacities. Allows a more robust collection of samples for culture
- Disadvantages: Need for sophisticated equipment and operating room time / staff. Visualization may be poor due to corneal edema / opacification, posterior synechiae, and dense vitreous debris.

Pars plana vitrectomy steps

- Standard 3 port setup
- A vitreous sample of 0.2-0.5mL is first obtained without infusion using gentle manual aspiration into a syringe - this yields an undiluted vitreous specimen
- Infusion is then initiated and core vitrectomy performed
- The AC is cleared for visualization as necessary
- In most cases, IOL need not be removed initially
- Aspiration of debris within the capsular bag, if able to be performed safely, is also helpful
- In the EVS, attempts were made to clear 50% or more of the vitreous.
- Also, in the EVS, no attempt was made to induce a posterior vitreous detachment if none was previously present

The correct choice of antibiotics depends upon culture-sensitivity reports, which would take a few days. The current rationale is to inject two antibiotics, one directed against gram-positive and another against gram-negative organisms. The current choice of intravitreal antibiotics includes- Vancomycin 1.0 mg/0.1 mL with Ceftazidime 2.25 mg/0.1 mL or Amikacin 0.4mg/0.1ml. Change of antibiotics is guided later after culture-sensitivity reports (Refer to Table 1).

Alternative intravitreal antibiotics in case of resistance to standard regimen include the use of oxazolidinone (linezolid), cyclic lipoglycopeptide (daptomycin), glycylicycline (tigecycline), carbapenem (imipenem) and fluoroquinolones (moxifloxacin, ciprofloxacin and levofloxacin)^[12], piperacillin-tazobactam. (Refer to Table 2).

Though the EVS did not demonstrate any additional benefit of systemic antibiotics in endophthalmitis, recent studies have shown the efficacy of systemic fluoroquinolones as they cross the blood-retinal barrier.^[13, 14] The recommended systemic antibiotics include meropenem (1gm., IV, every 8 hours), ceftriaxone (2 gm, IV, every 2 hours) + vancomycin (1g, I, every 12 hours).^[15]

Intravitreal corticosteroid has been recommended in a few studies, the same or one day after intravitreal antibiotics to tackle the inflammatory component associated.^[16,17] Systemic antibiotics can also be considered in people with diabetes and gram-negative infection.

Considerations of reinjection

- If the infection fails to stabilize or improve more than 48 hours after the first injection
- The EVS protocol recommended reinjection if the infection worsens 36-60 hours after the initial injection. If worsening or not improving, we can consider vitrectomy.
- Change of antibiotics to be considered once culture and sensitivity results are available.
- Repeat injection may increase the risk of retinal toxicity

3.5 PROGNOSIS

Visual prognosis depends on the type of organism and its virulence. Commonly isolated organisms from culture are gram-positive, coagulase-negative organisms, including *Staphylococcus aureus*, *Streptococcus* spp. and *Enterococcus* species. Other organisms include gram-negative bacilli and fungi. Though gram-negative organisms commonly *Pseudomonas* spp. constitutes 6% of cases, due to its high virulence and antibiotic resistance, it is associated with poor visual outcomes.^[18]

In the EVS, eyes with coagulase-negative *Staphylococci* were most likely to obtain 20/100 final visual acuity or better (84%). More virulent organisms, such as *Staphylococcus aureus*, *Streptococcal* species and gram-negative (*Pseudomonas*) organisms, were associated with worse visual outcomes.^[11]

3.6 ANTIBIOTIC RESISTANCE

A recently published study estimated an increasing antibiotic resistance of *Pseudomonas* spp. to fluoroquinolones, amikacin and ceftazidime in endophthalmitis, including an alarming increase in multi drug resistance, particularly in post-surgical patients.^[19] Despite aggressive treatment, prognosis in *Pseudomonas* endophthalmitis cases remains poor, with many cases requiring enucleation^[20] Rare reports of *Burkholderia contaminans* outbreaks have been described as occurring due to contamination of pharmaceutical products; its resistance to most antibiotics by its ability to colonize the lens capsule and formation of biofilm can cause significant problems in its management.^[21]

Usually, the incidence of endophthalmitis is very low in vitrectomized eyes, especially if silicone oil is used as a tamponading agent. A rare case report of *Pseudomonas* endophthalmitis has been reported following pars plana vitrectomy in a silicone oil-filled eye caused by *Pseudomonas aeruginosa* that was treated with piperacillin / tazobactam.^[22]

Several recent reports of endophthalmitis due to vancomycin-resistant *Staphylococcus aureus* and *Enterococcus* spp. have been reported,^[23,24,25] which responds well with Intravitreal quinupristin / dalfopristin^[26, 27, 28] and Intravitreal daptomycin in recalcitrant cases.^[29, 30, 31]

This part of the guideline has been drafted keeping in mind recent evidence and preferred practices. We understand that protocols would vary from institution to institution. While the patient is being managed following these norms, it is important to limit the cluster by ensuring the OT is limited or stopped until the root cause is ascertained. Early identification and treatment could help salvage function and structure. It is also important to alert other consultants / colleagues using the same operating room / theatre and inform the Senior Management of the hospital about the outbreak.

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The centre should conduct a surveillance of all patients operated on the days of the presumed cluster to proactively identify and treat any other patients of presumed endophthalmitis. The centre could also ideally liaise with a centre with capabilities of handling such cases. This would make it logistically easier to analyse outcomes and arrive at presumed etiology apart from ensuring that the patients have been provided the best possible care.

Tables 3.1: Commonly used intravitreal antibiotics after endophthalmitis

Antimicrobial agent	Name of drugs	Class of drugs	General spectrum of action	Mechanism of Action	Intravitreal dose
Antibiotics	Vancomycin	Glycopeptide	Gram-positive cocci, MRSA, clostridium, diphtheroid	Vancomycin acts by binding irreversibly to D-alanyl-D-alanine moieties of the N-acetylmuramic acid (NAM) and N-cetylglucosamine (NAG) peptides. Inhibits synthesis and cross-linking of the NAM / NAG polymers that form the backbone of the Bacterial cell wall.	1 milligram/ 0.1ml
	Ceftazidime	Cephalosporin (3rd generation cephalosporin)	Gram-negative cocci, Gram positive bacilli, gram-negative bacilli, pseudomonas aeruginosa	Ceftazidime interrupts cell wall synthesis via affinity for penicillin-binding proteins (PBPs).	2.25 milligrams/ 0.1ml
	Amikacin	Aminoglycoside	Gram-negative bacilli, pseudomonas aeruginosa	Amikacin interrupts bacterial protein synthesis by binding to the 30S ribosome of susceptible organisms.	0.4 milligram/ 0.1ml
Antifungals	Amphotericin-B	Polyene	Candida sp., Aspergillus sp., Fusarium sp., dematiaceous fungi	Amphotericin B binds with ergosterol, a component of fungal cell membranes, forming pores that cause rapid leakage of intracellular material and subsequent fungal cell death.	5-10 micrograms/ 0.1ml

	Voriconazole	Azole	Filamentous fungi, Yeast, Candida sp., Fusarium sp.	Voriconazole causes inhibition of cytochrome P450 (CYP 450)–dependent 14 α - lanosterol demethylation, a vital step in cell membrane ergosterol synthesis by fungi.	50-100 micrograms/ 0.1ml
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Table 3.2. Alternative antibiotics for use in case of drug-resistant endophthalmitis ^[12]

Organisms	Name	Class of drugs	General spectrum of action	Mechanism of Action	Intravitreal dose
Gram-positive organisms (GPO)	Linezolid	Oxazolidinone (fermentation by product of Streptomyces roseosporus)	Vancomycin resistant enterococci, methicillin resistant staphylococcus aureus	Inhibits initiation of protein synthesis by binding 23S rRNA of the 50S subunit of bacterial ribosome.	300 micrograms/ 0.1ml ^[32] (rabbits)
	Quinupristin /dalfopristin	Streptogramin (iso lated from Streptomyces pristinaspiralis)	Vancomycin resistant Enterococcus faecium, methicillin resistant staphylococcus aureus	Inhibits bacterial protein synthesis by interfering with function of 23S RNA (quinupristin : dalfopristin =3:7)	0.4 milligram/ 0.1ml ^[26- 28] (rabbits and case reports in humans)
	Daptomycin	Cyclic lipoglycopeptide	Vancomycin resistant Enterococcus faecium, methicillin resistant staphylococcus aureus, glycopeptide intermediate staphylococcus aureus, coagulase negative staphylococci, penicillin resistant streptococcus pneumoniae	Terminates bacterial DNA, RNA and protein synthesis and cell death by forming trans-membrane channels in cell membrane and depolarization of membrane potential.	200 micrograms/ 0.1ml ^[29-31] (case report in humans)
	Tigecycline	Glycylcycline (a derivative of minocycline)	Vancomycin resistant Enterococcus faecium, methicillin resistant staphylococcus aureus, glycopeptide intermediate staphylococcus aureus, coagulase negative staphylococci, penicillin resistant streptococcus pneumoniae	Inhibits bacterial protein synthesis by irreversibly binding to 30 S ribosomal unit	0.5-1 milligrams/ 0.1ml ^[33] (rabbits)

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Gram-negative organisms (GNO)	Imipenem	Carbapenem	Pseudomonas aeruginosa, K. pneumoniae, Enterobacter sp., Bacteroides sp., Fusobacterium sp., Also works on gram positive microorganisms such as S aureus, Streptococcus sp.,	Interrupts cell wall synthesis of various GPO & GNO and is a strong inhibitor of β - lactamases from some GNO resistant to most β - lactam antibiotics.	50 micrograms/ 0.1 mL ^[34,35] (case series in humans)
	Ciprofloxacin	Fluoroquinolones	Pseudomonas aeruginosa, Neisseria sp., Enterobacteriaceae sp., Also works on methicillin susceptible Staphylococcus aureus, streptococcus pneumoniae	Inhibition of the enzymes topoisomerase II (DNA gyrase) and topoisomerase IV, which are required for bacterial DNA replication, transcription, repair and recombination.	0.1 milligrams/ 0.1ml
	Levofloxacin	Fluoroquinolones	Pseudomonas aeruginosa, Neisseria sp., Enterobacteriaceae sp., Also works on methicillin susceptible Staphylococcus aureus, streptococcus pneumoniae	Same as above	0.1 ml of 0.5% ophthalmic solution ^[36] (rabbits)
	Moxifloxacin	Fluoroquinolones	Pseudomonas aeruginosa, Neisseria sp., Enterobacteriaceae sp., Mycobacteria sp., Also works on methicillin susceptible and resistant Staphylococcus aureus, streptococcus pneumoniae	Same as above	0.2 Milligrams / 0.1ml ^[37] (case report in humans)

Fungi	Miconazole	Azole	Candida sp., Fusarium, Curvalaria, and Aspergillus	Effects on respiration and cell permeability. It inhibits the growth of several species of Candida.	25 micrograms/ 0.1ml ^[38] (case series in humans)
	Caspofungin	Echinocandin	Candida sp. Resistant to azoles or Amphotericin B Aspergillus sp.	Blocks the synthesis of $\beta(1,3)$ -d- glucan of the fungal cell wall by non-competitive inhibition of the enzyme $\beta(1,3)$ -d- glucan synthase. $\beta(1,3)$ - d- Glucan is an essential component of the cell wall of numerous fungal species.	50 micrograms/ 0.1 ml ^[39, 40] (rabbits and mice)
	Micafungin	Echinocandin	For mild cases of Candida glabrata endophthalmitis	It inhibits an enzyme essential for fungal cell wall synthesis.	0.025 milligrams/ 0.1 ml (rabbits)

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COMMUNICATION WITH STAKEHOLDERS

4.1 DEALING WITH THE PATIENTS AND RELATIVES

Communication in the background of suspected endophthalmitis requires professionalism, patience and empathy, like when communicating any news that can negatively impact a patient's future. This becomes more challenging when there is a cluster and there is an element of fear that the eye care system in which the patient has sought care may have a part to play in the origin of the condition, subsequent treatment and the final outcome. Adding to the challenge is that the eye care provider is also facing psychological stress but must provide accurate, adequate, but sensitively delivered communication.

Once there is a suspicion of a cluster, communication must be tailored for each patient at risk depending on the extent of involvement.

There are many ways described to achieve the two important goals of ;

- a) Initially finding the right kind of words with understandable terminology, assessing the reaction from patients and caregivers and
- b) Subsequently tailoring information to inform the patient of the hope for the future regarding the treatment plans and expected outcomes.

The usual way is to determine what the patient knows, wants to know, give information in understandable amounts, react to the news and check for understanding.

However, an outbreak of a cluster poses the added challenge of rapid change in scenario, paucity of time in making difficult decisions and added treatment costs if a vitrectomy is indicated, which would not have been part of the original discussion.

It is recommended that the head of the unit or a senior consultant known to the patient or family communicate with the patient and caregivers.

4.2 SPIKES PROTOCOL

The SPIKES (Setting up, Perception, Invitation, Knowledge, Emotions with Empathy and Strategy or Summary) Protocol by Walter Baile has been widely used for the breaking of bad news in scenarios related to cancer but can be adapted for use in a situation like a cluster outbreak. The following section with each of these elements.

4.2.1 Setting up

The Team will discuss what to say before the conversation, including the vocabulary to be used, as it is important to be consistent among the team members. This is to be kept in mind even if one team member communicating mainly, as patient and caregivers will approach others in desperation, especially if the situation demands.

The physical space where communication takes place should preferably be a quiet place with no digital distractions, personal or public.

Remember to introduce yourself. The preferred body language for optimal communication includes sitting while speaking, maintaining an open posture and maintaining eye contact. The physician must minimise nervousness in tone and body language.

4.2.2 Perception

This will have been initiated during the informed consent process, where the possibility of infection, however low, has been mentioned.

It becomes challenging when the person communicating has not been a part of the original team obtaining the informed consent, so it would be advisable to have one such member present during the communication. It is important to be empathetic to the context and respect any coping strategies but provide sufficient information for further consent for diagnostic and therapeutic interventions.

4.2.3 Invitation

Ask the patient if he or she wishes to know the details of the medical condition and / or treatment, also requesting permission to share information.

Refer to the team collectively as 'we' rather than 'I' when referring to the provider. This becomes relevant in endophthalmitis as the eye care provider reviews information from several patients and comes to inferences, investigating and sharing available knowledge, sometimes publicly.

4.2.4 Knowledge

It is a good practice to use simple words to warn the patient when suspecting endophthalmitis or investigating patients who are not clinically symptomatic.

The information shared should be timely and updated at regular intervals. Periodically check patients' understanding. Be prepared for further questioning.

4.2.5 Empathy

Responding to the emotion expressed on receiving news of possible / probable / definite infection and its aftermath needs to be done with empathy and respect.

4.2.6 Strategizing for the subsequent steps

After summarizing the information provided so far, if the patient is ready for discussion, move on to an immediate treatment plan and escalate subsequently as necessary. Share responsibility for decision-making.

4.3 ANOTHER SIMPLE MODEL, that could be used is

- a) Prepare
- b) Assess understanding
- c) Disclose news
- d) Respond to emotions
- e) Offer to discuss implications
- f) Offer additional resources, including talking to more people
- g) Summarise
- h) Arrange a follow-up time
- i) Document the discussion in the medical record.

The last two additions in this model are crucial to communication regarding cluster endophthalmitis. It is equally important not to make judgmental comments, distort the truth, withhold or overload with information and most importantly, give false reassurances.

Effective communication with the patient and caregivers with honesty, empathy and concern reassures the family and physician. It protects from the onslaught of information or misinformation that the media may publicly share.

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INVESTIGATION INTO THE CAUSE

In every case of endophthalmitis, it is necessary to understand the possible causative factors. While a team could be established, the broad principle includes collecting information and reviewing each individual case to look for potential risks and causative factors. Patient care takes priority as you continue to take corrective and preventive action.

5.1 TEMPLATE FOR INFORMATION COLLECTION

The below template that could be used to collect information.

Preliminary details

Patient name :

Age / Gender :

MRN :

Place / Camp :

Any existing systemic illnesses :

Any earlier eye surgeries :

Pre-operative details:

Pre-op complaints :

Visual Acuity (UCVA & BCVA): LE

RE Clinical features:

B-Scan findings (if done) :

Pre-op medications (if any) :

Syringing /ROPLAS done: Yes / No If yes, status of NLD :

Intra Operative details:

Name of surgery:

Duration of surgery :

IOL type :

Details of medications used during surgery :

Order in the list of cases operated in that OT :

Quality of BSS checked against light :(if sample available from batch used or actual unit)

Batch no. of RL / BSS:

Expiry date of RL/ BSS used :

Batch no. of Visco:

Expiry date of Visco:

If suture used, Batch no. of Suture :

Expiry date of Suture :

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Suture was : Fresh/Autoclaved
Name of operating Surgeon :
Assisted by: Dr. Assistant staff :
Circulating staff :
Block administered by :
OT number :
Table (Left/right) (if applicable) :

Post - Operative Inflammation Details:

Date of post op inflammation :
Signs and Symptoms :
Investigations:
Patient-related Investigations done :
Investigation Results :

5.2 POSSIBLE RISKS OF CLUSTER ENDOPHTHALMITIS

Cluster endophthalmitis is defined as per the ESCRS and AIOS guidelines, two or more cases operated on the same day in the same operation theater (OT).

The following are the most probable causes of cluster Postoperative endophthalmitis (POE);

- a) Inadequate sterilization is an important cause of large-scale cluster infections, particularly if most cases operated on a given day are affected.
- b) Contamination of the irrigating fluids used during the surgery is the second common cause.
 - Usually, the gram-negative organisms are responsible - the commonest is *Pseudomonas aeruginosa* - from the irrigating fluids, Trypan blue solutions or viscoelastics.
 - The common association of *P. aeruginosa* is related to its capacity to reproduce in the presence of little or no nutritional substrates except water.
- c) Contaminated internal tubing of the Phacoemulsifiers is another common cause. Here again, *Pseudomonas* spp. is the commonest organism.
- d) Contaminated environment like the floor or the walls or the air conditioning system is usually not the cause of cluster infections. Though there have been instances of contamination from AC filters.

Risk Factors to be checked in case of cluster infection:

Sl.	Risk factors	Odds ratio
	Intra cameral inj. Cefuroxime given or not *	4.92
	Clear corneal vs. Scleral incision	5.88
	Type of wound closure (suture or suture less)	No evidence found
	Type of IOL material#	3.13
	Diabetic or non-diabetic	No evidence found
	Immune suppression or not	No evidence found

Equipment sterilization, disposable or reusable	No evidence found
Complication of surgery	4.95
A laboratory report of bacteriology specimen grows an organism that has a potential to affect many and causes an alert, e.g. Pseudomonas	
Two or more patients have an infection attributed to a species	
Inadequate autoclaving	

*as per current protocols, Vancomycin and moxifloxacin are used now

silicone intraocular lens were shown to have higher incidence, When using PMMA or Foldable lenses through a scleral incision, care should be taken to prevent ocular contamination.

5.3. MODEL OF INVESTIGATION

A Model of Investigation	
1.	Assemble an Investigative Team
	Act quickly and decisively to assemble a multidisciplinary team comprising of staff involved from the clinical and managerial disciplines. The team should meet regularly and scrutinize concern areas carefully.
2.	Determine the cause of the outbreak
	Identify common factors because 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). ¹⁹⁻
3.	Draft new protocol and recommendations
	We recommend the following main areas of investigation: (1) theatre environment; (2) pre-, peri- and post-operative practices; (3) instrument cleaning and sterilization; (4) equipment maintenance and (5) documentation, (6) handling and administration of medications, (7) Hand hygiene. New protocols should aim to overcome risks detected in the above areas. The importance of documentation cannot be over emphasized and is extremely useful in
	determining if any endophthalmitis cases contain common factors. For example, if all the cases occurred in one of the two theatres, it would indicate a focus of contamination in that theatre. 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 introducing new protocols is essential to monitor their effectiveness. The microbiology department must conduct continuous sampling of instruments to ensure a safe environment. Routinely educate patients, clinical and nursing staff to be highly alert to symptoms of Endophthalmitis. To prevent further outbreaks, it is necessary to exercise constant vigilance in detection, compliance with the protocols and scrupulous monitoring.

5.3.1 Constituting an investigating team

Whenever there is a cluster endophthalmitis, it becomes imperative to take immediate corrective action, look at the root cause that could have triggered the same and initiate preventive measures. Towards this, there is a need to constitute an Investigation Team. Immediately an Investigative team consisting of the following individuals can start the investigation:

- a) Ophthalmologist (Operating surgeon)
- b) Microbiologist (If available within the organisation)
- c) Theatre nursing staff (theater in-charge)
- d) Hospital manager
- e) A person qualified in infection control (if available)

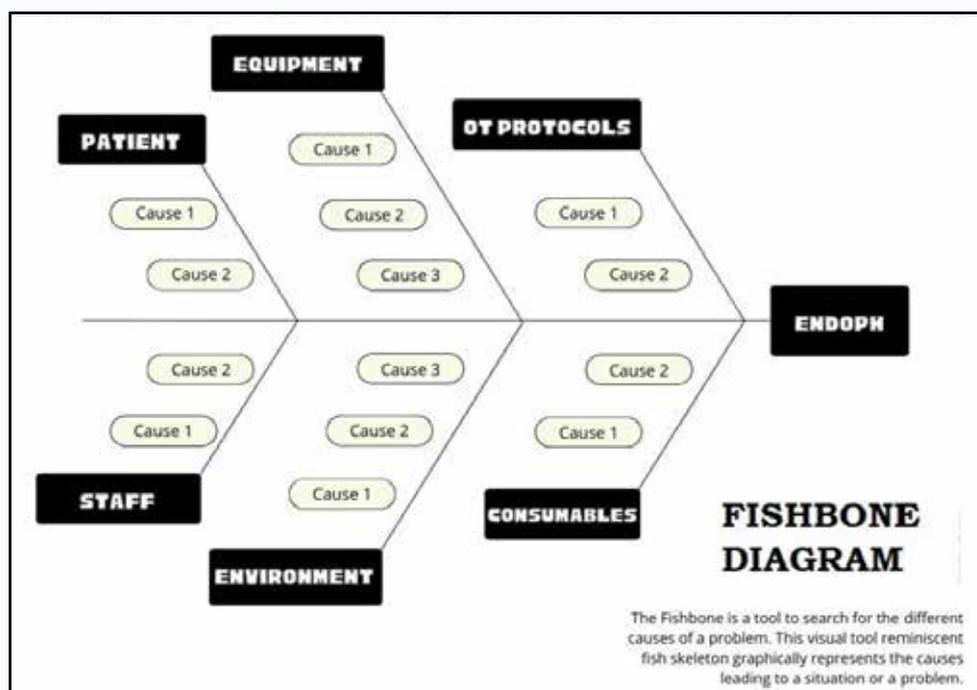
Once the (state / governmental) authority is informed, they may create an investigative team comprising of personnel as follows. Typically this investigative team would consist of:

- a) Ophthalmologist (Operating surgeon)
- b) Microbiologist (external local)
- c) Theatre nursing staff (theater in-charge)
- d) Hospital manager
- e) State Health Society representative (Preferably Ophthalmologist)
- f) A person qualified in infection control (if available)

Official spokes person: The investigation team to designate one person from the team – generally the hospital manager (to respond to media after the committee’s initial report in 24 hours).

5.3.2 Areas of Investigation & Root Cause Analysis

Do a brain storming session with concerned stakeholders and mention the possible reasons for endophthalmitis in the Fishbone analysis format below.



There could be various reasons contributing to endophthalmitis cases which can be listed under different categories.

- Environment around OT.
- Ongoing construction work around the operation theatre.
- Use of eye operation theatre for other than eye surgeries
- Pre, Intra, and post-operative practices (whether adhered to)

5.3.2.1 Preoperative Practices

- Lids and conjunctival sac prepared with 10% povidone-iodine.
- 5% Povidone Iodine instilled in the eye
- Thorough face wash done with soap
- All pre operative work up done on the previous day – contact procedures in particular.
- Proper application of the surgical drape to cover the eye lashes and eye brows.

5.3.2.2 Intra operative Practices

- Movement and access to theatres
- Everybody properly attired – Use OT dress, cap, mask and shoes
- It has been shown that face masks reduce bacterial Eye contamination of the peri operative area
- Routine practices, e.g. saline cups, instruments exposed for long periods etc. Reuse of instruments as per policy. Confirm sterilisation of these instruments.
- Confirm the use of a fresh set of instruments for each case.
- Information like the patient records, Surgeon's / assisting staff's name, Date and OR number, Type of surgery, IOL & saline batch number etc.
- Logbooks OR registers: duty roster, autoclave, presumed infection registers.

5.3.2.3 Post-operative practices

- Check for wound leak
- Re-surgery records & surgical notes
- Recording of intraocular tension
- Post operative care, change of dressing where relevant
- Application of medicine methodology & safe practices.

5.3.2.4 Cleaning and sterilisation 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 of consumables
- Proper functioning of the equipment e.g., Phacoemulsification, irrigation / aspiration handpiece and sensors.

5.3.2.5 Microbiological screening

- By taking culture from all appropriate places.
- Inspect all Sterile items – cannula, Visco elastics, Ringer Lactate or Balanced Salt Solution. If any container like drums are used for instruments to be autoclaved , sterile trolley, surgeon & assistant’s gloves – gown, microscope cap, etc.
- Unsterile items like the table, door, water, A.C., floor, shelves for drums and scrub area.
- Significance of the organisms identified must be decided.

5.4 CAPA REPORTS OF CORRECTIVE & PREVENTIVE ACTIONS

Correction / Management (Immediate action) – Document what has been done for the patient and also any immediate action taken based on the root cause analysis. This could include,

- Medical management of patient takes priority & should be completely documented
- Any surgical intervention needed and done. Consents for the interventions.
- Any other cases of infections reported on the same day.
- Need to send any offending agent found for further analysis. This too should be documented
- Based on the magnitude (Amber or Red) , a decision is made if surgeries should be discontinued and action is taken to prevent further infections.

Learning / Preventive action : (Action taken to prevent the occurrence of such incidents)

5.5. TO SUMMARISE - HOW SHOULD WE INVESTIGATE AN OUTBREAK?

- a) An outbreak is an infection control emergency; measures should be taken as soon as an outbreak is suspected. Begin preliminary evaluation and determine a baseline rate of infection.
- b) Confirm the existence of an outbreak. Alert other consultants / colleagues who are using the same OR. Inform Senior management of the hospital about the outbreak.
- c) Confirm the diagnosis using microbiological methods. Ensure cultures are taken from vitreous and aqueous samples and the culture plates are preserved. Ask the microbiology department to fully subtype any organisms grown from the second & subsequent cases (also the first, if the cultures have not yet been discarded). Send samples to a facility where it is possible.
- d) Develop line listings by identifying and counting cases of endophthalmitis. Describe the data in terms of time, place and person. Remember that cases may have been discharged from the hospital.
- e) Take immediate control measures; cross-check all the patients operated on the same day; look at changes that may have affected the infection rate, e.g. new staff, new procedures, new laboratory tests and health care worker to patient ratio, etc. Treat all affected patients and follow up with all others who have been operated on the same day or in the same operation theatre as the affected patients.
- f) Check all the cannulated instruments and if required, change them. Ask the company service engineers to check the internal tubing of the Phacoemulsifiers - peristaltic type (the older generation). Check Autoclave functioning with biological markers.

- g) The infection control committee should urgently review all likely relevant factors. If a formal committee is not in place - Ophthalmologist (Operating surgeon), Microbiologist (If available within the organisation), Theatre nursing staff (theater in-charge), Hospital manager, and a person qualified in infection control (if available) constitute the committee.

Ensure that you,

- Communicate information to relevant personnel
- Screen personnel and environment as indicated
- Write a coherent report (Preliminary and final).
- Summarize the investigation and recommendations to the appropriate authorities.
- Implement long-term infection control measures for the prevention of similar outbreaks.

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REPUTATION MANAGEMENT AT THE TIME OF A CRISIS

6.1 INTRODUCTION - REPUTATION

“The way to gain a good reputation is to endeavor to be what you desire to appear.” Socrates.

Every organisation dreads being in the media spotlight for the wrong reasons.

As soon as an outbreak occurs, most eye institutions undergo a media trial, with headlines that scream about their negligent act or would blame the operating surgeon. Even though, in many cases, there is evidence to show that due process was followed and other extramural causes had been the reason for the outbreak, the negative coverage tarnishes the image of the institution that would then take years to recover.

Two things are critical for all hospitals – the trust and reputation it enjoys with their stakeholders. Patients decide where to get their eyes operated based on what they hear from their neighbours and relatives. It takes years for the hospital to gain the trust of the community.

6.2 INFORMING WELL-WISHERS

While patients and their caregivers are key stakeholders, we should not forget our employees, suppliers, governmental and other service agencies supporting our eye care activities and finally, the donors.

Once a hospital’s reputation is damaged, it would be challenging to recruit quality human resources, including ophthalmologists, optometrists, admin, and support staff, as no one would want a tainted institution as part of their resume. Reputation management is crucial for hospitals since a good reputation can reduce the negative effect that adverse events can have on the perceptions of patients¹. Damage to the reputation can also affect the financial situation of a hospital. Since most institutions involved in community eye care partly depend on philanthropy and grants as a source of income, a threat to the hospital’s reputation will affect the hospital’s ability to raise funds².

We need to remember that since experience is a source of information, reputations can be formed by them, even though the public does not experience it directly, as long as this is passed on through word of mouth or via the media or other publications. How we treat our patients today can help form a positive reputation that could help us during any such crisis³.

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Things happen quickly during a crisis, but certain common factors⁴ will arise regardless of the reason for the crisis:

- There is insufficient information about the incident and what is being done. While there will be pressure to respond for the hospital simultaneously, there is a tendency for others to speculate.
- You can easily lose control of the message or the narrative. Rumors fly across all communication channels, each telling their side of the story that may not necessarily be accurate.
- In today's connected world, things will escalate quickly. Video and photos get shared almost instantly on social media and opinions get formed before you even have a chance to decide how to respond to the crisis at hand.^[5]
- There will be intense public scrutiny from the media and community members, considering the immediate impact on vision, which may sometimes be irreversible. There will be a demand for answers.
- Difficult and potentially hostile questions will be posed to us and it is natural to sound defensive and instinctively blame others as we feel attacked.
- While an outbreak crisis is immediate, it's a fire you must put out. We must remember that the damage from that fire can have a long-term impact on your reputation.

6.3 HAVE A PLAN READY

Rather than trying to figure out what to do in the middle of one. Do not be caught off guard. Your crisis plan should include the following:

- a) Designate the members of your crisis team and outline each team member's responsibilities. For example, who will speak to patients and attenders? Who will communicate to any hospital that patients are being referred to? Who will be the interface with any partner organisation involved in the outreach activities? Have the government agencies been notified if there is a cluster impending.
- b) Create checklists for various scenarios. What is the immediate care for the patient with endophthalmitis? What is the protocol for the transfer of patient(s)? What is the investigation modality of the consumables, process and theatre environment? Ensure that the registers and documents we need are available – patient records, inventory, purchase levels and microbiological surveillance.
- c) Have readily accessible stakeholder contact information. This would be partners, government officials, the senior leadership of the organisation, key opinion leaders among the eye care fraternity that could help, local Indian Medical Association leadership, VISION 2020 India, local professional body leadership and AIOS leadership who may be able to step in and support.
- d) Create a template for media statements and social media posts. You should have a template handy that can be used for the media interaction that mentions briefly:
 - Remember to apologize first and then act. Extending a heartfelt apology is a key step to moving forward. Not doing so adds fuel to the fire and delays changing the narrative in your favour.

- What was the incident and how many patients were impacted?
- What have you done to ensure their care and recovery are optimum
- What proactive measures have been taken to identify the root cause and that this is an investigation in progress.

If you have an existing plan, update it at least twice a year. Conduct training runs, if possible, so everyone knows what to do when a real crisis happens. Engaging a public relations firm that specializes in crisis communications and could interface with media could also be considered if you would have the ability to do so.

You must respond rapidly and transparently. The longer you wait, the more time you give someone else to frame the story.

Accuracy is important. Ensure you have all facts and only comment; inform others of what you are sure of. Where you don't know an answer, it is important not to hazard a guess or speculate.

Always express concern and compassion to the patients and their caregivers for whom the situation is dreadful and can be exhausting. You mustn't get defensive nor deflect the blame on others.

We often see on television, the spokesperson being escorted from the media softly saying, "no comment," this could work against you. Where possible, share information based on the guidelines above. Even if you're still assessing a situation, simply say that.

One that worsens this crisis is to present an un-unified front. When people hear varying stories from an organization, it starts to feel untrustworthy and disorganized. Avoid Knee-Jerk Reactions and freeze all external communication until you assess what's happening.

It does not help if you have the best of plans, but one of your staff goes and gives a media interview based on the information he/she has. We must ensure that the first external communication following the crisis is a well-thought-out response.

How would I feel if this happened to me? Stepping into the shoes of those affected often will help us get the proper perspective and ensure our responses and actions are correct.

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7.1 WHAT ARE THE LIABILITIES OF AN OPHTHALMOLOGIST AFTER GETTING A CLUSTER ENDOPHTHALMITIS?

Any medical practitioner is liable if s/he falls short of administering standard and due care on criminal and civil grounds. Medical Negligence can also be tried under the Indian Contract Act, 1872, Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002, the Consumer Protection Act, 2019 and various other legislations and regulations. Supreme Court, the apex judiciary in India, has the final say.

7.2 WHAT IS THE DEFINITION OF MEDICAL NEGLIGENCE?

Hon'ble Supreme Court in *Jacob Mathew vs. State of Punjab*, defined medical negligence as "the breach of duty caused by the omission to do something which a reasonable man, guided by those considerations which ordinarily regulate the conduct of human affairs would do or doing something which a prudent and reasonable man would not do."

Medical negligence is thus defined as a medical professional's conduct or omission (failure to act) that deviates from the established medical 'standard of care' or that of a reasonable person, resulting in harm or injury to another person (here, the patient). In other words, medical negligence is the '*failure to follow a reasonable standard of care by a healthcare professional*.' The type of medical service offered, the practitioner's expertise, training and experience and even the location of the treatment may all be considered when defining the acceptable level of care.

7.3 WHAT CRIMINAL PROCEEDINGS CAN BE TAKEN AGAINST AN OPHTHALMOLOGIST AFTER CLUSTER ENDOPHTHALMITIS?

The provisions of the *Indian Penal Code (IPC), 1860*, are broad in nature and do not expressly deal with "medical negligence." However, certain sections can be used to establish criminal culpability. For example, section 304A of the IPC (deals with the death of a person as a result of any rash or negligent act and carries a maximum sentence of two years in prison) is applied to both cases of accidents caused by rash and negligent motor vehicle driving and cases of medical negligence resulting in a patient's death. Other general provisions of the IPC, such as sections 337 (causing harm) and 338 (causing grievous hurt), are also frequently invoked in medical negligence trials.

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Supreme court judgements on medical negligence under criminal law in Jacob Mathew vs. State of Punjab case. There must be a gross or very high degree of negligence, resulting in more damages. Gross negligence can be described as *'the severe disdain for or reckless disregard for the safety of others.'* The term encompasses more than just carelessness or inaction. Thus, there must be an incidence of deliberate act that has the potential to cause foreseeable harm.

There must be an element of *mens rea* (guilty mind) or recklessness.^[3] The practitioner must have done or omitted to do something no sensible and prudent medical professional would have done or omitted to do in the given facts and circumstances.

7.4 WHAT ARE THE SUPREME COURT DIRECTIVES ON MEDICAL NEGLIGENCE?

Kusum Sharma vs. Batra Hospital and medical research centre: Two judge supreme court panel suggested that when determining whether a medical professional is guilty of medical negligence, the following principles must be borne in mind:

- Negligence is the breach of a duty exercised by omission to do something a reasonable man, guided by those considerations that ordinarily regulate the conduct of human affairs, would do or do something a prudent and reasonable man would not do.
- The negligence to be established by the prosecution must be culpable or gross, not the negligence merely based upon an error of judgment.
- The medical professional is expected to bring a reasonable degree of skill and knowledge and exercise a reasonable degree of care.
- A medical practitioner would be liable only where his conduct fell below the standards of a reasonably competent practitioner in his field. One professional doctor is not negligent merely because his conclusion differs from that of another professional doctor.
- It would not be conducive to the efficiency of the medical profession if no doctor could administer medicine without pressure and stress. It is our bounden duty and obligation of civil society to ensure that medical professionals are not unnecessarily harassed or humiliated so that they can perform their professional duties without fear and apprehension.
- Medical professionals are entitled to protection as long as they perform their duties with reasonable skill and competence and in the interest of the patients. The interest and welfare of the patients have to be paramount for medical professionals.

State of Punjab vs. Shiv Ram and Ors 2005: Husband and wife filed a suit against the State of Punjab, the appellant and a lady surgeon who was in the State Government's employment at the relevant time for recovery of damages to the tune of Rs.3,00,000/- on account of a female child born to them despite the wife-respondent No. 2 having undergone a tubectomy operation performed by the lady surgeon. SC observed that the methods of sterilization so far known to medical science, which are most popular and prevalent, are not 100% safe and secure. Despite the operation being successfully performed and without any negligence on the surgeon's part, the sterilized woman can become pregnant due to natural causes.

So, the doctor is not liable for the bad known outcome of the surgery when done with due care and competence.

Take home message in cluster endophthalmitis is you will not be liable for all the bad outcomes of treatment if you have done the treatment with due care and expertise.

Dr. Laxman Balkrishna Joshi v Dr. Trimbak Babu Godbole and Another (1969) 1 SCR 206

Bolam v Friern Barnet Hospital Management Committee,

A young man had an accident that resulted in a fracture of the femur of his left leg. After the x-ray, the boy was taken to the operation theatre, where his injured leg was put in plaster splints and moved to a room. Subsequently, the boy developed difficulty in breathing and coughing, and his condition deteriorated. He expired the same night despite the emergency treatment administered by the appellant.

The Trial court held that the appellant had undertaken reduction of the fracture without caring to give anesthesia and that excessive force was used in the process, which resulted in shock, causing the patient's death and awarded damages. Supreme Court agreed.

The Court observed that a person who held himself out ready to give medical advice and treatment implied that he possessed the skill and knowledge for the purpose. Such a person owed his patient certain duties, viz., a duty of care in deciding whether to undertake the case, a duty of care in deciding what treatment to give or a duty of care in administering that treatment. A breach of these duties gave the patient a right of action for negligence.

Similarly, in a cluster endophthalmitis case, we should follow all the standard procedures for management as laid down by a professional body of experts.

The Bolam test was created in 1957 as a result of the judgment of the House of Lords in *Bolam v Friern Barnet Hospital Management Committee*, which said that a doctor might be able to escape a lawsuit for negligence if he can show that other medical practitioners would have behaved in the same manner.

The *Bolam test*, which argues that a doctor is not negligent if what he has done would be approved by a responsible body of medical opinion in the relevant specialty at the time, remains the principal test to assess 'standard of care.'

Essentials to Constitute Medical Negligence. There are three fundamental components of negligence: 'duty' 'breach' and 'resulting harm'. That is, to establish negligence, it must be shown that the person owed a duty of care to the plaintiff and that duty was breached, causing him/her to suffer damage.

Essentials of Medical Negligence in Tort Law. The Supreme Court has stated that a claim for medical negligence against a doctor in tort (for civil liability) can succeed when it is proved that either: he does not possess the requisite skill he professed to have possessed or he did not exercise such skill with reasonable competence.

7.5 WILL CLUSTER ENDOPHTHALMITIS AMOUNT TO RES IPSA LOQUITOR?

A.H. Khodwa vs. State of Maharashtra. The patient had undergone sterilization following childbirth. While doing the procedure, the doctor left a mop inside the patient's abdomen. As a result, peritonitis developed and the patient died a few days later. The doctor conducting the procedure was judged to be negligent. This amounts to *res ipsa loquitur* or gross negligence.

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Cluster endophthalmitis cannot be taken as Res Ipsa loquitor, if the doctor has taken all necessary precautions for the Theatre asepsis

7.6 IS THE CONSENT IMPORTANT IN CLUSTER ENDOPHTHALMITIS?

Yes. All patients should have given written informed consent for surgery in their own handwriting, which mentions the remote possibility of endophthalmitis. Blanket consents are not valid in the court of law. So if printed formats are used for consent, the patient and witness should sign below after writing that they have understood everything and agree to surgery. Any re- intervention would also need consent signed again.

Samira Kohli vs Prabha Manchandha case, the Supreme Court held that unless in a life saving situation or unless the patient is minor, unconscious, or insane, informed consent is mandatory from the patient in all non-emergency procedures.

7.7 WHAT ARE THE RELEVANT PROVISIONS FOR DOCTORS UNDER THE INDIAN PENAL CODE 1860, INDIAN EVIDENCE ACT 1872 & CODE OF CRIMINAL PROCEDURES 1973 IN RELATION TO CLUSTER ENDOPHTHALMITIS

Indian Penal Code, 1860

Section 90: Related to consent: Consent is given under fear or misconception: Consent is not such a consent as is intended by any section of this Code if a person gives the consent under fear of injury or under a misconception of fact and if the person doing the act knows or has reason to believe, that the consent was given in consequence of such fear or misconception; or Consent of insane person. Or Consent of a child under twelve years of age.

Section 269: Negligent act likely to spread infection dangerous to life: Whoever unlawfully or negligently does any act which is and which he knows or has reason to believe to be, likely to spread the infection of any disease dangerous to life shall be punished with imprisonment of either description for a term which may extend to six months or with fine or with both.

Section 270: Malignant act likely to spread infection of disease dangerous to life: Whoever malignantly does any act which is and which he knows or has reason to believe to be, likely to spread the infection of any disease dangerous to life shall be punished with imprisonment of either description for a term which may extend to two years or with fine or with both.

Section 304 and 304-A: There is a lot of discrepancy while applying these sections in cases of professional negligence by doctors. Most of the time, the police register cases of professional negligence deaths under Sec. 304 of IPC. According to this Section, the offence is non-bailable. This causes the doctors a lot of hardship, a bad reputation and mental agony.

The police should register the cases of deaths due to medical negligence under Sec. 304-A of IPC, where the offence is bailable, the doctor can be released on bail. The judgment has been passed by the Bombay High Court in Criminal Revision application no. 282 of 1996 (*Dr. Mrs. Mrudula S. Deshpande vs. the State of Maharashtra*) dated 28th November 1998(3). The basic difference is that in Sec. 304, there is an intentional act of negligence; in 304-A, the act is never done to cause death.

Section 319: Hurt: Whoever causes bodily pain, disease or infirmity to any person is said to cause hurt.

Section 320: Grievous hurt: The following kinds of hurt only are designated as “grievous”:-

(1) Emasculation. (2) Permanent privation of the sight of either eye. (3) Permanent privation of the hearing of either ear. (4) Privation of any member or joint. (5) Destruction or permanent impairing of the powers of any member or joint. (6) Permanent disfiguration of the head or face. (7) Fracture or dislocation of a bone or tooth. (8) Any hurt that endangers life or causes the sufferer to be in severe bodily pain during the twenty-day period or unable to follow his ordinary pursuits.

Section 338: Causing grievous hurt by an act endangering the life or personal safety of others. Whoever causes grievous hurt to any person by doing any act so rashly or negligently as to endanger human life or the personal safety of others shall be punished with imprisonment of either description for a term which may extend to two years or with a fine which may extend to one thousand rupees or with both.

Section 491: Related to a breach of contract. Breach of contract to attend on and supply wants of helpless Person: Whoever, being bound by a lawful contract to attend on or to supply the wants of any person who, by reason of youth or of unsoundness of mind or of a disease or bodily weakness, is helpless or incapable of providing for his safety or of supplying his wants, voluntarily omits so to do, shall be punished with imprisonment of either description for a term which may extend to three months or with fine which may extend to two hundred rupees or with both.

Section 499: Related to defamation. Defamation: Whoever by words either spoken or intended to be read or by signs or by visible representations, makes or publishes any imputation concerning any person intending to harm or knowing or having reason to believe that such imputation will harm, the reputation of such person, is said, except in the cases hereinafter excepted, to defame that person

Indian Evidence Act, 1872

The Indian Evidence Act 1872 is an adjective law that comprises a collection of rules governing the admission of evidence in Indian courts of law, as well as related concerns. Sections

45 and 114 A of the 1872 Act are considered while attaching the importance of medical jurisprudence with Indian laws.

Section 45: This provision deals with the opinions of experts. When the Court has to develop an opinion on a point of foreign law, science or art or on the identification of handwriting, the opinions of individuals with expertise in the same are considered relevant facts. Such individuals are referred to as experts.

7.8 DEFINITIONS IN LAW THAT ALL OF US SHOULD KNOW

Crime or offence means any act or omission contrary to any law or statute for the time being in force.

Summons is the process of the court asking the opposite party to appear and answer the allegation preferred by the party who has brought an action.

Warrant means an order issued by the court, magistrate or a competent judicial authority, directing a police officer to make an arrest, seize or search or to do any other work incidental to the administration of justice.

A *Warrant case* is related to an offence punishable by death, life imprisonment or imprisonment for more than two years. Example: If a doctor helps a pregnant woman get rid of the child or causes its death after birth.

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Cases other than warrant cases are *Summons cases*. If a doctor negligently uses an infected syringe or instrument, resulting in an infection to an uninfected patient, it exemplifies a Summons case.

Cognizable offences are those in which a police officer may arrest without a warrant, according to Schedule I of the Criminal Procedure Code (CPC).

Non-cognizable offences are those in which a police officer can't arrest without a warrant, e.g. a doctor knowingly disobeying a quarantine rule is liable to be punished with imprisonment for up to 6 months or a fine.

Bailable Offences are those in which any law can grant bail for the time being in force. In such cases, bail is a matter of right. The court can't refuse bail and the police have no right to keep the doctor in custody. If any police officer puts a doctor in detention in such cases, he is liable for the offense of wrongful confinement under Sec. 340-342 of IPC.

Non-Bailable offences are offences other than the bailable or an offence in which bail can't be granted. These are serious offences for which a person may be convicted and imprisoned for more than ten years. For example, offences under the Transplantation of Human Organ Act 1994.

Presumption of innocence: Law presumes that a person is innocent till the guilt is proven. The onus of proof is on the prosecution.

Mistake of law: "Ignorantia juris non excusat, means ignorance of law or mistake of law (existence or mistaken understanding) is not excusable. An erroneous or wrong conclusion of law is not a valid defense. For example, if a doctor carries out a prenatal test intended to abort a female fetus, he can't avoid prosecution by saying that he/she was unaware of any law which punishes such an act.

Mistake of fact is a situation where a person, not intending to do an unlawful act, does so because of a wrong conclusion or understanding of fact. The guilty mind was never there while doing the act. The person may not be held responsible in such cases.

Res Judicata: This doctrine of law means "the things have been decided." According to this principle, once the case is completed between two parties, it cannot be tried again between the same parties. Suppose a patient sues a hospital for any wrong, damages or malpractice and the things are decided, he cannot subsequently sue the doctor again separately for the same negligence.

Res Ipsa Loquitur is a situation of gross negligence or rashness. The things are so obvious that they "speak for themselves." Most of the time, there is no need for any proof of negligence in such cases. Common examples include giving a blood transfusion to the wrong patient, operating on the wrong side of the body or to the wrong patient.

7.9 CAN A DOCTOR BE ARRESTED AFTER CLUSTER ENDOPHTHALMITIS?

Doctors have no immunity against arrest (as any other citizen of India) for various criminal acts as per the provisions of the IPC or CPC of India. Illegal organ trading, unlawful sex determination etc. are non-bailable offenses.

But the question is whether a doctor be arrested for ;

- a) alleged medical negligence during the day-to-day care of a patient?
- b) unexplained hospital deaths like SIDS (sudden infant death syndrome) etc.?
- c) post-operative complication or failure of surgery?

- d) not attending or refusing a patient (who was not already under his care) who becomes serious or dies? and
- e) not attending a case of a roadside accident?

If a patient or relatives lodge FIR, the police may arrest the doctor. Hence better to proactively inform and approach in cases where we feel that the patients or relatives may create trouble as follows:

- a) The doctor should lodge an FIR that a particular incident has happened in my hospital.
- b) A crisis management committee may be formed at each Taluka or District level. The committee shall include doctors, social workers, legal personalities, politicians, press reporters etc. The committee members may meet the police officers, request a complete investigation of the incident and avoid prosecution until the guilt is proven. The committee can also request the press reporters not to give unnecessary publicity to such cases.

The *Government of Kerala (G.R. no. 3231/SS-B4/92/Home dated 20.09.1993)* has issued the following instructions if there are any cases of criminal negligence against a private practitioner, doctor or private hospital. According to G.R., the investigating Deputy Superintendent of Police shall refer the case to a panel of Superintendent of Police, Commissioner of Police, District Medical Officer or Principal of Medical College. If the views differ, the opinion of an apex body consisting of the Director of Health Services and an expert in that particular specialty may be taken. The affected doctor is also free to approach the apex body with appeals.

7.10 WHAT ARE THE LEGAL RIGHTS OF AN ARRESTED PERSON?

The arrested person shall be communicated with the particulars of the offence and the ground for arrest. If the offence is bailable, then the person should be informed, and the arrangement for bail may be made. If the police officer refuses to release such a person on bail, he will be liable for damages for wrongful confinement. Sometimes a police officer may register an offence under Sec. 304 of IPC instead of 304-A to detain the accused doctor. In such cases, officer may have to face serious consequences.

The person shall not be subjected to more restraint than necessary to prevent his escape. If any offensive weapons belong to the arrested person, these weapons may be seized. The arrested person must be produced before a magistrate having jurisdiction in that case. No police officer shall detain an arrested person for more than 24 hours unless a special order from a magistrate is obtained.

Anticipatory Bail: To avoid frivolous accusations, anticipatory bail is provided. This may be granted as protection in non-bailable offences. It is the direction to release the applicant on bail if there is an arrest. Once granted, it remains in force. Pre-requisites for anticipatory bail are: (i) there must be reasonable apprehension of arrest, (ii) the alleged offence must be non-bailable, and (iii) the registration of FIR is not necessary.

Procedure for Bail: The accused is required to execute a personal bond at the police station with or without surety. The surety may be a close relative, a friend or a neighbor, who is required to undertake to pay the said amount in case of absconding of the accused.

7.11 WHAT ARE LEGAL DO'S AND DON'TS IN CLUSTER ENDOPHTHALMITIS?

- Inform the police whenever necessary.
- Extend all possible cooperation to the police.
- Furnish copies of medical records to police, court or relatives whenever demanded. Consent of the patient may be taken while providing information to the police.
- Follow the legal procedures or provisions.
- Have valid informed consent for the treatment.
- Preserve the documents and records, specially in medico-legal, controversial, or complicated cases.
- Involve medical associations, medico-legal cells and voluntary organizations whenever a legal problem arises.
- Consult your lawyer before giving any reply.
- Don't become panicky.
- Don't manipulate or tamper with the documents.
- Don't do unlawful or unethical acts.
- Don't neglect the treatment while completing legal formalities, especially in a serious or emergency situation.

The bench of Justices Markandeya Katju & R M Lodha ruled that, "*courts must first refer complaints of medical negligence to a competent doctor or a panel of experts in the field before issuing notice to the allegedly negligent doctor. This is necessary to avoid harassment of doctors who may not be ultimately found to be negligent. We further warn the police officials not to arrest or harass doctors unless the facts come within the parameter laid down in Jacob Mathew's case; otherwise, the policemen will themselves have to face legal action*".



REPORTING AN OUTBREAK - STATUTORY REQUIREMENTS

Currently, there is no official advisory that states the statutory requirement to inform any government authority about an outbreak of cluster endophthalmitis. The hospital is expected to notify the local DBCS (District Blindness Control Society) in charge to start the proper investigation process in case of an outbreak.

According to the AIOS task force guidelines¹, it is expected that the notification of an outbreak of cluster endophthalmitis be made to the following:

- Hospital authority and hospital infection control committee in writing.
- For National Programme for Control of Blindness & Visual Impairment [NPCB VI]- related surgeries, notification should be sent to the following:
 - a) Government authorities,
 - b) Indian Medical Association local chapter,
 - c) State Ophthalmic Society,
 - d) Deputy Director,
 - e) Civil Surgeon
 - f) and State Ophthalmological Society to seek help.

Time and again, the local government authorities learn about the outbreak from the media, not the hospital administration. In case of an outbreak, the hospital administration should report the outbreak to DBCS and from there on, the DBCS head can start forming an investigative team.

These outbreaks should also be reported to state and national authorities to monitor endophthalmitis trends nationally.

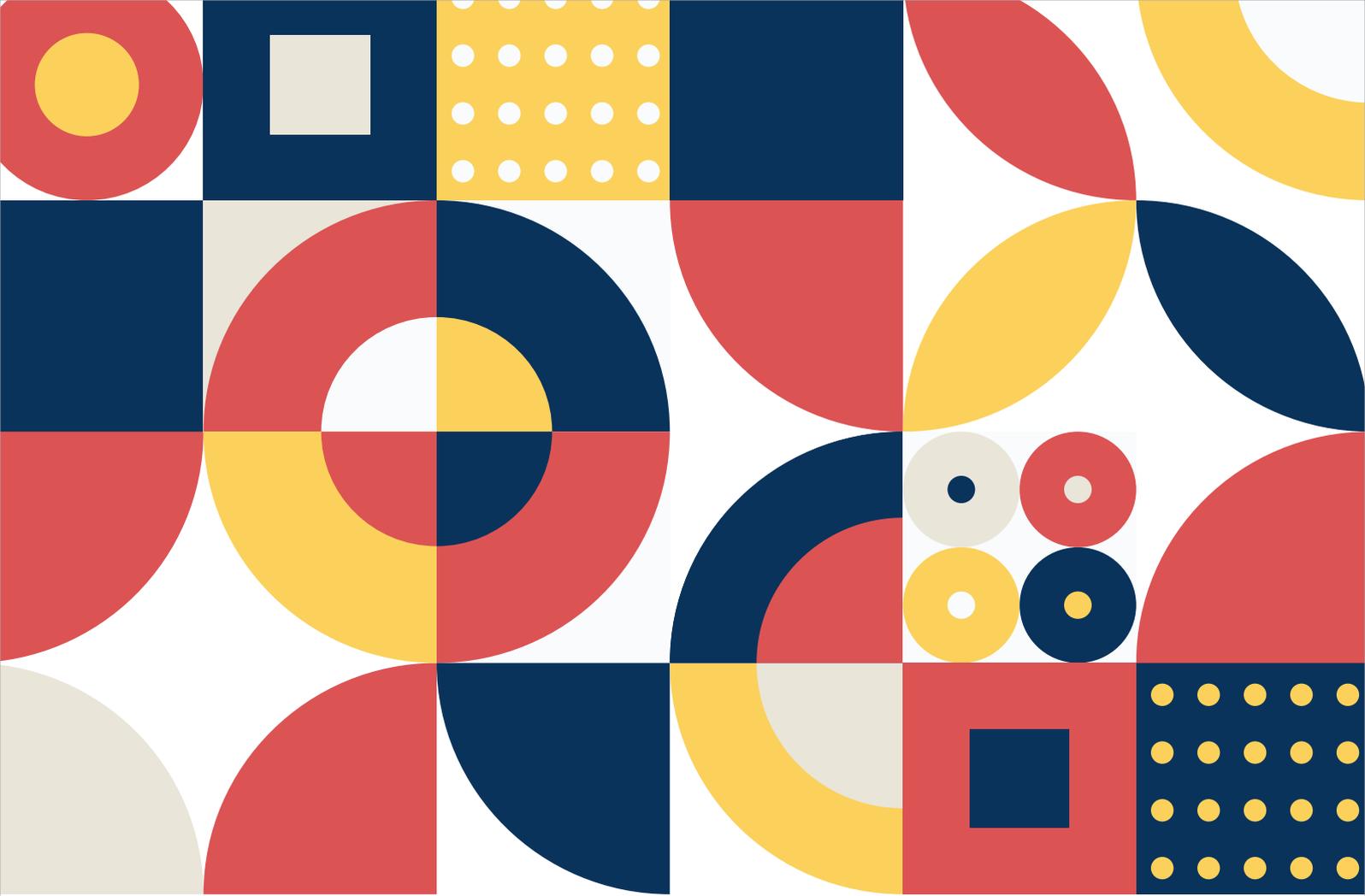
Such a system is in place in the UK, where postoperative endophthalmitis cases are usually reported to the hospital risk management team via the incident reporting system. ² All incidents reported locally, usually are shared nationally with the National Reporting and Learning System to detect national trends. Incidence is regularly monitored via electronic patient records, incident reporting or both.

According to the Indian penal code, a preliminary FIR can be filed in a case of endophthalmitis if sabotage is suspected.

If the hospital administration has evidence of unlawful activity or suspects any tampering with surgical supplies or surgical space, they can file an FIR at the nearest police station.

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