### MESSAGE FROM THE CHAIRMAN

# The Pressures and Risks of Keeping Current

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

ew diagnostic, therapeutic, and surgical advances force eye surgeons to decide whether, when, and how to incorporate these new techniques and approaches into their practice. These changes also raise questions about how a particular standard of care develops, ways to learn and assess new skills, and duties of disclosure and consent. This issue of the *Digest* uses OMIC's 25 years of ophthalmic claims experience to help those who embrace — or resist — change to weigh their options.

At some point after the announcement of new devices, drugs, or clinical guidelines, many OMIC policyholders contact OMIC's confidential Risk Management Hotline. A few, the enthusiastic early adopters, want a consent form or suggestions on how to quickly incorporate the change. They may spend insufficient time analyzing the risks or consequences of the approach. Others have watched what seemed to be a promising innovation lead to unanticipated problems with patients, insurance companies, and regulatory agencies. They feel they are best served by a "wait and see" approach. But a common thread among the calls is the concern that failure to implement the latest "advance" could be construed as failure to meet the standard of care and lead to liability.

Part of the anxiety stems from the fact that the "standard of care" is a legal, not a medical, measuring stick. It is determined in each malpractice claim by the sworn testimony of expert witnesses who may not agree on what the standard requires, much less on whether the particular physician fulfilled the duty to provide that level of care. In the final analysis, juries and courts determine the standard in the case before them when they render a verdict. Rather than look to the standard of care, physicians tend to measure themselves by the "standard of practice," that is, by what other ophthalmologists in their region or area of expertise usually do. If most competitors offer a new device or use a new technique, the ophthalmologist may feel pressured to follow suit, especially in an area where there is significant marketing of physician services. If most colleagues allow unlicensed staff to perform certain tasks, the eye surgeon may have fewer qualms about delegating that service. Using the standard of practice as a barometer may not be a safe

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I recently returned from Orlando, where I attended the annual meeting of the Florida Society of Ophthalmology (FSO). There I observed how different ophthalmic entities can work together to provide outstanding scientific and educational programs,

address advocacy and political

issues of importance to Florida

ophthalmologists, and support ophthalmic specific risk management education for ophthalmologists. As an invited speaker engaged in the scientific program only, I had a unique opportunity to observe the FSO, AAO, and OMIC, each with different goals and leaders, present a unique, over-the-top program that was scientifically stimulating, politically meaningful, and in the best interest of patients needing eye care in Florida.

The OMIC risk management program highlighted the beneficial relationship among the three groups. The program faculty included past FSO president and OMIC committee member Bradley Fouraker, MD, OMIC committee member Steven Rosenfeld, MD, OMIC risk manager Anne Menke, RN, PhD, and FSO general counsel Bruce May, who has represented the FSO before the Florida legislature for more than 20 years.

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### Eye on OMIC

### **OMIC**

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Photos by Mike Shore

### **Safe Surgery Checklist for ASCs**

ommunication breakdowns are the primary cause of 70% of serious adverse events reported to The Joint Commission. Nowhere is clear and consistent communication more important than in the operating room.

In the 2012 ASC payment rule published last year, the Center for Medicare and Medicaid Services outlined its requirements for a new ASC quality reporting program. While the quality measure reporting requirements do not take effect until October 1, 2012, a requirement that all ASCs begin using a standard surgical checklist was implemented January 1 and will be taken into account for determining whether an ASC will be subject to a 2% penalty in future years.

To help ophthalmic ASCs meet this requirement, the American Academy of Ophthalmology and OMIC asked key ophthalmic societies to join them in developing an ophthalmic-specific surgical checklist that can be adapted as needed. Developed in partnership with the American Society of Cataract and Refractive Surgery, the American Society of Ophthalmic Registered Nurses, and

the Outpatient Ophthalmic Surgery Society, the checklist divides surgical care into three phases: sign-in before anesthesia, time-out before incision, and sign-out before transfer from the OR to the post-anesthesia recovery room. The checklist can be adapted to meet the needs of patients having many kinds of procedures. It is available online at www.omic.com and www.aao.org/advocacy/reimbursement.

### OMIC Nominee Chosen for AAO Leadership Program

OMIC committee member Denise R. Chamblee, MD, is one of twenty ophthalmologists chosen to participate in the Academy's Leadership Development Program Class of 2013. Dr. Chamblee of Newport News, VA, was nominated by OMIC and identified by the AAO via a competitive selection process as an ophthalmologist with the potential to become a leader in ophthalmology. Over the course of the yearlong program, participants attend four education sessions that address a variety of leadership, advocacy, and association governance topics. Program graduates are facilitated into leadership positions both locally and nationally.

### Message from the Chairman

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During the program we learned that over the past 18 months, ophthalmologists in Florida have been fighting legislative efforts to expand optometry's scope of practice and empower the Florida Board of Optometry to determine which oral medications optometrists could prescribe. The FSO, with assistance from the AAO Office of State Affairs and financial support from the AAO Surgical Scope Fund, was able to defeat the bill despite tremendous pressure on state legislators from optometrists. This is the third consecutive year that Florida ophthalmologists and the AAO have banded together to successfully thwart optometry's efforts to expand its therapeutic privileges.

We further learned the details of how the FSO convinced the legislature to pass a bill requiring a uniform cataract consent form that provides liability protection for surgeons who perform cataract surgery by separating known complications of surgery from adverse events not considered to be accepted complications of cataract surgery. The law is unique in requiring use of a procedure-specific consent form for

cataract surgery and lens implantation in Florida. Dr. Fouraker contacted the OMIC Risk Management Department in 2011 for help in preparing the document that was approved by the FSO and adopted by the Florida State Board of Medicine in February 2012.

This successful collaboration between OMIC and the FSO is the result of OMIC's very popular cooperative venture program, which currently includes 45 state and subspecialty ophthalmic societies. Cooperative ventures support and promote attendance of OMIC insureds at state and subspecialty society meetings and give OMIC a platform to present ophthalmologists with risk management educational materials and strategies. In the past year, more than 1,200 insureds have attended an OMIC risk management cooperative venture seminar, collectively earning over \$1 million in premium discounts as a result. If your state or subspecialty society does not have a cooperative venture agreement with OMIC, I encourage you to contact Deena Mader at dmader@omic.com to discuss the process.

> John W. Shore, MD Chairman of the Board

### **Policy Issues**



### **Equipment Leasing Liability**

### By Kimberly Wynkoop OMIC Legal Counsel

or various reasons, insureds may lease their medical equipment to other practitioners in the community. The tool may be the only one of its kind in the community and the insured may want to make it accessible to other practitioners trained in its use or accommodate an itinerant ophthalmologist. In addition, leasing the equipment could help the insured recoup some of its cost. Insureds should examine their liability for others' use of their equipment and know what their professional liability insurance does and does not cover. This issue was previously addressed in the Winter 2007 Digest: it is being discussed again in response to insureds' inquiries about leasing the femtosecond laser.

In general, when an OMIC insured (the lessor) enters into a formal lease agreement to provide space and equipment to another ophthalmologist (the lessee) and the lessor is not providing other health care-related services under the agreement, its liability should, at least theoretically, be limited to that of a landlord or lessor. This is most clear when the lessor leases its office space and equipment for use when the lessor's physicians are not themselves occupying the space or using the equipment.

### **General Negligence**

Nonetheless, there are liabilities associated with this landlord/tenant or lessor/lessee relationship. First, there is general negligence, which occurs when the lessor has breached its duty to act reasonably. For example, injured parties have argued that a lessor was liable for failing to inspect equipment and discover defects likely to cause injury; failing to deliver operating manuals to the lessee; and failing to warn a lessee of equipment defects of which the lessor knew or should have known.<sup>1</sup> OMIC's policy does not cover any liability of the lessor arising out of the lessee's use of the leased equipment or

space, as this is a general liability, not a medical professional liability, exposure.

### **Products Liability**

Lessors must also be aware of their exposure for products liability. This theory of liability provides that people who sell products in a defective condition that makes them unreasonably dangerous are subject to liability for harm caused to the end user or consumer. This liability is applied "strictly." This means that no showing of negligence or wrongdoing on the part of the seller is required for it to be found liable. Courts in many jurisdictions have applied strict liability to lessors in addition to product manufacturers and retailers. The general reasoning of the court is that these people place the goods on the market knowing that they will be used without inspection for defects.<sup>2</sup>

OMIC's policy excludes coverage for products liability. Lessors will want to ensure that they carry general liability insurance that covers not only negligence but strict products liability.

#### **Professional Liability**

The lessor may be exposed to additional liability risks if the lessee's physicians use the space and/or equipment concurrently with the lessor's physicians or if the lease agreement provides for the lessor to extend services beyond that of a typical landlord/lessor. For instance, the lessor may credential utilizers or maintain, calibrate, or operate the equipment on behalf of the lessee. The lessor's liability exposure will depend upon the services the lessor provides and how the situation is perceived by patients. This liability may fall under the professional liability umbrella as direct patient treatment or vicarious liability for others' direct patient treatment.

If there is no formal lease agreement and the outside utilizers are given open access to the owner's space and equipment, or when a lease agreement calls for the lessor to perform tasks outside of the traditional landlord/ lessor realm, OMIC would treat the arrangement as an "outpatient surgical facility" (OSF). Subject to underwriting review, compliance with OMIC's OSF requirements, and payment of any applicable premium, coverage may be extended to the OSF for its direct liability and its vicarious liability arising from the professional services rendered at the facility.

### **Leased Employees**

Ideally, when lessees use equipment leased from an OMIC-insured group. they should provide their own qualified staff to assist them. However, if the lessees do not have anyone qualified to assist and they need the lessor to provide staff trained and skilled in performing procedures on the equipment, then the lessor should formally lease the employee as well as the equipment to the lessee in order for the lessee's policy to respond (assuming the lessee is OMIC insured or has similar policy coverage). In this case, the lessee's policy would extend coverage to the leased employee while that person was rendering services on behalf of the lessee. The lessor's policy would not cover the leased employee for the work he or she did for the outside utilizer. The policy covers non-physician employees only while they are acting within the scope of their employment by and for the direct benefit of the Insured.

If the employee is not formally leased to the other ophthalmologist, but is simply "loaned," the work by the employee again is not for the direct benefit of the employer and therefore is not covered under the employer's policy. And, under OMIC's policy, since the borrower has not formally leased the employee, the employee might not have coverage under the borrower's policy. Employees, therefore, should ensure that they are covered under a lessee's or borrowing ophthalmologist's policy before agreeing to work for them. If not, the employee should obtain his or her own policy with an appropriate carrier.

- 1. Weinberg KP. "Florida Court Buries Graves Amendment Regarding Lessor Liability Claims and Financial Responsibility." *Monitor Daily*. October 2008. www.monitordaily.com.
- 2. "Finance Lessors Not Subject to Strict Products Liability." Herr & Zapala, LLP. www.mylawfirm.com, accessed June 25, 2012.

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### The Pressures and Risks of Keeping Current

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approach, especially if what physicians are doing is contraindicated by a regulation or law (e.g., California law restricts subjective refraction to ophthalmologists and optometrists; nonetheless, unlicensed, highlytrained staff regularly perform this task if directed to do so). Finally, there are often competing yet accepted approaches to a condition or procedure (known as "the accepted minority"). Physicians need a way to measure the risks and benefits of changing their practice.

#### **Does it Clearly Benefit the Patient?**

One risk management approach is to base the decision, at least in large part, on its potential impact on the patient. A few relatively recent examples provide some guidance. Within hours of the first presentation at a retina meeting about using offlabel bevacizumab (Avastin) to treat age-related macular degeneration, OMIC policyholders called the Hotline and asked us to develop a consent form. Before doing so, staff and Board members conducted a risk assessment. Avastin for the treatment of AMD is an example of an advance at the safer end of the risk spectrum for patients. It was targeted at a disease that without treatment could lead to severe vision loss, and the available alternatives were not as effective (indeed, Avastin seemed able to actually improve vision rather than slow the progression of the disease). In concert with the clear benefit for the patient were the low risks and costs for the physician: there was a quick and relatively simple learning curve for the ophthalmologist, since intravitreal injections had long been part of retina practice, and the acquisition and implementation costs were minimal.

OMIC felt the patient safety and professional liability risks were low, and quickly developed and posted an informed consent document and risk management recommendations for it. Retinal surgeons began to offer it within a relatively short period of time, and ophthalmologists who

didn't offer it to their patients could have been challenged, if not criticized, in the event of a lawsuit. The benefit to patients, including cost-savings, was so evident that even with the added risks associated with compounding pharmacies and off-label use, ophthalmologists have continued to administer Avastin even after ranibizumab (Lucentis) was approved. Ophthalmologists who use Avastin rarely have called the OMIC Hotline or Claims Department. OMIC's initial analysis of the patient safety and liability risk has proved accurate.

The same drug used in a different patient population, however, continues to raise questions about risks that are difficult to gauge. The neovascularization associated with retinopathy of prematurity has been treated with Avastin in clinical trials and off-label for individual patients. There is, as yet, no clear consensus on dosage, repeat injections, and the long-term systemic risk for infants whose brains and lungs need the VEGF that Avastin blocks. The drug also appears to change the natural history of the disease, causing very late recurrence. OMIC is monitoring the situation closely and urges all policyholders considering its use for ROP to speak to our risk manager.

### Are There Steep Learning Curves and Acquisition Costs?

Two recent examples in cataract surgery have more complex risk/ benefit analyses and adoption rates and show the importance of conducting a cost and risk assessment for the physician. The first example is the advent of "premium" intraocular lenses (IOLs). These lenses offered patients the ability to reduce their dependence upon glasses or contact lenses and to have less residual astigmatism. They also presented physicians and ambulatory surgery centers (ASCs) with a new revenue source once the regulatory hurdles were removed: in 2003, the Centers for Medicare & Medicaid Services (CMS) decided to allow patients to upgrade to these IOLs. The benefit of premium IOLs was not as pervasive or as clear cut as it had been for Avastin. Not all patients felt the need to "throw away their glasses" and some felt that reduced spectacle wear was not worth the higher fees associated with these IOLs. Other patients were poor candidates due to comorbidities. Some did not have the money to pay the surgeon and ASC the additional charges for premium IOLs even if they wanted to acquire them. And despite the revenue potential, most ophthalmologists did not, and still do not, implant these lenses. The early adopters tended to be refractive surgeons who had already purchased the recommended diagnostic equipment and, just as importantly, had worked hard to create a team trained to meet the high expectations of patients who pay cash for ophthalmic procedures.

**OMIC** staff and Board members discussed the new devices. As monofocal IOLs with glasses or contact lenses were an adequate alternative, OMIC's opinion was that surgeons should not feel any pressure to offer premium IOLs and advised them to use their own judgment when deciding whether to implant them. However, given the potential benefit to patients, OMIC felt that all cataract surgeons should inform patients about premium IOLs and refer patients who desired them to other surgeons in the area. Accordingly, OMIC developed and posted sample patient information materials and consent forms as well as risk management recommendations (available at www.omic.com).

Cognizant of the financial incentives to implant premium IOLs, OMIC was concerned that advertising might overstate the benefits and surgeons might devote inadequate chair time to screening candidates and helping patients make appropriate choices. These concerns have been validated. Allegations of fraudulent advertising and consumer fraud have surfaced. Moreover, ophthalmologists dealing with unhappy premium IOL patients have frequently called the



Hotline. Fortunately, dissatisfaction has been well-handled by most surgeons (many of whom have refunded the extra cost) and lawsuits have been infrequent, with a low percentage of settlements or plaintiff verdicts (see "Are Patients Who Choose Premium IOLs a Malpractice Risk?" in the Summer 2011 Digest at www.omic.com).

Most recently, OMIC staff and Board members have been discussing femtosecond laser cataract surgery (FLCS). The laser can be used to perform the anterior capsulotomy, lens fragmentation, corneal incisions, and astigmatic relaxing incisions, and early studies laud the reproducibility and accuracy of the capsulotomy, and the lower amounts of energy used during phacoemulsification.

Manufacturers of these lasers face obstacles to implementation, however. From the patient benefit perspective, the many theoretical advantages have not resulted in statistically significant improvements in patient outcomes. Indeed, there is no peer-reviewed evidence to support claims of superiority. 1,2 As cataract surgery is a covered benefit, physicians operating on Medicare patients may not charge extra for using the laser to perform the incisions, capsulotomy, or other steps in the cataract procedure. Nor may they raise the fees associated with premium IOLs to offset the costs.<sup>3</sup> And the costs are significant, with high acquisition prices plus click fees for each use. While ophthalmologists may charge patients for astigmatism reduction and use the laser to perform AK instead of manual LRIs, patients may not want to pay for it. Early adopters face steep learning curves and longer operating times and must find ways to manage the changes to patient flow, especially when the laser is located outside the room where cataract surgery is performed.<sup>4</sup> Moreover, until surgeons acquire enough experience, their patients will experience higher complication rates.<sup>5</sup>

Similar to its reasoning with premium IOLs, OMIC encourages eye surgeons to decide for themselves

whether to purchase the equipment and incorporate this technique. Given the outcomes reported so far, OMIC does not feel that patients need to be informed of this option, but OMIC is developing a sample consent form and risk management recommendations, which will be sent to policyholders as soon as they are available.

### How "Preferred" Are Practice Guidelines?

Professional ophthalmology societies, especially the American Academy of Ophthalmology, invest considerable resources in the development of treatment guidelines. The documents clarify that the intent is to "provide characteristics and components of quality care," not to set a legal standard of care to be adhered to in every instance or to advise on a particular patient. OMIC adds similar disclaimers to its clinical risk management recommendations.

Nonetheless, ophthalmologists wonder how they will fare if they do not keep current with the research or change their own practice patterns. A recent call to the Hotline provides a pertinent example. The comprehensive ophthalmologist had just returned from her state society meeting, where the postoperative management of YAG patients had been discussed. She learned that many ophthalmologists no longer have patients wait an hour for an IOP check, routinely perform dilated eye exams, or see patients as frequently in follow-up. OMIC staff reviewed with the physician the AAO's Preferred Practice Pattern on "Cataract in the Adult Eye" (revised in 2011 and available at www.aao.org). In its discussion of posterior capsule opacification, the PPP recommends that the surgeon monitor IOP only in high-risk patients in the early postoperative period and noted that "a routine dilated fundus examination was unlikely to detect retinal pathology that requires treatment in the absence of symptoms." The surgeon faced some decisions. Based upon the PPP, she could monitor IOP on high-risk patients only. She could

also choose to forego dilated eye exams and instead educate all patients about the risks and symptoms of retinal detachment. Her initial reaction was to continue to practice the way she had been trained, feeling the extra caution benefited patients. Other than the inconvenience of waiting around, there was no harm in monitoring IOP on all patients. OMIC agreed. On the other hand, OMIC's claims data shows that dilating eves is not without risk, as some patients have fallen or had motor vehicle accidents on their way home from the exam, and all experience a period of decreased vision. In the end, the physician decided to consult with colleagues at nearby tertiary care centers and review the PPP in its entirety before deciding how to respond.

### **Use Your Best Judgment**

As these examples show, it is helpful to engage in a risk analysis as part of the decision to change practice patterns. Peer-reviewed articles and clinical guidelines provide detailed guidance. The risk manager of your professional liability insurance company can provide insight on patient safety and liability risks. Many ophthalmologists have found it useful to keep a folder of pertinent articles, presentations, and notes from discussions with colleagues, as well as evidence of training courses, proctoring, and mentoring in the event their competency is called into question.

- 1. Kent C. "Femto Cataract: Do We Really Need This?" and "Laser Cataract: Better Outcomes May Follow." *Review of Ophthalmology*. April 2012.
- 2. Vukich JA. "Update on Laser Cataract Surgery." Cataract & Refractive Surgery Today. February 2012.
- 3. AAO, ASCRS Guidelines for Billing Medicare Beneficiaries When Using the Femtosecond Laser.
- 4. Khodabakhsh AJ. "Early Adopters' Experiences with Laser Cataract Surgery." *Cataract & Refractive Surgery Today*. February 2012.
- 5. Bali SJ, Hodge C, Lawless M, Roberts TV, and Sutton G. "Early Experience with the Femtosecond Laser for Cataract Surgery." *Ophthalmology*. 2012; 119: 891-899.



### **Closed Claim Study**

## **Records Alteration and Inadequate Training Related to Phakic Implants**

By Ryan Bucsi, OMIC Senior Litigation Analyst

#### **ALLEGATION**

Negligent phakic implant OS resulting in acute glaucoma, iris entrapment, and an enlarged pupil.

#### **DISPOSITION**

A jury awarded the plaintiff \$1 million.

#### **Case Summary**

19-year-old patient presented to an OMIC insured for an evaluation of LASIK versus implantation of Phakic intraocular lenses. The insured recommended Phakic intraocular lenses over LASIK and noted that Phakic intraocular lenses would have to be done off-label since the patient was outside the FDA label use age range of 24 to 45. The insured discussed this off-label use with the patient and the patient signed consent forms for the surgeries. The insured performed Phakic implant surgery first on the right eye and 10 days later on the left eye. On postoperative day 1 following the second surgery, the patient complained of extreme pain and had an intraocular pressure of 47 OS. The insured tapped the eye and the pressure was reduced to 23. On postoperative day 2, the pupil remained dilated at 8 mm and was nonreactive, even in low light. During the next year, the pupil remained non-reactive and the patient complained of glare, halos, tearing, blurriness, redness, flashing, itching, and hazy visual acuity OS. The insured diagnosed iridocorneal adhesion and performed surgery to remove the adhesion OS. There was no improvement, so the insured performed an ICL exchange procedure. The pupil remained non-reactive and disfigured due to damage to the iris resulting in glare when exposed to higher intensity light.

### **Analysis**

Through discovery it was learned that the insured did not document contemporaneously with the care provided. During his deposition, the insured testified that he added notations to the record for completeness and that these notes were made within a month or so after treatment. The patient requested her records in the summer of 2006 and plaintiff counsel requested her records via subpoena in 2008. There were entries in the 2008 chart that were not contained in the 2006 copy. A key addition was that the patient was monitored for 2 hours versus 1 hour as written in the original note following the Phakic implant procedure OS. A jury could have viewed this as self-serving

since the plaintiff's expert criticized the insured for failing to properly monitor the intraocular pressure in the hours following surgery. Although the insured had performed 12 prior Phakic implant surgeries and thousands of intraocular lens implants in cataract patients, he had not disclosed to the patient that she would be his first "off-label" Phakic implant case. Lending credibility to the allegation of inadequate experience, a representative for STARR Surgical testified that the company would have required the insured to undergo additional training to purchase and use Visian Implantable Collamer Lenses beyond the course he took in 2000 since it did not include proctoring. As a result of the challenges associated with defending this case, the decision was made to admit liability and try the case on damages only. The plaintiff's demand was \$5.7 million and OMIC offered \$500,000. The jury awarded the plaintiff \$1 million.

### **Risk Management Principles**

OMIC insureds regularly hear about the importance of not altering or adding to chart notes; however, it still occurs from time to time and significantly complicates the defense of a case. The first correspondence that the OMIC Claims Department sends out to insureds when a case is opened includes this admonition: "Maintain, absolutely, the integrity of the patient's medical record. Do not alter, delete, or make corrections or deletions to the record. Make sure the original record is kept in a safe location." This admonition should indeed be followed. When a new procedure is going to be performed it is important to make sure that the proper training and proctoring has occurred. The provider should be aware of what training is necessary and required so that a facility or manufacturer cannot come back later and proclaim that the training received was inadequate. Furthermore, as a part of the informed consent process, the ophthalmologist should consider disclosing to the patient the amount of experience he/she has performing the specific procedure. Informing the patient of limited experience diminishes plaintiff counsel's argument that if the patient had known this, he/ she would not have had the procedure. Choose patients wisely when first performing new procedures, and if a patient does not respond as expected or has a poor outcome, it is advisable to get a second opinion sooner rather than later.

### Risk Management Hotline



### Surgical Experience: Acquisition and Disclosure

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

olicyholders often call the OMIC Risk Management Hotline to discuss the risks associated with new techniques and technology. They wonder how much training is required and if and how they should talk to patients about their training and experience. The Closed Claim Study in this issue demonstrates that seeking such advice is prudent, as the physician's level of expertise may become the focus of a malpractice lawsuit.

How much experience is needed in order to present oneself as qualified?

There is no clear-cut answer. but the surgeon will be held to the standard of a reasonably prudent eye surgeon. While physicians are expected to be lifelong learners and continue to hone their skills, the acquisition of new knowledge and skills requires careful preparation. Certainly, any training required or recommended by an equipment manufacturer should be completed, as well as the review of pertinent peerreviewed literature. If the technique or technology is significantly different than that of the surgeon's experience, additional formal training may well be needed, such as skill transfer classes or practice on cadaver or animal eyes, followed by observation of experienced surgeons and surgical assisting. Once the physician feels ready to treat patients, it would be prudent to ask a senior colleague to serve as proctor (this may even be required in order to obtain privileges at a hospital or ASC). The proctor, an impartial observer with documented training and experience in the skill in question,

provides an objective evaluation and is able to attest that the surgeon has demonstrated competency. Finally, the ophthalmologist must feel that he or she is ready to perform the new skill.

I have been asked to proctor another ophthalmologist. Are there precautions I should take?

Yes. First, ensure that you are licensed in the state where the proctoring will take place and have been granted privileges at the facility. Clarify with the credentialing department whether your role will be limited to observing and reporting or whether you are expected to intervene if there is a patient safety risk, and share that information with the physician being evaluated. In addition, ask if proctoring is considered a confidential peer review activity. Confirm that you and the physician whom you will be proctoring have professional liability insurance at adequate limits for the procedure. Ask the surgeon to inform the patient that you will be observing the surgery. Be candid and objective in your evaluation.

I just purchased a femtosecond cataract laser. I completed my training from the manufacturer and have been proctored. Do I have a legal duty to tell my patients how many procedures I have done using the laser?

There is only a small body of case law governing voluntary disclosure of experience during the informed consent discussion, but one of the most famous cases highlights the risks of not discussing experience. A neurosurgeon disclosed the risks of death, stroke, and blindness to a patient who had a basilar aneurysm, stated he had done the procedure to treat it several times, and quoted a mortality rate of 2%. The patient had no prior neurological impairment but was an incomplete quadriplegic after the procedure. During the trial, the

surgeon admitted that he had done only two cases, making it seem as if he had inflated his experience. Experts testified, moreover, that he had underestimated the risk: the mortality rate ranged from a low of 11% with very experienced surgeons to a high of 20 to 30% for those surgeons with limited experience. The jury awarded the plaintiff \$6.2 million. On appeal, the Wisconsin State Supreme Court ruled that a reasonable person facing the need for an operation to treat a basilar aneurysm would have wanted to know that the neurosurgeon had little experience in the surgery and that the mortality and morbidity rates differed based on experience. In addition to mandating the disclosure, the court felt that the surgeon should have discussed the option of referral to a tertiary care center. In his analysis of the decision, OMIC Vice President Paul Weber noted that there is no clear rule on when the surgeon should talk about comparative risk and that such comparative risk data might not be available. He encouraged ophthalmologists to see the procedure from the patient's perspective. If, as a patient, the eye surgeon would want to know the level of expertise and experience of the surgeon, he or she should disclose experience (see "Trends in the Duty of Informed Consent" at www.omic.com).

What if a patient asks me about how many procedures I have done?

Here the legal answer is clear. Physicians do have a duty to answer truthfully when asked about their experience and results. When discussing results, it is important to distinguish results from clinical trials or studies from personal experience or that of the entire practice. Overstating one's results may seem relatively harmless, but it has been construed as false advertising or fraud and has led to settlements of otherwise defensible care.

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### Calendar of Events

**OMIC** continues its popular risk management courses this summer and fall. 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 Inakamura@omic.com for questions about OMIC seminars, CD/DVD recordings, or computerbased courses.

#### **August**

- 10 Weapons for Insurance in Ophthalmology: Risk Management Strategies You Need to Know. Women in Ophthalmology.\* Kingsmill Resort, Williamsburg, VA; 11:30 am–12:20 pm. Register with WIO at (414) 359-1610 or go to www.wioonline.org.
- 11 A Day in the Life of an Ophthalmologist. Michigan Society of Eye Physicians and Surgeons. Grand Hotel, Mackinac Island, MI; 11:05 am. Register with MiSEPS at (313) 823-1000 or go to www. miseps.org.

#### September

9-13 Malpractice Case Studies.
Pennsylvania Academy of
Ophthalmology.\* Three locations:
Monroeville on 9/11; Harrisburg
on 9/12; Philadelphia on 9/13;
11:15 am–12:15 pm. Register with
the PAO at (717) 909-2692 or go
to www.paeyemd.org.

- 21 North Carolina Tort Reform. North Carolina Society of Eye Physicians & Surgeons.\* Grandover Resort, Greensboro, NC; 3:00–4:00 pm. Register with Nancy Lowe at (919) 833-3836, ext. 111, or nlowe@ncmedsoc.
- 27-29 Malpractice Claims Studies. Table Rock Regional Meeting—Arkansas\*, Kansas\*, Missouri\*, Oklahoma.\* Big Cedar Lodge, Ridgedale, MO; time TBA. Register at www. tablerockroundup.org.

#### November

11 OMIC Forum: Top Ten Indemnity Payments in 2011.
Annual Meeting of the American Academy of Ophthalmology.
North Hall B, Level 3, McCormick Place, Chicago, IL; 2:00–3:30 pm.
Sign in onsite in the presentation room.

- 12 Medical Ethics in the Hot Seat: How Compliance with the Academy's Code of Ethics Can Turn a Good Litigation Defense into a Great One. Annual Meeting of the American Academy of Ophthalmology. Room \$105BC, McCormick Place, Chicago, IL; 9:00–10:00 am. Sign in onsite in the presentation
- 12 Why Take the Risk? How to Create an Effective Risk Management Strategy. Annual Meeting of the American Academy of Ophthalmology. Room S505AB, McCormick Place, Chicago, IL; 12:45–1:45 pm. Sign in onsite in the presentation room.