

Mitigating The Risk Of Endophthalmitis Claims

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Financial Disclosures

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Why This Topic?

-  The devastating outcome to vision if not diagnosed and treated in a timely fashion
-  Most frequently occurs after cataract surgery and intravitreal injections: the 2 most frequently performed ophthalmic procedures
-  Recent uptick of endophthalmitis in children post strabismus surgery
 - ~ Concerning given historically low incidence
 - ~ This increase may not be statistically significant, but we are continuing to monitor



Focus Areas

Informed Consent

Postoperative Concerns

Medical Record Documentation

Applying risk management strategies in these areas can prevent the chance of a claim or mitigate the damage.

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Learning Objectives

Identify the purpose of a thorough, procedure-specific informed consent, including patient-specific risks.

Provide clear postoperative instructions to patients

Implement effective protocols for responding to postoperative complaints.

Document care in a timely manner, including the rationale for medical decision-making and management

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Risk Management

Differential Diagnosis

Document the diagnoses you're considering
Rule out the most vision-threatening conditions first

Document your plan

Confirm that the patient understands next steps


Monitor test results and consults to determine future care

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All OMIC Claims vs. Endophthalmitis Claims


Payments 2018-2022*	All Claims 2018-2022*	Endophthalmitis Claims 2018-2022*
# Claims	1058	131 (12.4% of all claims)
% Claims with payments	20%	16%
Mean payment	\$262,201	\$286,428
Range	\$5k--\$2M	\$30k--\$875k
Total paid	\$56M	\$6M (10.7% of all payments)

*through 07/2022





Endophthalmitis Payments by Procedure Type 2018-2022

Procedure Type	Insureds	Expense	Indemnity
Cataract surgery	36 physicians, 17 entities	\$1,038,011	\$1,703,903
Intravitreal injections	10 physicians, 7 entities	685,963	2,584,999
Strabismus surgery	1 physician, 1 entity	149,717	850,000
PPV	1 physician	5,194	0
Retinal detachment	1 physician	182,325	875,000
All cases	49 physicians, 25 entities	2,061,210	6,013,902



Case 1:

Endophthalmitis Following Cataract Surgery

Case 1

Dec 15

78 YO referred by OD for evaluation of bilateral cataracts

- OS: significant amblyopia, BCVA 20/100
- OD: modest cataract, BCVA 20/30
- Documented consent, including risk of infection, loss of vision
- Patient agreed to proceed with cataract surgery OD



Jan 19

Cataract surgery OD

Complicated by iris prolapse
Required iridectomy and sutures at 2 corneal incisions



Jan 20

Post Op Day 1 Visit

- Patient c/o blurry vision, pain the night before
- Patient had not used any drops

Exam

- Inflammation, some hyphema, no hypopyon; IOP 26 corneal edema; incisions Seidel negative; no signs infection

Instructions

- Call with increased redness, pain, or decreased vision
- Use postop drops, avoid rubbing eye, patch at night, start Diamox
- Return to office next business day (Monday)



Jan 21

Saturday a.m. Post Op Day 2, Caregiver Calls Insured

Caller's Recollection

- Reported patient was feeling "more washed out"
- Increased pain, redness, discharge
- Insured said ok to wait until scheduled visit on Monday

Insured's Recollection

- Advised that Diamox can cause tiredness
- No changes with vision, pain, or redness
- Offered to see patient but patient declined

Plan

- Call if worsening pain, new redness, or decrease in vision
- Keep appointment on Monday
- Caller indicated understanding



Case 1

Jan 23

Post Op Day 4 Office Visit

- Infection obvious
- Patient reported bottle cap on drops was lost
- Immediately referred to retina; treated with IV antibiotics
- Scribe did not document discussion with patient re: bottle cap missing and warning about contamination
 - 8 days later visit note altered to include discussion
 - Not added as a late entry or addendum
 - Culture grew out Citrobacter koseri



Jan 28

- Patient underwent enucleation with placement of prosthesis



OMIC Review



- » Alteration of medical record could not be defended
- » Response to Saturday am call 1/21 was inadequate
- » Should have had a low threshold to examine patient in person due to:
 - Complicated cataract surgery in monocular patient
 - Elevated postop IOP
 - Swollen cornea
 - Blood in anterior chamber



Expert Opinions




Pros

- Appropriate candidate for cataract surgery
- Op report documents a difficult surgery (floppy iris)

Cons

- Need more detailed discussion of risks when fellow eye has limited vision
- Should have seen patient in response to call, even if patient reluctant
- Failed to document Saturday am call in record.
- Should have called next day (Sunday) to monitor status
- Late entries in medical record
- Physician entered a note in personal computer 9 days after family reported outcome and threatened litigation





Outcome

Settled for
\$750,000


- » Physician **\$450,000**
- » Group **\$300,000**

Risk Management



Risk Management


Documentation of Informed Consent



When patient is at increased risk or has specific risks, review in consent discussion

Document that those risks were discussed, and questions answered

In such cases the generic "RBAs discussed" is not sufficient



Risk Management

Late Entries to the Medical Record

» Is it necessary?

Have you received additional information after a patient encounter?

- **Acceptable** if done in the normal course of care
- **Not acceptable** if done upon notice of a claim or suit

» Consult with risk management or your defense counsel



Risk Management

Late Entries to the Medical Record

- » Must be made appropriately...if at all:
- Date with current date (not back-dated)
 - Refer to the original entry
 - For additional guidance, contact OMIC Risk Management or consult resources such as American Health Information Management Association (AHIMA): www.ahima.org



Risk Management

Late Entries to the Medical Record

Remember

- EHR metadata will track all activity
- Paper records will be examined by a forensics expert
- Even a properly executed addendum may compromise defensibility



Case 2:

Endophthalmitis Following Intravitreal Injection




Case 2

May 5

Anti-VEGF intravitreal injection, right eye, for PDR and diabetic macular edema in 48 yo diabetic with hx DR


- VA 20/20
- Drug-specific consent signed
- Betadine and Tetravisc applied for 5 minutes, then rinsed off. Cotton-tipped applicator without Betadine then placed on eye.
- Postop instruction sheet given: call with symptoms of pain, decreased vision, redness, swelling, sensitivity to light, discharge



May 8

Patient returned c/o PAIN and decreased vision

- External, fundus, and slit lamp exams appeared unremarkable
- B scan: revealed vitreous hemorrhage; no retinal tear or detachment
- Plan: return May 12




Case 2

May 12

Continued pain, decreased vision

- Exam: 2+ cell and flare, small hypopyon, VA = LP
- Diagnosis: traction RD, vitreous hemorrhage, preretinal membrane, uveitis
- Endophthalmitis not in differential
- Plan: surgery





May 13

Vitrectomy, membrane peel, scleral buckle, lensectomy, antibiotic injection, PRP

Culture grew gram-positive cocci/staph


Patient Remains Legally Blind (HM)






OMIC Review

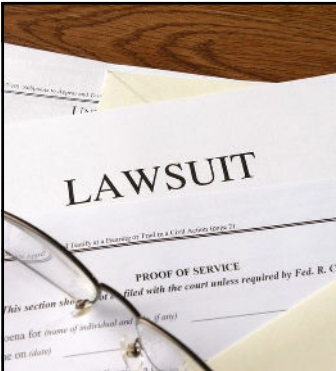
- Second cotton-tipped applicator without Betadine may have been a source of infection
- May have been difficult to diagnose endophthalmitis on May 8 (1st complaint)
- However, given complaint of pain, follow up should have been in 1-2 days, not 4 days later
- May 12: due to cells, flare, and hypopyon, required immediate tap and inject in office
- Delay caused infection to progress



Expert Opinions

- ▶▶ Patient had clear signs of endophthalmitis on May 8 (1st complaint)
- ▶▶ Endophthalmitis should have been diagnosed on May 8 and treated immediately
- ▶▶ May 12 - vitrectomy planned for next day yet no tap and inject done
- ▶▶ Delay caused eye to 'die'





Outcome



Settled for **\$350,000**

Risk Management



Risk Management


Differential Diagnosis

Risk Management

Informed Consent Concepts



- » Based on a patient's right to determine what happens to his or her own body.
- » More than the patient's signature on a consent form
- » A process of **communication** between the physician and patient that results in the patient's authorization to undergo a specific medical intervention
- » **Negligence:** failure to disclose information the patient needs in order to make an informed and voluntary decision
- » **Battery:** no consent, or treatment is substantially different from what was agreed upon



Risk Management


Informed Consent Process

- An assessment of patient competence to decide
- An assessment patient comprehension
- Communication/Education
 - Diagnosis
 - Nature and purpose of treatment or procedure
 - Risks, benefits, and alternatives
 - Risks and benefits of not receiving treatment
 - Informed refusal
- Documentation
 - Document the discussion in the medical record and on a procedure-specific consent form.





Risk Management

Postop Instructions



- Explain instructions verbally to patients
- Be specific about signs and symptoms to watch for and urgency of reporting
- Indicate how to reach you during office hours and after hours
- Give patient / caregiver printed or emailed instructions



Risk Management

Managing Postop Complaints

- Document the complaints and your assessment
- Advise patient of follow-up plan
- Instruct patient about what to watch for and report
- Monitor as needed, commensurate with level of concern for potential vision-threatening conditions



Risk Management Event Analysis - Goals

- » Can help address complication rates
- » Prevent recurrence and improve future outcomes
- » Make it hard for errors to occur, but easy for providers to detect, address, and report them
- » Support patient safety and reduce professional liability exposure





Risk Management Event Analysis - Elements

- » Analyze steps in pre-, intra-, and post-op regimens (e.g., medication choice, eye prep)
- » Evaluate overall systems in addition to the actions of a particular provider:
 - * Particular OR involved?
 - * Pattern with when surgery occurred (1st case, 4th case?)
 - * Consistent sterilization process?
- » Identify gaps
- » Implement corrective action plan






Risk Management Event Analysis - Takeaways


- » Conduct as soon as possible after the event
- » Maintain confidentiality; consult with an attorney
 - * Focus on patient safety issue instead of a specific case if there is no confidentiality protection available
- » See OMIC's "Responding to Unanticipated Outcomes" for more information.



Case 3:

Endophthalmitis Following Strabismus Surgery






OMIC Claims History


Endophthalmitis after Strabismus Surgery

2013-2017
0 Cases

2018-July 2022
3 Cases

- 2 cases remain open
- Investigation and evaluation are ongoing







Plan
Bilateral medial rectus surgery

Documented Informed Consent Discussion

- Risks
 - over- and under-correction
 - need for additional surgery
 - infection, scar, redness
 - possible need for glasses
- Father signed consent form


Feb 26
5yo boy with non accommodative esotropia







Fri, Mar 9
Bilateral Medial Rectus Surgery Without Complications

- First post op scheduled for 4 days
- Parents instructed to call surgeon if
 - » Eyeball pink or swollen
 - » Lids markedly red, swollen, or tender




Mon, Mar 12
Post Op Day 3

- **Early to mid afternoon**, ASC calls mother to check on patient
 - Mother reports no concerns, denies signs of infection
- **7:50pm** mother calls insured
 - Left eye is red temporally, can't open eye
 - Texted photo: normal lid, mild temporal chemosis and erythema
 - Rx: oral Keflex
- **Plan**
 - Call if worsening pain, new redness, or decrease in vision
 - Keep appointment tomorrow at 5pm
 - Mother indicated understanding


5pm Postop Visit
Post Op Day 4



Exam:
 OS = 2+ injection, 3+ cell and flare; fundus hazy, VA 20/70

Consult by retina colleague to r/o endophthalmitis vs. vitreous hemorrhage

Retina's diagnosis:
 Likely endophthalmitis



Immediately Sent For Treatment At Hospital

- Admitted for pain control, IV antibiotics, tap and inject, exam under anesthesia

Subsequently

- Multiple procedures to repair retinal detachments
- VA = BCVA 20/20 OD and HM OS



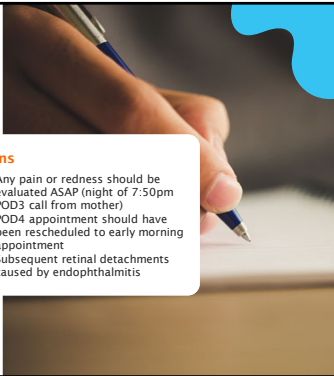
OMIC Review



- Outcome would not have changed if insured saw patient on the night of the mother's call
- At visit the next day, insured immediately referred patient to retina
- Care comports with AAO guidelines on managing suspected cases of endophthalmitis:
 - Refer to retina specialist within 24 hours
 - If retina not available within 24 hours, tap anterior or posterior segment for evaluation of pathogens



Expert Opinions




Pros

- Strabismus expert: met SOC
- Insured diagnosed and referred within 24 hours of 1st report of symptoms (from 7:50pm call POD3 to referral next day, 5pm visit)

Cons


- Any pain or redness should be evaluated ASAP (night of 7:50pm POD3 call from mother)
- POD4 appointment should have been rescheduled to early morning appointment
- Subsequent retinal detachments caused by endophthalmitis





Outcome
Settled for
\$850,000


Risk Management



Risk Management

Informed Consent



- » Use procedure-specific consent forms
 - Memorializes the consent discussion
 - Provides patient with information
- » Be specific about risks:
 - X "loss of use of organ" versus
 - √ loss of vision, blindness, loss of eye
- » Retain signed form in medical record and give a copy to patient




Risk Management

Postoperative Instructions

- At-home care, follow up appointment
- Signs and symptoms to watch for
 - Indicate why reporting promptly is important
 - State risks of not calling in a timely manner
- Take time to answer all questions
- Explain how to contact you during clinic and after hours
- Provide a printed (and/or emailed) post op instruction sheet with all information discussed




Risk Management

Postoperative Calls Reporting Symptoms


- If any suspicion of vision-threatening symptoms, examine patient in person
- Visit is an opportunity to educate and reassure
- Telemedicine may be helpful but not always a substitute for in-person exam if
 - photo or video not clear enough for evaluation
 - equipment required for full evaluation and testing
 - when in doubt, convert to in-person exam
- And...always document interactions in a timely fashion and place in record

Risk Management


Schedule Postoperative Visits Earlier in the Day




Especially if visit is to evaluate postop complaint




Increases ability to secure earlier consults and treatment



May result in better outcome



Shows that physician is concerned and doing everything possible to prevent patient harm



Summary

Engage patients

- in an informed consent process that includes communication, education, and documentation (both in the medical record and in a procedure-specific consent form).

Use vigilance

- in monitoring and responding to postoperative complaints.

Communicate

- postoperative instructions to patients and implement methods to confirm patient understanding.

Document

- all patient interactions in a timely manner, including the rationale for medical decision making.

Analyze

- trends to address systems issues and improve outcomes.

Never

- alter the medical record. If you have questions about making a change to a record, consult your malpractice carrier.



Resources



Procedure-specific Consent Forms

<https://www.omic.com/risk-management/consent-forms/>



Telephone Screening

<https://www.omic.com/wp-content/uploads/2012/11/Telephone-Screening-Toolkit-Toolkit-Forms-1.docx>



Documentation Of Ophthalmic Care

<https://www.omic.com/wp-content/uploads/2020/03/Documentation-of-Ophthalmic-Care.pdf>



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