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Ophthalmic Risk Management Digest
OMIC DIGEST

Are Patients Who Choose Premium IOLs a Malpractice Risk?

By Anne M. Menke, RN, PhD
OMIC Risk Manager

Staff in OMIC 's Claims and Risk Management Departments field a significant number of calls from ophthalmologists about "premium" intraocular lenses (PIOLs), the name given to those IOLs for which patients are asked to pay extra. Questions range from whether physicians need to inform patients of the availability of PIOLs during the informed consent discussion to whether refunding the extra fees paid for them is an admission of liability. To determine if implantation of PIOLs has led to lawsuits, we conducted our first claims analysis of these lenses.

Thirty-four plaintiffs filed claims involving 47 PIOL implants against 40 OMIC-insured defendants. Thirty-five of these defendants were ophthalmologists, four were associated but separately-insured ophthalmology practices, and one was a separately-insured ambulatory surgery center. Forty-four of the PIOLs were implanted during cataract surgery and three during refractive lens exchange. We compared PIOL claims to cataract and refractive surgery claims; the former share the same procedure and the latter presumably have similar refractive goals and payment issues. **Graph 1** on page 4 shows the number and type of PIOLs implanted, while **Graph 2** gives the percentage of open, closed, and total claims for PIOL, cataract, and refractive claims. PIOL claims are still very infrequent and there are more open than closed claims, but it is too soon to predict whether claims from these relatively new devices will increase over time.

Many malpractice claims are dropped before a lawsuit is even filed and most close without any money being paid to the plaintiff. **Table 1** on page 5 provides three more severity indicators: the median (middle), mean (average), and highest payments for PIOL, cataract, and refractive claims compared to all OMIC claim payments. Premium IOLs have the smallest percentage of claims that close with an indemnity payment, as well as the lowest median, mean, and high payments. In OMIC's experience to date, PIOL claims are considered very low frequency/very low severity, while cataract claims are high frequency/moderate severity, and refractive surgery claims are low frequency/moderate severity. OMIC does not have data on the prevalence of use of PIOLs, so we cannot draw any conclusions about the relative risk of premium versus monofocal IOLs.

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MESSAGE FROM THE CHAIRMAN

This summer I was flying on Southwest Airlines and picked up the June issue of *Spirit*, the magazine published by the carrier. It contained several articles celebrating the airline's 40th anniversary. The lead article, "40 Lessons to Learn from Southwest,"[1] intrigued me. Each lesson was a vignette on an aspect of the company that senior management felt was important to its success. As I was reading, I realized that several lessons could be applied to OMIC's success.

Target the overcharged and underserved. OMIC helped lower malpractice premiums in many states where ophthalmologists were subsidizing higher risk specialties.

The Web ain't cool, it's a tool. OMIC was an early adapter of web technology as a vehicle to disseminate risk management documents to a nationwide audience of policyholders. Every year, thousands of risk management documents are accessed through OMIC.com.

See your business as a cause. Not only does OMIC provide liability insurance, it partners with the American Academy of Ophthalmology and other ophthalmic organizations to improve

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Eye on OMIC

OMIC

The Ophthalmic Risk Management Digest is published quarterly by the Ophthalmic Mutual Insurance Company, a Risk Retention Group sponsored by the American Academy of Ophthalmology, for OMIC insureds and others affiliated with OMIC.

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OMIC Honored with Special Recognition Award

At the annual meeting of the American Academy of Ophthalmology in Orlando, OMIC was honored with the Special Recognition Award. This award is presented to an organization for "outstanding service in a specific effort or cause that has improved the quality of eye care." OMIC is truly honored to receive this award because it recognizes that by improving patient safety and education, our unique program has reduced the risk of litigation against our policyholders and all ophthalmologists. OMIC's vast library of patient education materials has become a major web-based resource for ophthalmologists worldwide.

Accolades bestowed upon our company in 2011 are a reflection of the hard work and dedication of our Board and staff and the loyalty of our insureds. In addition to the award from the Academy, OMIC ranked #1 among PIAA (Physician Insurers Association of America) companies in two long-term financial benchmarks, combined and operating ratios. As a result, AM Best upgraded our creditor rating to A+ (Outstanding). OMIC was also featured on the cover of *Risk and Insurance Magazine* as one of America's most successful insurance captives and ranked #10 out of 255 medical malpractice insurers on SNL Financial's list of the top 20 best performing mid-sized commercial insurance companies.

OMIC Declares 2011 Dividend

After another year of favorable claim experience and operating results, OMIC's Board approved a 20% dividend for all active physician insureds as of December 31, 2011, to be applied as a credit to 2012 renewal premiums. OMIC has declared dividends 17 of the past 21 years, averaging nearly 10% per year since 2006. This represents thousands of dollars per insured in returned premium and is significantly higher than other carriers' dividends during this time period. Since business commenced on September 30, 1987, OMIC has declared policyholder dividend credits totaling approximately $31 million.

Message from the Chairman

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quality of care for ROP, LASIK, and other eye care services ophthalmologists provide.

Beware of imitators but take them as a compliment. Many other insurance carriers have adopted OMIC's underwriting guidelines and use our risk management information for their insured ophthalmologists.

In 2012, OMIC will celebrate its 25th year of providing professional liability insurance for members of the American Academy of Ophthalmology and risk management education for ophthalmologists worldwide. OMIC has enjoyed phenomenal growth and success during its 25-year history that parallels Southwest Airlines in certain respects.

Of course, OMIC doesn't compare in size and capitalization to Southwest Airlines, yet there are similarities worth mentioning. Both companies were started in response to unfavorable market forces and a desire to provide an alternative to existing providers in their industry. Both companies struggled in the beginning to overcome tremendous roadblocks to success. Both companies stuck to their core principles and goals and grew the company from within under the direction of dedicated leaders and the support of loyal employees. Both companies had strong, intuitive, and tenacious executive leadership. In the case of Southwest, it was Herb Kelleher and Rollin King who directed its early growth and established its corporate branding. In OMIC's case, Bruce Spivey, MD, and Reggie Stambaugh, MD, were the glue that held the company together through the early years. They established the corporate structure that would blend the company's board of directors and staff into a successful team.

Finally, Southwest Airlines and OMIC have earned the respect and loyalty of a growing customer base and, as a result, both companies have cornered substantial market share within their respective industries. With growth and success comes the responsibility of living up to one's reputation. And this, I believe, is another goal both companies share.

John W. Shore, MD
Chairman of the Board

1. "40 Lessons to Learn from Southwest." *Spirit Magazine.* Southwest Airlines, June 2011, http://www.spiritmag.com/.

Advertising Premium IOLs

By Kimberly Wynkoop
OMIC Legal Counsel

Ophthalmologists have both a legal and ethical obligation to truthfully advertise their services. This article will address issues to be aware of in advertising premium IOLs and the implications for coverage when improper advertising occurs. Much of this information was adapted from the American Academy of Ophthalmology 2008 Policy Statement: *Guidelines for Refractive Surgery Advertising.*

Both the Federal Trade Commission Act and the Federal Food, Drug, and Cosmetic Act prohibit false and deceptive or misleading advertising. The FTC has primary jurisdiction over the advertising of health care services, over-the-counter drugs, and devices. The FDA has jurisdiction over product labeling for prescription drugs and medical devices, and advertising of prescription drugs and medical devices that a licensed practitioner must authorize for sale, distribution, or use. Note that patient information brochures, seminars, and videos may be considered advertising.

State licensing authorities also regulate physician advertising and can impose disciplinary action against physicians who engage in false and deceptive advertising. In addition, every state has general laws and rules against false and misleading commercial claims. The American Academy of Ophthalmology has ethics rules which apply to advertising issues as well, most directly, Rule 13. *Communications to the Public.*

Under FDA regulations, advertising FDA-approved devices by brand name and model is permissible as long as a brief statement of the device's intended uses and all relevant warnings, precautions, contraindications, and side effects are provided in the advertisement. Ads do not need to incorporate all informed consent disclosures, but they must not contradict them. If the device's FDA premarket approval orders include requirements that promotional materials contain specific risk information, those must be adhered to.

There are additional precautions to take when advertising FDA-approved premium IOLs that the ophthalmologist may use off-label. While it is legal under the "practice of medicine" exception for physicians to use FDA-approved devices off-label, advertising this use is prohibited.

The FTC requires that advertisers have a "reasonable basis" for advertising claims at the time they are made. This will usually require "competent and reliable" scientific evidence that may include the physician's own outcomes alone or in combination with other clinical studies, preferably those that have been peer reviewed or replicated in other studies.

If using a testimonial, the particular patient's experience must be typical or representative of the experiences generally achieved by the physician's patients, or else a clear and conspicuous disclosure of the results generally achieved by the users of the product or device must be included. Note that some states prohibit the use of patient testimonials.

As with LASIK advertisements, ophthalmologists should avoid ads that begin: "Throw Away Your Glasses" or have images with the same message. Even if the ad text states that the premium IOL "may correct your presbyopia and nearsightedness and may eliminate your need for glasses or contacts," consumers are still likely to infer from the dramatic opening statement or image that if they select cataract or refractive surgery with use of a premium IOL, they will achieve perfect vision and be free of any need for glasses. Since the surgeon cannot guarantee this outcome, the claim is subject to legal challenge.

Another advertising pitfall is the use of statements such as, "We use premium IOLs so you get the best results." This implies that premium IOLs produce better results than standard IOLs (or other procedures). Such a statement should be avoided unless the physician has competent and reliable scientific evidence to support it.

A statement that you can legally make is: "The Food and Drug Administration has determined that the premium IOLs we use are safe and effective for cataract surgery." The Federal Food, Drug and Cosmetic Act was amended to allow references to the FDA-approved status of medical devices in advertisements.

Aside from action by the FDA, FTC, state agency, or the ophthalmologist's professional society(ies), false or misleading advertising could lead to lawsuits against the physician by patients alleging lack of informed consent or fraud. In turn, this could result in uninsured risk as a result of the denial of the claim or termination of coverage by the ophthalmologist's malpractice insurer.

Patients may prevail in a claim of lack of informed consent where aggressive advertising has occurred. The patient may allege that the overstated benefits misled him or her into agreeing to undergo the surgery without fully understanding or appreciating the consequences and alternatives. In this way, the advertisement destroys the validity of an otherwise properly executed consent form.

OMIC's underwriting requirements for refractive surgery (which includes the use of premium IOLs for refractive lens exchange) state that advertisements must not be misleading, and must not make statements that guarantee results or cause unrealistic expectations. Violation of these underwriting requirements may cause termination of the policy or denial of coverage of a claim based on the violation. In addition, Exclusion III.B.1 of the policy provides that OMIC will defend insureds against allegations of medical malpractice that include false, misleading, or deceptive advertising or other fraudulent acts, but not if the claim is based solely on the advertising or fraud claim. Even then, the policy will not cover damages or supplementary payments for such claims.

Are Patients Who Choose Premium IOLs a Malpractice Risk?

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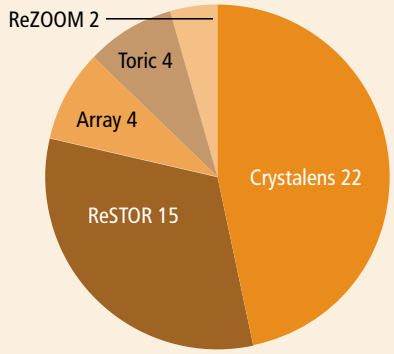
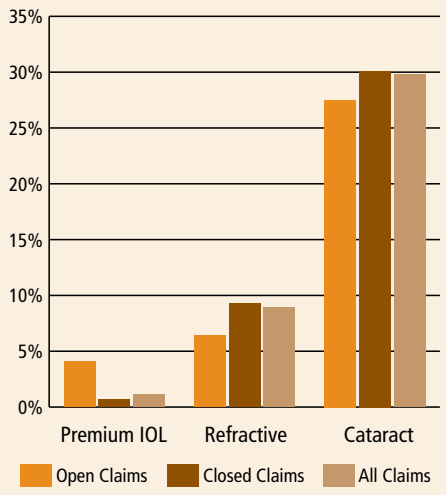
GRAPH 1.
FREQUENCY OF PIOL CLAIMS BY TYPE



Premium IOL Causation Analysis

OMIC has developed a method of analyzing the primary driving force behind malpractice claims against ophthalmologists. In this analysis, which we call CPSP, we look at four factors: clinical, physician, system, and patient. Clinical issues are areas of controversy or of limits in knowledge or diagnostic/treatment modalities. They are identified during the investigation of a claim and derived in part from the opinions of physician expert witnesses. System issues cannot be attributed to a single individual; instead these are processes in which many individuals and entities are involved. **Table 2** shows the primary and secondary causes of claims for premium IOLs in open and closed claims brought by 34 plaintiffs. System issues predominate; patient factors contribute about half as often, followed by clinical and physician ones. While physicians are the least likely contributor to claims against them, there is still much they can do to protect themselves starting with a review of the four contributing factors.

GRAPH 2. FREQUENCY AS PERCENTAGE OF OMIC CLAIMS



Candidacy issues emerged as the primary **clinical** issue: experts opined that the appropriateness of premium IOLs was not adequately evaluated for patients with multiple sclerosis, glaucoma, dry eye disease, posterior vitreous detachments, and monfocal IOLs in the fellow eye. Issues frequently seen in monofocal IOL cases were also found, such as when surgery is indicated, how long patients who wore contact lenses must be out of them before the IOL is chosen, and how to determine the dominant eye for monovision.

Experts pointed to faulty **physician** judgment as the most frequent way that ophthalmologists contribute to claims. An ophthalmologist was criticized by both plaintiff and defense experts for leaving an IOL whose haptic broke during surgery in the patient's eye, since the defect could lead to the decentration issues the patient later encountered (this elderly patient did not pursue the claim). Plaintiff and some defense experts felt that repositioning a dislocated IOL five times caused the retinal detachment the patient developed (the case settled for $215,000, of which OMIC paid $122,500).

Six **system** issues were identified (followed by the number of resulting claims): communication among team members (2), the diagnostic process (2), documentation (5), equipment (3), informed consent (20), the litigation process (4), and sterilization (1). Issues are presented for open and closed claims, but specific case examples are only provided for closed claims.

Communication breakdowns are more likely to occur when many physicians are involved in care, and when there are frequent patient hand-offs from one provider to another or from one setting to another. "Wrong" IOL and "wrong" patient errors are the most common examples of these communication breakdowns in ophthalmology, and one case occurred in this series. The ophthalmologist had correctly chosen and ordered the PIOL, but no one on the team had noticed that it was not in the OR. When the physician asked for it, he indicated the correct power but not that it was a PIOL. With the patient's permission, he immediately exchanged the IOL, and he and the ASC performed the exchange at no charge to the patient (the suit settled for $15,000 on behalf of the physician; the ASC refused to contribute and blamed the physician for the mishap).

The *diagnostic process* is one of the most complex tasks physicians perform. Certain scenarios frequently lead to allegations of delay in diagnosis, as is the case for some open claims in which multiple providers and specialties tried to find the cause of non-specific symptoms, such as headache or decreased visual acuity.

Documentation issues included omissions and additions. Experts criticized ophthalmologists' failure to document the specifics of the informed consent discussion, the process of aligning toric IOLs during surgery, and to note complications that occurred during surgery in the operative report. They questioned the accuracy of the medical record when physicians relied heavily upon templates, when scribes documented too uniformly at each visit, and when electronic medical record systems did not individualize the content for each specific patient or visit.

Equipment problems were the primary factor in two PIOL claims. A defective plunger caused a capsular rupture and prevented the ophthalmologist from implanting a Crystalens. The surgeon documented the equipment problem, disclosed

TABLE 1. COMPARISON OF INDEMNITY PAYMENTS				
	PREMIUM IOL	CATARACT	REFRACTIVE	ALL OMIC
MEDIAN	$20,000	$62,500	$50,000	$75,000
MEAN	$42,281	$121,499	$128,146	$149,463
HIGH	$122,550	$1,000,000	$983,772	$3,375,000
Median = Middle Claim of Series			Mean = Average (Total $/# Paid Claims)	

it to the patient, reported it to the hospital and the manufacturer, and offered subsequent care at no cost (the plaintiff dropped the suit). A registered nurse who had no prior experience with phacoemulsification equipment caused a corneal abrasion (the non-OMIC ASC settled the case; the physician was dismissed).

An allegation of lack of *informed consent* accompanies many malpractice claims but rarely turns out to be the pivotal factor. PIOL claims proved to be an exception to this trend, as informed consent issues were the primary factor in eleven cases, and a secondary factor in nine. We concluded that an inadequate informed consent process was the single most important driver of PIOL malpractice claims. See **Hotline** article for recommendations on how to improve the consent process.

The *litigation process* itself was the primary factor in three claims and a secondary factor in one. In some cases, expert witnesses appeared to act as an advocate for the attorney who hired them rather than as neutral experts who explain the medicine. One physician accepted a referral from the plaintiff attorney and agreed to examine and treat a patient who was not satisfied with the quality of her vision provided by her Crystalens implant. The plaintiff expert testified at trial that the defendant ophthalmologist had erroneously placed the IOL in the sulcus, despite documented exams by three prior ophthalmologists that the IOL was in the capsular bag (the jury returned a defense verdict). In another case, the plaintiff expert did not carefully review the medical records provided by the plaintiff attorney and certified that the care was substandard; when challenged by the defense attorney during his deposition, the plaintiff expert acknowledged that far from substantiating his criticisms, the medical record demonstrated that the ophthalmologist had met the standard of care (a motion for summary judgment was granted).

Defense expert witnesses can also surprise the attorneys who hire them. A patient in her forties with preoperative visual acuity of 20/40 was offered cataract surgery with a PIOL. The plaintiff expert felt a more careful preoperative exam would have noted a posterior vitreous detachment, which he believed led to an inferior retinal tear. The defense expert was initially supportive and noted that the tear did not impact the patient's vision. Only during deposition did the defendant and defense attorney learn that their expert was critical of the failure to perform glare testing before recommending cataract surgery (the timing of this reversal of opinion led to a $45,000 settlement).

Patient factors played an important role in PIOL claims, second only to system issues. Accepting an unsatisfactory outcome requires more resiliency than some patients possess or can develop; mental health issues thus were a primary cause in three and a secondary cause in seven claims. One patient had bilateral Crystalens implants but was not satisfied with the quality of her distance vision, so she asked that her distance vision be improved with LASIK at the cost of near vision. Although she acknowledged the need for glasses before she had the refractive procedure, she nonetheless filed a claim and wrote to the medical board when she then had to wear the glasses (the claim was dismissed, and the medical board supported the care). The feeling that the ophthalmologist "must have been done something wrong" was strongest in patients who developed a cascade of complications requiring multiple office visits, medications, consultations, and procedures. A patient with a long eye and a history of prior LASIK surgery experienced a ruptured capsule during surgery to implant a ReSTOR lens; postoperatively, she had a hyperopic surprise and developed bullous keratopathy. Not surprisingly, she was unhappy when her final visual acuity after an IOL exchange and DSAEK was only 20/80 (there was strong defense support for the care and the statute of limitations had expired; the defense motion for summary judgment was granted and the case was dismissed).

TABLE 2. PRIMARY AND SECONDARY CAUSES OF PREMIUM IOL CLAIMS				
	CLINICAL	PHYSICIAN	SYSTEM	PATIENT
PRIMARY	3	5	20	6
SECONDARY	6	2	18	9
TOTAL	9	7	38	15

As specialists who develop and incorporate new technology at a rapid pace, all ophthalmologists can learn from this early report on malpractice claims related to premium IOLs and implement measures to ensure that patients are carefully selected as candidates for the latest advances and are fully engaged in the decision and care process. The AAO recently published a *Focal Points* module on MFIOLs and AIOLs in which authors Steven I. Rosenfeld, MD, and Terrence P. O'Brien, MD, provide a systematic approach to determining the cause of the patient's complaint and how to best address it.[1]

1. "The Dissatisfied Presbyopia-Correcting IOL Patient." *Focal Points: Clinical Modules for Ophthalmologists.* American Academy of Ophthalmology, September 2011.

Closed Claim Study

Defense Verdict in Alleged Negligent Placement of Crystalens

By Ryan Bucsi, OMIC Senior Litigation Analyst

ALLEGATION

Negligent placement of a Crystalens in the sulcus resulting in a lens exchange.

DISPOSITION

Defense verdict.

Case Summary

A 45-year-old female patient was diagnosed with cataracts OU and underwent an uncomplicated cataract surgery OD with placement of a Crystalens. The insured ophthalmologist recommended the Crystalens implant because it might allow the patient to be free of glasses and have fewer starbursts and halos. At the first postoperative examination, the patient's uncorrected vision was 20/20 OD. At the second visit, the patient's uncorrected visual acuity remained 20/20 OD, but she complained of blurry, tunnel vision, and poor distance vision. At the third follow-up examination, uncorrected visual acuity decreased to 20/50, corrected to 20/25 OD, with complaints of halos and starbursts. The insured recommended a second opinion, which revealed an uncorrected visual acuity of 20/30 corrected to 20/20 OD near, with the Crystalens in good position. The patient self referred to another ophthalmologist whose examination revealed uncorrected 20/30, 20/20 corrected distance vision with J3 at near with the Crystalens in good position. The patient consulted an attorney and was referred to an ophthalmologist he utilized as an expert in medical malpractice cases. This ophthalmologist's exam revealed 20/50 uncorrected visual acuity and 20/20 OD corrected. The plaintiff expert ophthalmologist performed a lens exchange procedure and placed an AMO model ZA9003 posterior chamber intraocular lens OD. During trial, the plaintiff's vision was 20/30 uncorrected, corrected to 20/20 at distance OD, with 20/25+1 corrected at close distance.

Analysis

The plaintiff expert testified that he did not recommend a lens exchange; rather, the patient requested it due to continuing complaints of blurry vision from "jiggly lines," glare, halos, and tunnel vision. The patient reported that the lens exchange procedure improved her visual acuity but did not alleviate the halos and starbursts. The plaintiff expert testified that during the lens exchange the Crystalens was in the sulcus. He opined that the lens must have been incorrectly placed there by the OMIC insured although this expert admitted he did not use and had no experience with Crystalens implants. The OMIC insured and both subsequent treating ophthalmologists maintained that the Crystalens was in the capsular bag when they examined the patient. OMIC's defense expert testified that it was possible for a lens to move from the capsular bag to the sulcus, and he noted that the plaintiff's vision was correctable to 20/20 OD postoperatively. OMIC believed the insured's care was defensible. First, there was support from an expert with significant experience using Crystalens implants and from two subsequent treating ophthalmologists that the lens was properly positioned, while the plaintiff expert was a "hired gun" with no experience using Crystalens. Second, the OMIC insured would relate well to a jury as "an expert" on behalf of his own defense, and the defense counsel had previously and successfully tried cases against this plaintiff attorney. The only hesitation in taking this case to trial was the venue, which had a reputation for plaintiff-oriented juries. Nevertheless, OMIC was confident that a jury would return a defense verdict, and the case proceeded to trial. After two days at trial and 90 minutes of deliberation, the jury returned with a unanimous defense verdict for the OMIC insured.

Risk Management Principles

In addition to a signed written consent form for cataract surgery with a Crystalens, the insured documented his conversations with the patient regarding the Crystalens. The informed consent specifically mentioned double vision or ghost images, shadows in the peripheral vision, floaters or flashes of light, and halos or reflections from lights. The insured's records were complete and it was easy to follow his thought processes throughout his treatment of this patient. When he could find no objective reason for the patient's postoperative complaints, he referred the patient for a second opinion, which confirmed a good result and proper positioning of the Crystalens. During litigation, the insured set aside adequate time to meet with defense counsel in preparation for deposition and trial testimony. Although a well-qualified defense expert was hired by OMIC, it was defense counsel's opinion that the insured's trial testimony had the greatest impact on the jury. As this case demonstrates, active participation by the insured in defense of a medical malpractice case can significantly contribute to a favorable outcome.

Risk Management Hotline

Maintaining an Effective Informed Consent Process

By Anne M. Menke, RN, PhD
OMIC Risk Manager

In nearly all PIOL claims we reviewed, ophthalmologists had lengthy informed consent discussions with patients and asked them to sign detailed procedure-specific forms before surgery; yet, patients alleged lack of informed consent. What happened? Almost inevitably, a breakdown in physician-patient communication occurred after surgery when patients experienced side effects or complications, or did not quickly achieve spectacle independence or the quality of vision they wanted—and for which they paid thousands of dollars out of their own pockets.

Q What information was missing from the initial informed consent discussion in the PIOL claims?

A Ophthalmologists can do a better job of identifying, evaluating, disclosing, and documenting the presence of systemic or ocular comorbidities that could impact the quality of the visual outcome:

"As you know, you are a glaucoma suspect. My review of the visual field and OCT results show no signs of active disease, so I feel you are an appropriate candidate for a PIOL. You may be at increased risk, however, for optic nerve damage and vision loss if your intraocular pressure rises during or after surgery, or if you develop swelling and need to be on steroid eye drops for a prolonged period of time. Are you willing to go forward knowing you could have this problem?"

Eye surgeons can also educate patients about areas of clinical uncertainty:

"Not all ophthalmologists agree that patients with a monofocal IOL in one eye are good candidates for a premium IOL in the other eye, so I want to talk to you about the drawbacks for you of implanting this type of IOL."

Q Why do you recommend relating postoperative problems with the consent the patient signed before surgery?

A Although patients hear and read information about potential complications, they tend to emphasize the benefits, minimize the risks, and assume that these problems will not happen to them. When they face disappointing outcomes, some patients may fear that something they did caused it. Others may decide the surgeon was at fault, probably in agreeing to implant the premium IOL rather than insisting on a monofocal one, or in not preventing or better managing the complication. Ophthalmologists can help patients by "normalizing" the outcome: far from being a surprise, perioperative complications are expected in a certain number of cases, despite the best efforts of patients and surgeons alike, and that is why they are discussed before every surgery. When physicians listen to patients' concerns with empathy rather than defensiveness, they promote emotional healing and strengthen the physician/patient relationship.

Q Should I discuss the extra charges as part of informed consent?

A Unmet expectations and confusion over what services were covered by the extra charges led to dissatisfaction in a number of cases. One patient called her ophthalmologist when she received a bill for toric IOLs from the ASC. Trying to be helpful, a staff member at the practice explained that the ASC orders and provides the IOL. Convinced that the ophthalmologist had double-billed her, she filed a claim alleging fraud (it was dismissed). ASCs already receive $105 for the IOL as part of the surgical fee, so a recent AAO Coding Bulletin on PIOLs advises them to collect the extra fee for the PIOL, both to clarify the billing process for the patient and to avoid the appearance of splitting fees with the surgeon.[1] Ophthalmologists may prevent billing surprises by providing patients with an itemized account of the professional services they will provide and clearly indicating whether the fee covers any additional surgery needed to optimize the quality and precision of the visual outcome. ASCs would be well-advised to provide details about their fees as well as part of the admission process.

Q At what point should I consider refunding the extra amount the patient has paid for a PIOL?

A Some patients may ask for a refund as soon as a problem arises, others may not bring it up at all. If you were not able to implant a PIOL, consider refunding the extra fee right away. If after doing everything you can to improve the refractive outcome and address any complications, the patient still is not satisfied, consider a refund then. Whether or not to offer a refund is a business decision and not an admission of liability.

OMIC risk management staff are here to assist you. Call the confidential Hotline at (800) 562-6642, ext. 641.

1. Vicchrilli S. "Coding for Premium IOLs." *AAOE Coding Bulletin*. American Association of Ophthalmic Executives, October 2011, www.aao.org.

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Calendar of Events

OMIC will continue its popular risk management courses in 2012. Upon completion of an OMIC online course, CD/DVD, or live seminar, OMIC insureds receive one risk management premium discount per premium year to be applied upon renewal. For most programs, a 5% risk management discount is available; however, insureds who are members of a cooperative venture society (indicated by an asterisk) may earn an *additional discount* by participating in an approved OMIC risk management activity. Courses are listed here and on the OMIC web site, **www.omic.com**.

Contact Linda Nakamura at (800) 562-6642, ext. 652, or lnakamura@omic.com for questions about OMIC's risk management seminars, CD/DVD recordings, or computer-based courses.

January

26 *Malpractice Case Studies*
Contact Lens Association of Ophthalmologists (CLAO)*
Caesar's Palace, Las Vegas, NV; 4:10–5:05 pm. Register with CLAO at http://www.clao.org.

February

11 *Malpractice Case Studies*
Ohio Ophthalmological Society*
Hilton at Easton, Columbus, OH; 2:40–3:40 pm. Register with OOS at (614) 527–6799 or tbaker@ohioeye.org.

24 *Malpractice Case Studies*
New England Ophthalmological Society (NEOS)*
Back Bay Event Center, Boston, MA; 11:45 am–1:00 pm. Register with NEOS at http://www.neos-eyes.org.

March

10 *Malpractice Case Studies*
Illinois Association of Ophthalmology (IAO)*
Stephens Conference Center, Rosemont, IL; 11:00 am–noon. Register with IAO at (847) 680-1666 or http://www.ILeyeMD.org.

24–28 *Malpractice Case Studies*
American Association for Pediatric Ophthalmology & Strabismus (AAPOS)*
Grand Hyatt, San Antonio, TX; date and time TBA. Register with AAPOS at (415) 561-8505 or http://www.aapos.org/meeting/annual_meeting_folder/registration.

Holiday Closure

OMIC will be closed Monday, December 26, 2011, and Monday, January 2, 2012, and will operate on a dramatically reduced schedule December 27–30. If you have an urgent matter and must speak to a staff member during the holidays, please call (800) 562-6642, ext. 609, and leave a message. Staff will check this message line throughout the week and return urgent calls in a timely manner. Non-urgent calls will be returned on Tuesday, January 3. The OMIC staff wishes you and your family a safe and happy holiday.