OMIC
OPHTHALMIC MUTUAL INSURANCE COMPANY
A Risk Retention Group

Risk Management Recommendations

Sponsored by the American Academy of Ophthalmology

Endophthalmitis Malpractice Claims

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Purpose of risk management recommendations

OMIC regularly analyzes its claims experience to determine loss prevention measures that our insured ophthalmologists can take to reduce the likelihood of professional liability lawsuits. OMIC policyholders are not required to implement risk management recommendations. Rather, physicians should use their professional judgment in determining the applicability of a given recommendation to their particular patients and practice situation. These loss prevention documents may refer to clinical care guidelines such as the American Academy of Ophthalmology's *Preferred Practice Patterns*, peer-reviewed articles, or to federal or state laws and regulations. However, our risk management recommendations do not constitute the standard of care nor do they provide legal advice. Consult an attorney if legal advice is desired or needed. Information contained here is not intended to be a modification of the terms and conditions of the OMIC professional and limited office premises liability insurance policy. Please refer to the OMIC policy for these terms and conditions.

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Infection is a risk of all surgeries. Endophthalmitis is a particularly worrisome type of infection because it can lead to severe vision loss, blindness, and loss of the eye. Some types of complications are hard for patients to understand. They are familiar with infections, however, and realize that they can occur after surgery. This common knowledge makes it harder for plaintiffs in endophthalmitis claims to allege lack of informed consent. In order to prove that their outcome was caused by malpractice and not the result of a known complication, plaintiffs must show that some aspect of the health care team's treatment was below the standard of care.

OMIC published the results of its first analysis of endophthalmitis malpractice claims in 2006.[1] At that time, endophthalmitis claims made from 1987 to 2005 accounted for 6% of OMIC claims and 5% of indemnity payments. Cataract surgery was the most frequently performed procedure, and ophthalmologists were concerned about distinguishing between infectious endophthalmitis and the inflammatory condition called TASS (toxic anterior segment syndrome). The study was updated by reviewing claims between 2006 and 2017.[2] During this

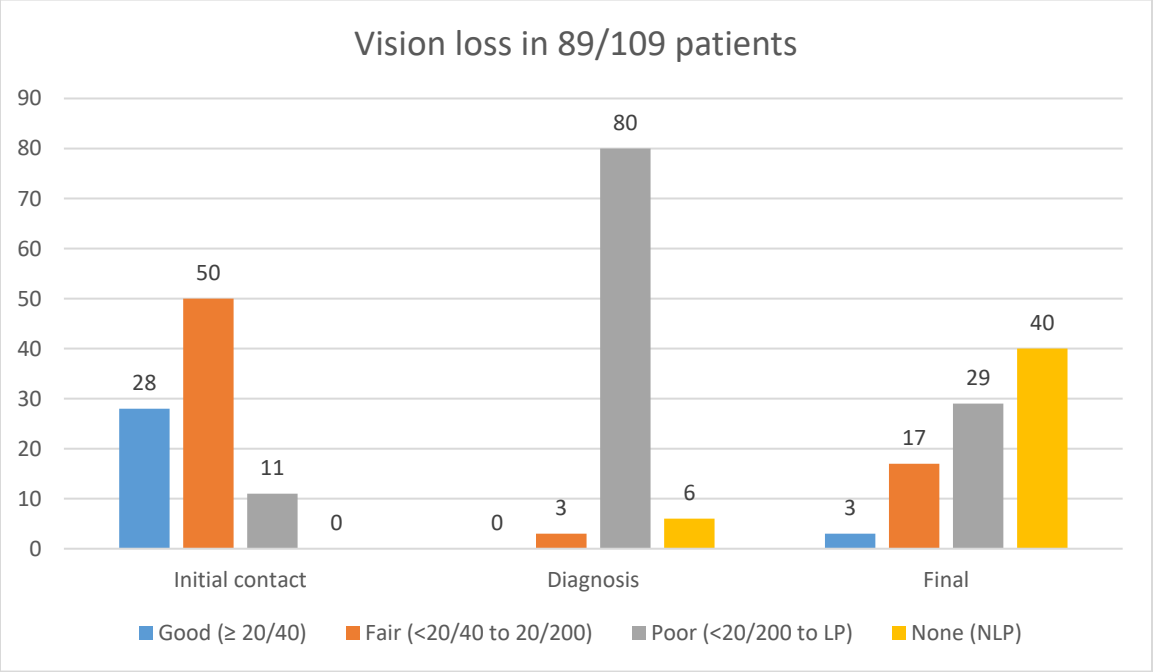
[1] Menke AM. Endophthalmitis and TASS: Claims Results and Lessons. *Ophthalmic Risk Management Digest.* 16:2, 2006. https://www.omic.com/wp-content/uploads/2012/12/Digest-Spring-2006.pdf.
[2] Menke AM. Endophthalmitis Claims Update. *Ophthalmic Risk Management Digest.* 28:2, 2018. https://www.omic.com/wp-content/uploads/2018/10/Digest-No-2-2018-WEB-FINAL-rw.pdf.

time interval, intravitreal injections became the most frequently performed procedure, and clinical debates about the type, timing, and route of infection prophylaxis have taken center stage.[3] After presenting the new data, recommendations on how to decrease the likelihood of these claims will be discussed.

Plaintiff and defendant characteristics

The 167 endophthalmitis claims analyzed in this study were made by 109 plaintiffs. There was one minor patient aged 10; the adult patients ranged in age from 23 to 89 years old. Complete data on visual acuity was available in 89 of the 109 plaintiffs. The vision loss shown in **Figure 1** explains why they filed malpractice claims. While 31% of plaintiffs had good vision prior to the procedure, only 0.3% did after (good = ≥ 20/40). The percentage of plaintiffs with fair vision dropped from 56% to 19% (fair = <20/40 to 20/200). Conversely, those with poor vision prior to the procedure increased from 12% to 33% (<20/200 to LP). Most significantly, the number with no vision increased from 0 to 45%, and 73% of these underwent evisceration or enucleation.

Figure 1. Change in visual acuity



[3] Williams G. Chairman's Message. *Digest*, 2018: Volume 28, Number 2. "We know from the IRIS Registry that the incidence of endophthalmitis following both cataract surgery and intravitreal injection is approximately 1 in 2,000 procedures. However, injections far exceed cataract surgery and continue to grow. Already the IRIS Registry has recorded over 10,000,000 injections."

The majority of plaintiffs (72%) developed endophthalmitis following cataract surgery (58) or intravitreal injections (21: Avastin 12, Eylea 5, Kenalog 1, Lucentis 3). Others filed claims after pars plana vitrectomy or PPV (13), trauma (5), systemic infections (4), and corneal transplants (3). The remaining 5 plaintiffs alleged malpractice after an IOL exchange, a secondary IOL, PRK, pterygium, and strabismus surgery.

The specialty practiced by the ophthalmologists facing endophthalmitis claims coincides with the precipitating event. Comprehensive ophthalmologists and their practices account for 54% of the claims (90), followed by retina and retina practices at 37% (62). The remaining defendants, in descending order, were ASCs (6), cornea MD/practice (4), glaucoma MD/practice (2), refractive MD/practice (2), and strabismus (1).

Endophthalmitis claims data

Endophthalmitis remains a rare complication of ophthalmic procedures, and malpractice claims stemming from this infection are rarer still. **Table 1** compares endophthalmitis claims to OMIC claims overall for the period from 2006 to 2017. The endophthalmitis claims accounted for 5% of OMIC claims (slightly lower than the 6% in the prior study period), and 8% of payments (higher than the prior period's 5%). While only 20% of overall OMIC claims in the study closed with an indemnity payment, endophthalmitis claims required payments 27% of the time. The mean and median payments were also higher for endophthalmitis, but not significantly so. However, the highest payment for endophthalmitis was $900,000, substantially less than the $3,375,000 paid for an ROP case during this period.

Table 1. Endophthalmitis claims from 2006 to 2017

	Endophthalmitis claims	**All OMIC claims**
Number of claims	167 (5% of all claims)	3158
Number of open claims	21	319
Closed with indemnity payment	40/146 = 27%	570/2839 = 20%
Mean payment	$233,634	$213,278
Median payment	$175,00	$125,000
Range	$9,000 to $900,000	$450 to $3,375,000
Total amount paid	$9,579,005 (8% of payments)	$121,568,265

Ophthalmology experts opined on the care provided in 137 of the 167 claims (24 closed before a review and 6 open claims had not yet been reviewed at the time of the study). As noted above, the vast majority of defendants (124) were comprehensive ophthalmologists (COs) and retina specialists (RSs). Reviews were deemed positive (met the standard of care (SOC), mixed, or negative. Positive reviews outnumbered negative ones for both COs and RSs:

- 52 COs reviewed: 30 met SOC, 10 mixed SOC, 12 below SOC.
- 25 CO practices reviewed: 16 met SOC, 1 mixed SOC, 8 below SOC.

- 36 RSs reviewed: 27 met SOC, 3 mixed SOC, 6 below SOC.

OMIC made indemnity payments to 40 plaintiffs. **Table 2** provides the details in descending order of the percent of paid endophthalmitis claims per clinical category. The most payments were for infections following cataract surgery claims, the highest mean (average) payment was for PPV, and the highest overall was for an intravitreal injection. Payments were made to four plaintiffs despite expert support, either to avoid trial in plaintiff-friendly venues or at the request of the policyholder. While there was more than one defendant in many claims, only one resulted in payments on behalf of multiple defendants. This claim was made by an 82-year-old woman against four ophthalmologists and two practices. Prior to an IOL exchange, she had 20/100 vision. After contracting endophthalmitis, she lost all vision and required enucleation. Despite strong support for the care, three of the physicians and one of the groups chose to settle to avoid trial in a plaintiff-friendly venue; each contributed $100,000.

Table 2. Indemnity payments in endophthalmitis claims from 2006 to 2017

Clinical category	Payments/plaintiffs	% All Payments	Mean	Range
Cataract surgery	18/51	45%	$197,500	$9,000 to $850,000
Intravitreal injection	9/21	22.5%	$175,000	$20,000 to $900,000
IOL exchange	4/1	10%	$100,000	$100,000
Corneal transplant	2/3	5%	$210,000	$140,000 to $280,000
Endogenous	2/4	5%	$222,500	$145,000 to $300,000
Pars plana vitrectomy	2/13	5%	$675,000	$475,000 to $875,000
Trauma	2/5	5%	$257,000	$240,000 to $275,000
PRK	1/1	2.5%	$300,000	$300,000

Factors impacting clinical outcomes

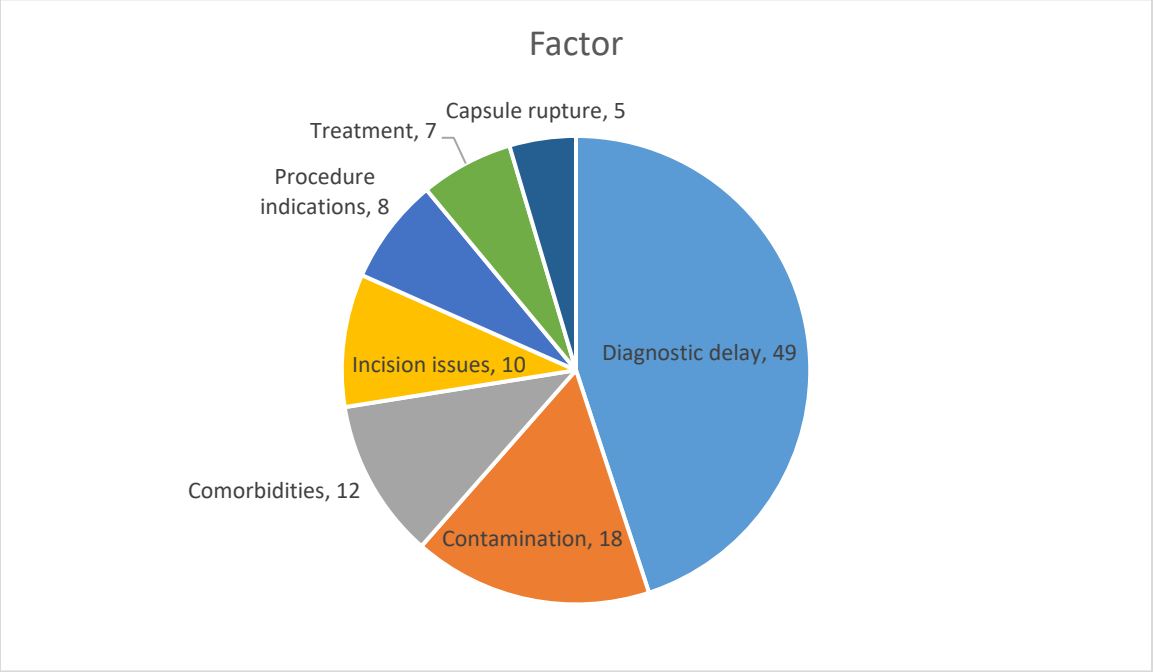
What do malpractice claims filed by plaintiffs who experienced endophthalmitis indicate about how to improve care? What lessons should ophthalmologists heed to decrease the likelihood of a malpractice claim? **Figure 2** shows the main factors impacting the patient's outcome. Including procedure indications as a factor might seem odd, but patients would not have developed postoperative endophthalmitis if they had not undergone the procedure. When experts opined that the procedure was not indicated, defense of the care became severely compromised. One such plaintiff with early cataracts had 20/25 vision and no documented visual complaints or glare testing. The claim settled for $235,000.

Diagnostic delay is by far the most frequent driver of these claims. OMIC has devoted a number of *Digest* issues to the persistent, significant problem of diagnostic error.[4] Difficulty in determining a rare diagnosis is readily understood. It is harder to explain why ophthalmologists

[4] See the issues on giant cell arteritis, diagnostic errors overall, diagnostic errors in pediatric patients, and failure to diagnose retinal detachments in the Publications section at www.omic.com.

do not recognize common complications, such as an infection that occurs in the early post-procedure period. The prevalence and enduring nature of diagnostic delay indicates that complex, multifactorial issues are at play, such as burnout, distractions, and EHR problems. Some of the recommendations discussed below may seem obvious and basic, but they bear repeating since these proposed actions fall within the ophthalmologist's control and can lead to better outcomes.

Figure 2. Factors affecting the clinical outcome or claim resolution



The importance of developing a **differential diagnosis** that includes and rules out the most serious condition cannot be overemphasized. Endophthalmitis must always be taken into consideration when patients report vision loss or pain soon after procedures like cataract surgery and intravitreal injections, especially when these problems are handled by phone. One plaintiff was treated for increased intraocular pressure the day after cataract surgery that was complicated by rupture of the posterior capsule. The following day, the patient called twice to report ongoing pain, nausea, and vomiting. Defense and plaintiff experts criticized the ophthalmologist's decision to call in prescriptions for Lortab and Phenergan, opining that the patient needed to be examined promptly. The claim settled for $250,000.

Experts repeatedly emphasize the need to take and document a **thorough patient history**, which includes clarifying the timing and severity of symptoms, and asking about comorbidities that can increase the risk of infection, and mask or delay its presentation. As part of the history, ophthalmologists should ask if patients have other infections, since they may not readily report such conditions if they seem unrelated to their eye problem. One ophthalmologist learned

during litigation that a plaintiff who developed fungal endophthalmitis following an intravitreal injection was being treated for a fungal foot infection. The claim was dismissed.

Patients may avoid providing truthful answers about drug or alcohol abuse. One plaintiff failed to disclose current IV drug abuse, even when asked several times about it. The ophthalmologist had documented the negative responses, and experts supported the ophthalmologist's care, so the claim closed without a payment. When eliciting sensitive information, explain to the patient that you cannot diagnose and treat the eye condition without this knowledge.

Two patients who were eventually diagnosed with endogenous endophthalmitis were hospitalized when an ophthalmologist was asked for a consult. These claims show the importance of carefully reviewing the hospital medical record, consulting with treating physicians, and performing an adequate exam. The first had a history of leukemia and had recently been diagnosed with sepsis. An ophthalmologist was asked to evaluate the patient's complaint of headache. Defense experts supported the care, but felt the diagnosis might have been made earlier if the sepsis had been taken into account in the differential diagnosis. The claim was dismissed. Another patient had complications from abdominal surgery. An ophthalmologist was called when the patient developed eye pain and swelling. Experts found the exam inadequate, since the ophthalmologist did not evaluate both eyes, dilate them, or check for a red reflex. All felt the diagnosis was missed. This claim settled for $300,000.

Even with prompt diagnosis and appropriate treatment of endophthalmitis, some patients have poor outcomes. To improve the defensibility of your care, describe the presence or absence of signs indicative of infection, the decision-making process used to determine the most likely diagnosis, and your plan for monitoring the patient's condition. When you are unsure of the diagnosis, follow up promptly with the patient in person or by phone. A number of patients in the claims studied were confused about the symptoms of endophthalmitis, when to contact the ophthalmologist, and how urgently treatment was needed. Patient education about endophthalmitis is crucial. Education is discussed in detail at the end of this article.

Infection prophylaxis is multifaceted, involving perioperative management of comorbidities as discussed above, disinfection of the surgical site, careful construction and monitoring of incisions, prevention of contamination, and the use of prophylactic antibiotics. Perhaps surprisingly, the use of prophylactic antibiotics never became the focus of a claim or led to a settlement in the study claims. As consensus guidelines on prophylactic antibiotic use are developed, ophthalmologists should continue to exercise their professional judgment.

Contamination, alleged by 18 plaintiffs, resulted in 9 payments. These claims highlight the importance of using aseptic technique for intravitreal injections. One defendant faced 7 claims, and lack of expert support led to a total of $1,185,000 in indemnity payments. In another suit, a defendant proceeded with a corneal transplant even though the tissue was dropped on the

floor of the OR. The plaintiff, who learned about the incident after developing endophthalmitis, received a settlement of $280,000. In another case, at the end of a cataract procedure, a nurse noted a crack in the infusion bottle. The surgery center admitted this was the most likely cause of the endophthalmitis and agreed to the plaintiff's request of $9,000 to cover out-of-pocket expenses.

Incision management was the main problem in 10 claims. Incisions need to be carefully constructed during surgery, and checked for leakage when patients report symptoms of a possible infection. Defense experts in one case felt that the initial incision for a pterygium surgery was too deep, increasing the likelihood of the infection. The medical review panel in the state supported the care, however, and the claim was not pursued. One patient had five sutures placed during cataract surgery in 2006. After the third of five sutures broke, the ophthalmologist did not check for a wound leak or replace the suture, and the patient soon developed endophthalmitis. The experts criticized how the defendant managed the sutures. The plaintiff did not follow through with the claim before the statute of limitations expired, so there was no payment.

Treatment issues were raised in 7 claims against retina specialists. Plaintiff experts focused on the timing of treatment after referral, and the choice of tap and inject versus PPV for initial treatment. They cited the Early Vitrectomy Study (EVS), which compared these two treatment modes in patients following cataract surgery or secondary IOL implantation. Although a few plaintiff experts used the EVS to criticize the type of treatment following PPV, defense experts pointed out that determining whether to do an early vitrectomy does not apply to patients who have already had one. There was only one indemnity payment related to treatment; the $50,000 payment was made at the defendant's request.

Patient education

A number of plaintiffs who filed a claim against OMIC insureds after developing endophthalmitis inadvertently delayed their own diagnosis and treatment. They either did not report symptoms or chose to delay seeing a retinal specialist. Delay in initiating treatment can lead to a worse outcome. Experts reviewing such claims try to determine whether the defendant could have handled the situation better. Our Claims Department, in conjunction with the defense attorney, also evaluates how a jury might respond to actual or implied criticism of a plaintiff for their part in the delay when they have lost vision or gone blind. Here are questions policyholders often have about this situation, as well as recommendations on how to better educate patients.

Q: We provide each patient instructions on when to call us after surgery. My patient did not follow these instructions. What could I have done differently?

A: Plain-language experts feel that patients need to see the most important information first. They are most likely to read key instructions that are placed at the beginning of the document.

The instructions need to be short, simple, and clear. The printed documents from your EHR may not be easy for patients to read, and the information they need the most may be hard to find. Instead, use a short document that starts like this:

> "Patients can have problems after eye surgery (or an eye injection). We need your help to watch for them. Please call our office right away if you have these problems: 1) Pain that is getting worse, or 2) Vision that is getting worse."

You can provide information about the normal postoperative course and the time of the follow-up appointment after you have discussed vision-threatening symptoms that need to be reported to you. As an alternative, some ophthalmologists send short post-procedure instructions via text to patients who choose to receive them, and encourage the patients to text back questions or concerns.

Q: My patient called to report pain after cataract surgery. I wanted her to go see a retina specialist right away, but there is no specialist in our town. She was not willing to drive one hour to be examined at the academic center. When she sued me, she said I never told her she needed urgent care. How could I have explained this better?

A: Providing care over the telephone is challenging. Obtaining "informed refusal" this way is even more difficult. When patients indicate that they will not follow your medical advice, you need to take steps to ensure that they understand the possible consequences. You might say something like this:

> "Mrs. Harrison, I understand that your husband does not want to drive for one hour in the dark. However, I am very worried about your eye. You could have a serious infection. If the infection is not treated right away, you could lose vision. You might even go blind in that eye."

To confirm that patients understand your warning, ask them to repeat it back to you:

> "I want to make sure that I have explained why I am worried. Could you please tell me what might happen if you don't get care right away?"

You might also ask if an adult child, neighbor, or volunteer from a local organization could drive the patient to the appointment. Be sure to document the conversation as soon as possible.

Q: I heard that during the informed consent discussion, I should point out complications for which the patient is at increased risk? Is that true?

A: Yes. Such a discussion might have helped patients in the study who had poorly controlled diabetes mellitus or were taking immunosuppressant medications. You might counsel a patient this way:

> "I want to talk to you about how your cancer treatment might affect you after your eye surgery. Surgery can cause infection. Your cancer treatment will make it harder for your

body to fight an infection. So it's really important that you call me right away if you have any problems after the surgery. Here is the list of the problems I want to know about."

This review of endophthalmitis claims reveals actions ophthalmologists can take to help patients achieve the best clinical outcomes. It also indicates ways to make appropriate care more defensible. Key actions include more careful evaluation of post-procedure problems and better patient education. Patients can feel overwhelmed when preparing for eye surgery. Educating them about serious complications during the consent process, in postoperative instructions, and over the phone could help them achieve a better outcome.

Need confidential risk management assistance? OMIC-insured ophthalmologists, optometrists, and practices are invited to contact OMIC's Risk Management Department at (800) 562-6642, option 4, or at riskmanagement@omic.com.