



The ROYAL COLLEGE of
OPHTHALMOLOGISTS

Ophthalmic Services Guidance

Managing an outbreak of postoperative endophthalmitis

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1. Introduction

The aim of this document is to provide advice on the identification and management of an outbreak of post ophthalmic procedure (post-op) endophthalmitis. The guidance will concentrate particularly on cataract surgery, but the principles and much of the detail are applicable to other intraocular procedures including intravitreal injections. As much is possible is based on published evidence but, in the absence of published high quality evidence for many aspects, expert consensus has been used to make recommendations.

Acute endophthalmitis is a severe intraocular inflammation presumed to be due to entry of microbes into the eye during the perioperative period. It is identified usually in the first two weeks after surgery and presents as a red painful eye with severe anterior uveitis, often with fibrin and hypopyon, and vitritis. It is not always culture positive. It is one of the most serious postoperative complications of intraocular procedures and, despite treatment, often results in a very poor visual outcome. The incidence in the developed world is low, approximately 0.1-0.08%, with an incidence in the UK (as determined by BOSU in 2004⁵) of 0.14% after cataract surgery and approximately 0.02-0.06% after intravitreal injections.

Many units may face a possible or actual cluster of cases (“outbreak”) of post-op endophthalmitis at some point and a logical method of investigating and tackling this is key to reducing harm to patients and minimising operational disruption to the ophthalmology service.

A summary sheet and check list is included at the end

2. Sources of causative microorganisms

Most cases of sporadic isolated postoperative endophthalmitis arise from the patient’s own commensal bacteria (Staphylococci and Streptococci) and are mainly (60-80%) gram positive cocci. However, clusters of cases have a greater likelihood of arising from some particular source of contamination and have a much greater chance of being gram negative bacteria (Coliforms or Pseudomonas) or fungal with potentially worse outcomes.

Sources of contamination in outbreaks include:

- Contaminated intraprocedural solutions both extraocular (e.g. povidone iodine, saline) and intraocular (e.g. irrigating fluid, intracameral drugs including antibiotics, anti-VEGF, dyes and viscoelastic). This is the commonest source in clusters.
- Contaminated phaco machines including tubing and phaco probes
- Inadequate ventilation systems providing poor air change rate per hour in the operating environment
- Defective sterilisation procedures
- Miscellaneous e.g. defective, contaminated or dirty instruments
- Some have more than one source
- In approximately 20% there is no obvious or identifiable source

3. Routine prophylaxis against endophthalmitis

The low incidence of endophthalmitis makes it difficult to obtain robust evidence of the efficacy of preventative measures in reducing its occurrence. Although this is not a full guideline on how to avoid endophthalmitis, and detailed guidance and assessment of the evidence exists within The Royal College of Ophthalmologists' [cataract guidelines](#) and elsewhere, there are a number of areas where there is general consensus on what is good ophthalmic theatre practice or likely to offer a benefit:

Operating theatre general measures

- Rigorous theatre procedures including thorough hand washing, following strict theatre discipline to maintain sanctity of preparation and sterile areas to avoid contamination, separation of clean and dirty areas and minimization of unnecessary theatre traffic.
- Proper environmental cleaning.
- Maintain and monitor performance (annual preventive planned maintenance – PPM schedule) of theatre/clean room ventilation/airflow systems to appropriate standards.
- Following manufacturers' guidelines regarding single use of instruments.
- Follow manufacturers' guidelines on cleaning, disinfection and sterilisation of instruments and devices. Ensure theatres and the sterilizing unit comply with appropriate related standards.

Preoperative

- Avoidance of intraocular procedures in patients with significant active non-ocular infections
- Treatment of patients with blepharitis, significant lid malpositions (e.g. entropion with lashes abrading ocular surface), infective conjunctivitis and nasolacrimal infections prior to procedure.

During procedure

- Skin preparation with povidone iodine or chlorhexidine if allergic to povidone iodine.
- Povidone iodine solution 5% instilled into the conjunctival sac prior to commencement.
- Good draping technique to isolate the lid margins and lashes from the surgical field.
- Ensuring all equipment, intraocular lenses, viscoelastics, drugs and solutions are from a reliable source.
- Rejection of instruments which are damaged, faulty or show signs of poor cleaning such as debris or deposits. Do not clear blocked instrument lumens e.g. of an irrigation-aspiration cannula during the procedure as sterility may then be uncertain.
- Excellent surgical wound construction and good wound closure.
- Avoidance of serious intraoperative complications especially posterior capsular rupture and vitreous loss and avoidance of overly prolonged surgery.
- Prophylactic antibiotics in accordance with the RCOphth (or equivalent) surgery and procedure guidelines where indicated. It is not currently mandated by the College to use intracameral antibiotics in cataract surgery as long as

endophthalmitis rates are satisfactory but it is worth noting that some authors believe it to be superior to other methods of delivery, such as topical and subconjunctival.

- Any other procedure which, after the preparation of this guide, is shown with good statistical support to be effective and safe.

Preventive measures

Suggested by some authors, but for which there is little consensus or evidence, include:

- Non-touch technique as far as possible, avoiding contaminating the functional end of instruments.
- Rejection of lens implants which have inadvertently contacted the lid margins.
- Wear facemasks in theatre, especially scrub nurses and surgeons.
- Preoperative topical broad spectrum antibiotics.
- Injecting lens implants rather than folding them with forceps, in order to reduce the possibility of contact with the lid margin.
- Single use/disposable instruments.
- Single use medications.
- Postoperative antibiotic drops (regimens vary but usually one-two weeks).

4. Treatment of cases

It is beyond the bounds of this document to detail the treatment of endophthalmitis. However, it is important, even if briefly, to mention two important points of principle:

1. This is a condition where time is of the essence. It is crucial that cases are diagnosed early and treated as an emergency. If there is enough clinical suspicion of endophthalmitis, treatment should not be delayed waiting for microbiological confirmation or the effects of a trial of steroids.
2. **All** units or surgeons undertaking intraocular surgery or intravitreal injections, whether within the NHS or independent sector, have a duty to ensure their patients can access emergency assessment and treatment of endophthalmitis. All patients should be warned what to look out for postoperatively and given clear information on where to go or whom to call if they are concerned. There should be **clear agreed pathways** for care if a provider of the procedure is not able to offer emergency post-procedure care.

5. Active monitoring of incidence and investigation of isolated cases

Postoperative endophthalmitis cases should be reported to the hospital risk management team usually via the incident reporting system. All incidents reported locally are normally shared nationally with the National Reporting and Learning System to detect national trends.

For cases of endophthalmitis which have arisen at another unit, the ophthalmic clinical lead and the operating consultant of the source unit must be informed about the case by the receiving/treating unit so that they can incident report and investigate. In the unfortunate event that the source unit does not seem to reply/act/engage, whether NHS or independent, the commissioner should be notified directly.

Ophthalmology audit or clinical governance meetings should include a regular complications and morbidity slot which should consider any cases of endophthalmitis and examine any predisposing factors or areas for action, learning or improvement.

Electronic patient records can facilitate continuous audit and surveillance, and identify even a small rise in endophthalmitis cases or other complications which might not otherwise be evident.

Either via electronic patient records, incident reporting or both, incidence should be regularly monitored. Departments should have a system for identifying and acting upon any rise in incidence or cluster of cases.

Report to the Medicines and Healthcare products Regulatory Agency, and to the manufacturers, any problems with drugs or devices.

6. How many cases comprise an outbreak?

This is a difficult question to answer as random clusters mimicking an outbreak may occur from time to time. With such a low background incidence, even one or two extra events during a short time frame can raise concerns but may turn out not to be significant and may be followed by an unusually long period with no cases so that the frequency over a longer time frame may be within acceptable limits.

It is important to consider the possibility that more than one case in a short time frame may have arisen from a preventable and recurring cause.

7. What should raise particular concerns?

- Analysis of the cases demonstrate a common organism especially an unusual organism
- Analysis of the cases demonstrates the same apparent underlying cause or concern
- Analysis of the cases demonstrates the cases related clearly to only one team member, one surgeon, one theatre/site, one session in the week (for all of these especially if significantly out of proportion to the relevant share of surgical activity), a particular instrument or consumables batch number.
- Two or more cases have arisen during the same theatre list.
- A rate that is significantly over that expected in the modern era; in cataract surgery this might perhaps be >0.4% and above; and a rate that is >0.8% should be taken extremely seriously.
- Cluster occurring over a very short time frame e.g. days to weeks.

- Some have used statistical methods or charts to ensure a sensible balance between complacency and overkill. There are a number of methods (see references). It is wise to involve the local microbiologist in determining the best local method for this and even wiser to have done so proactively before any suspected cluster rather than reactively after concerns have been raised.

8. Actions once suspicions have been raised

The degree of action will of course depend on both the rate of occurrence, any suspicious factors and whether the problem persists. Operational factors have to be taken into consideration but the first duty is to minimise patient harm.

Keep detailed records of all action taken and minute any meetings.

Decision as to whether or not there is an outbreak (see above) based on frequency, possible statistical analyses and identification of common factors in the cases.

9. Notification and involvement of others, raising awareness, detecting cases

- Alert colleagues: make them aware of the cases so far, ask if there are other cases not yet reported, advise a high degree of suspicion and to report any further cases.
- Ensure incident reports are completed for any cases.
- Alert the lead clinician, clinical director and the medical director.
- If receiving multiple cases from another provider, their clinical lead and medical director must be notified and take action. If their response is deemed inadequate, contact their commissioner.
- Involve the hospital consultant microbiologist and hospital infection team at an early stage.
- Involve the risk team and consider notifying commissioners.
- With risk team notify MHRA and manufacturers if devices or drugs are clearly implicated.
- Consider establishing a multidisciplinary team to manage and investigate (ophthalmologists, nurses, theatre staff, managers, risk, microbiology, infection control).
- Verify that patients are fully aware of postoperative danger symptoms.
- Consider resuming day two or day three follow-up if this is not normally undertaken.
- Ask neighbouring units if they also have noticed an increased incidence of endophthalmitis.

10. Immediate actions to improve prophylaxis/prevent further cases

- Ensure that established agreed theatre procedures and preventative measures are robust and being followed and remind staff about them.
- Cease bilateral simultaneous cataract surgery where performed
- Temporary closure of theatre(s) or provision of the procedure: give serious consideration to cessation of all intraocular surgery in the interests of patient safety whilst investigating the cause.

11. Investigation

1. Review cases urgently and examine:

- Patient/surgical risk factors such as blepharitis, nasolacrimal disease, immunosuppression/diabetes, concurrent systemic infection etc, vitreous loss, duration of surgery, postop wound leak, non-compliance with prescribed drops.
 - Surgeon factors surgical and draping technique.
 - Common hospital factors such as draping and procedural technique, antibacterial prophylaxis, surgeon, nursing staff and other personnel, theatres, solutions, drugs, viscoelastics, intraocular lenses, disposable and non-disposable equipment, which autoclave used, on which day of the week, which position on the list and at what time of day patients were operated. Track batch numbers of solutions, drugs, disposables and lenses.
 - Ensure there is appropriate documentation of practices, instrumentation and drugs.
2. Note any procedure or environment which coincided with or recently preceded the outbreak.
3. Microbiological analysis of intraocular tap samples, looking for a common organism or subtype - fully subtype any organisms (investigation methods to determine the source of these outbreaks use a combination of phenotypic [routine culture, biochemical profiles of the organism, antibiotic susceptibility patterns]^{8,10,17} and molecular [e.g. 16s PCR polymerase chain reaction in culture negative specimens/tap]).
4. Environmental considerations: building works in or nearby, poor condition of estates, level of cleanliness, clutter and ergonomics, separation of dirty and clean areas and condition of equipment. Confirm that the ventilation/ air-flow is appropriate and tested in consultation with the infection control team. Check what other cases (e.g. dirty cases) are being performed in the theatre or nearby from theatre records.
5. Microbiological sampling: may include microbiological sampling/culture from irrigating solutions, extra and intracameral solutions and drugs, viscoelastics. Sample phaco sets (tubing, phaco and I/A handpieces) and phaco machine, air filters and ventilation units, and environmental swabbing of theatre areas.

6. Review theatre practices: independent observation of practices such as door closures, staff movements, facemasks, drugs and instrument prep and use, solution and drug handling etc.
7. Review surgical techniques and IOL handling.
8. Assess that all equipment and disposables are functional and used according to manufacturer's instructions, are in date and appropriately serviced. Confirm single use where instruments are so designated.
9. Assess efficacy of cleaning and sterilization processes, in particular examine how reusable hollow bore equipment lumens are rinsed or cleaned. Arrange for professional assessment of the hospital sterilizing service. Look actively by examining instruments for damage or debris and blocked lumens.

Address the specific cause if one is found

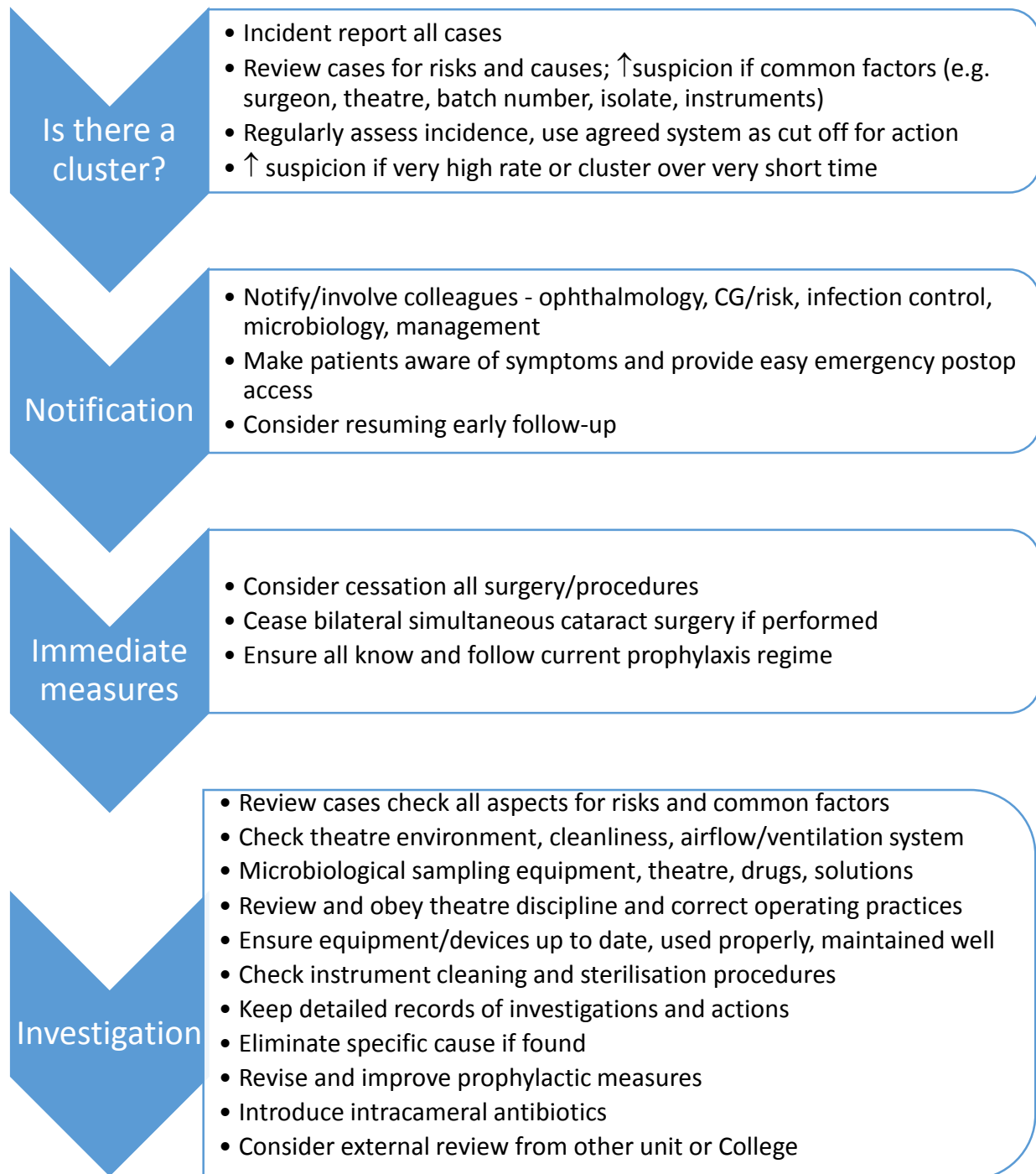
Actions when a specific cause cannot be found

- Review and revise current prophylaxis protocol and re-examine and if possible improve any other relevant preop, intraoperative and postoperative care and theatre activities.
- Consider introducing extra prophylaxis measures (see above) e.g. intracameral antibiotics
- Consider an external review by a neighbouring unit or The Royal College of Ophthalmologists.

12. Summary

Units should have robust protocols for endophthalmitis prevention, and methods to monitor the incidence. It is important to identify a significant rise in incidence and analyse and learn from sporadic cases. The discovery or suspicion of an outbreak of endophthalmitis should prompt a rapid, systematic and open investigation to attempt identification and remedy of any possible cause. Patient safety is paramount and may involve temporary cessation of intraocular procedures.

13. Flow chart - Coping with a cluster of postoperative endophthalmitis



14. References

1. Endophthalmitis after intravitreal Injection: prevention and management. Wykoff C, Flynn HW. *Retina* 2011;31:633-5.
2. American academy of Ophthalmologists Intravitreal statement 2015. <http://www.aaopt.org/clinical-statement/intravitreal-injections--november-2008>
3. Endophthalmitis after intravitreal injections: incidence, presentation, management, and visual outcome. Dossarps D, Bron AM, Koehrer P, et al. *Am J Ophthalmol* 2015;160:17-25.
4. Intravitreal Injections at the Massachusetts Eye and Ear Infirmary: analysis of treatment indications and post injection endophthalmitis rates. Englander M, Chen TC, Paschalis Ei et al. *Br J Ophthalmol* 2013;97:460-465
5. Surveillance of endophthalmitis following cataract surgery in the UK. Kamalarajah S, Silvestri G, Sharma N, Khan A, Foot B, Ling R, Cran G, Best R. *Eye* 2004; 18: 580-7.
6. Monte–Carlo simulation of random clustering of endophthalmitis following cataract surgery. Sparrow JM. *Eye* 2007; 21: 209–213.
7. The use of control charts in monitoring postcataract surgery endophthalmitis. Chiam PJT, Feyi-Waboso A. *Eye* 2009;23:1028-31.
8. A statistical approach to an outbreak of endophthalmitis following cataract surgery at a hospital in the West of Scotland. Allardice GM, Wright EM, Peterson M and Miller JM. *Journal of Hospital Infection*, 2001;49:23-29.
9. The role of external bacterial flora in the pathogenesis of acute postoperative endophthalmitis. Speaker MG, Milch FA, Shah MK et al. *Ophthalmology* 1991; 98:639-49.
10. Endophthalmitis isolates and antibiotic sensitivities: a 6-year review of culture-proven cases. Benz MS, Scott IU, Flynn HW, Unonius N, Miller D. *Am J Ophthalmol* 2004;137:38-42.
11. Prophylaxis of endophthalmitis with topical povidone –iodine. Speaker MG, Menikoff JA. *Ophthalmology* 1991;98:1769-75.
12. Bacterial endophthalmitis prophylaxis for cataract surgery: an
13. evidence-based update. Ciulla TA, Starr MB, Masket S. *Ophthalmology* 2002;109:13-26.
14. Prophylaxis of postoperative endophthalmitis following cataract surgery: results of the ESCRS multicenter study and identification of risk factors. ESCRS Endophthalmitis Study Group. *J Cataract Refract Surg* 2007; 33: 978-988.
15. Antibiotic prevention of postcataract endophthalmitis: a systematic review and meta-analysis. Kissel L, Flesner P, Andresen J, et al. *Acta Ophthalmologica* 2015;93:303-17.
16. Perioperative antibiotics for prevention of acute endophthalmitis after cataract surgery. Gower EW, Lindsley K, Nanji AA et al. *Cochrane Database Syst Rev*. 2013 Jul 15;(7):CD006364.
17. Reflective consideration of postoperative endophthalmitis as a quality marker. Kelly SP, Mathews D, Mathews J, Vail A. *Eye* 2007;21: 1419-26.
18. Medicines and Healthcare products Regulatory agency: www.mhra.gov.uk

19. An investigation into postoperative endophthalmitis and lessons learned. Mandal K, Hildreth A, Farrow M, Allen D. *J Cataract Refract Surg.* 2004;30:1960-5.
20. Post-operative endophthalmitis: the application of hazard analysis critical control points (HACCP) to an infection control problem.
21. Baird DR, Henry M, Liddell KG, Mitchell CM and Sneddon JG. *Journal of Hospital Infection,* 2001; 49:14-22.
22. A model for the management of an atypical endophthalmitis outbreak. Anderson OA, Lee V, Shafi S, Keegan D, Vafidis G. *Eye* 2005 19:972-80.
23. A cluster of acute-onset postoperative endophthalmitis over a 1-month period: investigation of an outbreak caused by uncommon species, Akçakaya A, Sargin F, Hasbi Erbil H, Yazıcı S, Yaylalı SA et al. *Br J Ophthalmol* 2011;95:481-484.
24. Endophthalmitis outbreaks following cataract surgery: Causative organisms, etiologies, and visual acuity outcomes. Pathengay A, Flynn HW, Isom RF, Miller D. *J Cataract Refract Surg* 2012; 38:1278–1282.
25. Endophthalmitis occurring after cataract surgery.; Jabbarvand M, Hashemain H, Khodaparast M, et al *Ophthalmology* 2016;123:295–301.
26. Effectiveness and Safety of an Intracameral Injection of Cefuroxime for the Prevention of Endophthalmitis After Cataract Surgery With or Without Perioperative Capsular Rupture. Papinaud DV, Gillies MC, Domerq C et al. [JAMA Ophthalmol.](#) 2016 May 2. doi: 10.1001/jamaophthalmol.2016.1351. [Epub ahead of print]
27. Endophthalmitis after cataract surgery: a nationwide prospective study evaluating incidence in relation to incision type and location. Lundstrom M, Wejde G, Stenevi U, Thorburn W, Montan P. *Ophthalmology* 2007;114:866-870.
28. Efficacy of intracameraland subconjunctival cefuroxime in preventing endophthalmitis after cataract surgery. Yu-Wai-Man P, Morgan SJ, Hildreth AJ, Steel DH, Allen D. *J Refractive Surgery* 2008; 34:447- 451.
29. ESCRS Guidelines for Prevention and Treatment of Endophthalmitis
30. Following Cataract Surgery: Data, Dilemmas and Conclusions 2013. Bary P, Cordoves L, Gardner S. www.es CRS.org.

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