

New data on risks of endophthalmitis and how to decrease the likelihood of related malpractice claims.



The OMIC Digest

Endophthalmitis malpractice claims update

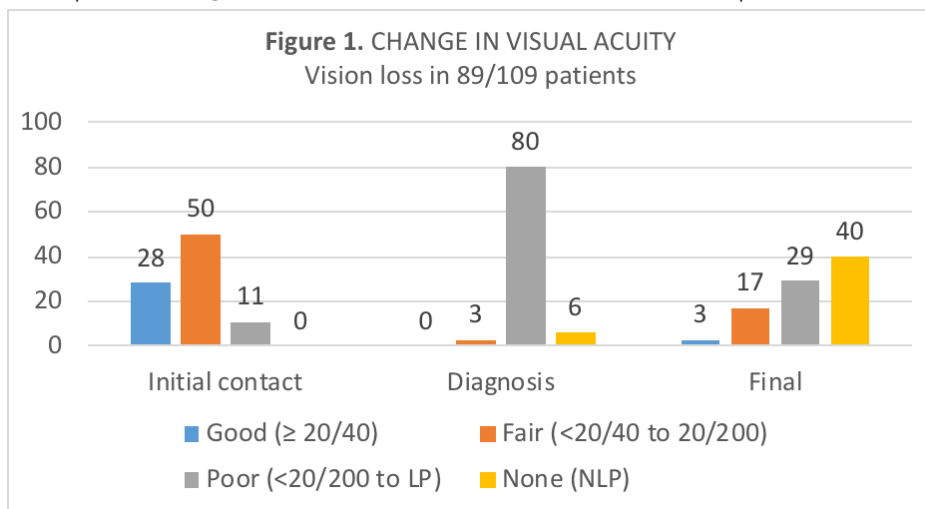
ANNE M. MENKE, RN, PHD, OMIC Patient Safety Manager

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. 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). This issue of the Digest will present information on endophthalmitis



MESSAGE FROM THE CHAIR

GEORGE A. WILLIAMS, MD, OMIC Board of Directors

Stuff happens.

At the most basic level, insurance is a rather simple business involving the assumption of risk. The risk may be a hurricane, car accident, fire, illness, or medical liability. Virtually anything can be insured. In order to assume risk, we must understand the probability that an adverse event will (not may) occur. That probability is then applied across a

covered population. The cost of risk is determined by frequency (how often) and severity (how much in cost) of an adverse event. The cost is distributed across the population as individual premiums and deductibles.

Every service we provide our patients has risk and, regardless of how hard we try, there is no way to completely eliminate it. Simply put, stuff happens. Among the most feared risks for an ophthalmologist is endophthalmitis. Fortunately, the frequency of endophthalmitis is low. Unfortunately, the visual consequences of endophthalmitis are often dire and therefore the severity may be high. This issue of the Digest discusses the OMIC experience with endophthalmitis.

claims reported between 2006 and 2017. During this 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. After presenting the new data, I will discuss ways to decrease the likelihood of claims.

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



EYE ON OMIC

No rate changes and another significant dividend paid in 2019

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After more than a decade of unusually strong balance sheets and healthy income statements, there are some indications that results are returning to historical norms for the medical malpractice insurance industry. While claim frequency remains stable, severity continues to climb. Furthermore, loss reserve “takedowns” from prior years have run their course and are no longer available to mask some carriers’ operating deficiencies.

Takedowns occur when more money was set aside to pay for claims than was ultimately needed. As losses came in lower than expected industry-wide, some of the money set aside to pay claims was released and flowed directly to the company’s bottom line as income.

OMIC’s business itself has consistently earned a profit over many years. Since 2007 our combined ratio, which measures a company’s underwriting profitability, has averaged 70%. A ratio below 100% indicates that we are profitable based on our operations alone, before any income or gains from investments are considered.

This operating advantage has allowed OMIC greater flexibility in rating and dividend returns for more than a decade.

MESSAGE FROM THE CHAIR

continued from page 1

The low frequency of endophthalmitis sometimes leads to surgeons’ complacency or even denial. We all know the signs and symptoms of endophthalmitis, but we may think or hope that the post-procedure inflammation we see is sterile. Since endophthalmitis is a recognized complication, when it is recognized and treated in a timely manner, OMIC rarely loses a lawsuit regardless of outcome. Such cases are vigorously defended. Conversely, we almost always lose when the diagnosis or treatment is delayed.

Although we can’t eliminate the risk of endophthalmitis, we must do all we can to minimize the risk. Attention to sterile technique has always been critical, but as Anne Menke notes, so is patient engagement. An engaged, educated patient is our first line of defense.

The face of endophthalmitis is changing. Historically, the most common cause of endophthalmitis has been cataract surgery.

OMIC’s premium-to-surplus ratio of 0.19 to 1 is arguably the best in the industry. At the same time, OMIC’s rates in the vast majority of the U.S. are significantly lower than our competitors’ and our average dividend returns during the past decade have averaged nearly three times higher than the industry’s.

These favorable operating results have been sustained for more than thirty years. Since 1987, OMIC’s dividend return has averaged approximately 10% per year, compared to an industry average much lower. This means that for OMIC insureds, our program has been one of the best investments around.

We are able to achieve these results primarily due to our better defense of claims, lower relative operating costs, superior investment returns, and your continued support of our company.

Due to OMIC’s continued healthy balance sheet, we are pleased to report that current insurance rates will be extended through 2019 in all states and territories. **Your Board has also approved another significant policyholder dividend equal to 15% of your 2018 annual premium to be paid upon renewal in 2019.**

With the explosion of intravitreal injections, that is certain to change. 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 power of such large numbers provides OMIC with a potent risk management tool. That is why OMIC has been a strong supporter of the IRIS Registry.

This support is another example of the unique synergy between OMIC and the American Academy of Ophthalmology. Of course, this is one of the many advantages OMIC has over other malpractice carriers; just what you would expect from a company of ophthalmologists for ophthalmologists. When stuff happens, OMIC will be there for you.

What will OMIC pay for if I am sued?

KIMBERLY K. WYNKOOP, ESQ, OMIC General Counsel

You probably know the limits of liability you carry for your medical professional liability insurance. But have you wondered what these limits pay for?

Many insureds carry \$1 million per claim/\$3 million aggregate limits. This means they have \$1 million to pay damages for each claim that comes in that policy year, and the total coverage for claims made that policy year is \$3 million, no matter how many claims are made. So, if five claims were made that policy year and each settled for \$200,000, the insured would have used \$1 million of their total \$3 million aggregate. If three claims were made that policy year and each settled for \$1 million dollars, the insured would have reached their aggregate limit and no more funds would be available to pay other claims made that year. (Remember that the aggregate only applies to claims made in a single policy year; each year there is a separate aggregate.) Exceeding one's aggregate limit would be very unlikely to occur. No one in OMIC's 30 year history has ever done so. Such a large number of claims, worsened by the high severity of the losses, would be worrisome to the company as well as the insured.

Damages

The damages covered within the policy limit include money paid as compensation to others as a result of a claim alleging injury from an error or omission in your provision of professional services. The damages – money to be paid to the claimant – could result from a demand letter sent to you by an injured patient asking for compensation because of alleged substandard care. Or, if a plaintiff sues you, damages might be paid if a settlement is reached or the plaintiff wins at trial.

Damages include prejudgment interest. A jury might determine that the plaintiff should be awarded

\$100,000 for their injury. However, three years may have passed between when the injury occurred and when the jury verdict was entered. The court could award interest accruing on the \$100,000 over that time. This interest is covered within the policy limit.

Damages also include any legally-required payment of the claimant's legal expenses. For instance, if the state's laws say that when a plaintiff wins at court the defendant has to pay for the plaintiff's attorney fees, the policy would cover these fees within the limit of liability.

Supplementary Payments

Your policy also provides supplementary payments. These are monies paid in addition to, not out of, your limits of liability for a covered claim. The most significant of these supplementary payments is claim expenses, i.e., your legal fees to defend to the claim, and related costs such as expert witness fees. Keep in mind that claim expenses must be incurred or approved by OMIC to be covered. Some insurance policies include claim expenses within the limits of liability. These are often called "wasting policies." They substantially decrease the amount of money the insured has to pay an award of damages. It can cost well over \$100,000 in attorney fees to take a claim through trial. In such a case, under a wasting policy, the insured would have only \$900,000 left to pay any damages awarded.

Another supplementary payment is post-judgment interest. This means all interest on the amount of any judgment within the policy limit that accrues after entry of the judgment and before OMIC has paid the judgment. Premiums on appeals bonds authorized by OMIC are also paid in addition to the limits of liability.

OMIC also pays reasonable expenses, other than loss of earnings,

incurred by the Insured at OMIC's request in the investigation or defense of the claim. For example, OMIC may ask the insured to provide not only the claimant's medical records, but copies of the practice's policies and procedures manuals. OMIC would reimburse the insured for the cost of this reproduction and delivery.

At the Insured's request, OMIC will also pay an insured's loss of earnings, up to \$500 per day and \$250 per half day, when OMIC asks the insured to attend any court proceeding, trial, mediation, or arbitration involving the claim. However, attendance at the Insured's own deposition or the deposition of others is not a "court proceeding" and does not qualify for these supplementary payments.

Non-covered Sums

Neither the policy limits nor supplementary payments cover punitive damages, exemplary damages, treble damages, or any other increase in damages resulting from multiplication of compensatory damages. These damages are often awarded when intentional acts are alleged or for extremely egregious behavior. Many states do not allow insurance companies to pay punitive damages since the point is to punish the wrongdoer, i.e., the insured. Fines, penalties, and the return, reimbursement, or restitution of governmental payments are not covered for claims of injury to a patient due to your treatment. (These should not be confused with fine and penalty payments for billing errors and other regulatory matters, which are covered under the Additional Benefits section of the policy). Finally, expenses for services rendered by the Insured to the claimant (e.g., the cost of follow up treatments by the insured to remedy the injury) are not covered. These should be covered by the insured. Please see your policy for all terms, conditions, and exclusions.

Endophthalmitis malpractice claims update

continued from page 1

plaintiffs had good vision prior to the procedure, only 0.3% did after (good = $\geq 20/40$). 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 enucleation or enucleation.

The majority of plaintiffs (72%) developed endophthalmitis following cataract surgery (58) or intravitreal injections (21: Avastin 12, Eylea 5, Lucentis 3, Kenalog 1). 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. **Table 1** compares endophthalmitis claims to OMIC claims overall. The endophthalmitis claims reported from 2006 to 2017 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

	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	\$175,000	\$125,000
Range	\$9,000 to \$900,000	\$450 to \$3,375,000
Total Amount Payment	\$9,579,005 (8% of payments)	\$121,568,265

during this period.

Ophthalmology experts opined on the care provided in 137 of the 167 claims (24 closed before a review and 6 open claims have not yet been reviewed). 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.
- 11 RS practices reviewed: 10 met SOC, 0 mixed SOC, 1 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.

Factors Impacting Clinical Outcomes

So how can we use this data to improve care and 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

Clinical Category	Payments / Plaintiffs	Percent of all Claims	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



Figure 2. FACTORS AFFECTING THE CLINICAL OUTCOME OR CLAIM RESOLUTION

Diagnostic Delay (49) Contamination (18) Comorbidities (12) Incision Issues (10)
 Procedure Indications (8) Treatment (7) and Capsule Rupture (5)

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. Difficulty in determining a rare diagnosis is readily understood. It is harder to explain why ophthalmologists 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.

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. 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 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 condition, 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.

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. The Closed Claim Study on page 6 highlights the importance of using aseptic technique for intravitreal injections. In 7 claims against one defendant, lack of expert support led to a total payment of \$1,185,000. 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

continued on page 7



CLOSED CLAIM STUDY

Endophthalmitis outbreak following intravitreal injections

RYAN M. BUCSI, OMIC Claims Manager

Allegation

Negligent anti-VEGF and dexamethasone injections.

Disposition

Seven of eight patients' cases settled on behalf of the OMIC-insured professional entity for \$20K, \$110K, \$125K, \$175K, \$175K, \$185K, & \$395K for a total of \$1,185,000.

One patient did not pursue legal action.

On 1/26/16 and 1/27/16, a non-OMIC ophthalmologist at an OMIC-insured practice injected 8 patients, aged 64 to 94, with Avastin or Eylea to treat neovascular age-related macular degeneration. The patients' visual acuities in the eyes to be injected ranged from 20/25 to 20/150. The ophthalmologist added dexamethasone to the anti-VEGF medication. The dexamethasone was withdrawn from the same single-dose vial for all 8 patients. The ophthalmologist used the needle included with the Eylea kit to puncture the dexamethasone vial after puncturing the Eylea vial. The prepackaged Avastin needle was used to puncture the dexamethasone vial and then was used again to inject the patients. Betadine and Navobay Hypochlorous solution was used to prep for the treatment. Following the injections, the ophthalmologist pressed on each of the treated eyes with his bare finger to check the pressure. Each patient returned within 2 to 3 days complaining of decreased vision and pain and was diagnosed with endophthalmitis. Despite treatment, each patient lost visual acuity. The visual acuities post-injection ranged from 20/200 to hand motion.

Analysis

OMIC's retained expert opined that both the non-OMIC ophthalmologist and the OMIC-insured practice failed to meet the standard of care. The expert criticized the following aspects of the care. None of the consent forms for Avastin and Eylea mentioned anything about the addition of dexamethasone. The records were sloppy and inaccurate with no specific operative note. Adding steroids to an anti-VEGF medication was unnecessary: there are no clinical trials demonstrating that adding steroids increases the effectiveness of Avastin or Eylea. Puncturing a single-dose vial multiple times with the needle from the Avastin or Eylea, and then using the same needle to inject the patient, was beneath the standard of care. Pressing on the eye with a bare finger after injecting the anti-VEGF medication to check the pressure could have contributed to the infection.

The expert also raised concerns about the drugs used to anesthetize the eye. The patients received subconjunctival injections of Marcaine and Lidocaine. It is unclear why Marcaine was used, since the anti-VEGF procedure only lasts a

few minutes. The drugs were presumably drawn from separate vials using the same syringe, another possible source of infection. The expert also questioned the pre-injection preparation using both Betadine and Navobay Hypochlorous solution. There is nothing in the literature to support the use of Hypochlorous solution before an intravitreal injection. The ophthalmologist should have just used Betadine.

The expert also criticized the role the staff at the OMIC-insured practice was asked to play. The technicians—not the physician—obtained informed consent for the injections. In addition, the technicians at times drew up the dexamethasone from the single-use vial and added it to the Avastin or Eylea, compounding the drug when the MD should have done so. The technicians, like the ophthalmologist, did not wear gloves when handling the patients. After washing or sanitizing their hands, the ophthalmologist and the technicians adjusted the chair numerous times, then touched the patient, which was another possible source of contamination.

Takeaway

Seven of the eight patients filed lawsuits against the ophthalmologist and practice. From OMIC's perspective, these cases were indefensible and needed to be settled versus trying each of these 7 cases in front of 7 different juries. OMIC felt that the treatment by the non-OMIC insured ophthalmologist was likely the source of this endophthalmitis outbreak, especially since he touched the eyes following each injection with his bare hand. However, there were multiple potential sources of endophthalmitis in these cases, including the way the dexamethasone was added to the anti-VEGF medications. Therefore, OMIC settled these 7 cases on behalf of our insured entity. The multispecialty carrier for the ophthalmologist placed the blame for this endophthalmitis outbreak solely on the OMIC-insured technicians and opined that the ophthalmologist met the standard of care. The other carrier also questioned the credentials of our retained expert and championed its insured as a much more qualified expert in the field of ophthalmology. Eventually, the multispecialty carrier settled the cases on behalf of the ophthalmologist.



Endophthalmitis education for patients

ANNE M. MENKE, RN, PHD, OMIC Patient Safety Manager

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. Our experts reviewing such claims try to determine whether the defendant could have handled the situation better.

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. 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 important that you call me right away if you have any problems after surgery. Here is the list of problems I want to know about."

Endophthalmitis malpractice claims update continued from page 5

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. A claim wasn't filed before the statute of limitations expired, so there was no payment.

Treatment issues were raised in 7 claims against retina specialists, with a payment made (for \$50,000) on only one. 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.



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8 *ROP Update. Liability Risks of "Off-Protocol" Treatment Decisions. Children's Hospital of Philadelphia*

January

11 *Lessons Learned from Medical Malpractice Lawsuits. Connecticut Society of Eye Physicians (CSEP) Meeting*

February

8 *Comanagement. Kansas City Society of Ophthalmology & Otolaryngology Meeting*

15 *Topic to Be Announced. New Orleans Academy of Ophthalmology (NOAO) Meeting*

23 *Do's and Don'ts in the Era of Electronic Medical Records. Ohio Ophthalmological Society (OOS) Meeting*



The study of endophthalmitis in this Digest reveals actions ophthalmologists can take to help patients achieve the best clinical outcomes and make appropriate care more defensible, e.g., more careful evaluation of post-procedure problems and better patient education.

Lead Article References:

¹Menke 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>.

²See 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.



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