Evidence-Based Medicine:  
A New Paradigm  
Or Cookbook Medicine?

Joel Horovitz, MD, FACS  
Maimonides Medical Center

The interest in Evidence-Based Medicine (EBM) has increased over the past few years as new technologies make it easy for health care professionals to gain access to vast amounts of medical information. Dr. Joel Horovitz of Maimonides Medical Center shares various aspects of the EBM movement and notes that physicians can make sound decisions for individual patients based on the results reported by their peers and predecessors.

The concept of Evidence-Based Medicine was first introduced by Gordon Guyatt, a Canadian epidemiologist, in 1992. He defined EBM as “the explicit use of the best clinical evidence, coupled with the physician’s expertise and the patient’s values”. Guyatt based his opinions on the 1972 work of Archibald Cochrane of Britain in which the latter opined that physicians should have the best clinical data based on randomized trials to provide optimal care to patients. Today, the Cochrane Collaboration, an independent group consisting of health care specialists who review biomedical trials, is widely recognized for its depth and reliance on the best data available. However, the majority of physicians do not use EBM in their day-to-day decision-making, and recent hospital report cards indicate that EBM precepts are not being used to their fullest extent.

The practice of EBM is not new; then why is there debate on this seemingly cogent idea?

Many physicians equate EBM with cookbook medicine, claiming that the idea of basing medical practice on the best available evidence robs them of their personal experience and intuition. Defenders of EBM maintain that these criticisms reflect opinion based medicine (OBM) and decry such assumptions.

Under-use of Known Therapies

The Institute of Medicine (IOM), based in Washington, D.C., reported that in 2004 less than one-half of physicians in the United States prescribed beta blockers and aspirin to patients after an acute myocardial infarction. The randomized trials proving the benefit of this practice were carried out more than a decade ago and should be applied to all such patients. Similarly, well-accepted rules for the appropriate use of prophylactic antibiotics have been widely disseminated by the Centers for Disease Control, but a 1996 New York State Department of Health study showed that many physicians did not use prophylactic antibiotics correctly.

In a recent study on antibiotic prophylaxis for major surgery, Bratzler DW et al (Arch Surg. 2005; 140: 174–182.) focused on more than 34,000 Medicare patients and catalogued the use of antibiotics. The findings are as follows:

1) 55.7% of patients received the first dose within one hour of the start of the procedure.
A Message from the Editor

Dear Readers:

Welcome to the inaugural issue of *infocus*. It has been an exciting few months as we have brought together *Focus* and *Health Care Risk-Link*, a natural evolution given the direction these publications have taken in recent years. *infocus* enables us to analyze the latest trends in the changing health care industry, the techniques of risk management and the policies shaping our professions. It offers you greater access to FOJP Service Corporation’s expertise in health care education and risk management services, and serves as a forum for ideas at the intersection of policy and academia.

For this issue, we could not have considered a more apt feature than Evidence-Based Medicine, which has origins dating back to early-19th century France, and remains a significant topic for clinicians and health care practitioners. The subject’s newfound popularity has been driven by several factors, including the explosion of clinical knowledge, rising patient expectations and technology’s evolving sophistication. As EBM concepts develop, we thought this would be a good time to refine the discussion.

Also in this journal, we offer refractive surgeons several strategies to proactively manage the risk of claims and lawsuits. The featured article highlights the importance of communication and documentation—key elements in the care process—in minimizing risk exposure. Other articles offer an overview of national patient safety goals developed to reduce preventable medical errors, and initiatives launched by independent organizations to promote patient safety and hospital quality.

We look forward to the dialogue that *infocus* and its contributors will generate, and encourage readers to send letters with suggestions and comments to the editor at focusedit@fojp.com.

In the meantime, we hope you will enjoy this issue as much as we did putting it together.

Margaret Brubaker
Putting the Brakes on Junk Science

Resurgence of Frye Rule Seen as Effective Tool Against Meritless Cases

Barbara S. Finger, Esq.
Wenick & Finger, P.C.

In a courtroom, where juries and judges are arbiters of disputes between parties who have failed to reach an agreement, juries are generally fair and reliable. But the problem arises when jurors lack the expertise to decide medical issues accurately, and expert witnesses exploit scientifically naïve judges with theories disguised as science. In this article, the author documents the resurgence of the Frye rule that serves as a standard to evaluate the adequacy of scientific testimony.

Judges have often times allowed the plaintiff’s bar to offer “junk science” in support of spurious allegations of malpractice to relatively unSophisticated jurors. The difficulty at trial has been demonstrating to jurors the fallacy and weakness of such evidence. From the perspective of jurors, who lack the scientific background to evaluate such testimony, efforts to point out shortcomings are perceived as nothing more than a “battle of the experts”. Historically, judges have taken the position that they cannot filter “legitimate” medicine from that which is driven by litigation—as long as a person with an MD degree is willing to testify to that medicine under oath.

However, in the past few years, defense lawyers have had a new and more effective weapon against such evidence. They have resurrected a relatively old decision, Frye v. The United States, 293 F.1013 (D.C. Cir. 1923), as a pretrial tool to convince judges to keep juries from ever hearing this junk science. Frye requires evidence to be “generally accepted in the scientific community” before it is admitted in court. Of late, lawyers who defend doctors and hospitals have used Frye as an effective weapon to dismiss meritless malpractice actions.

Without Frye, the only way to have a malpractice action dismissed is to move for summary judgment. Such a motion requires the defendant doctor to show that (1) the care provided was in accord with good and accepted medical practice, and (2) there are no “substantial questions of fact” with regard to either the appropriate standard of care or the question of whether it was met. The appellate courts have clearly directed the trial courts to deny the motions if they find even the slightest question of fact as to those two issues. The reason is that courts are loath to substitute their judgment for that of the jurors, who are charged under our system with resolving questions of fact. Thus, until recently, such motions have been ineffective vehicles for dismissal of malpractice actions.

A Standard of Evaluation

The resurgence of Frye has given the courts a standard by which to evaluate the adequacy of scientific testimony, and has proven to be a much more effective tool against meritless cases. In order to prevail in a malpractice action, a plaintiff must offer expert testimony that the defendant departed from accepted standards of medical practice and that such departure caused harm to the plaintiff. In the absence of expert testimony, a plaintiff is unable to prevail and the case must be dismissed. A successful pretrial challenge under Frye that precludes the plaintiff’s expert requires dismissal of the case.

Frye has other advantages over summary judgment motions. Under Frye the plaintiff must convince the court that the proffered evidence has been generally accepted in the scientific community. In order to prevail under a Frye motion, the party attacking the testimony need only make a facial showing that a particular “concept, principle or methodology offered by the proposed expert opinion has not been generally accepted in the relevant scientific community,” DeMeyer v. Advantage Auto, 9 Misc. 3d 306, 797 N.Y.S. 2d 743 (Sup Ct, Wayne Co. 2005). If the party challenging the testimony succeeds in making that threshold showing, the burden of proof shifts to the

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plaintiff to establish that the methodology or concept offered by their expert has been “generally accepted in the scientific community”.

The situation is reversed in a summary judgment motion. There, the defense is required to convince the court that there are no substantial issues of fact. In effect, the defense must prove a negative, which is much more difficult.

**Burden of Proof**

In determining whether to admit evidence challenged under *Frye*, the courts apply a “weight” test, simply looking at whether there is sufficient acceptance in the scientific community supporting the theory to warrant its introduction at trial. The court does not take on the role of assessing the validity of scientific evidence. Rather, it looks to the plaintiff to prove that the scientific community has endorsed the theory.

*Frye* has been particularly effective in challenging issues of causation. To prevail at trial, a plaintiff must prove that the challenged medical treatment played a role in the claimed injuries. In *Heckstall v. Pinkus*, 19 A.D. 3d 203, 797 N.Y.S. 2d 445 (1st Dept. 2005), the court relied on *Frye* in precluding an expert from testifying that Bupropion, a psychotropic medication prescribed to aid in smoking cessation, led to plaintiff’s death. In that case, the plaintiff took two doses of Bupropion and thereafter suffered a fatal arrhythmia. The defendant moved to preclude plaintiff’s expert from testifying that Bupropion could generally cause an arrhythmia and in fact was the cause of the arrhythmia that led to plaintiff’s decedent’s death. The Appellate Division held that the trial court should have precluded plaintiff’s expert, noting that the defendants had succeeded in showing that plaintiff was unable to cite a single case where Bupropion had caused arrhythmia or death, and the plaintiff failed to present any clinical or epidemiologic data or peer reviewed articles causally linking Bupropion to death from arrhythmia.

In *Lewin v. County of Suffolk*, 18 A.D. 3d 621, 795 N.Y.S.2d 639 (2nd Dept. 2005), the Appellate Division precluded plaintiff from offering testimony that Malathion, a pesticide, had caused the infant plaintiff’s birth defects. Following *Frye*, the court looked at whether this theory had any support in the medical community. When plaintiff conceded that there was no evidence linking in utero exposure to Malathion in birth defects, the court precluded plaintiffs’ expert from so testifying and thus granted summary judgment to the defendant.

However, plaintiffs have been able to overcome *Frye* challenges. In *Marsh v. Smyth*, 12 A.D. 3d 307, 785 N.Y.S. 2d 440 (1st Dept. 2004), the Appellate Division held that a plaintiff’s expert could testify that the positioning of an arm board during surgery caused a palsy in the plaintiff’s long thoracic nerve. The plaintiff had undergone a hysterectomy to treat her ovarian cancer. Thereafter, she developed severe pain and weakness in her right arm and shoulder, which was diagnosed as a long thoracic nerve palsy. Plaintiff argued that her arm had been hyperabducted during the surgery, thus leading to the nerve damage.

Although the trial court granted the motion to preclude plaintiff’s proffered testimony, the Appellate Division reversed it. The *Marsh* court held there was sufficient showing by plaintiff that this theory had general acceptance in the medical community, and that pretrial preclusion was an improper application of the *Frye* standard. The court’s error in this instance was using *Frye* to look at the credibility of the testimony, thus essentially substituting its opinion for that of the jury.

**Higher Level of Scrutiny**

Perhaps the most heartening use of the *Frye* rule to the defense bar has been its use to preclude testimony of a pediatric neurologist, who is known as a “plaintiff’s expert”. That physician has testified many times in support of plaintiffs to blame management of a delivery for a child’s subsequent developmental problems, including cerebral palsy. He has testified that elevated intrauterine pressure, particularly when coupled with Pitocin, caused cerebral palsy. Using *Frye*, courts have precluded this physician on several occasions from offering such testimony. In *Saulpough v. Kraffe*, 5 A.D. 3d 934, 774 N.Y.S. 2d 194 (3rd Dept. 2004), the Appellate Division held that the absence of any “controlled studies, clinical data, medical literature, peer review or supportive proof “that the expert’s theory was generally accepted by the medical community’s”, warrant preclusion of his testimony and dismissal of the case.”

Similarly, in *Lara v. New York City Health and Hospitals Corporation*, 305 A.D. 2d 106, 757 N.Y.S. 2d 740 (1st Dept. 2003), the First Department, which covers the Bronx and New York Counties, held that this expert was appropriately precluded from testifying that a delivery, “which is precipitated but involves no significant bleeding and is otherwise uneventful,” was a competent producing cause of an infant’s cerebral palsy that presented six months after birth. The court noted that plaintiff was unable to come forward with any reported formal studies to support this theory, and thus the proposed testimony was appropriately precluded.

In conclusion, *Frye* is continuing to live up to its promise as an effective tool for those who seek to require scientific rigor and validity to the litigation of alleged medical malpractice.

Absence of any controlled studies or medical literature to support theory can lead to case dismissal.
One of the most distressing moments in a physician’s professional life is being named in a medical malpractice lawsuit. Yet it can and does happen, everyday, even to physicians who take pride in the quality of care they provide and the rapport they enjoy with patients. Nothing can shake a physician’s self-esteem more than being served with legal papers. We may even wonder if physicians could possibly be as harmful as the plaintiff’s attorney suggests. Few medical professionals would argue that an aggrieved victim of a careless, unethical physician deserves a day in court. However, the prevailing opinion among physicians is that the majority of malpractice cases involve questionable plaintiff assertions made against competent and qualified colleagues.

Over the past several years, LASIK has become the main surgery doctors use to correct vision in the United States. Its popularity lies in reducing dependence on spectacles and contact lenses, allowing people to more freely pursue their career choices or hobbies. The US Food and Drug Administration’s Web site notes that the technology is new and the first laser approved for LASIK eye surgery was in 1998. Therefore, the long-term safety and effectiveness of LASIK surgery is not yet known. Certain complications are unavoidable, and there are no long-term data available for current techniques. As a result, refractive surgeons have become attractive to personal injury lawyers as possible targets for litigation. For when it comes to surgery, 99% is not good enough. Anything less than 20/20 vision (without any other visual artifacts) can prompt malpractice lawyers into action with the promise of huge rewards. No matter how significant the vision improvement, if that patient is unhappy with the result, the physician becomes the target.

This trend has profound implications for your practice. Suddenly, everything that a patient sees and hears, including every interaction with you and your staff, could be magnified and scrutinized at a deposition. What you do and do not write in the chart takes on new importance. Devoting proper attention to patient communication and documentation can go a long way toward appeasing that rare, unhappy patient and reducing the risk of a lawsuit.

Departure from Traditional Approach
Many of us have seen and heard advertising in newspapers and on radio for laser vision correction surgery as well as other kinds of cosmetic surgery. The intense competition for self-paying elective surgery patients has generated multimillion dollar advertising campaigns in print, broadcast and online media. However, this is a major departure from the traditional approach where a doctor’s reputation is spread by “word-of-mouth” from satisfied patients and fellow colleagues.

Despite its wide reach, advertising has the potential to promise more than one can deliver. Laser vision advertisements proclaiming, “You can throw away your glasses and contact lenses after LASIK!” gives consumers an unrealistic view of guaranteed surgical success. Even with subsequent informed consent, a number of unhappy patients have successfully argued that they were lured into elective surgery with false promises, and have used newspaper advertisements as evidence. To counteract this trend, many medical organizations have developed guidelines for...
It is essential to convey a consistent message about the benefits and risks of elective surgery.

It is in your best interest to be as familiar with these guidelines as attorneys and risk managers.

Patients often visit your Web site or call your office to gather more information on the surgery. It is essential that you convey a consistent message about the benefits and risks of elective surgery. When it comes to Web site information and telephone conversations, instruct your staff to be upbeat instead of misleading the caller about surgery. The reality is that many consumers are well informed about laser vision surgery but some feel that LASIK is as risky as a haircut. Expressions like “It’s a slam dunk!” or “You’re the perfect candidate” play into these misconceptions. What may seem like simple enthusiastic chatter will appear intentionally manipulative when quoted at a deposition. A better approach is to provide a Web site and call center with accurate general information that emphasizes the need for interested consumers to appear for a personal consultation.

During consultation, an examining physician should assess physical characteristics that qualify a patient as a good surgical candidate. As part of this process, it is a good idea to evaluate the patient’s personality as well. A patient who demands perfection to be happy and does not appreciate the uncertainties inherent in any medical procedure is a hard-to-please patient and best avoided. Likewise, recognize that patients who express hostility or disdain toward other physicians may confront you in the same way. Regardless of the patient’s traits or views, never guarantee outcomes and be forthright about short- and long-term expectations.

In one case, a 40-year-old patient, who was a nurse at one of the major hospitals in New York City and had been wearing glasses since his teens, was interested in laser treatment for his myopia. The patient appeared to be a good candidate for surgery. After talking through the risks, benefits and alternatives, we agreed to go ahead. We performed photorefractive keratectomy (PRK) and the patient was healing well. After two or three weeks, the patient returned to the office in anger stating, “You gave me unequal pupils!” We offered several indepth explanations, which did not help. Finally, at our suggestion, he consulted a neuroophthalmologist. A few days later, the consultant called me saying, “We solved the problem! We found an older photo of the patient and it clearly shows anisocoria (unequal pupils).”

**Review the Risks with Patients**

This experience highlights the importance of asking patients to look at everything that they will be using as a benchmark to check themselves against following refractive surgery. Human nature can keep patients from noticing the ordinary so that after surgery, they turn anxious and start looking for things that might have gone wrong. By helping patients realize their visual imperfections such as rays, halos and nighttime glare ahead of time, physicians can make the recovery process much smoother.

At some high-volume surgery centers, a patient may meet the surgeon minutes before surgery, and later be seen by an optometrist for pre- and post-operative care. While this may not affect the quality of care, it can present opportunities for unhappy
Whether you go over information in a conversation or use a more formal presentation, review the risks of surgery with the patient in advance.

patients to claim they did not get enough time to discuss the risks of surgery with the surgeon. This issue of adequate physician-patient communications was at the center of a LASIK case in New York State where the plaintiff was awarded $7.25 million but the amount was later reduced to the limits of the doctor’s insurance. The plaintiff’s attorney was able to paint the image of a high-volume surgical center as a “LASIK factory” where the doctor missed important details because of the heavy patient schedule.

Hefty awards in LASIK cases emphasize the need for physicians to take the time to review the risks of surgery with patients. Whether you go over information in a conversation or use a more formal presentation, such as a video, this review should take place in advance. The same applies to consent forms, which you should plan to give to patients at least one day ahead of surgery. At that time, you should also document the date so that you have a record of when the patient received the form. The problem with handing out consent forms immediately before surgery is that it allows unhappy patients to claim that they had little time to review the document or were told “It is just a formality—sign the form and don’t worry about it.” Again, by following these suggestions, you can emphasize your conscientious efforts to ensure that patients understand the potential procedural risks.

As a final precaution during this preoperative process, physicians should conclude their examination with written documentation noting that “The risks, benefits and alternatives (including but not limited to…) were discussed with the patient and all the patient’s questions were answered.” You can also document the length of time that the discussion required. In the legal world, if it is not in writing, it did not happen. Documenting your conversation with the patient is your best protection against a later claim of inadequate informed consent.

Following surgery, patients facing slow vision recovery are often nervous, frustrated or even angry. While normal post-LASIK conditions such as fluctuating vision may be routine for you, they can disturb and alarm patients. By showing concern and providing explanations early on, you can pave the way for a smoother relationship down the road. When these types of situations occur, it is essential for the surgeon to see and spend time with patients to discuss what has happened as well as the likely outcome. If you co-manage your patients with an optometrist, you should establish a process for referring patients back to you at the earliest opportunity.

It is important to maintain a record of the care you provide by documenting patient complaints, time spent in discussion, and the plan agreed to by you and the patient. In discussions with your patient, physicians should be upfront about what happens during surgery, why it happens and the resulting prognosis. Reassure patients that healing varies and explain how their healing process is different from others.

Establish Strong Bonds with Patients

Also, you might consider giving these patients your cell phone number to offer a way to reach you. (Contrary to expectation, in our experience, patients have respected the privilege of having a physician’s cell phone number.) It is also helpful to alert your staff to patients of concern so they are prepared to be extra accommodating and responsive with those patients. The last thing a physician wants to do is inadvertently abandon or brush off patients. By being accessible and providing thorough and honest explanations, patients could view you as an advocate instead of an adversary.

For all the successful procedures that have been performed, one does not have to look far to find descriptions of the complications with LASIK and other laser vision procedures. The Internet is full of such stories. The problem is that patients who do not have strong relationships with their physicians are likely to believe that they too are victims of the many negative stories they read about on the Web.

Patients will continue to use the Internet as a source of medical information. This makes it even more pressing for physicians to work hard to establish strong bonds with their patients and be aware of the information they are getting. If you can maintain a solid relationship of mutual trust and respect with your patients, they will be less likely to look to the Web or an attorney for solutions when faced with unexpected circumstances.

In our experience, by observing these strategies for advertising guidelines, information accuracy, personality assessment, advance consent, thorough documentation, and effective patient communication, physicians will discover new ways to manage and reduce risks in refractive surgery.
This case involves a patient who underwent bilateral LASIK surgery by an insured ophthalmologist. The patient alleged the surgery was improperly performed, resulting in permanent visual distortions and the need for multiple subsequent procedures.

**Case Details**

A 51-year-old attorney contacted a chain of LASIK surgery centers after seeing a print ad for a low introductory price. He presented to one of the centers for an evaluation of candidacy for correction of near-sightedness. An optometrist’s examination revealed that without correction the patient’s visual acuity was limited to counting fingers but was correctable to 20/20. He deemed the patient a suitable candidate for surgery; the risks were discussed and surgery was scheduled for the patient’s next visit.

When the patient returned for surgery he met with the center’s surgical counselor, who reviewed the risks and benefits, as well as the nine-page operative consent paragraph by paragraph. The patient initialed each page, and met the insured ophthalmologist just before the surgery. The ophthalmologist briefly reviewed the risks and benefits, and had the patient sign the informed consent. The bilateral LASIK surgery was performed, and abrasions occurred in both eyes.

The following day, the patient returned and was seen by the ophthalmologist. The patient complained of blurry vision in both eyes. On examination, there was full epithelization in both eyes, and the uncorrected visual acuity was right eye 20/60, left eye 20/50.

Three days post-surgery, the patient was seen by the ophthalmologist in his private practice office. However, there is no documentation for this visit.

Five days post-surgery, the patient returned to the LASIK center, and was seen by another ophthalmologist. The uncorrected visual acuity was right eye 20/40, left eye 20/25. On examination the right eye flap had stria (small folds) and resolving DLK (an inflammation under the surgical flap); the left eye flap had micro folds. The case was discussed with the insured ophthalmologist.

Two days later the ophthalmologist saw the patient at the LASIK surgery center. The uncorrected visual acuity was right eye 20/40, left eye 20/20. The right eye flap was re-lifted, loose epithelium was seen, and the flap was re-draped. The patient returned the next day, and saw the ophthalmologist. On examination, the edges of the right eye flap were aligned. Follow-up in one week was planned, but this was the patient’s last visit with the ophthalmologist.

Later that day, the patient had discomfort in the right eye. He called the LASIK center, but the ophthalmologist was not informed of this call. The patient then sought treatment with another eye physician who removed loose epithelium from the right eye, and re-lifted the flaps of both eyes. Afterward, the uncorrected visual acuity was right eye 20/40, left eye 20/25, and with corrective lens was 20/20 in both eyes. The patient complained of persistent visual distortions, including glares, halos and fluctuations in visual acuity. This physician documented the residual problems were due to bilateral de-centered ablations (off center removal of corneal tissue) caused by the LASIK surgery. At that time, there was no treatment available for this complication. In 2003, with the new technology, the de-centered ablations were corrected, and the symptoms improved. This physician also performed a right eye keratotomy for astigmatism, and several LASIK procedures to refine the visual acuity.

**Investigation**

Investigation revealed the insured ophthalmologist was an independent contractor at the LASIK center, and was paid fee for service per eye. He saw six to 20 patients a day, and performed five to six LASIK surgeries a day. The physician’s role in the treatment course was determined by the center’s policy, which was driven by the aim to provide care, while keeping the cost down. Therefore, the pre-operative evaluation and lengthy consent discussion were done by staff, and not the surgeon.

The patient testified that during the evaluation, he was told a different ophthalmologist would perform the surgery. Then just before the surgery, he met the insured ophthalmologist who carried out the procedure. The patient did not have the opportunity to research the surgeon’s credentials and factor that information into his decision-making process.
On a recent exam the patient had no visual disturbance related to de-centration. Centered ablations are a risk of LASIK surgery, the degree was not significant, and needed, and this does not indicate a departure from the standard of care. De-subsequent ophthalmologist re-lifted both flaps. Sometimes, several re-lifts are common, and a re-lift of the left flap was not indicated. It is unknown why the re-lift the right flap was sound and timely. The finding of loose epithelium is the surface under it is an exact fit, and after the laser re-shaping, the surface is range. The development of DLK is common and was appropriately treated. The visual acuity improvement was within the expected surgery. The operative occurrence of abrasions is not unexpected and they were appropriately treated. The ophthalmology expert found the case completely defensible. The pre-operative evaluation was thorough, and the patient was an appropriate candidate for the surgery. The operative occurrence of abrasions is not unexpected and they were appropriately treated. The visual acuity improvement was within the expected range. The development of DLK is common and was appropriately treated. The development of folds in the flap is also common because when the flap is made, the surface under it is an exact fit, and after the laser re-shaping, the surface is concave. The folds may or may not affect vision, and the decision to intervene is a judgment call. The ophthalmologist’s decision to observe, re-evaluate and then re-lift the right flap was sound and timely. The finding of loose epithelium is common, and a re-lift of the left flap was not indicated. It is unknown why the subsequent ophthalmologist re-lifted both flaps. Sometimes, several re-lifts are needed, and this does not indicate a departure from the standard of care. De-centered ablations are a risk of LASIK surgery, the degree was not significant, and on a recent exam the patient had no visual disturbance related to de-centration. The right eye keratotomy for astigmatism and the subsequent enhancement LASIK procedures were unrelated to the surgery by the insured ophthalmologist.

Resolution
The case went to trial and resulted in a defense verdict. Although no indemnity was paid, legal costs amounted to $220,000.

Conclusion
Angry patients are more likely to bring lawsuits than those who feel their physical and emotional needs were addressed by their physician. A perception of care that is rushed combined with a complication and inability to speak with the physician results in an angry patient. It increases the likelihood of a malpractice lawsuit despite sound medical care. The few minutes it takes to see the care through the patient’s eyes can save a physician untold hours of grief from a lawsuit. Further, if a lawsuit occurs, a well documented record will bolster the defense of the case.

Five Risk Reduction Strategies
Physicians must be aware that although they may be independent contractors at a care facility, the patient does not make that distinction. The care facility sets policy, which may expose them to risk. The LASIK center’s policy restricted the patient-physician encounter to minutes before surgery. Regardless of the policies, the practitioner must ensure that the standard of care is met.

The attending physician is ultimately responsible for the informed consent discussion. Other providers may offer information, but the attending physician must ensure that the risks, benefits and alternatives are thoroughly discussed with the patient. Finally, the attending must include adequate documentation of this discussion.

It is likely the time span for the informed consent discussion was somewhere between the estimates offered by the patient and the ophthalmologist. The physician’s urgency may not be expressed in words, but is often through body language. Even if the physician has a limited time to speak to patients, effective communication can take place if patients sense they have the physician’s undivided attention.

Even if key elements in the care process such as communication of critical information, scheduling of appointments, timely receipt of lab results, availability of treatment records or staff’s behavior are outside the control of physicians, they should report concerns to the appropriate individuals who can address system problems. Also, physicians must follow-up to ensure breakdowns in the care process are investigated and corrective action implemented. This reduces the risk exposure for future patients in their care.

Errors in documentation, such as the wrong provider’s name, imply a lack of attention to detail, and a jury will translate this to mean a sloppy approach to care. Documenting positive or expected findings is as important as documenting abnormal findings. If a form has multiple fields detailing exam findings and the fields are left blank, a plaintiff’s attorney could say the physician failed to properly examine, or worse the physician was hiding something. At the least, it could be surmised that the physician didn’t care enough to complete the documentation. Further, all care visits must be documented. In a lawsuit, the care can be defended if the documentation supports a thorough assessment, plan of care and clinical rationale for decision-making. However, gaps in documentation are difficult to defend. The care may be sound, but if the documentation is inconsistent or lacking, the case becomes more attractive to a plaintiff’s attorney.
2) 92.6% of patients received the appropriate antibiotics.
3) Prophylaxis was discontinued within 24 hours of the procedure in only 40% of cases.

Despite evidence of effectiveness of antibiotics to prevent surgical site infections—a major contributor to patient injury, mortality and health care costs—Bratzler concludes that “substantial opportunities exist to improve the use of prophylactic antibiotics for patients undergoing major surgery”.

Another example of failure to apply the findings of EBM studies was recently published by Khel et al (JACS, Feb. 2006). They looked at patient care after colonic surgery in 1,082 patients in six countries, including the United States. They found that many EBM concepts related to colon surgery were “not applied optimally in clinical practice across Europe and the United States. These findings indicate a potential for major improvements in outcomes and a reduction of costs if peri- and postoperative care can be adjusted to be in line with published evidence”. The kinds of practices they looked at were simple, such as avoiding nasogastric tubes and the use of early oral feeding.

Training in EBM
I think the main reason physicians do not accept EBM in their daily practice is a direct result of their training. Certainly in surgery, the chief surgeon is always right and medical students are taught to perform exactly as they are told. This broad acceptance of low-level evidence is completely pervasive, allowing physicians “to become resistant to ideas that do not conform to our preconceived notions” (Harken, Arch Surg, Nov. 2002).

Despite physician reluctance, organized medicine has firmly accepted EBM as a mandatory goal. In 2001, the Accreditation Council for Graduate Medical Education published its list of the six core competencies that must be taught in all residency programs. Two of them directly embrace EBM—practice-based learning and improvement (PBLI) and systems-based practice (SBP).

The requirements for PBLI include a) analysis of practice experience using systematic methodology; b) location, appraisal and assimilation of evidence from scientific studies related to health problems; c) application of knowledge of study designs and statistical methods of appraisal of clinical studies, and d) use of information technology to manage information, access online medical information and support individual education. Thus, in 2006, all doctors must use EBM as a basic tenet of their education and continue to use it for lifelong learning. Also, in 2005, the American College of Surgeons began collaborating with the Canadian Society of General Surgeons to introduce evidence-based surgical reviews on its Web portal. All surgeons will have to show evidence of participation in this endeavor.

Skills Impacting on Care
The goals of EBM are simple to follow if certain skills are available. The first requirement is asking an answerable question concerning a patient problem—these arise daily in clinical practice. The next steps are performing a literature search and then analyzing the data to assess their quality and validity. After applying the results to the patient, physicians then determine the effectiveness of the intervention. Although it seems straightforward, the application of certain aspects of EBM can be problematic, especially for the seasoned physician. The two aspects that may be the most difficult are 1) efficient data gathering and 2) the use of appropriate statistical tests. In the past, all articles published were based on probability—the p value ≤ 0.05 became the accepted standard. This meant that the probability of a finding due to chance alone was less than 5%. EBM, however, emphasizes the use of likelihood ratios, odds ratios and the number needed to treat (NNT) when analyzing the results of studies. As most seasoned physicians received little training in statistics, this new requirement for learning is daunting. There are books that can be consulted to update statistical knowledge in an easy way.

Bloodletting using leaches was the accepted treatment for most diseases in the early 19th century. Pierre Louis, a provincial French physician, used his extensive patient database to study the question in people with a variety of infections. He found that early bloodletting was associated with an increase in mortality and recommended that the practice be abandoned. He was derided by the French medical establishment but he persevered and eventually the practice fell out of use. In the year before his writing (1833), France imported 42 million leaches for medical use. Dr. Louis was one of the first physicians to use epidemiologic principles to formulate appropriate therapy.
Lifelong Learning

The ability to do a rapid search of the relevant literature is even more overwhelming to the computer-challenged physician. However, this skill is really the cornerstone of lifelong learning—a precept that is essential for every physician. Medical knowledge is increasing exponentially and the current generation of medical evidence is so multifaceted that it is increasingly difficult for providers to stay up-to-date even within their specialties. It is estimated that MEDLINE® will abstract more than one-half million papers a year (and they only abstract about 4,000 of the 15,000 journals worldwide).

The skill of an effective literature search must be learned by practice. Adept use of the computer and the Internet are essential. The wide use of wireless connectivity and portable computers will make instant accessibility to literature a reality. This is a skill that is required of all doctors.

There are numerous Web sites that can be relied upon to give accurate information. Some are free but all require knowledge of Boolean search terms to limit a needlessly large number of papers to review.

Conclusion

Physicians are at risk if they do not adhere to the recommended treatment principles that are evidence-based. It is clear that the standard of practice will be judged by the best clinical evidence unlike the present situation in which the courts give credence mainly to opinion or expert based medicine. Important to the defense, in litigation, is the demonstration that applicable standards of care have been followed and documented in the record. I believe that the practice of medicine bolstered by EBM is the most effective method of ensuring the best care for our patients. It also ensures that physicians will remain up-to-date in patient treatment and are open to new ideas as they emerge in the future.

selected URLs that yield quality information on evidence-based medicine:

www.pubmedcentral.nih.gov
This US National Institutes of Health-operated Web site offers free and unrestricted access to life sciences research reports.

www.cebm.net
This Web site is run by UK-based Centre for Evidence-Based Medicine to promote related resources to interested consumers worldwide.

www.jr2.ox.ac.uk/bandolier
This Web site is the electronic version of Bandolier, an independent journal about evidence-based health care, written by Oxford scientists. It is a source of information for both health care professionals and consumers.

www.cebm.utoronto.ca
This University of Toronto-operated Web site offers tools for developing, disseminating and evaluating resources that can be used to practice and teach EBM for health care professionals from several clinical disciplines.

www.cochrane.org
This Web site carries systematic reviews of health care interventions and promotes the search for evidence in the form of clinical trials and other studies of interventions. It is run by the Oxford-based Cochrane Collaboration and named for the British epidemiologist, Archie Cochrane.

www.bestbets.org
Best Evidence Topics (BETs) were developed in the Emergency Department of Manchester Royal Infirmary, UK, to provide evidence-based answers to clinical questions, using a systematic approach to reviewing the literature. This Web site allows users to browse or search a large database of BETs while allowing readers to submit their own works.

www.sicsebm.org.uk
The Scottish Intensive Care Society (SICS) Evidence-Based Medicine Group Web site provides resources for critical care with guidelines and a CAT (critically appraised topics) collection.

wwwahrq.gov
This Web site of the US Agency for Healthcare Research and Quality offers relevant scientific literature to produce evidence reports and technology assessments.

www.ebmny.org
This Web site provides health practitioners and librarians with education and training in EBM, and the information resources and computer competencies required to teach EBM. The site is managed by the New York Academy of Medicine in partnership with the Evidence-Based Medicine Committee of the American College of Physicians, New York Chapter.

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Q&A: How is EBM incorporated into practice at Maimonides Medical Center, and what are the procedures for review?

DR. HOROVITZ: At Maimonides, we begin with house staff training in EBM. Twice a week, we create Critically Appraised Topics, or CATs. A patient with a problem is presented and a clinical question is asked that can be answered through an evidence-based search. The residents then conduct a literature search and make recommendations to answer the question. This is presented to the group in a subsequent session. A free software program called CATmaker is used to format the result. The surgical staff has a library of CATs, or CAT bank, available for reference that can be helpful when treatment questions arise. These evidence-based practices are not guidelines but constitute a recommendation for a specific treatment situation. The physician then makes a decision whether to apply the recommendation, and whether it is timely. Evidence can change over time so it is important to date CATs and other searches that are made for treatment purposes.

Through training and administrative emphasis in the clinical area, greater use of EBM can be expected. At Maimonides, I distributed copies of “Evidence-Based Medicine: How to Practice and Teach EBM” (by David L. Sackett, Sharon E. Straus, W. Scott Richardson, William Rosenberg, and R. Brian Haynes) to all surgeons. This book provides a good introduction to the principles of EBM and how to use it and communicate it to others.

EBM is a voluntary activity but in a hospital setting the departmental chair maintains responsibility for reviewing the clinical practice of physicians in the department. It is important to review incidents and, more importantly, near misses as they provide us an opportunity to learn from our mistakes. EBM is an effective process for improvement and an important tool to advance patient safety.
In the past few years, several independent organizations have started to provide consumers and purchasers of health care with the information they need to make informed choices on health care. In the following articles, the author reviews some of those initiatives aimed at improving hospital quality and promoting transparency within health care.

Diane Desaulniers
Contributing Writer

HealthGrades Offers Medical-Cost Reports To Help Patients Shop for Health Care

Price shopping is a given in everything from auto insurance to appliances. That capability has finally reached the health care community. The latest initiative by HealthGrades, Inc. introduces Medical-Care Cost Reports that allow consumers to access and compare pricing information for more than 55 hospital-based procedures across the country.

According to HealthGrades, a health care rating and consulting firm that plays an influential role in efforts to improve patient safety and care, few consumers have any idea what medical procedures are likely to cost until after they are performed. These reports eliminate that guesswork for each procedure by including the list price charged by the hospital, the average negotiated amount that health plans pay and the remaining out-of-pocket fee for consumers with insurance. Since costs vary dramatically by region, each report is customized based on a consumer’s zip code, age, gender and insurance.

Apart from cost information, this Colorado company offers consumers, through its Web site (www.healthgrades.com), access to report cards for assessments and ratings on physicians, hospitals and nursing homes. It counts among its members more than 260 client hospitals that routinely compare the various ratings and profile information to help improve the quality of care. Underwriters have come to rely on HealthGrades’ reporting and methodology to assess risk and verify background information for medical liability insurance purposes.

Perhaps this attention to quality ratings is paying off.

Signs of Improvement

In its fourth annual Hospital Quality and Clinical Excellence Study (2006), released in February, HealthGrades noted that quality of care is improving. This study of nearly 39 million hospitalizations at non-federal hospitals from 2002–2004 found that mortality rates and relative risks are indeed dropping. Yet the institutions in the top 5% were the ones that demonstrated an across-the-board commitment to safety and quality initiatives. These Distinguished Hospitals for Clinical Excellence (DH-CE) have instituted excellence in all categories of care to yield mortality rates that are 27% lower than other U.S. hospitals. The study also found that patients faced a 14% lower risk of post-operative complications at DH-CE institutions. And thanks to the emphasis on quality performance, these top-ranked hospitals made improvements as much as 40% faster, further reducing risk and saving patients’ lives.

In addition to this annual ranking, HealthGrades’ Report Cards provide free comparative ratings on hospitals in a particular area as well as fee-based Quality Reports for a particular hospital, nursing home or physician. These comprehensive reports...
The Leapfrog Group, comprising more than 170 organizations and other large private and public health care buyers, issues a voluntary survey for participating hospitals to evaluate their progress toward reaching the recommended safety standards. At the end of 2005, almost half (966) of the targeted urban and suburban hospitals had completed the annual comprehensive online survey that covers everything from general facility information through specific care assessments, and had posted the results on Leapfrog’s Web site (www.leapfroggroup.org). In addition, more than 254 hospitals outside of the 28 regions had responded to the survey on their own initiative, without a formal request, notes Leapfrog’s Web site.

The Leapfrog Group developed three initial quality and safety leaps in 2000, triggered by an Institute of Medicine (IOM) report revealing that between 44,000 to 98,000 deaths due to preventable medical errors occur each year in hospitals. The first three leaps intended for urban hospitals to reach certain safety standards are: Computer Physician Order Entry (CPOE), Evidence-based Hospital Referral (EHR) and ICU Physician Staffing (IPS). In April 2004, the group expanded its focus by creating a fourth leap that applies to both urban and rural hospitals. This “leap” is actually a score that allows consumers and others to assess a hospital’s success at implementing the remaining safe practices from the National Quality Forum.

Consumers can use information to compare and find physicians from a database of more than 600,000 entries. However, HealthGrades is quick to point out that discrepancies may occur between its results and those of health care organizations. The company provides an extensive FAQ section addressing specific questions about this particular issue. And for further clarification, the Web site includes a number of white papers that explain the various methodologies used to perform ratings for each type of health care institution.

Incentive for Hospitals

HealthGrades represents a growing trend for consumers to be selective about their health care providers. So from a marketing standpoint, being accurately represented on the HealthGrades Web site puts health care facilities on the competitive scale and into the consumer mindset. Plus, taking a proactive stance and providing “grading” information shows an ongoing commitment to patient quality and safety initiatives. And finally, as “pay for performance” measurements become increasingly significant in fee structures, bonuses and even patient co-pay amounts, it makes solid fiscal sense for the health care community to make good Report Card grades a top priority.

Leapfrog Survey Notes Increase in Responses from Hospitals

The annual survey measuring the quality and safety of hospitals by the Leapfrog Group shows a rise in the number of responses, suggesting more hospitals are coming forward to inform the public about their progress on achieving patient safety goals.

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The Institute for Healthcare Improvement (IHI) along with other organizations kicked off the 100,000 Lives Campaign in January 2005 to save as many lives over the course of 18 months. The campaign’s goal is to challenge hospitals to actively make changes to improve the quality and safety of patient care. Since its start, more than 3,000 hospitals have signed on, made targeted improvements and saved 60,185 lives (as of February 27, 2006).

While many hospitals are looking at a number of quality initiatives and the need for change, the 100,000 Lives Campaign stresses the immediacy to act. It makes saving lives the goal, sets a deadline for completion (June 14, 2006) and targets six changes that are instrumental in preventing avoidable patient deaths. These changes include deploying rapid response teams at the first sign of patient decline and establishing procedures to deliver evidence-based care to prevent heart attack deaths in acute myocardial infarction patients. Hospitals are also urged to implement steps to prevent ventilator-related pneumonia and central line and surgical site infections. Other recommendations call for hospitals to conduct medication reconciliation to prevent adverse drug events (ADEs). Participation is free with the expectation that hospitals will apply at least some of the recommended changes and report back to IHI with the results. The hospitals that have signed on include the five that make up UJA-Federation group of hospitals (Beth Israel Medical Center, Long Island Jewish Medical Center, Mount Sinai Hospital, Montefiore Medical Center and Maimonides Medical Center). For more details about the campaign, along with a wide range of valuable resources for health care improvement, refer to the IHI Web site (www.ihi.org/IHI/Programs/Campaign).

In mid-March, Leapfrog launched its 2006 survey and the deadline for the first report of this survey is June 30. New data will be available on the Leapfrog Web site in July.

### URLs for organizations that offer quality reports on health care:

- **www.qualitycheck.org**
  The Quality Check Web site supported by the JCAHO along with several private companies offers free quality reports and comparative checks for its accredited institutions.

- **www.hospitalcompare.hhs.gov**
  The Web site of US Department of Health and Human Services (HHS) enables users to select and compare hospitals’ quality of care information for four conditions impacting adult patients: heart attack, heart failure, pneumonia and surgical infection prevention.

- **www.hospitals.nyhealth.gov/index.php**
  New York State’s Department of Health Web site offers information such as physician and hospital profiles. (Many states in the United States have similar sites.)

- **www.medicare.gov/NHcompare**
  Federal Nursing Home Compare Web site provides detailed information about the performance of every Medicare and Medicaid certified nursing home in the country.

- **www.nydoctorprofile.com**
  The New York State Physician Profile Web site allows users to find profiles for all licensed doctors who are registered to practice in the state. Information about the doctor’s education and any legal actions taken against the doctor can be obtained by searching on any doctor’s name.

### 100,000 Lives Campaign Nears Target Date

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JCAHO: Targeting Trouble Zones

Proposed Goals Include Patient Suicide Prevention, Disruptive Staff Behavior

Since 2002, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has been pinpointing specific requirements for improving safety for patients, residents and clients of health care organizations nationwide. To facilitate implementation, separate listings for National Patient Safety Goals (NPSG) are available that outline the particular goals that apply to each type of health care organization. To give health care groups a head start with compliance, the JCAHO released its proposed 2007 NPSG last year with an effective date of January 1, 2007.

Looking Ahead

The first of five proposed goals for 2007 addresses the need to discourage disruptive staff behavior (condescending language, refusal to answer questions, verbal abuse, etc.), which has been shown to quash morale and negatively impact patient safety. Other goals aim to reduce errors by requiring orientation for temporary or agency workers; improving staff recognition and response to changes in patients’ conditions; and implementing processes to prevent health care worker fatigue—a serious threat to patient safety. And finally, proposals call for hospitals to assess patients’ risks for suicide (one of the leading causes of death in the United States) and improve medication safety related to the use of anticoagulation therapy.

Looking Back

Reviewing the list for 2006, six goals were added and four retired (having been successfully implemented by health care organizations). Here is a brief look at the additional NPSG requirements in the areas of caregiver communications, medication labeling, active involvement in patient care and patient risk for pressure ulcers.

Goal 2E —Caregiver Communications

Patient information is continuously handed off when they are transferred between physicians, units or facilities, during staff shift changes, and with lab and other testing results. Yet, these handoffs have been identified as potential trouble zones for safe patient communications. In response, the JCAHO created Goal 2E, which requires health care facilities to implement a standard procedure to ensure the reliable hand off of accurate, up-to-date information about a patient’s care, treatment, services, condition and any actual or anticipated changes.

Goal 2D —Medication Labeling

The JCAHO added this goal to address the risky yet routine practice of transferring medications and other solutions from their original containers into unlabeled containers on the sterile field in perioperative settings. In an effort to eliminate the potential for errors in medication administration, Goal 2D requires health care organizations to accurately label all medications, solutions and containers such as syringes, basins and cups in perioperative and other procedural settings.

Goal 13 —Encouraging Active Participation in Patient Care

Experience shows that when patients and their families actively participate in care decisions, it can improve overall patient safety. This goal addresses the need for health care organizations (particularly home care and assisted living facilities) to create an environment that encourages patients and their families to get involved with care. Specifically, Goal 13A requires these institutions to define and communicate the means for patients to report concerns about safety and encourage them to do so.

Goal 14 —Preventing Health Care-associated Pressure Ulcers

Pressure ulcers (decubitus ulcers) are a tremendous problem in health care settings, particularly with long-term care. As many as three million adults are estimated to have pressure ulcers with treatment costs ranging from $500 to $40,000 per ulcer. Yet most pressure ulcers can be prevented through early prediction, identification and treatment. Goal 14A calls for health care organizations to establish procedures to assess and periodically reassess each patient’s risk for developing a pressure ulcer and then take action to address any identified risks. With this type of proactive plan, caregivers should be able to manage their patients’ care more successfully.

Retired Goals

JCAHO removes goals that have been substantially met by health care organizations. This year, it has been able to effectively retire the following goals:

- **Goal 3A**—Improve the safety of using medications by removing concentrated electrolytes from patient care units.
- **Goal 5A**—Reduce the risk of health care-associated infections by complying with current Centers for Disease Control and Prevention (CDC) hand hygiene guidelines.
- **Goal 5B**—Manage any cases where a health care-associated infection was associated with a patient’s unanticipated death or major permanent loss of function.
- **Goal 9A**—Reduce the risk of patient harm resulting from falls by periodically assessing each patient’s risk for falling, including their medication-related risks, and taking action to address those risks.

For a complete listing and indepth discussion of these 2006–07 goals, information on the accreditation process and other JCAHO initiatives, visit the JCAHO Web site at www.jcaho.org.
FOJP Upgrades Web Site!

FOJP Service Corporation has upgraded its Web site (www.fojp.com) to provide information on various services to health care and social service agencies. The site is designed to provide easy access to physicians, hospitals and long-term care facilities. By clicking the various categories on the home page, users can find out more about our insurance and risk management programs, how to participate in risk management courses, find answers to insurance questions, or learn more about our back issues of FOCUS and Health Care Risk-Link publications.

We hope that with the new Web design and easy-to-use navigation tools, we can help make your work easy and more efficient.

FOJP Promotes Two Key Executives

Effective April 1, Perry Perlmutter, FOJP Service Corporation’s Chief Financial Officer became a Senior Vice President, and Bob Stanyon, head of Risk Management, a Vice President.

Perry joined FOJP in 2004 as Vice President and CFO. He works with the professionals in the Finance Department—and with captive managers, auditors, rating agencies, and actuaries—to ensure the integrity of our finances. His responsibilities include budgeting, accounting, premium allocation, management reporting, and internal controls.

Perry came to FOJP after a distinguished 20-year career at Reliance National Insurance Company, where he held a series of financial executive positions. When he left that company to join FOJP, Perry was First Vice President of Finance, in charge of the finance, corporate accounting and treasury functions of the company.

Bob joined FOJP in 1986 as a Risk Control Coordinator. After a brief tour as a hospital risk manager, he returned to FOJP in 1988 as Associate Director of Risk Management Operations and then Director, Risk Management. In 2001, Bob was promoted to Assistant Vice President, Risk Management and Research.

Before coming to FOJP, Bob was a clinical laboratory supervisor, primarily in microbiology, and for eight years thereafter a registered nurse. His clinical experience included neurology and cardiac critical care at Columbia-Presbyterian Medical Center and then coordination of cardiology clinical trials at the College of Physicians and Surgeons at Columbia University. Bob is a board member and past president of the Association for Healthcare Risk Management of New York.

Call for Articles

in focus encourages physicians, risk managers and other health care practitioners to submit articles on issues of critical interest to our community. The summer issue of in focus will be published in August 2006. Contributions received by June 30, 2006 have the best chance of acceptance.

Double-spaced, 2,000–3,000-word articles may be submitted to focusedit@fojp.com. in focus will also consider 1,000–2,000-word essays on recent policy issues. Articles should conform to conventions in The Chicago Manual of Style, 15th Edition. Citations must follow the form of endnotes.

For more information contact: Managing Editor, FOJP Service Corporation, 28 E. 28th St., NY, NY 10016 E-mail: focusedit@fojp.com