

Virtual Mentor
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FROM THE EDITOR

More Than Meets the Eye—Ethics in Modern Ophthalmology

This issue of *Virtual Mentor* explores some of the key ethical questions in ophthalmology that will impact patients and clinicians and engage ethicists today and for years to come as the field continues to advance. What are the responsibilities of ophthalmologists to patients, other practitioners, and society?

This month's authors focus primarily on two dimensions of responsibility to the patient: resisting the lure of commercialism and going the extra mile to provide the best possible care. Resisting the influence of industry can be a significant challenge for ophthalmologists. Yvonne M. Buys, MD, professor in the University of Toronto Department of Ophthalmology and Visual Sciences and co-director of the Glaucoma Unit at the University Health Network, warns physicians of the prevalence of "spin" in industry-funded studies of new drugs and exhorts them to read articles in their entirety and consider the source in order to make more accurate judgments about which products will be most beneficial to patients. Steven R. Kaufman, MD, elucidates the potential conflict of interest created by the fee-for-service reimbursement system and manufacturer rebates that confronts physicians as they decide between treatments for age-related macular degeneration.

But good business and good ethics don't have to be mutually exclusive, argues Penny A. Asbell, MD, MBA, professor of ophthalmology at Mount Sinai School of Medicine and director of its Cornea Service and Refractive Surgery Center. Her case commentary tackles the challenges ophthalmologists face in defending their practices from the encroachment of online contact lens purveyors and other practitioners; she advises physicians to focus on improving and expanding the services they provide to attract and retain patients. (An excerpt from the *AMA Code of Medical Ethics* covers the related topic of selling and dispensing drugs and other health-related products in the physician's office.)

Thomas A. Oetting, MD, professor of clinical ophthalmology at the University of Iowa, also emphasizes the importance of going above and beyond to provide high-quality care in his case commentary about how residents can work to offset the elevated risk they bring to patient surgeries. Helping keep the physician informed about the latest developments in the care of the eye are Usha Rao, MD, senior resident in ophthalmology at Baylor College of Medicine, who provides an overview of the recent advances in understanding and treating glaucoma, and Michael Hughes, BCO, who introduces the reader to artificial eye makers—ocularists—and how they tailor their creations to the patient. Brad Feldman, deputy editor in chief of the

American Academy of Ophthalmology's EyeWiki online encyclopedia, explains this novel initiative's contributions to ophthalmological education.

Ophthalmologists' duties to society are explored in the health law and medicine and society sections. Paul Steinkuller, MD, of Baylor College of Medicine and Texas Children's Hospital discusses the physician's responsibility to impaired drivers to protect them and others on the road. Dr. Steinkuller cites and we reprint the AMA *Code of Medical Ethics* opinion on the physician's duty to impaired drivers and society. Kiran Motaparthy, MD, from the department of dermatology at Baylor College of Medicine, raises questions about the social and ethical import of cosmetic blepharoplasty to alter the characteristically Asian eyelid.

Lastly, two commentators consider the ophthalmologists' relationship with other practitioners. Andrew Lee, MD, professor and chair of the ophthalmology department at The Methodist Hospital, writes about the importance of respect and mutual consideration in the referral-consultant relationship. Kristin E. Schleiter, JD, LLM, state government affairs analyst for the American Academy of Pediatrics, gives a short history of the recent scope-of-practice struggles between ophthalmologists and optometrists in Oklahoma and West Virginia.

We hope readers leave the pages of this month's *Virtual Mentor* with an enhanced appreciation of the art and science of ophthalmology and the ethical questions that accompany advances in the specialty.

Ashvini K. Reddy, MD
PGY-3
Department of Ophthalmology
Baylor College of Medicine
Houston, Texas

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CLINICAL CASE

Managing Risk in Cataract Surgeries Performed by Resident Ophthalmologists

Commentary by Thomas A. Oetting, MD

Dr. Harvey, a first-year resident in ophthalmology, greets Mr. Walter, a retired veteran seeking surgery for a cataract in his right eye. After taking his seat, Mr. Walter states that the vision in his right eye has progressively worsened over the past decade, and now he cannot read, do puzzles with his grandchildren, or drive safely. Mr. Walter's best corrected visual acuity is 20/160 in the right eye, and, other than a dense cataract in that eye, the remainder of his examination is unremarkable. An attending physician also examines Mr. Walter; he recommends replacement of the lens that has the cataract and suggests that Dr. Harvey take the case.

Dr. Harvey explains the individual steps of the cataract surgery to Mr. Walter and reviews potential complications, including retinal detachment, need for further surgery, and blindness. She tells him that she is a resident physician and will be performing his surgery under the supervision of an attending physician, but she does not reveal that, although she has performed cataract surgery in animal eyes and using surgical simulators, she has never before performed cataract surgery on a human eye.

Mr. Walter does not inquire about her level of experience, and Dr. Harvey does not disclose the details of her surgery training. When Dr. Harvey asks if he has any further questions, Mr. Walter smiles, shakes her hand, and states that she seems like a kind, wonderful person, and that he trusts her with his vision.

At the conclusion of their interview, Mr. Walter is asked to give informed consent.

Commentary

This case brings up three important issues.

1. Residents should identify who they are and that they will be operating with faculty.
2. A surgery resident's early cases are attended by more patient risk than later cases.
3. Residents should make up for the increased risk that learning brings by enhancing patient care.

Identify Yourself

Most patients do not understand our system of training fully. Some may understand that being in a teaching hospital means that residents are involved in their surgery. Others may not even know the difference between residents and medical students. But whatever their level of familiarity, our patients expect to be told who is operating

on them. D.M. Wisner at Penn State conducted a survey of patients in which an overwhelming majority indicated that they should be notified if a resident were going to assist or perform their surgery [1].

My worst experience with a patient in my 20 years of medicine was when I was not clear before the procedure that a resident would be helping. After hearing me instruct the resident during surgery, the patient confronted me and asked if a resident participated in the procedure. The patient was upset and felt betrayed. That incident taught me to be clear with patients that residents will participate in their care, and I have asked our residents to do the same. The good news is that, when properly informed, patients will generally entrust residents with their care. Kenman Gan from the University of Alberta showed that over 95 percent of patients agreed to allow residents' participation in their surgery [2]. My experience at Iowa is similar, and I have found that informed patients welcome well-supervised residents.

Learning Curve

Several studies have shown that risk to patients decreases with the number of surgeries a resident performs. Brad Randleman [3] at Emory showed that in residents' first 80 cases, patients were more likely to have such complications as vitreous loss than in subsequent cases. In a study of our program at the University of Iowa, Gina Rogers [4] showed that the first 60 cases carried greater risk of sentinel complications than subsequent cases.

This data is very troubling to surgery educators. Even with very experienced surgery preceptors at Iowa and Emory, operations performed by the residents at the beginning of their learning curve are attended by complications that are not eliminated by faculty oversight. This may not be true for every resident, but there is a statistically significant difference in complications between groups of early cases and groups of later cases. The additional risk of early cases means we as educators must search for ways to hasten our students' progress along the learning curve so that they not only attain proficiency sooner (i.e., the *number* of cases with additional risk is reduced), but add less risk to *every* case (i.e., the *amount* of additional risk in even the very first case is reduced).

With some enhancements in the surgery curriculum, we at Iowa were able to reduce patient risk [4]. Rogers showed that early cases (the first 60) in the enhanced curriculum were no more risky than the subsequent cases in the old curriculum. This was exciting because it gives us hope that, with the use of formative feedback, deliberate practice, simulators, and structured wet lab work, we may be able to make early cases less risky for our patients. However, even with the enhanced curriculum in the Rogers study, the first cases still presented more risk of complication than later cases. So, despite experienced faculty at Emory and Iowa and an enhanced curriculum at Iowa, our patients are taking on extra risk with more junior surgeons.

Why should patients accept this risk? Many patients in settings where residents operate have limited options for their care, but this does not justify putting those

patients at additional risk. In other words, the fact that a patient can only afford to seek care in a public hospital doesn't give the resident or the system the right to provide higher-risk care. It is ethically imperative for the hospital, faculty, and—I think most importantly—for the resident to look for ways to limit this risk to our patients. At the same time, residents must work to add to the benefit side of the risk-benefit equation, bringing the ratio closer to care available outside of the teaching institutions.

Adding Benefit as a Resident

I think residents can add value to the care that patients receive that could offset the increased risk that comes with their status as learners. One way, outlined nicely in this case, is to have a close, positive, and supportive relationship with patients that comes from the additional time residents spend with them. An enhanced patient relationship can improve the patient's experience both before and after surgery. Increased vigilance for complications—a more attentive preoperative search for risk factors and close attention to pre- and postoperative care—could balance the increased risk of the surgery.

My experience at the University of Iowa is that our residents provide exceptional pre- and postoperative care, surpassing that afforded by most private practice clinics. I can recall numerous instances when our residents have identified and brought problems to the attention of more senior surgeons. Hence, I think that the net effect of having a resident surgeon involved in patient care can be positive.

Summary

In my experience, informed patients usually allow residents to participate in their surgery and realize the benefits that residents can bring to their care. I think it is important for residents to realize that their inexperience can add risk for patients. Doing so will encourage residents to minimize this risk and look for ways to improve patient care. Resident surgeons must make use of the resources that they have—wet labs, videos, and opportunities to assist—to speed their learning. Teaching institutions must continue to search for ways to help by investing in teachers and their equipment. Finally, residents should enhance patients' preoperative and postoperative period as much as possible, so that the risk-benefit ratio is optimized for those who are having surgery performed by residents.

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Thomas A. Oetting, MD, is a professor of clinical ophthalmology at the University of Iowa in Iowa City, where he has been on the faculty for the past 13 years. He is the ophthalmology residency program director and chief of the Iowa City VA Eye Clinic.

Related in VM

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CLINICAL CASE

The Referral-Consultant Relationship

Commentary by Andrew G. Lee, MD

Dr. Nichols, a well-established comprehensive ophthalmologist, refers Mrs. Smith to Dr. Weiman, a specialist at an academic health science center, for a second opinion on the management of her glaucoma. A warm note from Dr. Nichols to Dr. Weiman details Mrs. Smith's 15-year history of glaucoma, refractory to multiple medical therapies and laser treatments. In his referral letter, Dr. Nichols states that, because conservative measures have failed and Mrs. Smith now has advanced glaucoma, he has offered Mrs. Smith a trabeculectomy, which Mrs. Smith has agreed to have in the coming month. Because Mrs. Smith seemed hesitant about surgery on prior visits and has expressed interest in participating in clinical trials with newer pharmacologic agents, Dr. Nichols is referring her to Dr. Weiman for consultation, specifically for her opinion on any additional conservative therapies that could be attempted before proceeding with the trabeculectomy.

Dr. Weiman greets Mrs. Smith, who professes her satisfaction with Dr. Nichols' care—she has been his patient for over two decades—and is equally delighted to have Dr. Weiman's opinion. Dr. Weiman examines Mrs. Smith and notes that both her optic nerves are prominently cupped and she has peripheral visual field defects that fully correspond to the appearance of her optic nerves. Her central vision is threatened by disease progression, and her intraocular pressure is elevated in both eyes despite good compliance with her medications.

Dr. Weiman tells the patient that her examination confirms Dr. Nichols' findings, and she agrees that a trabeculectomy is indeed the best option for Mrs. Smith. She explains that there are no clinical trials Mrs. Smith would qualify for with her advanced glaucoma without risking further vision loss. Dr. Weiman concludes by wishing her luck with her surgery, but as she is exiting the room, Mrs. Smith says, "Well...I just have one more question."

"Dr. Weiman," she begins. "I'm glad you agree with Dr. Nichols. The fact that you're both a professor and a glaucoma specialist means that you have great expertise with patients like me, and I don't think I can trust my eyes to anyone but the best. I've been very happy with my care from Dr. Nichols, but I would prefer that you perform my surgery."

Commentary

In this case, Dr. Nichols referred his patient to Dr. Weiman "specifically for her opinion on any additional conservative therapies that could be attempted before

proceeding with the trabeculectomy.” The consulting physician, Dr. Weiman, presumably has both the extra medical knowledge and superior fellowship-based training and experience to provide such an opinion. In his referral letter, Dr. Nichols wrote that because conservative measures had failed and Mrs. Smith now had advanced glaucoma, he has proposed a trabeculectomy, which Mrs. Smith has agreed to have shortly. I believe that Dr. Nichols’s intent is perfectly clear here, and that the consultant, Dr. Weiman, should provide the opinion that was asked of her, namely that there are no “additional conservative therapies” for Mrs. Smith and that she should proceed with surgery by the referring doctor, Dr. Nichols, as planned. Dr. Weiman did exactly what a glaucoma consultant is supposed to do in this setting: she provided the patient care that was requested and rendered the opinion. In this situation the referring doctor, not the consultant, is the center of the clinical decision-making process. The consultant should not usurp the role of the referring physician.

Mrs. Smith changes the dynamic, however. In my experience, regardless of how long the encounter has been, whenever the patient says “one more thing, doctor...,” whatever follows that phrase is actually something very important to the patient and, in neuro-ophthalmology, often the critical piece of information that can make or break a case (e.g., “One more thing, doc...does it matter that my mother had the same optic nerve problem when she was 20 years old?”). She drops the bombshell: “I would prefer that you perform my surgery.” The patient, of course, is free to make this request and should indeed make her own decisions about her surgeon and surgery. To me, the question is *not* whether or not the patient can choose a new surgeon, it is about how a consulting doctor should communicate with the patient and the referring doctor about this potential change in their respective patient-doctor and doctor-doctor relationships.

Although there is obviously no single correct answer to this situation, let me give my impressions. I believe that the consultant ophthalmologist has an obligation to express to the patient her confidence in the surgical abilities of the referring physician (if true) and to explain to the patient that the reason for the referral was to confirm the decision to proceed with surgery and not to do the actual surgery. (The potential negative impact on the consultant’s referral base—not just Dr. Nichols, but others as well—of “patient-poaching” is a real and important consideration, but it is a business issue, not an ethical one, in my view.)

The responsibilities of the referring ophthalmologist are to provide the consultant with the clinical information, ask specific questions, and define whether the consultation is for an opinion (e.g., surgery or no surgery?) or is an actual transfer of care to the consultant (if surgery is recommended, Dr. Weiman is free to go ahead and do it). Ideally, the referring physician would tell the patient all of this before sending her to the consultant: “Mrs. Smith, I am referring you to Dr. Weiman, a glaucoma specialist, for a second opinion regarding surgery, and if she agrees that you need it then I will schedule your surgery as planned next month.”

When confronted by the awkward request that she perform the surgery instead of Dr. Nichols, I believe Dr. Weiman should take the time to explain the situation and recommend that if Mrs. Smith insists on having her surgery done by a glaucoma specialist, that she return to Dr. Nichols to make this request and cancel her surgery in person. This is common courtesy. The patient in this setting has an obligation to her referring doctor to inform him of her choice. In addition, Dr. Weiman should not take the expedient, easy, yet unprofessional road of agreeing that day to perform Mrs. Smith's surgery.

Finally after the visit, Dr. Weiman should do the professional thing and give Dr. Nicholas a "heads-up" on the results of the encounter, reporting: "(1) Mrs. Smith does have severe glaucoma, as you correctly diagnosed; (2) as you suspected, no further conservative measures are available; (3) you should proceed with surgery, and...one last thing. Mrs. Smith mentioned wanting to have her surgery here with me, but I told her that she should return to you to discuss that as an option, and I did not agree today to perform her surgery."

Common courtesy demands no less from a consultant in such a situation, and a phone call in this circumstance is better for the referring doctor than finding out in a letter or by other impersonal means that the consultant has just scheduled surgery on his patient. Dr. Weiman will also be able to avoid ending up with a reputation (deserved or not), as many in academia have, for stealing patients.

Andrew G. Lee, MD, is chair of the Department of Ophthalmology at The Methodist Hospital in Houston, Texas, and professor of ophthalmology in neurology and neurological surgery at Weill Cornell Medical College in New York City. Dr. Lee serves on the editorial boards of the *American Journal of Ophthalmology*, the *Canadian Journal of Ophthalmology*, and *Eye*, and he has published seven textbooks. Dr. Lee has a special interest in the ACGME competencies in ophthalmology.

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Although Dr. Lee is a member of the ACGME Residency Review Committee (RRC), the views expressed in this article represent his personal views and should not be construed as representing the ACGME or the Residency Review Committee.

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CLINICAL CASE

Contact Lens Prescribing and Dispensing by Ophthalmologists

Commentary by Penny A. Asbell, MD, MBA

Dr. Brenner, an ophthalmologist who had been practicing in the same city for over a decade, noticed that an increasing number of patients in his community were simply requesting their contact lens prescription in his clinic and ordering them online instead of through his office, resulting in reduced revenue for his practice.

Over the next couple of years, as more ophthalmologists established themselves in his area and some patients elected to have refractive surgery with other specialists, his practice generated less revenue, and Dr. Brenner was forced to make changes in the way he ran his office. He began working longer hours, participating in more community outreach efforts, and reducing the salaries of his office staff.

To retain patients and revenue, Dr. Brenner began to prescribe mostly varieties of contact lenses that are not easily available over the internet and implemented a policy requiring patients to purchase their first month's supply of lenses from him. There was no change in the quality of contact lenses provided to patients, and the policy was outlined in paperwork that patients reviewed and approved prior to their office visit.

Commentary

The case brings to mind the often-discussed conflict between ethical behavior and business decisions, and it illustrates that many times the conflict is perceived rather than real.

Our eye specialist, Dr. Brenner, believes that he will generate greater revenue by prescribing "private-label" contact lenses. If he is selling lenses only differentiated by their packaging and higher cost, his behavior is at best dishonest, even if he's not deceiving patients outright. Hiding costs or increasing them beyond market rate typically backfires; patients catch on and seek care elsewhere.

Practical considerations aside, ethics alone obligates physicians to provide patients with sound, accurate information about the treatment options, including the risk and benefit of each alternative. Dr. Brenner can dispense private-label contact lenses ethically and as a way to enhance revenue if they are in fact unique—as are "customized wavefront" contact lenses, not available over the Internet or from other contact lens outlets. In that case, he would be providing a unique service and, perhaps, a better product and could charge accordingly, if it were the best choice for the patient.

Dr. Brenner's policy of utilizing offbeat brands not typically available over the Internet and requiring initial purchase from his office may in fact be ethical, even if it might not be especially helpful to his bottom line. It depends on the written material he provides and the clarity with which he spells out his policy. It may even be ethical to require that the first pair of lenses be secured from his office if the purpose for doing so is to confirm good fit and comfort, as determined in a follow-up visit, where adjustments can be made if needed. Generally, a contact lens prescription should not be issued until the fitting process is complete, and this typically includes a follow-up exam soon after trying new lenses. Dr. Brenner should point out to his patients that he cannot be of any help to them if they are dissatisfied with the lenses they purchased online. He has no control over the quality or accuracy of the prescription.

Given the current nature of contact lens marketing, it can be simpler and more ethical to separate the cost for fitting the lens (professional fee) from the cost of the lenses (material and handling fee). This separation of service from goods is fair to both patients and practitioners, and allows the charges to reflect what is actually being provided. This transparency lets patients know what they are paying for, and their satisfaction will help develop loyalty to the practice and maybe even referrals of new patients.

A better plan for increasing revenue and enlarging his patient base would be to expand his services. If Dr. Brenner adds to his skills by handling specialized lens fitting—such as contact lenses for keratoconus and post-LASIK patients or customized lenses—he will enhance the practice's reputation for individualized service and bring in these new patients.

In short, ethical behavior does not have to be bad for business. This is as true for a medical practice as for any other type of business. Good ethics can be a cornerstone of your service and distinguish you from the competition, including internet outlets.

Penny A. Asbell, MD, MBA, is a professor of ophthalmology at Mount Sinai School of Medicine in New York City, where she is director of the cornea and refractive services division. Her research uses basic, translational, and clinical research approaches to explore new treatments for corneal disease and new devices to correct refractive errors. She is an active lecturer worldwide.

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MEDICAL EDUCATION

The EyeWiki Initiative

Brad Feldman, MD

Over the past two decades, resources in ophthalmology, as in other medical fields, have steadily moved from the printed page to the web page. Access to these resources has varied; copyrighted materials such as journal articles and textbooks are generally available only to paying customers, whereas online databases like WebMD's e-Medicine offer free and unlimited access. As the public and the medical community have become more accustomed to free and instantaneous access to information, the demand for encyclopedic, high quality, up-to-date, online medical libraries has led to the advent of medical wikis, web sites that allow users to edit pages from their browsers.

The first successful wiki, Wikipedia, was launched in January of 2001 and revolutionized the concept and format of encyclopedias. This online encyclopedia, which now boasts more than 15 million articles in 200 languages, was initially conceived of as a feeder project to Nupedia. The story of how Wikipedia quickly overtook Nupedia provides a lesson in the enormous potential for collaboration online.

Briefly, Nupedia was an online encyclopedia project that followed a traditional route of content creation. Carefully vetted, highly qualified volunteers contributed content, which was then reviewed by the editors prior to being posted online. Within a year, however, only 12 articles were completed for the Nupedia site. In contrast, the Wikipedia feeder project allowed any user—literally, anyone with Internet access—to post content online instantly, and let other users edit these materials in real time. Within one month, this new wiki encyclopedia format resulted in the publication of 1,000 articles, and within a year it had surpassed 20,000 articles.

Articles on medical topics were by then numerous on Wikipedia. The availability of medical information on Wikipedia has sparked debate within the medical community. The advantages of the wiki format are clear: rapid content creation, ongoing editing to update articles as medicine evolves, and a simple platform that allows users from across the world to contribute.

But questions arose almost immediately about how to ensure quality and accuracy on a web site where no one is held accountable for contributions. Those who defend Wikipedia argue that, over time, the network of users removes and replaces incorrect information, and notices that information is incomplete or needs revision are now placed in the articles. But what about the damage that could be done by allowing

false or misleading information regarding medical conditions or pharmaceuticals to remain online—even for a brief period?

Successful medical wikis such as Medpedia, AskDrWiki, and Ganfyd have worked around this likely problem by requiring that all contributors register, declare their affiliations, and certify that they are medical professionals. Any registered user who contributes false information can then be easily monitored and, if necessary, have his or her editorial privileges revoked. While these requirements limit the editorial base of these wikis, the benefits in terms of quality are clear.

When, in late 2009, the American Academy of Ophthalmology (AAO) recognized the demand for a free online database of eye disease, it determined that the best way to meet this need was with an ophthalmologist-controlled wiki, and it created EyeWiki [1]. EyeWiki uses the same MediaWiki software that powers Wikipedia to create an easy-to-use editing platform.

To ensure high-quality articles, only ophthalmologists are permitted to register as users. Each user is required to provide his or her real name, affiliations, financial disclosures, and contact information. Every article is assigned to one of ten subspecialty areas within ophthalmology, and each subspecialty area is overseen by an editorial board. The editorial boards are maintained and overseen by an editor in chief and a deputy editor in chief. This structure ensures that every article on EyeWiki is monitored by qualified editors, in addition to the communal monitoring by users. Any user or editor can edit any error or report it to the editorial board. If incorrect information is repeatedly posted by a single user, that user will be blocked from editing the site by members of the editorial boards.

The intended audiences for EyeWiki are ophthalmologists, medical professionals, and medical trainees, and the site content is written at a level consistent with the needs of these groups. The web site is also an excellent resource for those patients and nonmedical professionals who seek a deeper understanding of eye diseases. As with any encyclopedic resource, EyeWiki is not meant to be a substitute for professional advice or expert medical opinions, and it may best serve as a starting point for research and information gathering rather than as an end point.

EyeWiki was launched on July 7, 2010 after being seeded with 94 articles by the editorial staff. In the 3 months since its launch, the site has been viewed over 165,000 times, with 240 registered users making more than 6,500 contributions and edits to articles. The project has received sponsorship from the most prominent organizations within ophthalmology, as well as from state ophthalmologic societies, and appears well positioned to grow considerably over the coming years. So far, the quality and self-regulation of the site has been very satisfactory. The test will be to see how AAO manages the site as the amount of content and number of users grows.

References

1. EyeWiki web site. <http://eyewiki.aao.org>. Accessed October 26, 2010.

Brad Feldman, MD, is a board-certified ophthalmologist and a fellowship-trained cornea specialist who works with the Philadelphia Eye Associates and serves on two teaching services at the Wills Eye Institute in Philadelphia. He is the deputy editor in chief of the American Academy of Ophthalmology's EyeWiki and chairman of the academy's young ophthalmologist international subcommittee.

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THE CODE SAYS

The AMA *Code of Medical Ethics*' Opinions on the Sale and Dispensing of Health-Related Products

Opinion 8.06 - Prescribing and Dispensing Drugs and Devices

(1) Physicians should prescribe drugs, devices, and other treatments based solely upon medical considerations and patient need and reasonable expectations of the effectiveness of the drug, device or other treatment for the particular patient.

(2) Physicians may not accept any kind of payment or compensation from a drug company or device manufacturer for prescribing its products. Furthermore, physicians should not be influenced in the prescribing of drugs, devices, or appliances by a direct or indirect financial interest in a firm or other supplier, regardless of whether the firm is a manufacturer, distributor, wholesaler, or repackager of the products involved.

(3) Physicians may own or operate a pharmacy, but generally may not refer their patients to the pharmacy. Exceptionally, a physician may refer patients to his or her pharmacy in accord with guidelines established in Opinion 8.0321, "Conflicts of Interest: Health Facility Ownership by a Physician." Physicians may dispense drugs within their office practices provided such dispensing primarily benefits the patient.

(4) In all instances, physicians should respect the patient's freedom of choice in selecting who will fill their prescriptions as they are in the choice of a physician and, therefore, have the right to have a prescription filled wherever they wish. (See Opinions 9.06, "Free Choice," and 8.03, "Conflicts of Interest: Guidelines.") Physicians should not urge patients to fill prescriptions from an establishment which has entered into a business or other preferential arrangement with the physician with respect to the filling of the physician's prescriptions.

(5) A third party's offer to indemnify a physician for lawsuits arising from the physician's prescription or use of the third party's drug, device, or other product, introduces inappropriate incentives into medical decision making. Such offers, regardless of their limitations, therefore constitute unacceptable gifts. This does not address contractual assignments of liability between employers or in research arrangements, nor does it address government indemnification plans.

(6) Patients have an ethically and legally recognized right to prompt access to the information contained in their individual medical records. Since a prescription is part of the patient's medical record, the patient is entitled to a copy of the physician's prescription for drugs or devices, including eyeglasses and contact lenses. Therefore,

physicians should not discourage patients from requesting a written copy of a prescription.

This opinion is a consolidation of previous Opinions 6.04, “Fee Splitting: Drug or Device Prescription Rebates;” 8.06, “Drugs and Devices: Prescribing;” and 8.07, “Gifts to Physicians: Offers of Indemnity.”

Opinion 8.063 - Sale of Health-Related Products from Physicians’ Offices

“Health-related products” are any products that, according to the manufacturer or distributor, benefit health. “Selling” refers to the activity of dispensing items that are provided from the physician’s office in exchange for money and also includes the activity of endorsing a product that the patient may order or purchase elsewhere that results in direct remuneration for the physician. This Opinion does not apply to the sale of prescription items which is already addressed in Opinion 8.06, “Prescribing and Dispensing Drugs and Devices.”

Physicians who engage in in-office sales practices should be aware of the related guidelines presented in Opinion 8.062, “Sale of Non-Health-Related Goods from Physicians’ Offices;” Opinion 8.06, “Prescribing and Dispensing Drugs and Devices;” Opinion 8.032, “Conflicts of Interest: Health Facility Ownership by a Physician;” Opinion 3.01, “Nonscientific Practitioners;” Opinion 8.20, “Invalid Medical Treatment;” as well as the reports from which these opinions are extracted.

In-office sale of health-related products by physicians presents a financial conflict of interest, risks placing undue pressure on the patient, and threatens to erode patient trust and undermine the primary obligation of physicians to serve the interests of their patients before their own.

(1) Physicians who choose to sell health-related products from their offices should not sell any health-related products whose claims of benefit lack scientific validity. When judging the efficacy of a product, physicians should rely on peer-reviewed literature and other unbiased scientific sources that review evidence in a sound, systematic, and reliable fashion.

(2) Because of the risk of patient exploitation and the potential to demean the profession of medicine, physicians who choose to sell health-related products from their offices must take steps to minimize their financial conflicts of interest. The following guidelines apply:

(a) In general, physicians should limit sales to products that serve the immediate and pressing needs of their patients. For example, if traveling to the closest pharmacy would in some way jeopardize the welfare of the patient (e.g., forcing a patient with a broken leg to travel to a local pharmacy for crutches), then it may be appropriate to provide the product from the physician’s office. These conditions are explained in more detail in the Council’s Opinion 8.06, “Prescribing and Dispensing Drugs and

Devices,” and are analogous to situations that constitute exceptions to the permissibility of self-referral.

(b) Physicians may distribute other health-related products to their patients free of charge or at cost, in order to make useful products readily available to their patients. When health-related products are offered free or at cost, it helps to ensure removal of the elements of personal gain and financial conflicts of interest that may interfere, or appear to interfere, with the physician’s independent medical judgment.

(3) Physicians must disclose fully the nature of their financial arrangement with a manufacturer or supplier to sell health-related products. Disclosure includes informing patients of financial interests as well as about the availability of the product or other equivalent products elsewhere. Disclosure can be accomplished through face-to-face communication or by posting an easily understandable written notification in a prominent location that is accessible by all patients in the office. In addition, physicians should, upon request, provide patients with understandable literature that relies on scientific standards in addressing the risks, benefits, and limits of knowledge regarding the health-related product.

(4) Physicians should not participate in exclusive distributorships of health-related products which are available only through physicians’ offices. Physicians should encourage manufacturers to make products of established benefit more fairly and more widely accessible to patients than exclusive distribution mechanisms allow.

This opinion is based on the report “[Sale of Health-Related Products from Physicians’ Offices](#),” adopted June 1999.

Clarification of Opinion 8.063

Do the guidelines discussing the sale of health-related products (8.063) and the sale of non-health-related goods (8.062) apply to physicians’ practice web sites? Yes. The physician who provides or sells products to patients must follow the above guidelines regardless of whether the products are provided in the physician’s office or through a practice web site. Adopted December 2000 as “Addendum III: Council on Ethical and Judicial Affairs Clarification on Sale of Products from Physicians’ Offices (E-8.062 and E-8.063)

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THE CODE SAYS

The AMA *Code of Medical Ethics*' Opinion on Reporting Impaired Drivers

Opinion 2.24 - Impaired Drivers and Their Physicians

The purpose of this report is to articulate physicians' responsibility to recognize impairments in patients' driving ability that pose a strong threat to public safety and which ultimately may need to be reported to the Department of Motor Vehicles. It does not address the reporting of medical information for the purpose of punishment or criminal prosecution.

(1) Physicians should assess patients' physical or mental impairments that might adversely affect driving abilities. Each case must be evaluated individually since not all impairments may give rise to an obligation on the part of the physician. Nor may all physicians be in a position to evaluate the extent or the effect of an impairment (e.g., physicians who treat patients on a short-term basis). In making evaluations, physicians should consider the following factors:

(a) The physician must be able to identify and document physical or mental impairments that clearly relate to the ability to drive.

(b) The driver must pose a clear risk to public safety.

(2) Before reporting, there are a number of initial steps physicians should take. A tactful but candid discussion with the patient and family about the risks of driving is of primary importance. Depending on the patient's medical condition, the physician may suggest to the patient that he or she seek further treatment, such as substance abuse treatment or occupational therapy. Physicians also may encourage the patient and the family to decide on a restricted driving schedule. Efforts made by physicians to inform patients and their families, advise them of their options, and negotiate a workable plan may render reporting unnecessary.

(3) Physicians should use their best judgment when determining when to report impairments that could limit a patient's ability to drive safely. In situations where clear evidence of substantial driving impairment implies a strong threat to patient and public safety, and where the physician's advice to discontinue driving privileges is ignored, it is desirable and ethical to notify the department of motor vehicles.

(4) The physician's role is to report medical conditions that would impair safe driving as dictated by his or her state's mandatory reporting laws and standards of medical practice. The determination of the inability to drive safely should be made by the state's department of motor vehicles.

(5) Physicians should disclose and explain to their patients this responsibility to report.

(6) Physicians should protect patient confidentiality by ensuring that only the minimal amount of information is reported and that reasonable security measures are used in handling that information.

(7) Physicians should work with their state medical societies to create statutes that uphold the best interests of patients and community and that safeguard physicians from liability when reporting in good faith.

Report: Issued June 2000 based on the report “Impaired Drivers and Their Physicians,” adopted December 1999.

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[Legal Vision Requirements for Drivers in the United States](#), December 2010

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JOURNAL DISCUSSION

Evidence-Based Medicine: Can You Trust the Evidence?

Yvonne M. Buys, MD

Alasbali T, Smith M, Geffen N, et al. Discrepancy between results and abstract conclusions in industry- vs. nonindustry-funded studies comparing topical prostaglandins. *Am J Ophthalmol.* 2009;147(1):33-38.

At the end of a busy clinic day a drug representative sits you down to discuss her product. She produces a glossy advertisement highlighting the drug's efficacy with various graphs and references. She then provides a copy of a peer-reviewed article that compares her product to a competitor's. Without even reading the article you can guess what the conclusions will be—that the rep's product is better—but to confirm, you skim the abstract and, as suspected, the abstract conclusions state that this company's product performed better than the competitor's. You also notice that the study was funded by your visitor's company. A week earlier, a representative from the competing company made a similar visit, but in that case the peer-reviewed abstract concluded that *their* product was superior. You look for that article and find that the study was funded by the competitor.

In medicine, we are trained to base decisions on evidence. In deciding which medication to prescribe, for example, there are a variety of considerations: efficacy, side effects, contraindications, ease of use, and cost, among others. Comparing medications from different classes often makes decisions regarding first-line treatment relatively easy; however, when a group of medications produce a given clinical result by means of the same mechanism, the decision may not be as clear. Decisions should be evidence-based, but can we trust the evidence? And *which* evidence is most trustworthy?

In 1997, Pharmacia introduced a novel medication, latanoprost, for the treatment of glaucoma. As a result of this medicine's superior efficacy, daily administration, and relatively small number of side effects, latanoprost quickly became the first-choice drug for treating glaucoma—in industry terms, a “blockbuster.” This fact did not go unnoticed by the pharmaceutical competition, which subsequently developed drugs with a similar mechanism of action (“me-too” products), including travoprost (Alcon) and bimatoprost (Allergan). The end result is a variety of products with similar mechanisms of action competing for the same market share. Manufacturers of competing drugs fund studies of their respective products both to create opportunities for clinicians to gain experience with their products and to contribute to the peer-reviewed literature. Their ultimate objective is to influence the decisions of prescribers. Does industry funding of these studies bias results?

In hopes of answering this question, we searched the literature up to November 2007 for peer-reviewed articles on studies that compared the ocular hypotensive efficacy of topical prostaglandins. We reviewed each article to determine whether the findings for the main outcome measures were statistically significant and then compared the statistical findings in the results section to the language in the abstract conclusions. The publications were also divided up into industry-funded and non-industry-funded categories, the results of which were compared.

There were 39 eligible publications, of which roughly 75 percent reported on industry-funded research. In those industry-funded-research articles, there was agreement between the results of the main outcome measure and conclusions in the abstract 38 percent of the time, but in 62 percent of publications, there was disagreement between the results of the main outcome measure and the abstract conclusions. Among the nonindustry-funded studies, the agreement between the results of the main outcome measure and the abstract conclusions was 100 percent ($p=0.0006$). In publications of the industry-funded research, only 24 percent found a statistically significant main outcome measure, but 90 percent had pro-product conclusions [1].

You may wonder about the high percentage of pro-manufacturer conclusions in the cases where the main outcome results were not significant. Such conclusions result from authors' emphasis on surrogate outcomes, minimizing nonsignificant main outcomes and reporting numerical rather than statistically significant differences. Emphasizing secondary outcomes and ignoring the results of the main outcome measure is a process referred to as "spin." Some studies look at multiple comparisons in attempts to find an outcome of statistical significance. This is referred to as "data dredging."

These findings are certainly not unique to ophthalmology or publications on prostaglandins. A recent report of published randomized controlled trials with nonsignificant main outcome measures found evidence of spin in 58.3 percent of the abstracts [2]. In addition, there are many studies in the literature outlining the effect of industry bias in publications involving a variety of diseases and therapies [3-19].

Physicians must be aware that it is essential to read literature carefully. One cannot rely solely on the abstract but should read papers in full, focusing on methodology and reading the complete results, because the prevalence of spin is greater in abstracts than in the main text [2]. It is equally important to read the disclosures to determine if a potential for bias exists.

In our study, 4 of the 39 publications did not include published disclosures. By contacting the authors directly, we discovered that 3 of these publications were industry-funded [1]. The International Committee of Medical Journal Editors policy states that "all participants in the peer review and publication process must disclose all relationships that could be viewed as presenting a potential conflict of interest" [20]. In June 2007, when we reviewed the disclosure policies of all indexed English-language ophthalmology journals, we were able to find published web-based policies

for authors in 79 percent, for peer reviewers in 7 percent, and for editors in 5 percent of the journals. After we contacted the editors directly, these results changed to 100 percent for authors, 60 percent for peer reviewers, and 33 percent for editors (not counting 5 journals that did not respond to the question regarding authors and 12 journals that did not respond to the question regarding peer reviewers and editors) [21].

Going forward, measures need to be taken to minimize the possibility of industry bias. Although some have suggested that industry should be prohibited from funding studies, this is unlikely to occur, especially in view of decreased funding by government and nonprofit organizations. Currently, authors and editors have significant responsibility for upholding the integrity of published literature, and perhaps stronger policies are required both for disclosure of potential conflicts and presentation of results. Ultimately, however, it is readers who must take time to read articles in full, and not simply rely on the abstract, before drawing their own conclusions.

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Yvonne M. Buys, MD, is a professor in the Department of Ophthalmology and Visual Sciences at the University of Toronto and the co-director of the Glaucoma Unit at the University Health Network. She is the immediate past president of the Canadian Glaucoma Society, glaucoma section editor for the *Canadian Journal of Ophthalmology*, and treasurer and board member of the Canadian Ophthalmological Society.

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CLINICAL PEARL

Diagnosing, Preventing, and Treating Glaucoma

Usha S. Rao, MD

The term “glaucoma” refers to a range of disorders that cause progressive damage to the optic nerve. Glaucoma was long defined as gradual vision loss due to elevated pressure in the eye. The elevated pressure is the results of a “clogging” of the trabecular meshwork, the apparatus through which intraocular fluid (or aqueous humor) drains out of the eye. It is now known, however, that, although intraocular pressure is a leading risk factor, other mechanisms are clearly involved [1]. A third of people with glaucoma do not have elevated intraocular pressure (it may even be low) [2], and those with high pressure do not necessarily develop glaucoma. Alterations in the lamina cribosa and fluctuations in perfusion pressure are thought to play a role, but the exact etiology of these changes remains unknown. The diagnosis is now made on the basis of two criteria: visible damage to the optic nerve and loss of peripheral vision [2].

Clinical Presentation

Glaucoma is known as a “silent killer” of vision because it is frequently asymptomatic until later stages. (It is estimated that up to 50 percent of people with the disease remain undiagnosed [1] and in developing countries, the percentage is even higher [3].) Pain is not a feature of the disease until the intraocular pressure is extremely high, and since central vision is spared for a long time—it may remain 20/20 even when the condition is very advanced—patients may not notice the initial peripheral visual field loss. In children, enlargement of the eye can occur with increased intraocular pressure, along with sensitivity to light and clouding of the cornea [4].

Classification

There are several types of glaucoma. Primary open-angle glaucoma (POAG) is the most common type, affecting over 3 million Americans [1]. This type of glaucoma has three typical features: (a) an intraocular pressure consistently above 21 mmHg in at least one eye; (b) an open, apparently normal anterior chamber angle; and (c) glaucomatous optic neuropathy or visual field defect. In acute angle-closure glaucoma, elevated intraocular pressure is caused by an anatomical obstruction of the trabecular meshwork by the peripheral iris. The condition is characterized by the sudden onset of severe pain, blurred vision, and redness [5]. Patients who have optic nerve damage with normal intraocular pressure are said to have normal-tension glaucoma. Optic nerve damage that develops as a complication of another medical or eye condition, such as trauma or certain eye tumors, is referred to as secondary glaucoma [6].

Diagnosis and Prevention

Early detection through regular and comprehensive dilated eye exams is the key to preventing damage from glaucoma. Glaucoma can develop at any age, but after the age of 40, every person should have a regular eye exam every 1 to 3 years, depending on risk factors. African Americans, people of Hispanic origin, anyone over the age of 60, and those with a family history of glaucoma are at increased risk.

This exam should include a measurement of intraocular pressure and an examination of the optic nerve, which shows a characteristic excavated or cupped appearance as more and more nerve fibers are damaged [6]. If the optic nerve appears abnormal, a perimetry or visual field test should be done to evaluate the patient's peripheral vision more precisely. Various other imaging modalities can be used to analyze the optic nerve further [1]. A survey done for the Glaucoma Research Foundation found that 74 percent of roughly 1,000 respondents had their eyes examined once every 2 years, but only 64 percent of those examined received a dilated eye exam, which is the best way to identify suspected glaucoma [1].

Treatment

Early treatment can prevent progression of the disease in a majority of people. Unfortunately, there is no cure, and vision, once lost, cannot be regained. Up to 10 percent of patients continue to lose vision despite proper treatment [1]. Compliance is crucial to the efficacy of glaucoma treatment. Since the condition is often asymptomatic, many patients do not take their treatment seriously [2].

Currently available treatments for glaucoma work by lowering the pressure in the eye [2]. Large randomized trials have shown that lowering intraocular pressure effectively prevents disease progression, even in normal-tension glaucoma [7]. Pressure can be reduced with eyedrops, laser treatment, surgery, or a combination of these methods.

Pressure-lowering drops are the most common treatment for glaucoma and usually the first-line treatment. Because these drops vary in their effect on the eye (some reduce fluid production, others speed up drainage) [6], a combination of several eyedrops may be used. Each type of drop is associated with its own set of adverse effects, and not all patients are candidates for every type of drop.

Laser treatment or surgery can be used when medical treatment has not produced the desired intraocular pressure or when patients do not adhere to their eye drop regimen [6]. Both modes of treatment aim to increase aqueous humor drainage from the eye. Laser treatment is usually attempted prior to surgery; since it tends to provide less reduction in intraocular pressure, it is considered appropriate in less severe cases. Oral medications such as acetazolamide are frequently used, along with eyedrops, to control pressure until surgery can be performed. (They are generally only used in these temporary circumstances, because their side effects can be very bothersome, and chronic use could lead to severe adverse events [1].)

Current research is investigating the effect of medications used in other neurodegenerative disorders, such as Alzheimer disease and multiple sclerosis, on progression of glaucoma. There is hope that what works in one neurodegenerative disorder might work in another [2].

The treatment of pediatric glaucoma differs somewhat from that of glaucoma in adults [1]. In addition to compliance challenges and efficacy concerns, most of the commonly used eyedrops carry particular risks for children (for example, brimonidine drops have been shown to cause central nervous system depression in children). Though medications are the initial and, often, the mainstay treatment for juvenile open-angle glaucoma and some pediatric secondary glaucomas [5], surgery is the main intervention for primary congenital glaucoma and pediatric closed-angle glaucomas.

Conclusion

According to the World Health Organization (WHO), glaucoma is thought to be a leading cause of blindness worldwide, second only to cataracts. It presents the most significant public health challenge, however, because it is irreversible. In their paper on global visual impairment statistics gathered by the WHO, Resnikoff and colleagues found that the world population aged 50 years and older had increased by 30 percent since 1990 [3]. Glaucoma will become an increasingly pressing concern as the population ages, and it is our responsibility to educate the public about preserving vision before it is too late.

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Usha S. Rao, MD, is a third-year ophthalmology resident at Baylor College of Medicine's Cullen Eye Institute in Houston, Texas. She is pursuing a fellowship in glaucoma and plans to have a career in an academic environment, where she can participate in the education of residents and fellows.

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HEALTH LAW

Legal Vision Requirements for Drivers in the United States

Paul G. Steinkuller, MD

While there are strict federal vision standards for commercial licensing, there are no such international standards, and there are no federal standards for unrestricted noncommercial passenger vehicle drivers' licenses in the United States. Individual states and the District of Columbia have their own vision requirements for initial and renewal licensing. These requirements can vary widely [1].

Defining Visual Disability

The World Health Organization lists several categories of visual disability. Low vision is defined as visual acuity between 20/60 and 20/200 or corresponding visual field loss to less than 20 degrees in the better eye with best possible correction. Blindness is defined as visual acuity of less than 20/400 or corresponding visual field loss to less than 10 degrees in the better eye with the best possible correction [2].

The Social Security Administration of the United States declares a taxpayer disabled for economic purposes and eligible for supplemental security income when the best corrected visual acuity is 20/200 or worse in the better eye, the visual field is limited to 20 degrees or less in the better eye, or both [3].

The generally accepted testing parameters are: uncorrected visual acuity in each eye, best corrected visual acuity (BCVA) in each eye, and binocular or monocular horizontal visual fields. Some states ask about monocularity, diplopia, impaired night vision, and a history of retinitis pigmentosa or other possibly progressive deteriorating eye disease.

Unrestricted Licenses

An unrestricted license allows its owners to drive without corrective lenses, in any location and for any distance, in all light conditions, both day and night, on any road, at any legal speed, and in any normally equipped vehicle, without additional or special mirrors. By far the most common restriction is that requiring the use of corrective lenses when driving.

License Restrictions

Restrictions based on vision testing vary from state to state and include mandated use of corrective lenses, limiting driving to sunrise to sunset only, prohibiting freeway driving, restricting the area in which driving is allowed, and requiring additional mirrors (left and right outside, wide-angle, panoramic, and fender-mounted). Montana issues an area-restricted license, specifying, for example, home to grocery

store, driving for medical needs, or driving to church. Most states have provisions that allow drivers to use telescopic lenses and to demonstrate competency with other visual assistance devices when necessary.

The testing parameter that varies least from state to state is visual acuity. All states have visual acuity requirements for licensure, and all but 3 have set the minimum best corrected visual acuity (BCVA) requirement at 20/40 in the better eye. Georgia requires a BCVA of at least 20/60 in at least one eye; for New Jersey and Wyoming the requirement is 20/50.

Horizontal visual field requirements are more varied. Sixteen states have no required visual field testing unless the individual has been referred to an eye care practitioner after failing a visual acuity test or because the visual acuity test was passed using special telescopic lenses. For the 34 states with a binocular horizontal visual field requirement, 15 stipulate 140 degrees; for the other 19 states, the range is from 105 degrees to 130 degrees; Maine requires 150 degrees. Several states list the horizontal dimension of the visual field of applicants with only one useful eye; this ranges from 55 degrees (Kansas) to 105 degrees (Arkansas). Some states, including North Carolina and Texas, will not issue any driver's license to a person with a homonymous hemianopia (loss of vision in the right halves or the left halves of both eyes).

Only Kentucky has a vertical visual field requirement: 25 degrees above and below the fixation point.

Some states list the ages at which routine vision testing must begin; in some states repeat testing starts as early as age 62, but is more commonly age 65 or 70. The frequency of follow-up testing is variable. In Illinois, at age 87, applicants must start taking annual vision (and road) tests.

Unique State Restrictions

Massachusetts has a color vision requirement: "Drivers must be able to distinguish the colors red, green, and amber. If applicants or licensees cannot distinguish the colors red, green, and amber a license is not possible." In Mississippi, applicants who fail the eye care specialist's depth perception test are restricted to a maximum speed of 45 mph. Ohio requires that applicants referred with vision restrictions go to an eye care specialist affiliated with the Ohio State University School of Optometry or Vision Rehabilitation of Akron and, if needed, attend training and evaluation at one of those two institutions. In Utah, applicants who fail all parameters of vision testing may not be issued a license "except in meritorious circumstances."

While it stands to reason that drivers with poor visual acuity, limited visual fields, or both would be more prone to motor vehicle accidents, there have been no published reports to substantiate that contention. Nevertheless, establishing strict national vision and vision testing standards for noncommercial passenger vehicle driver licensing would eliminate state-to-state inconsistencies, simplify the comparison of

accident rates in different states, and may, if adequately established and strictly enforced, help eliminate poor vision as a cause of motor vehicle accidents.

The physician's duty to report potential physical and mental conditions that may impair a patient's ability to drive has been a subject of interest for some time. In 1997, the Council on Ethical and Judicial Affairs of the American Medical Association studied the issue and recommended that physicians assess driving risk in cases of concern and have open discussions with patients and their families about any risk of damage to self and others [4]. In some cases, negotiating a workable driving plan with patients can render reporting unnecessary. In those situations where clear evidence of substantial driving impairment implies a strong threat to patient and public safety, and where physicians' advice to discontinue driving privileges is disregarded, physicians have an ethical duty to notify the state department of motor vehicles of the patient's safety-related medical condition. This duty exists even when reporting impaired drivers is not mandated by law [4].

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Paul G. Steinkuller, MD, is an associate professor of ophthalmology at Baylor College of Medicine and a pediatric ophthalmologist at Texas Children's Hospital in Houston. He is a member of the American Association for Pediatric Ophthalmology and Strabismus, the Harris County Medical Society, and the American Academy of Ophthalmology. He wanted to be a pilot, but myopia forced him into medical school and he found he enjoyed it; he likes children, puppies, small mammals, medical students, and residents.

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POLICY FORUM

Ophthalmologists, Optometrists, and Scope of Practice Concerns

Kristin Schleiter, JD, LLM

Introduction

The average person may not think much of the difference in practice and training of psychiatrists and psychologists, or of ophthalmologists and optometrists. Yet a key distinction exists within each pair: a medical degree. As nonphysician practitioners advocate for expansion of their scope of practice into areas long considered the purview of medicine, physicians have fought back, arguing that their experience and training are central to patient safety. In the last decade, the clash between ophthalmologists and optometrists has focused on eye surgery.

Education and training are the primary differences between ophthalmologists and optometrists [1]. An ophthalmologist is a physician who “specializes in the refractive, medical and surgical care of the eyes and visual system and in the prevention of disease and injury” [2]. After obtaining an undergraduate degree, ophthalmologists must complete four years of schooling at an accredited medical school and a 3- or 4-year residency program, 3 years of which must be in ophthalmology. Only after this can ophthalmologists become licensed to practice medicine and perform surgery. Ophthalmologists may become certified by the American Board of Ophthalmology, which requires, in addition to the aforementioned schooling, serving as primary surgeon or first assistant to the primary surgeon on a minimum of 364 eye surgeries and performing well on the state licensing examinations, both written and oral [1].

Optometry differs on several accounts. The practice of optometry commonly includes examining the eye for vision prescription and corrective lenses and examining, diagnosing, treating, and managing disorders of the eye and visual system. But optometrists’ education does not include medical school. After undergraduate education, optometrists must complete 4 years of an accredited optometry college, after which they are awarded the Doctor of Optometry degree. Some optometrists also undertake an optional 1-year residency program to enhance their experience in a particular area [1].

Optometrists are licensed by their states to provide primary vision care and nonsurgical management of certain eye diseases and must pass the licensing exam of the National Board of Examiners in Optometry. In some states, optometrists have attempted to expand their scope of practice to include the performance of laser and nonlaser eye surgery [1]. Organizations including the American Medical Association

(AMA) have expressed concern that optometrists are using the legislature to expand their scope of practice into areas of medicine [3, 4].

Most states prohibit optometrists from performing surgery, and statutes often specify that the license to practice optometry does not include the right to practice medicine. Meanwhile, the licensing statutes of such states as Colorado and North Carolina specifically exclude surgery from their definitions of the practice of optometry [5]. In some states, the law on optometrists' right to perform surgery is evolving. Some of these statutes delineate between laser and nonlaser surgery. And since 1997, for example, there have been 46 attempts in 21 states by optometry organizations to legislate surgery privileges [5]. All but one of these attempts were blocked.

Oklahoma

After an unsuccessful attempt by the Oklahoma board of optometry to issue regulations extending optometrists' scope of practice to include the performance of surgery, the Oklahoma state legislature enacted a law in 1998 authorizing optometrists to perform laser surgery procedures [1, 3, 6]. This bill also granted the Oklahoma Board of Examiners in Optometry the sole authority to determine what constitutes the practice of optometry [3].

The issue was revisited in 2004, after the Oklahoma attorney general issued an opinion addressing the state board of optometry's authority to expand optometrists' scope of practice past statutory limits [1, 5]. The opinion said that the Oklahoma Board of Examiners in Optometry "would need 'statutory authority' from the Oklahoma legislature before it could certify optometrists" to do more than the procedures endorsed by the 1998 law [7].

Oklahoma lawmakers reacted to the attorney general's opinion by passing legislation that allowed the state board of optometry to authorize optometrists to perform certain nonlaser surgery procedures, in effect stripping traditional oversight bodies (e.g., the governor, attorney general, or state medical board) of their ability to regulate the practice of optometry [1, 3, 5, 8]. The medical and osteopathic communities strongly opposed this bill. Testimony to the Oklahoma state legislature emphasized that, while certain scope of practice expansions were appropriate—ophthalmologists had previously supported optometry's efforts to "get privileges for punctal plugs, corneal foreign body removal, and last epilation," to name a few—optometrists had not proven that they possessed the education and training necessary to perform surgery [9].

Shortly after the bill was passed, the Oklahoma Board of Optometry used their newfound authority to pass a rule that further expanded optometrists' scope of practice, allowing optometrists to perform nonlaser surgical procedures, including the use of scalpels and insertion of needles directly into the eye within the state [1, 3]. At the time, the AMA opposed the legislation, arguing that, without education or training in surgical skills or incisions and subsequent tissue reactions, the scope of practice expansion put patients at serious risk [3]. Moreover, the AMA argued,

ophthalmologists' understanding of the patient as a whole might allow them to recognize an eye condition optometrists may consider routine as an indication of something serious (e.g. malignant tumor, AIDS, multiple sclerosis) [3]. Despite strong objection by the AMA and other organizations, the rule stood, making Oklahoma the only state to date that allows nonphysicians to perform laser surgery [1].

West Virginia

A similar attempt to expand optometrists' scope of practice was recently made in West Virginia. After the state legislature amended its law regulating optometrists [10], the West Virginia Board of Optometry proposed amendments to its rule on optometrists' prescriptive authority [11]. The board stated that the amendment was necessary to clarify its rules, but it went far beyond this stated purpose.

According to analysis by the AMA, the American Association of Ophthalmology, and the West Virginia State Medical Association, the board's amendment expanded optometric scope of practice to include the prescribing of pharmaceuticals that have systemic effects—an expansion beyond the intent of the West Virginia legislature [4, 13, 14]. For example, the proposed amendment includes language “extensively debated and specifically rejected” by the state legislature that would have given the board open-ended authority to determine which injectable pharmaceutical agents West Virginia optometrists would be allowed to administer [12]. In contrast, the state legislature's existing language specifically limited injections to the administration of epinephrine to treat emergency cases of anaphylaxis or anaphylactic shock [12]. The proposed rule would also allow the board to authorize optometrists to sell pharmaceuticals by injection directly to the patient, a practice prohibited in the case of oral or topical agents [13].

The board's actions were characterized as attempts to circumvent the legislative process, using its regulatory authority to pass provisions that had been removed or amended in the state legislature's deliberations over the optometry practice act bill [12]. The debate over the West Virginia Board of Optometry's proposed amendments is ongoing.

The Future

While some suggest that the trend is toward an expanded scope of optometric practice, history suggests that Oklahoma is an outlier. Most states—including those that have entertained proposals by optometrists to expand their scope of practice—have chosen not to allow optometry's practice to expand into surgery and other areas of medicine. Government facilities such as the Veterans Affairs Palo Alto Health Care System are considering changes to policy after scope expansions resulted in litigation due to preventable medical error [14]. In 2010 alone, however, there have been state efforts by Alaska, New Mexico, and Oklahoma to expand optometrists' scope of practice to include surgery [15]. It is highly unlikely that these efforts will be the last.

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Kristin E. Schleiter, JD, LLM, is a state government affairs analyst for the American Academy of Pediatrics in Elk Grove Village, Illinois. She analyzes the impact of state health care legislation and provides strategic guidance for the pediatric medical community in its ongoing advocacy efforts. Prior to working for the AAP, Ms.

Schleiter worked for the Council on Ethical and Judicial Affairs of the American Medical Association. Ms. Schleiter received both her law degree and master's of law in health law from Loyola University Chicago School of Law, where she was a contributing writer for the *Annals of Health Law*.

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MEDICINE AND SOCIETY

Blepharoplasty in Asian Patients: Ethnic and Ethical Implications

Kiran Motaparthy, MD

Surgical creation of a superior palpebral fold, known as the double-eyelid operation, is the most popular cosmetic surgery in Asia and the third most frequently requested surgery (including noncosmetic procedures) among Asian Americans [1]. The literature on this procedure has focused mainly on the evolving technical aspects; fewer works have discussed the ethical implications of a surgery that has the potential to alter a feature characteristic of ethnicity.

Background

Broadly speaking, upper eyelid blepharoplasty procedures in Asians may be divided into two categories: external incisional techniques and nonincisional or suture ligation techniques [1]. While a detailed explanation of these procedures exceeds the scope of this article, current and past surgical techniques have focused on three key anatomical features of Asian upper eyelids. At least 50 percent of Asians have a single eyelid, which is to say the eyelid has no supratarsal crease [2]. Additionally, Asians tend to possess a greater number of eyelid fat pads and a larger amount of subcutaneous and suborbicularis fat than members of other ethnic groups, and the periorbital fat is lower [1]. These qualities of the periorbital fat compartment in the upper eyelids contribute to the “puffiness” of the single eyelid, further obscure the supratarsal crease, and may produce pseudoptosis [2].

A third anatomical difference between the upper eyelids of Asians and Caucasians is the presence of an epicanthal fold, which obscures the medial canthus (inner corner) and gives the eye a relatively narrow appearance [2]. This fold is universally present among humans at birth but is only seen in 2 percent of non-Asian adults [1], while the incidence in Asians may be as high as 90 percent [2].

Historical Perspective

The Japanese surgeon Mikamo was the first to publish on the double-eyelid technique, detailing the creation of a supratarsal crease in the upper eyelid in 1896; this innovation occurred in the context of the cultural westernization of Japan in this era [3]. In his original article, Mikamo described the single eyelid as “monotonous and impassive” and labeled the double eyelid as physiologically normal and “more attractive” [4]. While Mikamo was the first surgeon to westernize the eyelid of Asians, several authors report that his intent was to create a unique Japanese aesthetic that mirrored the kind of double eyelid that occurs naturally in the Asian population [1, 3]. Other authors argue that the desire for the more expressive, alert

appearance felt to be conveyed by the double eyelid predates Western influences in Asia [2].

Controversy

It is important to note that this procedure has been condemned by some as an effacement of defining ethnic feature [5]. Sociologist Eugenia Kaw, for example, suggested that Asian American women's decisions to undergo upper eyelid blepharoplasty may be influenced by racial stereotyping [6]. Kaw notes that Caucasian patients usually undergo upper eyelid blepharoplasty to remove redundant skin resulting from aging, while Asian women who undergo eyelid surgery are younger (between 18 and 30 years of age) and do not typically seek to reduce the signs of aging [6]. In Kaw's studies, Asian American women who requested these procedures often associated their own features with descriptors of "dullness" and "passivity," and sought out more typically Caucasian features such as the double eyelid at least partly due to associations in the popular media between distinctively Asian features and negative personality traits, mental characteristics, and physical descriptions [6]. Some young women may see the procedure as a rite of passage, and some Asian American families obtain the surgery for their daughters because they view it as a social credential [5].

Current Trends: Striking a Balance?

How should physicians who perform blepharoplasty on Asians respond to the ethical concerns raised by the attitudes and motivations surrounding this procedure? Increasingly aware of ethnocultural issues, many surgeons have adopted techniques to produce the double eyelid without fully westernizing its appearance [5]. In fact, several authors claim that most Asian patients do not seek a fully westernized appearance. These authors advise against techniques that would diminish distinctive ethnic characteristics and recommend instead several surgical techniques designed to deliver a natural-appearing double eyelid while still making the eye appear larger [1, 2, 7].

McMurdy asserts that patients today are not usually seeking the classic westernized eyelid, which would require removal of large amounts of fat and skin and liberal manipulation of the epicanthal fold [2]. McMurdy and several other surgeons recommend more conservative resection, preservation of the epicanthal fold [2, 8], and creation of a parallel supratarsal crease (as opposed to the semilunar crease more typical of the upper eyelids of Caucasians) [1]. However, physicians advocating this balanced approach to the blepharoplasty note that a minority of patients do seek to westernize their appearance; surgeons should be wary of this possibility [7].

Current surgery literature and Kaw's research appear to differ in their estimates of the number of patients seeking a westernized appearance rather than a more natural Asian or individualized aesthetic. While Kaw indicates that racial stereotyping influences most Asian American women's decision to pursue cosmetic surgery, these studies are based on small sample sizes [6]. Surveys of large groups regarding motivation to undergo blepharoplasty are currently unavailable.

Future Directions

Are patients who undergo double-eyelid procedures motivated to seek a unique aesthetic, to create their own standard of beauty? Or does this surgery promote ethnic standardization, reinforce racial stereotypes, and represent, as Kaw writes, “an attempt to heal a specific doubt about oneself that society has unnecessarily brought on” [6]? Given the hot-button ethical, cultural, and racial issues surrounding double-eyelid procedures, it seems prudent that physicians carefully examine the motivation and expectations of Asian patients selected for blepharoplasty.

Blepharoplasty has now been performed on Asians for more than a century [3], and, although there is debate as to whether or not it is a product of western influence [2], the popularity of the surgery indicates that it is here to stay. At least, some patients who seek this procedure are attempting to modify a feature linked to a racial or ethnocultural identity and its popularity suggests that negative stereotyping of ethnic features is powerful indeed.

All cosmetic surgery, however, seeks to alter features linked to an individual’s identity, and it may be difficult to truly understand a patient’s motivation to undergo such a procedure. Physicians should ask patients why they are seeking blepharoplasty without persuading or dissuading them. While no reason is invalid, the patient should be encouraged to reflect on his or her own expectations and motivations regarding the procedure and beliefs about ethnicity and appearance. This should allow practitioners to select appropriate candidates for surgery.

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Kiran Motaparthy, MD, is a resident in dermatology at Baylor College of Medicine in Houston, Texas, where he received his medical degree. His areas of interest include medical and cosmetic dermatology.

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IMAGES OF HEALING AND LEARNING

The Fourth “O” in Eye Care—Ocularists

Michael O. Hughes, BCO

The successful rehabilitation of an individual who has lost an eye requires the attention of several eye care specialists: ophthalmologists, optometrists, opticians—and ocularists. Ocularists are eye professionals whose work is to restore the appearance of an eye lost to trauma, disease, or congenital malformation. Although most eye loss is due to disease, accidents also cause a significant number; of course, only after all vision-saving procedures are exhausted is eye removal considered. Patients are generally referred by the surgeon who operated on the affected eye (often an oculoplastic ophthalmologist) and can tell them what to expect from the ocularist’s work. Those who self-refer must retain realistic expectations for the outcome of their appearance.

This unusual blend of art in medicine is an enterprise all its own. While the ocularist’s work has long been considered an art form, the eye-maker’s role in health care has rarely been clearly-defined. An artificial eye-maker creates custom ocular prostheses or prosthetic eyes, but what we give patients can be much more: improved self-image and the confidence necessary for patients to return to independent, productive living.

Ocular Implants

While evisceration, enucleation, and exenteration all entail the removal of eye tissue, enucleation, the removal of the eyeball from the orbit, remains the most common. Evisceration and enucleation are generally followed by insertion of an ocular implant. To be effective, the implant must reasonably reproduce the volume, position, and motility of the natural eye; it must retain a covering suitable for lubrication and it must neither migrate nor extrude.

The size, material, and placement of the implant depend on the surgeon’s work and the patient’s needs. Generally, a smaller implant is used when it is placed within the eyeball or its fascial capsule (Tenon’s capsule) or when it will be wrapped in another material. To increase covering tissue thickness, the implant is often placed behind the posterior Tenon’s capsule (see figure 1).

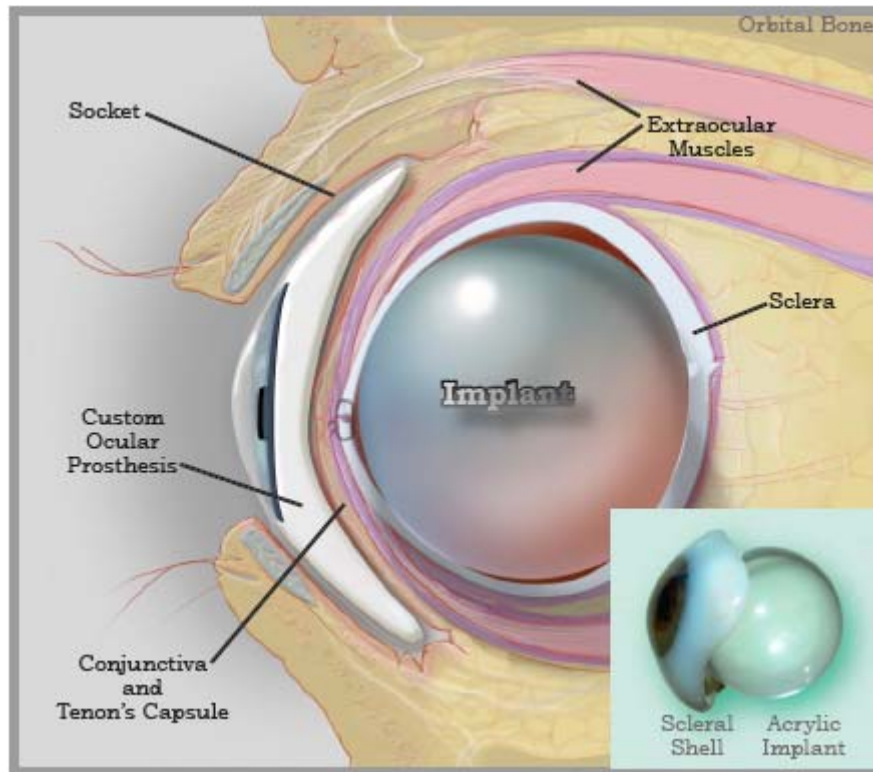


Figure 1. Illustration depicts a left post-evisceration eye socket in parasagittal section. The implant replacing the volume of the eye is placed inside the sclera. In front of the repositioned conjunctiva, the custom-made prosthesis is placed under the eyelids.

Proper sizing of the implant is crucial: too small an implant will cause possible migration, exophthalmos, or a deep sulcus. If too large an implant is used, pressure on the front of the implant may increase the risk of wound dehiscence, erosion, or implant exposure and infection. It is ideal for the ocular implant to provide 65-70 percent of the volume of the (lost) eye with the remaining volume taken up by the ocular prosthesis.

In evisceration, the sclera remains, while in enucleation, the extraocular eye muscles are either attached to the implant or cross-sutured and the anterior tissues (Tenon's and conjunctiva) are closed without tension. Two of the more difficult challenges for ophthalmologists and ocularists are superior sulcus deformities from inadequate orbital volume and eyelid ptosis or laxity.

The Ocularist's Work

Prosthetic eyes are often called "glass eyes" because, before the development of polymethyl-methacrylate plastics in the 1940s, prosthetic eyes and ocular implants were generally made of hand-blown glass, a technique that dates to the mid-1800s. (Cryolite glass is still used in parts of Eastern Europe.)

While careful postsurgery observation by other professional “Os” in eye care is often assumed to provide adequate evaluation of the socket, many irregularities are only discovered when the alginate mold (or “impression”) of the healed socket made in the ocularist’s office is examined. The initial visit to the ocularist usually takes place 6 weeks after surgery. Though most swelling has usually subsided by this time, only after 3 or 4 months is the healed socket’s shape stabilized.

Most ocularists begin by obtaining an alginate (gel) impression of the eye socket, the sensitive tissue which will house the prosthetic eye. (Although this is a painless procedure, some younger patients may find the one-minute setting time uncomfortably long.) Duplicating the socket shape precisely reduces irritation of the conjunctiva and maximizes the movement of the finished eye. When the proper fit is achieved, the lubricating tear system often operates normally. After the impression and fitting of a wax pattern, the resulting shape is cast in plastic.

Next, the ocularist hand-paints the iris and sclera using direct observation of the patient's unaffected eye, mixing a variety of pigments, lacquers, or oils onto the acrylic shape, bonded with liquid acrylic (see figure 2). The painting is sealed with acrylic, and a cornea of clear plastic is cast and cured under heat and pressure. Polishing the eye to a flawless surface ensures there will be smooth eyelid movement and no recesses to accommodate flora.

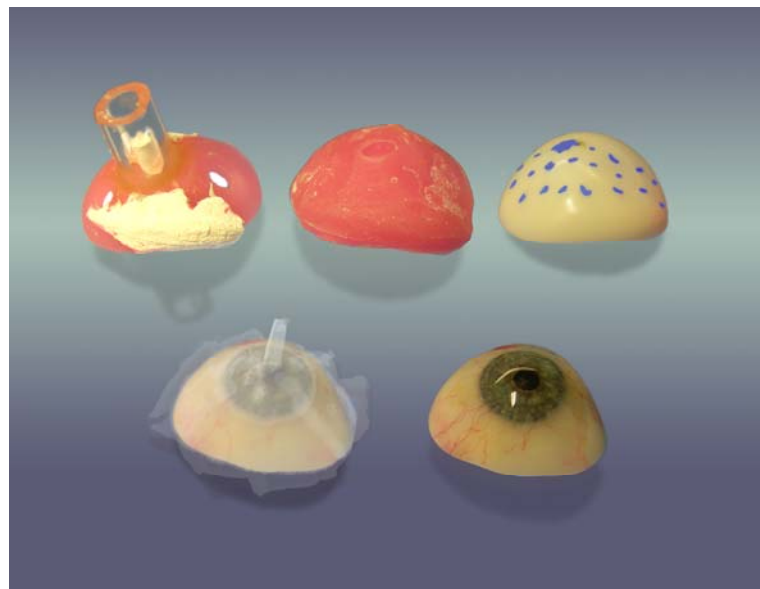


Figure 2. The process of fabricating an artificial eye in acrylic, as seen in stages:

- A. The gel impression (negative) of the socket
- B. The wax pattern cast from the impression and fitted further
- C. An acrylic shape sized to the socket and refined as to gaze
- D. The painted prosthesis just out of the mold and before polishing
- E. The final prosthesis ready to insert

When the finished eye is inserted, the patient is given a mirror to see his or her restored image (see figure 3). Care of the prosthetic eye is simple; new patients are often surprised to learn that they need not remove it for routine washing—a cleaning and polishing by the ocularist during each annual examination is sufficient.



Figure 3. Left: a monocular patient with an empty socket. Right: the patient wearing a prosthesis.

Refinements in surgical procedures, ocular implants (including materials) and custom hand painted prosthesis have made great improvements in the cosmesis and comfort of prosthetic eye wearers.

This brief article is merely an introduction to the profession of custom ocularistry—the fourth “O.” More information is available from the American Society of Ocularists and its journal, *The Journal of Ophthalmic Prosthetics*.

Further Readings

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Michael O. Hughes, BCO, is a board-certified ocularist who began working in prosthetics in 1982. He is the principal ocularist at the University of Virginia Department of Ophthalmology and maintains offices in Vienna, Richmond, and Roanoke, Virginia. Mr. Hughes is the senior editor of the *Journal of Ophthalmic Prosthetics*, the official journal of the American Society of Ocularists; he has been on its editorial board for more than 12 years.

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OP-ED

Drugs, Doctors, Profits, and Conflicts of Interest—Avastin versus Lucentis

Stephen R. Kaufman, MD

Fee-for-service private practice frequently generates conflicts of interest between the financial goals of the practice and the needs of a patient or the health care system at large. In fee-for-service-based practices, physician income is generally linked to the number of patients seen, the number of procedures performed, and, occasionally, the choice of therapeutics. Many physicians can now generate money by using more expensive medications, a situation that pharmaceutical companies can exploit by offering physicians inducements to use costlier drugs. For example, the choice ophthalmologists make when deciding between Avastin and Lucentis for the management of age-related macular degeneration (ARMD) illustrates how fee-for-service conflicts of interest might compromise patient care and burden the health care system.

Age-related macular degeneration is a leading cause of legal blindness (visual acuity 20/200 or worse in each eye) among senior citizens. The main cause of vision loss in exudative ARMD is new blood vessel growth (neovascularization) underneath the retina, which eventually results in permanent damage to the retinal photoreceptors from fluid leakage and bleeding underneath the retina and swelling of the retina itself. Scar tissue forms, leaving patients with poor central vision. Since the formation of new blood vessels leads to central vision loss and substantial visual disability in these patients, interventions have focused on impeding neovascularization in the eye through the use of vascular endothelial growth factor (VEGF) inhibitors, which induce regression of the new blood vessels and decrease retinal edema.

The development of effective VEGF inhibitors has had an effect on the management of age-related macular degeneration that is little short of miraculous. Prior to the introduction of these agents, patients with exudative ARMD generally lost vision, usually to degrees that severely compromised their reading, facial recognition, and driving abilities. The VEGF inhibitors have maintained or improved vision for a large fraction of patients, helping to preserve their quality of life. Originally used primarily to treat ARMD, VEGF inhibitors are now used in management of forms of diabetic retinal disease, glaucoma, and other eye conditions that may be related to aberrant blood vessel growth or retinal edema.

Though anti-VEGF treatment has had significant public health benefits, it has also raised some challenging ethical issues. Since their introduction in 2005, bevacizumab (Avastin) and ranibizumab (Lucentis) have been the two dominant

anti-VEGF agents on the market. Studies [1, 2] suggest the two drugs are comparable, but Medicare reimbursement for FDA-approved uses of Lucentis is over \$2,000 per treatment, while Avastin, which has been FDA approved for systemic (but not intraocular) use, costs Medicare less than \$55 per injection. This per-treatment cost difference can present a conflict of interest to treating ophthalmologists.

Looking at Benefits

In terms of efficacy, Lucentis is a smaller molecule than Avastin, and might more readily cross the retina (i.e., have greater effect), but it might also be cleared by the eye more quickly. Many ophthalmologists share my experience that Lucentis has a shorter duration of action and requires more injections over time than Avastin. Initial clinical trials with Lucentis involved monthly dosing for 2 years, and it appears that this regimen may be optimal for preservation of vision. Adding the injection procedure cost to the drug cost, the total cost of treatment for 2 years can exceed \$50,000 for one eye, and it is not uncommon for patients to need more than 2 years of treatment. To reduce these costs, many ophthalmologists increase the time between treatments for stable patients or choose to observe patients closely without treatment once they feel it is safe.

Because exudative ARMD is a leading cause of legal blindness among senior citizens, Lucentis has increased Medicare expenses for eye disease substantially, now amounting to over \$500 million per year. Were it not for Avastin's use, that figure would likely be about 150 percent higher [3]. From a health care finance standpoint, it is fortunate that Avastin also became available in 2005 and was quickly covered by Medicare. Since that time, it appears that most retinal specialists have chosen Avastin over Lucentis [4]. Still, many retinal specialists prefer to use Lucentis. Why might that be so?

Lucentis is FDA-approved for treating ARMD, having undergone thorough safety and efficacy testing for that condition. In contrast, use of Avastin in the eye is off label. Avastin was originally approved by the FDA for use in metastatic colon cancer, and there are no long-term ophthalmic studies. Nonetheless, short-term studies have documented Avastin's safety and efficacy for ARMD, and clinicians now have vast experience with the drug, with Avastin injections probably numbering in the millions.

Clinical experience has provided substantial evidence for Avastin's ocular safety, but some clinicians have raised concerns about the possibility of thromboembolic events. When Avastin was given systemically to colon cancer patients at a dose approximately 300 times greater than the ocular dose and given every two weeks (rather than every 4-6 or more weeks in the eye) the colon cancer patients (who have significant comorbidity and are on other anti-neoplastic agents) had a rate of thromboembolic events of 4.4 percent (the rate in the control population was 1.9 percent) [5]. If there is any increased risk of systemic thromboembolic events among patients receiving ocular Avastin treatment, it is likely very low.

The National Eye Institute's ongoing Comparison of AMD Treatment Trials (CATT) compares the safety and efficacy of Avastin to Lucentis. Initial results of the CATT will not be available until 2011. While the CATT will provide more definitive data, two nonrandomized trials comparing Avastin and Lucentis have indicated that the drugs have similar safety and efficacy. [1, 2].

Examining Costs

Deciding whether to recommend Avastin or Lucentis raises ethical issues that have significant implications for public health and health care financing. If a physician considered Lucentis marginally superior to Avastin, should the public health consequences of using a far more expensive drug trump what the doctor thinks is best for an individual patient he or she is treating at the moment?

I think society at large must decide how to allocate limited public health resources, and we as physicians are obliged to be advocates for our patients. However, it can sometimes be difficult to discern what is truly best for them. Physicians and practices stand to generate substantially greater income from Lucentis, a fact that could influence the choice between Avastin and Lucentis and generate conflicts between the financial goals of the practice and the needs of patients. For medications delivered in the office, Medicare reimburses drug cost plus 6 percent above average wholesale cost, which is a significant figure for a frequently used drug that costs clinicians \$1,995 per treatment. Further, if Lucentis requires more frequent injections than Avastin, using it increases the number of injection procedures that can be billed.

In addition to existing financial incentives to use Lucentis, the *New York Times* has revealed a secret rebate program in which Lucentis's manufacturer, Roche, has recently started to offer physicians financial inducements (about \$60 per dose) for prescribing large quantities of the drug and for increasing quarterly use. Many retinal specialists perform 1,000 injections per year, and some perform far more. Therefore, choosing Lucentis can generate substantial income without increasing physicians' work. Evidently, Roche is betting that increased revenue more than offsets the cost of the program. To the degree that Roche is correct that the rebate program influences physician choice, physicians are compromising what they regard as best patient care for the sake of financial gain.

Given the demand for anti-VEGF treatment, the physician's potential gain from using Lucentis is substantial. I would hope that this does not influence treatment decisions, and it may be that those who prefer Lucentis are genuinely convinced that it is more effective. However, our minds are very adept at rationalizing self-serving conclusions, and we humans often struggle to ascertain our true motives. Indeed, it appears that Roche expects physicians to be more influenced by financial considerations than they will admit in public, and perhaps than they will admit to themselves.

There is no easy resolution of this problem, particularly in a health care system that grants physicians considerable autonomy and, for the most part, still rewards them

on a per-treatment basis. Given that steadily rising health care costs are not sustainable, society might need to restrict physician autonomy. For example, Medicare might place limits on expensive treatments, such as Lucentis for ARMD. Medicare could require that certain criteria must be met—for example, proof that Avastin has not improved the patient's condition—before it will reimburse for Lucentis. Physicians greatly value their autonomy, yet our society might reasonably wish to curtail it if there are good reasons to believe that physician decisions are influenced by self-interest to the detriment of public health.

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Stephen R. Kaufman, MD, is an assistant professor in the Department of Ophthalmology and Visual Sciences at Case Western Reserve University School of Medicine in Cleveland, Ohio, a member of a private practice specializing in retinal diseases, and a participant in the Diabetic Retinopathy Clinical Research Network.

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Suggested Readings and Resources

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About the Contributors

Theme Issue Editor

Ashvini K. Reddy, MD, is a resident in the Department of Ophthalmology at Baylor College of Medicine in Houston, Texas. Her interests include pediatric eye disease, public health, and medical ethics.

Contributors

Penny A. Asbell, MD, MBA, is a professor of ophthalmology at Mount Sinai School of Medicine in New York City, where she is director of the cornea and refractive services division. Her research uses basic, translational, and clinical research approaches to explore new treatments for corneal disease and new devices to correct refractive errors. She is an active lecturer worldwide.

Yvonne M. Buys, MD, is a professor in the Department of Ophthalmology and Visual Sciences at the University of Toronto and the co-director of the Glaucoma Unit at the University Health Network. She is the immediate past president of the Canadian Glaucoma Society, glaucoma section editor for the *Canadian Journal of Ophthalmology*, and treasurer and board member of the Canadian Ophthalmological Society.

Brad Feldman, MD, is a board-certified ophthalmologist and a fellowship-trained cornea specialist who works with the Philadelphia Eye Associates and serves on two teaching services at the Wills Eye Institute in Philadelphia. He is the deputy editor in chief of the American Academy of Ophthalmology's EyeWiki and chairman of the academy's young ophthalmologist international subcommittee.

Michael O. Hughes, BCO, is a board-certified ocularist who began working in prosthetics in 1982. He is the principal ocularist at the University of Virginia Department of Ophthalmology and maintains offices in Vienna, Richmond, and Roanoke, Virginia. Mr. Hughes is the senior editor of the *Journal of Ophthalmic Prosthetics*, the official journal of the American Society of Ocularists; he has been on its editorial board for more than 12 years.

Stephen R. Kaufman, MD, is an assistant professor in the Department of Ophthalmology and Visual Sciences at Case Western Reserve University School of Medicine in Cleveland, Ohio, a member of a private practice specializing in retinal diseases, and a participant in the Diabetic Retinopathy Clinical Research Network.

Andrew G. Lee, MD, is chair of the Department of Ophthalmology at The Methodist Hospital in Houston, Texas, and professor of ophthalmology in neurology and

neurological surgery at Weill Cornell Medical College in New York City. Dr. Lee serves on the editorial boards of the *American Journal of Ophthalmology*, the *Canadian Journal of Ophthalmology*, and *Eye*, and he has published seven textbooks. Dr. Lee has a special interest in the ACGME competencies in ophthalmology.

Kiran Motaparathi, MD, is a resident in dermatology at Baylor College of Medicine in Houston, Texas, where he received his medical degree. His areas of interest include medical and cosmetic dermatology.

Thomas A. Oetting, MD, is a professor of clinical ophthalmology at the University of Iowa in Iowa City, where he has been on the faculty for the past 13 years. He is the ophthalmology residency program director and chief of the Iowa City VA Eye Clinic.

Usha S. Rao, MD, is a third-year ophthalmology resident at Baylor College of Medicine's Cullen Eye Institute in Houston, Texas. She is pursuing a fellowship in glaucoma and plans to have a career in an academic environment, where she can participate in the education of residents and fellows.

Kristin E. Schleiter, JD, LL.M., is a state government affairs analyst for the American Academy of Pediatrics in Elk Grove Village, Illinois. She analyzes the impact of state health care legislation and provides strategic guidance for the pediatric medical community in its ongoing advocacy efforts. Prior to working for the AAP, Ms. Schleiter worked for the Council on Ethical and Judicial Affairs of the American Medical Association. Ms. Schleiter received both her law degree and master's of law in health law from Loyola University Chicago School of Law, where she was a contributing writer for the *Annals of Health Law*.

Paul G. Steinkuller, MD, is an associate professor of ophthalmology at Baylor College of Medicine and a pediatric ophthalmologist at Texas Children's Hospital in Houston. He is a member of the American Association for Pediatric Ophthalmology and Strabismus, the Harris County Medical Society, and the American Academy of Ophthalmology. He wanted to be a pilot, but myopia forced him into medical school and he found he enjoyed it; he likes children, puppies, small mammals, medical students, and residents.

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