AMERICAN HEALTH CONSULTANTS

Same-Day Surgery

Covering Hospitals, Surgery Centers, and Offices for More than 20 Years

INSIDE

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Your advertising for LASIK can nullify informed consent

Consumer alert warns patients about risks and complications

Do you advertise LASIK (laser in situ keratomileusis) as "laser vision correction" and tell potential patients that they can "throw away their glasses" and "20/20 vision is guaranteed"? If so, you aren't giving patients the complete picture, which could void your informed consent, LASIK experts warn.

The "minor nuisance" complication rate is 1% to 5%, depending on the surgeon's experience, says **Richard L. Lindstrom**, MD, clinical professor of ophthalmology at the University of Minnesota and managing partner in Minnesota Eye Consultants, both in Minneapolis. "The rate of significant sight threatening complication is 1 per 1,000," Lindstrom says. "If your advertising says it's safe and easy . . . it can nullify informed consent." Problems with informed consent can translate into patient satisfaction problems or even lawsuits, LASIK experts warn.

In addition, the Federal Trade Commission (FTC) in Washington, DC, is on the offensive to warn patients about the risks and complications associated with the procedure. The FTC has issued an *FTC Consumer Alert* about LASIK that warns patients: "It's not for everyone." **(See complete alert enclosed in this issue.)** The FTC also has a brochure on Basic Lasik: Tips on Lasik Eye Surgery available. **(See copy of tips**

EXECUTIVE SUMMARY

The Federal Trade Commission has issued a consumer alert on LASIK eye surgery in response to concerns about patients being uneducated about the risks and complications associated with the procedure.

- Don't promise positive outcomes in your advertisements. Refer to the procedure as surgery, not laser vision correction.
- Discuss risks and potential outcomes with patients, including the possible need for second surgery.
- Be prepared for patients to question you about your success rate and the percent of your patients who return for enhancements.

enclosed in this issue. For ordering information, see resource box, at right.)

"We felt consumers weren't receiving sufficient information in the advertising — print or broadcast — about potential risks and complications associated with the procedures," says **Colleen P. Tressler**, senior project manager in the Office of Consumer and Business Education at the FTC.

With hundreds of thousands of patients having this surgery and a complication rate estimated at about 3%, "it stands to reasons that a significant number of consumers will experience problems," Tressler says. The brochure is designed to give potential patients a full picture about LASIK so they can make an informed decision about whether to have the surgery, she says.

To avoid having patients with unrealistic expectations, consider these suggestions:

• **Avoid certain wording in advertisements.** "Many people have been misled by ads that say you can throw away your glasses and don't discuss risks," says **Jane Aguirre**, vice president for ophthalmic practice at the American Academy of Ophthalmology in San Francisco. "Anyone who goes into surgery expecting a 100% outcome, and things don't go that way, they'll be disappointed," she warns. The academy cooperated with the FTC in developing the brochure.

Even if information on risks is included in advertisements, "some ads simplify, trivialize, and minimize surgical complications," says **R. Doyle Stulting**, MD, PhD, professor of ophthalmology at Emory University in Atlanta and chair of the Refractive Surgery Special Interest Group of the Fairfax, VA-based American Society of Cataract and Refractive Surgery. Part of the problem can be attributed to the size of the ads, Stulting says. They are relatively small and don't provide enough information on potential complications, he says, and adds that those problem are common for all advertisements.

Matthew Daynard, staff attorney in the Division of Advertising Practices at the FTC, agrees that the size of the ads is a problem. "But one could at least identify this procedure as surgery," he says, instead of "laser vision correction."

What words should you avoid? Throw away your glasses, 20/20 vision guaranteed, painless, easy, safe, "or any other unsubstantiated claim," Lindstrom says. For example, surgeons shouldn't say they're the most experienced in the world or that they developed the procedure, unless those statements are true, he says. **(See "Guidelines for Refractive Surgery Advertising" in this issue.)**

• **Determine whether the candidate is a good choice for LASIK.** Not everyone is a good candidate for LASIK, Aguirre emphasizes. "The surgeon's findings on the pre-op investigation are important."

According to the brochure, patients should meet the following qualifications:

— They should be at least 18 years old, and 21 for some lasers, "since the vision of people younger than 18 usually continues to change," it states.

— They should not be pregnant or breast-feeding "as these conditions might change the measured refraction of the eye."

— They should not be taking certain prescription drugs such as Accutane (Roche Laboratories,

SOURCES AND RESOURCES

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Additional copies of *Basic Lasik: Tips on Lasik Eye Surgery* are available from the Federal Trade Commission. Telephone: (877) 382-4357. Copies also are available on the Web site: www.ftc.gov.

COMING IN FUTURE MONTHS

- New infection control guidelines on instrumentation
- Protocol for prevention of Creutzfeldt-Jakob disease
- Update on extended recovery care
- Web sites that can save you time
- Efficiency tips for outpatient surgery

Nutley, NJ) or oral prednisone.

— Their eyes must be healthy and their prescription stable. "If you're myopic, you should postpone LASIK until your refraction has stabilized, as myopia may continue to increase in some patients until their mid- to late 20s," the brochure says.

— They must be in good general health. "LASIK may not be recommended for patients with diabetes, rheumatoid arthritis, lupus, glaucoma, herpes, infections of the eye, or cataracts," the brochure adds.

The brochure also advises potential patients that if they are happy wearing contacts or glasses, they might not want to undergo the procedure.

The brochure tells patients that they should ask their physicians whether they are candidates for monovision (correcting one eye for distance vision and the other eye for near vision.) "LASIK cannot correct presbyopia so that one eye can see at both distance and near," the brochure says. "However, LASIK can be used to correct one eye for distance and the other for near." If they can adjust to this correction, it might eliminate their need for wearing glasses, the brochure states.

• **Be prepared to answer questions from potential patients.** The brochure advises candidates to ask their surgeons these questions:

— How long have you been doing LASIK surgery?

— How much experience do you have with the LASIK procedure?

— How do you define success? What's your success rate? What is the chance for me (with my correction) to achieve 20/20? How many of your patients achieved 20/20 or 20/40 vision? How many patients returned for enhancements (additional surgery)? The brochure advises potential patients that, in general, 5% to 15% of patients return for enhancements.

— What laser will you be using for my surgery?

The brochure says candidates should make sure the surgeon is using a laser approved by the Food and Drug Administration (FDA). Currently, the FDA has approved lasers manufactured by VISX in Santa Clara, CA; Summit Technology in Waltham, MA; Bausch & Lomb in Dallas; Nidek in Fremont, CA; and ATC in St. Petersburg, Russia.

— What's involved in after-surgery care?

— Who will handle after-surgery care?

— What about risks and possible complications?

The brochure lists risks and potential complications, and information on what to expect before, during, and after surgery. Candidates also are given information on alternatives to LASIK, including photorefractive keratectomy, astigmatic keratotomy, and intrastromal corneal rings.

• **Ensure informed consent is complete.** Make sure you understand the potential patient's expectation, Aguirre advises. "If you're doing someone's eyes who's very dependent on them for vocation or work function, he needs to understand that he might have worse vision afterward than when he started," she says.

Tell patients about the most common complications: a halo effect at night, fluctuating vision and dry eye the first few months, and possible need for a second treatment, Lindstrom advises. Also tell them about the most serious potential complications: Flap complications and an inflammation or infection that, if not properly managed, can lead to loss of the best-corrected vision.

The bottom line is a simple one, Stulting says: "When [patients] agree to have any surgical procedure, they need to know the risks, benefits, and alternatives. They need to understand their chances of having an adverse reaction." ■

Involve employees in needlestick safety

OSHA standard to change by May 2001

By May 2001, inspectors from the Occupational Safety and Health Administration (OSHA) will start asking your employees if they are involved in selecting needlestick safety devices and will start asking to see your needlestick injury log.

The OSHA bloodborne pathogen standard

EXECUTIVE SUMMARY

The newly passed Needlestick Safety Prevention Act amends the bloodborne pathogen standard from the Occupational Safety and Health Administration to require the following by May 2001 for hospitals, surgery centers, and physician offices:

- You must involve employees in the selection of safety devices and work practice controls. Staff can be involved in trial runs with devices and offer feedback on how user-friendly they are.
- Employers with more than 10 employees must keep a sharps injury log with the type and brand of device; work area where the incident occurred; and an explanation of how the incident occurred. The log must maintain employee confidentiality.

SOURCE

For more information on requirements from the Occupational Safety and Health Administration (OSHA), go to the OSHA Web site (www.osha.gov) and click on "OSHA Offices" and then "Quick Link to Regional and Area Office Map" to find a regional contact.

was recently bolstered by the Nov. 6 passage of the Needlestick Safety Prevention Act, which added the new requirements and gives OSHA six months to amend its bloodborne pathogens standard. Providers should note: Between October 1998 and September 1999, OSHA issued 1,557 citations regarding the standard at 612 inspections. The fines totalled $1,191,849.

Added to the changes at the national level are several pieces of needlestick safety legislation that have passed at the state level. **(See list of state legislation, enclosed in this issue.)** The federal requirements are minimal for everyone, including hospitals, surgery centers, and physician offices. If your state law is stricter than the national legislation, you must meet the stricter state requirements.

Each year, one in seven medical professionals experiences a needlestick while caring for sick or injured patients, according to OSHA. To address this problem, OSHA compliance officers will add these two requirements:

• **Involve employees in selection of needlestick safety devices.** The new federal law requires that employers solicit input from nonmanagerial employees responsible for direct patient care, who are potentially exposed to sharps inquiries. Those employees should help identify, evaluate, and select effective devices and work-practice controls.

Involve employees in evaluating what devices are available on the market, advises **Melody Sands**, director of the Office of Health Compliance Assistance at OSHA in Washington, DC.

The products can be evaluated with a trial run, suggests **Robyn Silverman**, project officer at Plymouth Meeting-PA based ECRI, a nonprofit organization that provides information and technical assistance to the health care community.

Employees should evaluate whether the devices are user-friendly, Sands says. "They may like one device over another because it's easier to use or lends itself to a specific procedure," Sands says. **(See Product Evaluation Product Survey enclosed in this issue.)**

Technology has expanded tremendously in recent years, Sands and Silverman emphasize.

Silverman says, "They will be looking to make sure you're using devices that are safe and not ones that are older, when there are better devices out there."

• **Maintain a sharps injury log.** Employers must maintain a sharps injury log that contains, at a minimum, the following information:

— type and brand of device involved in the incident;

— department or work area where the exposure incident occurred;

— an explanation of how the incident occurred. **(See sample log enclosed in this issue.)**

Researchers will use these logs to evaluate the effectiveness of needlestick safety devices. The requirement doesn't apply to employers with fewer than 10 employees, Sands says. The log must maintain employee confidentiality, she adds.

OSHA compliance officers will ask to see the logs, she says. "Another thing OSHA can do is that the compliance officers can ask people, 'Do you have any incidents recorded?'" Sands says. "That's one way to check on the log." **(For more information, see stories on needlestick safety in *Same-Day Surgery*, October 1999, pp. 113 and 117.)**

[Editor's note: At press time, the final bill (Public Law 106-430) was not available on the Web. However, the U.S. House resolution is available by searching for HR5178 at the Web site: www.thomas.loc/gov.] ■

Various germicides meet different needs

Turnover needs, cost, ventilation determine choice

While the debate over sterilization vs. high-level disinfection of surgical instruments, specifically flexible scopes such as those used in endoscopy, same-day surgery managers still face the day-to-day question of which product to choose for their program's high-level disinfection. **(For more information, see "Controversy erupts over whether to disinfect or sterilize endoscopes," *Same-Day Surgery*, February 2000, p. 13.)**

"Obviously, steam sterilization is the ideal method for surgical instruments, but this is not an appropriate method for flexible scopes, and

EXECUTIVE SUMMARY

Because steam sterilization is not available to some same-day surgery programs or appropriate for all instruments, high-level disinfection is an important part of a surgery program's infection control efforts. While there are several disinfection agents available, not all of them meet every same-day surgery program's needs.

- Look at your need for equipment turnover time, cost, equipment compatibility, and ventilation capabilities as you evaluate products.
- Make sure you understand the manufacturer's recommendation for disinfection of your equipment to ensure a valid warranty.
- Remember to clean the equipment manually before disinfection.

not all freestanding same-day surgery programs have access to a sterilizer," says **Lawrence F. Muscarella**, PhD, director of research and development for Customer Ultrasonics, an Ivyland, PA-based company that manufacturers automatic washers and disinfectors.

"When looking at high-level disinfection, no one germicide is better than another," says Muscarella. "But different germicides are better for some programs because they meet needs that are specific to that surgery program."

Muscarella describes three scenarios that show how same-day surgery managers might determine which product meets their needs.

• Manager wants low-cost product with a proven track record.

If low cost, instrument compatibility, and a proven track record are the most important features for a same-day surgery manager, 2% glutaraldehyde is the most logical choice, says Muscarella. This product does require a well-ventilated area and does take a minimum of 20 minutes for high-level disinfection, he adds. A well-ventilated room is defined as one in which the air in the room is exchanged 10 times every hour, he explains.

The benefit is its compatibility with instruments, he explains; in other words, used properly, it does not cause rubber components to bend or lenses to fog, he says.

The same-day surgery staff at Strong Memorial Hospital in Rochester, NY, uses 2% glutaraldehyde and soaks flexible scopes for 22 minutes, says **Deborah G. Spratt**, RN, MPA, CNAA, CNOR, nurse manager of the operating room. "We've had no problems with this method, and we check with the manufacturers to make sure we follow their recommendations," she adds.

• Busy SDS program needs soaking times of less than 15 minutes.

High-volume programs that need to disinfect equipment more quickly might opt for a product such as Cidex OPA (Advanced Sterilization Products, Irvine, CA), says Muscarella. **(See list of vendors, p. 6.)** Soaking time for this product is generally 12 minutes, he adds.

Another option for programs that already own an automated reprocessor and want to cut soaking

SOURCES AND RESOURCES

For more information about high-level disinfection, contact:

- **Lawrence F. Muscarella**, PhD, Director of Research and Development, Custom Ultrasonics, 144 Railroad Drive, Ivyland, PA 18974. Telephone: (215) 364-8577. E-mail: q-net@email.msn.com.
- **Deborah G. Spratt**, RN, MPA, CNAA, CNOR, Nurse Manager, Operating Room, Strong Memorial Hospital, University of Rochester Medical Center, 601 Elmwood St., Box 624, Rochester, NY 14642. Telephone: (716) 275-9618. E-mail: deborah_spratt@urmc.rochester.edu.

For guidelines on cleaning endoscopes, contact:

- **American Society of Testing and Materials**, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959. Telephone: (610) 832-9585. Fax: (610) 832-9555. Web site: www.astm.org. *Standard Practice for Cleaning and Disinfection of Flexible Fiberoptic and Video Endoscopes* is available for download on the Web site, by fax, or by mail. The cost is $30, and credit cards only are accepted.
- **American Society for Gastrointestinal Endoscopy**, 13 Elm St., Manchester, MA 01944-1313. Telephone: (978) 526-8330. Fax: (978) 526-4018. Web site: www.asge.org. Infection control practice for endoscopes is available at no charge on the Web site.
- **Society of Gastroenterology Nurses and Associates**, 401 N. Michigan Ave., Chicago, IL 60611-4267. Telephone: (800) 245-SGNA or in Illinois (312) 321-5165. E-mail: sgna@sba.com. Web site: www.sgna.org. *Guidelines for the Use of High Level Disinfectants and Sterilants for Reprocessing of Flexible Gastrointestinal Endoscopes* is available for $5 for members of the society and $10 for nonmembers. Shipping and handling is $4.95.

time even more could be Rapicide, Muscarella says. The product was approved by the Federal Drug Administration in August 2000 for distribution. "We plan to market Rapicide early in 2001," says **R.C. Kippenhan**, director of discovery and development for MediVators in Eagan, MN. The product requires a five-minute soak time at 35 degrees Celsius, he adds.

• **Facility with poor ventilation has concerns about glutaraldehyde fumes.**

Although all germicides release vapors, some same-day surgery staff members with poorly ventilated areas are especially concerned about glutaraldehyde fumes, says Muscarella. If poor ventilation is a concern, there are a number of non-aldehyde germicides, he says.

"Sporox [Sultan Chemists, Englewood, NJ] and the Steris System 1 [Steris, Mentor, OH] are non-oxidizing methods of disinfection," Muscarella says. He does warn that there might be equipment compatibility issues with these products. "I recommend that you check with the manufacturer of both the equipment and the germicide to verify that this process will not damage the instrument." Written confirmation is important to keep any equipment warranties from being voided if there are problems, Muscarella adds.

No matter which method you choose to disinfect, manual cleaning of the instrument before disinfection is still an absolute must, says Spratt. There are a number of organizations that offer guidelines on cleaning endoscopes. **(See resources, p. 5.)**

VENDORS

For more information about specific products used for high-level disinfection, contact:

- **Cidex OPA**, Advanced Sterilization Products, 33 Technology Drive, Irvine, CA 92618. Telephone: (877) 672-6699. Fax: (949) 453-6353. Web site: www.cidex.com.
- **Sporox**, Sultan Chemists, 85 W. Forest Ave., Englewood, NJ 07631. Telephone: (800) 637-8582 or (201) 871-1232. Fax: (201) 871-0321. Web site: www.sultanintl.com.
- **Rapicide**, MediVators, 2995 Lone Oak Circle, No. 10, Eagan, MN 55121. Telephone: (800) 537-7324 or (651) 405-1661. Fax: (651) 405-1881. Web site: www.medivators.com.
- **Steris System 1**, Steris Corp., 9260 Progress Parkway, Mentor, OH 44060-1834. Telephone: (800) 548-4873 or (440) 354-2600. Fax: (440) 639-4450. Web site: www.steris.com.

"You get into trouble when you don't clean the instrument according to the manufacturer's recommendations prior to disinfection," Spratt says. "An enzymatic cleaner and friction with a brush is essential to reduce the bio-burden." ■

Same-Day Surgery Manager

Staffing challenges: a manager's headache

By **Stephen W. Earnhart**, MS
President and CEO
Earnhart & Associates
Dallas

As a company that manages hospital operating departments and ambulatory surgery centers (ASCs), we are seeing some interesting trends developing. We began noticing difficulties in finding experienced operating room staff about 24 months ago. The challenge was mostly in selected geographic pockets, i.e. rural areas where the staffing pool is shallow or highly urbanized union areas where it is difficult to draw staff away from lucrative benefit plans. However, now at the end of 2000, we are seeing a more widely dispersed challenge. What we are finding is very interesting and worthy of comment.

The first and probably most dramatic change is at the highest level of leadership in the facilities, i.e. the center administrator or department head. At this writing, my firm, Earnhart & Associates, is advertising for five new surgery center administrators and nurse managers. Normally, we would use word of mouth to find qualified individuals and fill these positions within a few weeks. Lately, we are advertising for a minimum of two months in addition to our normal efforts! Other firms that own and manage surgery centers report they are experiencing similar recruitment problems. If you find yourself in this situation, our experience is going back to the "old method" of advertising in the newspaper. We have not had much success in advertising via the Internet.

While that is a new wrinkle, what is even more

interesting is who is applying for these top spots. In the past (going back almost two decades), the vast majority of applicants for key management roles in the operating room environment has been female registered nurses. They typically had a minimum of 10 years direct operating room experience, of which half was in a management role and a strong mix of not-for-profit and for-profit exposure. Training and transition were relatively easy and smooth for a firm such as mine. That has changed considerably in the past two years.

The applicant for these top spots is showing a different profile than ever before. First, the majority of the applicants overwhelmingly are male — 80% at least. Further, they do not have direct operating room management experience. Unlike the past where the applicant would usually come out of the hospital or ASC marketplace, these individuals are coming out of the physician management companies or — this is surprising — the health care insurance environment. A number of individuals applying for these positions are past (or current) hospital administrators. Prepare yourself for a lot of hand-holding, training, and educating should you elect to go this route. With the right person it can work, especially on contracting, business negotiations, and cash management. But the individual has to be a rapid study and understand that the clinical input is the first priority.

The challenge for staffing is not just touching the management positions. More of the individuals applying for staffing positions in the ASC industry are coming out of the hospitals. It makes sense. According to SMG Marketing Group in Chicago, roughly 200 new ASCs are opening each year. The operating room environment requires highly skilled personnel with years of experience. But there are only so many people to go around. Hospitals have long been the proving ground for training O.R. personnel. (The "brain drain" of operating room personnel leaving to go to the for-profit companies is a constant frustration to hospitals.)

While these personnel are usually very well-trained in their areas, the transition from the not-for-profit, highly structured hospital environment to the more rapid pace of a highly time-efficient, cross-trained ASC has been a management challenge for all. These personnel (like many of us!) are older. Lifestyle and, most importantly, retirement plans are becoming a key factor in their decision to shift alliances. Also, they are very attuned to the conditions in which they wish to work. For example, most are more willing to work in a hospital / physician-joint ventured ASC than a physician-only center. Some will even chose where they work based upon the makeup of the physician partnership. The typical applicant is a savvy, cognizant individual who knows what he or she wants. The ability to cross-train these individuals is high, and they are usually agreeable to variable hours. Spend extra time explaining the internal resources available to them. It can be disarming for them to know that they might have to do it themselves and not have the ability to pick up the phone and call for someone else to do it.

The front-office staff also are facing challenges. This area is very susceptible to inexperienced personnel who have little billing and collection experience. The advent of ambulatory payment classifications and the sophistication required to handle the new systems, to say nothing of juggling cash management and dealing with the public, has put this front line of the surgical business in the spotlight. Pick your candidate well, and test them to see how they handle tricky situations such as accounts receivable.

How you deal with these challenges will directly effect your programs success as we go into the next century.

Send in your vote

I want to make this column more interactive. So, here is my challenge to you. I will share with you some innovative ways of dealing with these challenges, both from our experience and yours, but only if you vote to request it via e-mail. If the majority of my e-mail responders ask me to expand upon this topic, I will do it next month.

At the same time, if you want to add your suggestions or experiences to the column, please include that in your e-mail as well (although not necessary to vote). If you would like a different topic researched and written about, include that information as well. Please be sure to include your name as it appears on your *Same-Day Surgery* mailing label so that the newsletter can e-mail any future news bulletins to you. Send your vote to me directly at: searnhart@earnhart.com. ***(Sorry. No recounts will be allowed!)***

(Editor's note: Earnhart and Associates is an ambulatory surgery consulting firm specializing in all aspects of surgery center development and management. Earnhart can be reached at 5905 Tree Shadow Place, Suite 1200, Dallas, TX 75252. E-mail: searnhart@earnhart.com. Web: www.earnhart.com.) ■

The verdict is out on laparoscopic hernia repair

Lack of cost benefit means fewer select method

Laparoscopic procedures are usually hailed as a way to reduce length of stay, cut costs for patients and managed care companies, and return the patient to work sooner than open surgical procedures. While laparoscopic inguinal hernia repair does result in less pain and a quicker return to work,[1,2] experts have been less enthusiastic about its value to completely replace open repairs.

"About 15% to 20% of inguinal hernias are repaired laparoscopically," says **Lee L. Swanstrom**, MD, medical director of the department of minimally invasive surgery at Legacy Health Systems in Portland, OR. "Laparoscopic repairs are generally performed by surgeons who have a special interest and experience in laparoscopy," he adds.

There are several reasons many surgeons have not switched to laparoscopic repair of inguinal hernias, says Swanstrom. "Inguinal hernia repair is a minor surgery anyway and is usually performed on an outpatient basis, so the laparoscopic procedure doesn't make an inpatient procedure into an outpatient procedure," he explains.

For many surgery programs, the open procedure has lower costs associated with it because it has been performed for many years and has been evaluated in terms of cost containment for the past decade, he adds.

"We are just now beginning to negotiate package pricing for the laparoscopic procedure and address cost issues that will make the financial picture for both procedures more equal," says Swanstrom.

Recovery time following the laparoscopic procedure can be longer than recovery time for the open procedure because of the anesthesia requirements for each, says **Robert J. Fitzgibbons**, MD, professor in the department of surgery at Creighton University in Omaha, NE, and immediate past president of the American Hernia Society in Orlando, FL. The open procedure requires only local anesthesia, but the laparoscopic procedure requires general anesthesia since the abdominal cavity is distended with gas during surgery, he explains.

Same-day surgery managers and medical directors also have to be aware that laparoscopic hernia repair is a more difficult procedure to teach and to learn, says Swanstrom. The surgeon is working in the preperitoneal space for inguinal hernias rather than intra-abdominal space as in other procedures such as cholecystectomy, so there is less room to maneuver, he explains. For this reason, Swanstrom suggests that laparoscopic hernia repair have different credentialing criteria than other laparoscopic procedures. While each same-day surgery program needs to establish their criteria based upon the needs of its own patients and experience of its surgeons, the credentialing criteria should look for good training programs, a strong background in other laparoscopic procedures, and enough procedures to allow for the longer learning curve, he suggests. There is no magic number of procedures that Swanstrom can recommend for credentialing purposes because he says, "The number needs to be determined by the individual program and the experience of its surgeons."

The benefits of laparoscopic herniorrhaphy are less pain during recovery and an earlier return to normal activity for the patient,[1,2] says **George S. Ferzli**, MD, professor of surgery at the State University of New York's Health and Science Center in Brooklyn. Patients undergoing conventional hernia repair take four to six weeks to return to normal activity, while most patients undergoing the laparoscopic repair return to full activity in two weeks, says Ferzli. While same-day surgery managers cannot take reduced pain and increased productivity of the patient into account when justifying the costs of laparoscopic surgery, Ferzli points out, "As surgeons become more skilled, operating time decreases and costs decrease."

Another way to decrease costs of the procedure

EXECUTIVE SUMMARY

While laparoscopy has increased the number of procedures that can move from the inpatient to the outpatient surgical program, inguinal hernia repair is still predominately an open procedure. Proponents of the laparoscopic method say its use will increase for the following reasons:

- There is less postoperative pain and an earlier return to normal activity for patients.
- As surgeons gain experience with the laparoscopic method, costs associated with lengthier operating room times will decrease.
- The laparoscopic procedure provides a stronger repair than the open procedure.

SOURCES

For more information about laparoscopic hernia repair, contact:

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is to use no or fewer staples, says Swanstrom. Eliminating the use of staples is preferred by most surgeons because staples not only add cost but can cause bleeding, infection, or trapped nerves that result in postoperative pain, he says.

Although the laparoscopic procedure is a higher medical risk and open repair might be appropriate for most patients or surgeons, there are times that the laparoscopic is the far better choice, says Fitzgibbons. "With a bilateral hernia, we can repair both at the same time with no additional incisions," he explains. This is far less painful and much easier for the patient than the open procedures, he adds.

Patients with recurrent hernias are also good candidates for the laparoscopic repair because the procedure results in a stronger repair, says Fitzgibbons. "In the laparoscopic repair, we are placing the patch on the inside of the abdominal wall rather than the outside of the wall as we do in the open procedure."

When explaining the procedure to patients, Fitzgibbons always asks, "If you are repairing a tire, do you want the patch on the inside of the tire or the outside?"

References

1. Liem MSL, van der Graff Y, van Steensel CJ, et al. Comparison of conventional anterior surgery and laparoscopic surgery for inguinal hernia repair. *N Engl J. Med* 1997; 336: 1,541-1,547.

2. Juul P, Christensen K. Randomized clinical trial of laparoscopic versus open inguinal hernia repair. *Br J Surg* 1999; 86:316-319. ■

How to gain control of contract negotiations

Managed care contract negotiations often trigger trepidation and fear.

To eliminate these negative emotions, do your homework beforehand and realize that you do have control over the process.

The most important thing to remember is that negotiation means two parties are talking, says **Vicki Axsom-Brown**, administrator of Anderson Eye & Ear Associates / Medicus in Anderson, SC. Some same-day surgery managers dread negotiating a contract because they don't believe they have a lot of control and that they will have to accept whatever the managed care company is offering.

This simply isn't true, Axsom-Brown declares. "You can walk away from a contract if it is not good for your business, and you can offer to carve out certain procedures that are causing problems."

Many same-day surgery managers accept contracts just because someone says they need it, says **Douglas Peter**, vice president of managed care for Nashville, TN-based SymbionARC, which owns or manages 20 same-day surgery centers. "There is nothing wrong with saying no to a contract from a pure business decision perspective," he says.

How do you know when to say no or when to say yes? "Information and organization is the key," says Peter. Not only do you need to know your own business, but you also need to understand the market, the payers in your market, and which physicians are on the different panels, he explains.

Evaluate payers

To understand payers, look not only at their historical and current positions in your market, but also at the type of products they offer and the corresponding number of lives each covers, Peter says. "Do they offer HMO and PPO products, and how do benefits differ for in-network and out-of-network coverage?" he asks.

The difference between in- and out-of-network benefits is important because it shows how effective the payer can be in steering patients to you and other network providers, he says. Some payers offer small differences between the two types

EXECUTIVE SUMMARY

Same-day surgery managers can have control when negotiating a new managed care contract or a contract renewal if managers have gathered the necessary information and prepared a road map to follow during negotiations.

- Know as much as you can about the payer, the payer's products, and the payer's market position before you begin negotiations.
- Know everything about your mix of surgical cases, volume, and costs for your program.
- Develop a list that identifies the fees and terms that are most important to you. Prioritize your list so you can stay focused on the items for which you can compromise and the items for which you cannot.
- Prepare to use carve-outs if there is a procedure for which there is no compromise.

of benefits, so members don't have incentives to see in-network providers. "Why should I offer a discount to a payer when there is no advantage to me?" he asks.

Also, know which physicians are on different payer panels, Peter adds. This not only gives you a chance to make sure physicians on your staff can continue to perform surgery at your location, but you might see other physicians you'd like to attract to your program, he says.

Gathering information about payers in your market requires a good relationship with the payers and creative thinking, says Axsom-Brown. If you can't obtain information from the payers, physicians and family members of your surgery program staff can provide copies of benefits books and explanations of benefits (EOB) statements that describe benefits and physician panels.

Know who the decision makers are, says Axsom-Brown. "Be sure that when you start negotiations, you know if the person with whom you are talking is the decision maker or a messenger. The ideal situation is to talk directly to the decision maker, but that's not always possible." If you are dealing with someone who has to get approval from others, be aware that the process will take longer, she says.

Strive for a positive, ongoing relationship, she advises. Talk with them throughout the year, not just at negotiation times. And let them know when things are going well with the contract, not just when there are problems, Axsom-Brown adds.

Don't enter negotiations until you have analyzed your own business, advises Peter. Know the mix of surgical cases you handle and costs and net revenue per case, he says.

It is critical to know your volume for specific procedures as well as costs, says Axsom-Brown. You can't look just at the dollar reimbursement for individual procedures, she says. "Look to see if the higher reimbursements are only for procedures you rarely perform and the lower reimbursements for high-volume procedures," she suggests. If the procedure for which high reimbursement is offered only is performed a few times a year, the extra revenue might not be enough to offset or justify the lower reimbursement for the procedure you perform the most, she adds. **(For more negotiation tips, see related story, p. 11.)**

Because a same-day surgery manager and a payer use different language, make sure you understand what is said during negotiations and written into the contract, says Axsom-Brown.

"If a statement is made that you don't understand, rephrase it to make sure you are clear," she suggests. "Question anything in the contract you don't understand, and ask for definitions of terms before you sign."

Don't look only at rates when reviewing a contract, suggests Peter. Look at how you will get paid, what affects payment schedules, what time frame is considered prompt payment, and how assignments and amendments are addressed, he suggests. Also, be sure you understand the contract's term, termination, and renewal time frames, he adds.

"This is a legal, binding document, so if someone is not comfortable reviewing the contract, he or she should have an attorney review it," Peter adds. ■

SOURCES

For more information about negotiating with managed care companies, contact:

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- **Douglas Peter**, Vice President of Managed Care, SymbionARC, 3401 West End Ave., Suite 120, Nashville, TN 37203. Telephone: (615) 234-7900. Fax: (615) 234-7999. E-mail: dpeter@symbionarc.com.

Tips for negotiating a better contract

To ensure successful contract negotiations with managed care payers, be ready to sell yourself as a valuable asset to the payer, says **Vicki Axsom-Brown**, administrator, Anderson Eye & Ear Associates / Medicus in Anderson, SC.

"Make sure the payers know how you can help them provide better service to their own clients," she says.

Use the research you've gathered prior to negotiating to show this value, she suggests. If a payer is adding employers whose employees had typically been using you or your physicians as a provider, show this as an example of how you can help the payer by offering the new employees an easy transition into new coverage, she explains.

Use outcomes and trend data to support the fees you want, Axsom-Brown recommends. Also, find out what the payer has been reimbursing other providers for procedures.

"Explanation of benefits [EOB] statements that show the levels payers are reimbursing our competitors are very helpful," she says. She typically gets copies of these EOBs from family members of her own staff members, she explains.

This specific information demonstrates to the payer that the same-day surgery manager is knowledgeable. "This keeps the payer from saying 'No one else has asked for this fee before,'" says Axsom-Brown.

With fee schedules, the payer typically looks at the top 25 procedures and offers lower reimbursement for the top 10 most utilized services, then slightly higher reimbursement for the next 15, says Axsom-Brown.

Start with a game plan

When evaluating the fees, be sure you take into account the volume, she recommends. The higher reimbursement for the 15 procedures might not offset the reduced reimbursement for your most frequently performed procedures if you only perform them a few times each year, she explains.

Make sure you don't accept a loss or extremely low reimbursement if your high-volume procedures are the mainstay of your business, Axsom-Brown says.

Develop a game plan before you enter negotiations, she says. "Be realistic in your expectations." Axsom-Brown always develops a list of "must haves" for herself. Her list has is divided into three categories:

- "I can't live without."
- "Highly desirable, so I won't give up early."
- "Ice cream.

Have a category with items to give up

The "ice cream" category includes rates that she can live without, and these are generally among the first things she'll concede, she says.

"I complain about conceding any fees, but I know which ones are the most important to me," she says. By having some fees on which you are willing to compromise at the beginning, you set

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Editorial Questions

Questions or comments?
Call **Joy Daughtery Dickinson** at (229) 377-8044.

an agreeable tone for negotiations, Axsom-Brown explains. "You want to avoid an adversarial relationship and keep negotiations moving forward," she adds.

As negotiations continue, Axsom-Brown may compromise on other fees that she has described as highly desirable if she thinks it is necessary. Her prioritized list of "I can't live without" that she develops for herself prior to the negotiations keeps her focused on what is most important to her program.

A road map is important, says **Douglas Peter**, vice president of managed care for Nashville, TN-based SymbionARC, which owns or manages 20 same-day surgery programs. A same-day surgery manager should develop a proposal template that takes into account the surgery program's specific case mix and costs associated with procedures. The template can spell out priorities for the same-day surgery program and help the negotiator stay on track, he says.

When you reach an impasse on a certain procedure fee, you always have the option to carve it out of the contract, says Axsom-Brown. When you are not able to reach an acceptable compromise for a procedure's reimbursement, remove it from the contract and move forward with the negotiations, she explains. ■

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Advice on how to manage a successful SDS program

In the current regulatory and reimbursement environment, managing an outpatient surgery program can be overwhelming. For help on costing surgical procedures, containing costs, and surviving reimbursement changes, among other topics, attend the Seventh Annual Same-Day Surgery Conference March 4-6 in Orlando, FL. The conference is sponsored by American Health Consultants, publisher of *Same-Day Surgery*.

Topics will include advice on reprocessing, antibiotic resistance, hazards in the workplace, achievement of excellence, surgical trends and new technologies, accreditation, risk management, medical errors, the nursing shortage, the outpatient prospective payment system, and motivation of employees. The conference includes opportunities to network with your peers at lunches and a reception, as well as a Downtown Disney excursion.

For more information or to register, contact American Health Consultants, Customer Service, P.O. Box 740060, Atlanta, GA 30374. Telephone: (800) 688-2421. Fax: (800) 284-3291. E-mail: customerservice@ahcpub.com. ■

CE objectives

After reading this issue, the continuing education participant will be able to:

• Identify clinical, managerial, regulatory, or social issues relating to ambulatory surgery care and management. (See "How to gain control of contract negotiations.")

• Describe how those issues affect nursing service delivery or management of a facility.

• Cite practical solutions to problems or integrate information into their daily practices, according to advice from nationally recognized ambulatory surgery experts (See "Various germicides meet different needs.") ■

FTC Consumer Alert!

Getting the Clear Picture on Lasik Eye Surgery

August 2000

Tired of wearing glasses or contact lenses? Considering Lasik eye surgery? Lasik, one of the newest procedures for vision correction, is surgery to a very delicate part of the eye. And while hundreds of thousands of people have had Lasik, most very successfully, it's not for everyone.

The Federal Trade Commission and the American Academy of Ophthalmology advise you to get the clear picture on what you can expect before you sign up for the procedure.

Are you a good candidate for Lasik? Before you can weigh the risks and rewards, know that:

- You should be at least 18 years old and in good health.
- You should not be pregnant or nursing.
- You should not be taking certain prescription drugs, such as Accutane or oral prednisone.
- Your eyes must be healthy and your prescription stable.

Even if you have the surgery, you may not get the perfect vision you're hoping for. That's because 20/20 does not always mean perfect vision. And if you have Lasik to correct your distance vision, you'll still need reading glasses when you're around age 45. You also may need to return for additional surgery, called "enhancements," to fine-tune your vision. Remember that Lasik is too new to know if there are any long-term ill effects beyond five years after surgery and the procedure cannot be reversed.

If you decide to proceed, ask your surgeon the following questions:

- How long have you been doing Lasik surgery?
- How do you define success? What's your success rate? What is the chance for me to achieve 20/20?
- What laser will you be using for my surgery? Make sure your surgeon is using a laser approved by the U.S. Food and Drug Administration (FDA).
- What's involved in after-surgery care?
- Who will handle after-surgery care? Who will be responsible?
- What about risks and possible complications?
- What about side-effects? How long will they last?

For more information about Lasik, call the FTC toll-free, 1-877-FTC-HELP, and ask for the publication, Basik Lasik: Tips on Lasik Eye Surgery.

Where To Complain

The FTC works for the consumer to prevent fraudulent, deceptive and unfair business practices in the marketplace and to provide information to help consumers spot, stop and avoid them. To file a complaint, or to get free information on any of 150 consumer topics, call toll-free, **1-877-FTC-HELP** (1-877-382-4357), or use the online complaint form. The FTC enters Internet, telemarketing, and other fraud-related complaints into **Consumer Sentinel**, a secure, online database available to hundreds of civil and criminal law enforcement agencies worldwide.

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Basik Lasik: Tips on Lasik Eye Surgery

August 2000

Produced in cooperation with the American Academy of Ophthalmology.

If you're tired of wearing glasses or contact lenses, you may be considering Lasik eye surgery — one of the newest procedures to correct vision problems. Before you sign up for the surgery, get a clear picture of what you can expect.

The Facts

- Lasik is surgery to a very delicate part of the eye.
- Hundreds of thousands of people have had Lasik, most very successfully.
- As with any surgery, there are risks and possible complications.
- Lasik may not give you perfect vision. The American Academy of Ophthalmology (AAO) reports that seven out of 10 patients achieve 20/20 vision, but 20/20 does not always mean perfect vision.
- If you have Lasik to correct your distance vision, you'll still need reading glasses around age 45.
- Lasik surgery is too new to know if there are any long-term ill effects beyond five years after surgery.
- Lasik surgery cannot be reversed.
- Most insurance does not cover the surgery.
- You may need additional surgery — called "enhancements" — to get the best possible vision after Lasik.

Understanding Your Eyes

To see clearly, the cornea and the lens must bend — or refract — light rays so they focus on the retina — a layer of light-sensing cells that line the back of the eye. The retina converts the light rays into impulses that are sent to the brain, where they are recognized as images. If the light rays don't focus on the retina, the image you see is blurry. This is called a refractive error. Glasses, contacts and refractive surgery attempt to reduce these errors by making light rays focus on the retina.

Refractive errors are caused by an imperfectly shaped eyeball, cornea or lens, and are of three basic types:

- *myopia* — nearsightedness; only nearby objects are clear.
- *hyperopia* — farsightedness; only objects far away are clear.
- *astigmatism* — images are blurred at a distance and near.

There's also *presbyopia* — "aging eye." The condition usually occurs between ages 40 and 50, and can be corrected with bifocals or reading glasses.

Are You a Good Candidate for Lasik?

Lasik is not for everyone.

- You should be at least 18 years old (21 for some lasers), since the vision of people younger than 18 usually continues to change.
- You should not be pregnant or nursing as these conditions might change the measured refraction of the eye.
- You should not be taking certain prescription drugs, such as Accutane or oral prednisone.
- Your eyes must be healthy and your prescription stable. If you're myopic, you should postpone Lasik until your refraction has stabilized, as myopia may continue to increase in some patients until their mid- to late 20s.
- You should be in good general health. Lasik may not be recommended for patients with diabetes, rheumatoid arthritis, lupus, glaucoma, herpes infections of the eye, or cataracts. You should discuss this with your surgeon.
- Weigh the risks and rewards. If you're happy wearing contacts or glasses, you may want to forego the surgery.
- Understand your expectations from the surgery. Are they realistic?
- Ask your doctor if you're a candidate for monovision — correcting one eye for distance vision and the other eye for near vision. Lasik cannot correct presbyopia so that one eye can see at both distance and near. However, Lasik can be used to correct one eye for distance and the other for near. If you can adjust to this correction, it may eliminate or reduce your need for reading glasses. In some instances, surgery on only one eye is required. If your doctor thinks you're a candidate, ask about the pros and cons.

Finding a Surgeon

Only ophthalmologists (Eye MDs) are permitted to perform Lasik. Ask your Eye MD or optometrist for a referral to an Eye MD who performs Lasik. The American Academy of Ophthalmology website (www.eyenet.org) feature "Find an Eye MD" can provide you with a list of their members who perform Lasik. Ninety-five percent of all ophthalmologists (Eye MDs) are Academy members. Also, the International Society of Refractive Surgery website (www.LocateAnEyeDoc.com) will provide you with names of refractive surgeons.

Ask your surgeon the following questions:

1. How long have you been doing Lasik surgery?
2. How much experience do you have with the Lasik procedure?
3. How do you define success? What's your success rate? What is the chance for me (with my correction) to achieve 20/20? How many of your patients have achieved 20/20 or 20/40 vision? How many patients return for enhancements? In general 5-15% return.
4. What laser will you be using for my surgery? Make sure your surgeon is using a laser approved by the U.S. Food and Drug Administration (FDA). As of this

publication's printing, the FDA has approved five lasers for Lasik; they are manufactured by VISX, Summit, Bausch and Lomb, Nidek and ATC. Contact the FDA for updates.

5. What's involved in after-surgery care?
6. Who will handle after-surgery care? Who will be responsible?
7. What about risks and possible complications?

Risks and Possible Complications

Before the surgery, your surgeon should explain to you the risks and possible complications, and potential side effects, including the pros and cons of having one or both eyes done on the same day. This is the "informed consent" process. Some risks and possible complications include:

- Over- or under-correction. These problems can often be improved with glasses, contact lenses and enhancements.
- Corneal scarring, irregular astigmatism (permanent warping of the cornea), and an inability to wear contact lenses.
- Corneal infection.
- "Loss of best corrected visual acuity" — that is, you would not be able to see as well after surgery, even with glasses or contacts, as you did with glasses or contacts before surgery.
- A decrease in contrast sensitivity, "crispness," or sharpness. That means that even though you may have 20/20 vision, objects may appear fuzzy or grayish.
- Problems with night driving that may require glasses.
- Flap problems, including: irregular flaps, incomplete flaps, flaps cut off entirely, and ingrowth of cells under the flap.

The following side effects are possible, but usually disappear over time. In rare situations, they may be permanent.

- Discomfort or pain
- Hazy or blurry vision
- Scratchiness
- Dryness
- Glare
- Haloes or starbursts around lights
- Light sensitivity
- Small pink or red patches on the white of the eye

Surgery: What to Expect Before, During and After

Before: You'll need a complete eye examination by your refractive surgeon. A preliminary eye exam may be performed by a referring doctor (Eye MD or optometrist). Take your eye prescription records with you to the exams. Your doctor should:

- Dilate your pupils to fine-tune your prescription.
- Examine your eyes to make sure they're healthy. This includes a glaucoma test and a retina exam.
- Take the following measurements:
    - The *curvature* of your cornea and your pupils. You may be rejected if your

pupils are too large.
  - The *topography* of your eyes to make sure you don't have an irregular astigmatism or a cone-shaped cornea — a condition called Keratoconus.
  - The *pachymetry* — or thickness — of your cornea. You need to have enough tissue left after your corneas have been cut and reshaped.
- Ask you to sign an informed consent form after a thorough discussion of the risks, benefits, alternative options and possible complications. Review the form carefully. Don't sign until you understand everything in the form.
- If your doctor doesn't think Lasik is right for you, you might consider getting a second opinion; however, if the opinion is the same, believe it.

If you qualify for surgery, your doctor may tell you to stop wearing your contact lenses for a while before the surgery is scheduled because contacts can temporarily change the shape of the cornea. Your cornea should be in its natural shape the day of surgery. Your doctor also may tell you to stop wearing makeup, lotions or perfume for a few days before surgery. These products can interfere with the laser treatment or increase the risk of infection after surgery.

During: Lasik is an outpatient surgical procedure. The only anesthetic is an eye drop that numbs the surface of the eye. The surgery takes 10 to15 minutes for each eye. Sometimes, both eyes are done during the same procedure; but sometimes, surgeons wait to see the result of the first eye before doing the second eye.

The Surgical Procedure: A special device cuts a hinged flap of thin corneal tissue off the outer layer of the eyeball (cornea) and the flap is lifted out of the way. The laser reshapes the underlying corneal tissue, and the surgeon replaces the flap, which quickly adheres to the eyeball. There are no stitches. A shield — either clear plastic or perforated metal — is placed over the eye to protect the flap.

After: Healing is relatively fast, but you may want to take a few days off after the surgery. Be aware that:

- You may experience a mild burning or sensation for a few hours after surgery. ***Do not*** rub your eye(s). Your doctor can prescribe a painkiller, if necessary, to ease the discomfort.
- Your vision probably will be blurry the day of surgery, but it will improve considerably by the next day when you return for a follow-up exam.
- If you experience aggravating or unusual side effects, report them to your doctor immediately.
- Do not drive until your vision has improved enough to safely do so.
- Avoid swimming, hot tubs and whirlpools for two weeks after surgery.

Alternatives to Lasik

You may want to discuss some surgical alternatives to Lasik with your eye doctor:

- *Photorefractive keratectomy (PRK)* is a laser procedure used to reduce myopia, hyperopia and astigmatism without creating a corneal flap.
- *Astigmatic keratotomy (AK)* is an incisional procedure to reduce astigmatism.
- *Intrastromal corneal rings* are clear, thin, polymer inlays placed on the eye to

correct low myopia only.

For More Information

For more information about vision correction procedures, contact:

American Academy of Ophthalmology, P.O. Box 7424, San Francisco, CA 94120-7424; www.eyenet.org
The AAO works to advance the lifelong learning and professional interests of ophthalmologists to ensure that the public can obtain the best possible eye care.

American Society of Cataract and Refractive Surgery, 4000 Legato Road, Suite 850, Fairfax, VA 22033; www.ascrs.org
The ASCRS works to raise the standards and skills of anterior segment surgeons through clinical and practice management education. The Society also works with patients, government and the medical community to promote delivery of quality eye care.

International Society of Refractive Surgery, 1180 Springs Centre So. Blvd. #116, Altamonte Springs, FL; www.LocateAnEyeDoc.com
The ISRS provides scientific research, knowledge and information to all individuals who are interested in refractive surgery.

National Eye Institute, 31 Center Drive MSC 2510, Bethesda, MD 20892-2510; 301-496-5248; www.nei.nih.gov
The NEI conducts and supports research on eye diseases and vision disorders, and offers free publications for the general public and patients.

Food and Drug Administration, 5600 Fishers Lane (HFE-88), Rockville, MD 20852; 1-888-463-6332; (301) 827-4420; www.fda.gov
The FDA oversees the safety of food, cosmetics, medicines, medical devices, and radiation- emitting products and provides information on contact lenses, intraocular lenses, refractive surgery, and corneal implants for myopia.

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Source: Federal Trade Commission, Washington, DC. Web site: www.ftc.gov/bcp/conline/pubs/health/lasik.htm.

PRODUCT EVALUATION
PRODUCT SURVEY

HARBORVIEW MEDICAL CENTER

Date: _____ Requested By: _____

Product Info	Supplier Info
Product Name: _____	Supplier: _____
Product Description: _____	Phone: _____
Manufacturer: _____	Representative: _____

Product Function: _____

Purpose of Product ☐ Replace ☐ New ☐ Other: _____

Current Product: _____

Other Info	Financial Info
Covered by Novation/UHC Contract: ☐ Yes ☐ No	Annual $ Value: _____
Latex Free: ☐ Yes ☐ No	Unit Cost: _____
Clinical Engineering Review required: ☐ Yes ☐ No	

EVALUATION CRITERIA

	Agree (Circle)				Disagree		Comments
1. Product is easy to operate.....	5	4	3	2	1	NA	_____
2. Product is ready to use (little set-up time).....	5	4	3	2	1	NA	_____
3. Product requires minimal training initially.....	5	4	3	2	1	NA	_____
4. Product meets your clinical needs.....	5	4	3	2	1	NA	_____
5. Product meets your safety concerns.....	5	4	3	2	1	NA	_____
6. Product requires little maintenance	5	4	3	2	1	NA	_____
7. Patients seem comfortable with product.....	5	4	3	2	1	NA	_____
8. Product has easy to use packaging	5	4	3	2	1	NA	_____
9. I would recommend this product.....	5	4	3	2	1	NA	_____

Based on the above criteria, this product an acceptable replacement: ☐ Yes ☐ No

Comments: _____

_____

_____

_____

_____

Reviewer Name: _____ Date: _____

Source: Harborview Medical Center, Seattle.

Guidelines for Refractive Surgery Advertising

Statement of Purpose

These guidelines are designed to assist ophthalmologists in providing truthful, informative advertising of refractive surgery. In addition to their ethical obligations, ophthalmologists must be mindful of the legal obligations they have in connection with the promotion of their services.

These guidelines are not intended to address every possible advertising claim that could be made in support of refractive surgery. The guidelines address specific types of claims that could confuse consumers, and/or have been subject to Federal Trade Commission (FTC) review. Examples of permissible claims, as well as claims that might be considered to confuse or mislead consumers, are provided.

Legal Framework

The Federal Trade Commission Act, as well as similar state laws, prohibits false and deceptive advertising. Advertising that is literally true, but which conveys a misleading impression to reasonable consumers, may be unlawful. Claims made implicitly in advertising, as well as explicit claims, can give rise to deception. Deception also can occur through the omission of information if the absence of the information causes the advertisement to convey an inaccurate impression about a material fact. Thus, ophthalmologists should insure that statements made directly or by implication in informational, promotional, and advertising materials are accurate and do not deceive consumers.

One issue of current interest concerns the advertising of "off-label" surgical applications using a device approved by the Food and Drug Administration (FDA) (e.g. LASIK). *[Editor's note: LASIK is no longer "off-label."]* The decision to use the excimer laser outside the scope of the approved labeling is considered, by the FDA, to be a "practice-of-medicine" issue; that is, the FDA has recognized that "Good medical practice and patient interests require that physicians use commercially available drugs, devices, and biologics according to their best knowledge and judgment." Physicians should be aware, however, that advertising of off-label use, while not specifically prohibited, is also not protected under the "practice of medicine."

Definition of Advertising: In addition to print, radio, and television ads, other material such as patient informational brochures, seminars, and videos may be considered advertising for purposes of these laws. Privileged discussions between physicians and their patients are generally not regulated by the FTC, but may have other legal or ethical implications. Although seminars and brochures may be considered advertising by the FTC, physicians do have a responsibility to adequately inform patients about alternative therapies.

Accountability: Physicians and other advertisers are legally responsible for the truth and accuracy of their advertising, even if it is prepared by an ad agency or other third party.

Substantiation: Medical advertisers, particularly with respect to surgical procedures, are held to a higher standard than those who advertise consumer products. The FTC requires that advertisers have a "reasonable basis" for advertising claims at the time they are made. With respect to health and safety claims for surgical procedures such as RK and PRK, this will usually require "competent and reliable" scientific evidence that may include, depending on the claim, the physician's own outcomes alone or in combination with other clinical studies. Such clinical evidence is generally considered to be stronger if the study has been peer-reviewed and/or replicated in other studies. The advertiser must have adequate substantiation for a claim at the time the claim is made.

Informed consent: Advertising need not, and as a practical matter cannot, incorporate all of the elements of appropriate informed consent disclosures. FTC staff have stated that certain advertising claims may require disclosure of material information appearing in informed consent forms **(see Safety Claims, Example 1, p. 2)**. Also, advertising may not contradict disclosures of risk made in informed consent forms, and informed consent forms will not compensate, legally or ethically, for misleading statements made in advertising.

Testimonials: A patient endorsement or testimonial will be construed by the FTC as a representation that the particular patient's experience is typical or representative of the experiences generally achieved by the physician's patients, unless there is a clear and conspicuous disclosure to the contrary. In addition, physicians should be aware that some states prohibit the use of patient testimonials by physicians.

Advertising Claims

Prospective refractive surgery patients have differing needs and expectations and may experience differing surgical outcomes. Accordingly, advertising claims are not a substitute for discussions between the ophthalmic surgeon and a prospective surgery patient regarding the patient's own needs and expectations and the range of possible outcomes.

Efficacy Claims

Example 1: Printed at the top of a newspaper ad is the banner: "Throw Away Your Glasses!" A reasonable consumer may infer from this ad that he or she will be permanently free of all forms of corrective lenses (for presbyopia and hyperopia as well as myopia) as a result of the surgery. Even if the ad makes reference to nearsightedness, there is a substantial risk that a significant number of consumers would infer from the ad that if they underwent the procedure, they would achieve 20/20 vision and would be free of glasses, including glasses for reading or occasional use. Since the surgeon cannot guarantee that the prospective patient would be permanently free from all glasses, the claim is subject to legal challenge.

Example 2: A print ad headline states, "Throw Away Your Glasses," or features a drawing of spectacles within a circle with a line crossed through it. Other text within the ad states that refractive surgery "may correct your nearsightedness and astigmatism and may eliminate your need for glasses or contacts." Although the use of the word "may" is intended to qualify the "no more glasses" claim, the claim is likely to be understood by consumers, in light of the more prominent headline or drawing, to be as unqualified as in Example 1. To avoid confusion, the overall message of an ad should not be inconsistent with the "fine print" qualifiers.

A further modification of the above claim, such as: "may correct your nearsightedness and astigmatism and may allow you to function without glasses or contacts for many activities," avoids possible ambiguities about the need for reading glasses or glasses for occasional use.

Example 3: A radio ad includes the text: "See naturally with refractive surgery!" The reasonable consumer would interpret "seeing naturally" or similar terms such as seeing clearly to mean "seeing without glasses." Again, this kind of claim should be avoided for the same reasons as for Examples 1 and 2, above.

Example 4: An ad picturing a smiling patient and physician states: "If you can read the small print, but can't see well at a distance, visit Drs. Smith and Jones to learn more about RK (or PRK) — our typical nearsighted patient — after refractive surgery — no longer needs glasses for many activities." Such an ad is acceptable. It suggests that RK or PRK will treat only nearsightedness and informs consumers about the possible need for glasses for other activities.

Example 5: An ad states: "98% of our patients see 20/40 or better postoperatively — good enough to pass a driver's test in most states!" Since the ad explicitly claims a result for a particular physician group's patients, the physicians will need a study or analysis of patient records to substantiate the claim. In addition, this ad might be understood by some consumers to mean that since they can pass a driver's vision exam, they might not need to wear glasses for other activities. This potential problem with the ad could be eliminated by a reference to the fact that patients may still need or desire glasses for some activities.

Safety Claims

Example 1: An ad states: "Find out more about PRK — the safe and easy alternative to glasses!" The terms "safe" and "safe and easy" have attracted the concern of the FTC, as have promotional materials that fail to disclose certain risks that may be considered to be important by a prospective patient. Generally, it is not appropriate for an ad to state that RK or PRK is safe and easy. Any ad that suggests that RK or PRK is safe should include a qualifying statement such as: "Like all surgery, RK (or PRK) surgery has some risks; we will discuss these with you during your consultation."

In addition, it is the position of the FTC staff that advertising containing certain claims may also need to contain relevant disclosures in order not to be considered deceptive. An FTC staff document relating to RK and PRK advertising expresses the following admonition: "representations made about safety or efficacy of RK or PRK may, in certain circumstances, require disclosures of material information about health risks or limitations associated with the surgery to prevent deception. For example, an advertisement containing express or implied representations that the surgery is safe may also need to contain information about any significant risks associated with the surgery, and for PRK, with the particular laser in use."

Example 2: A print ad states that, "unlike other procedures, PRK laser vision correction doesn't involve knives or cuts to the eye." Although it is true that the Excimer laser does not use a blade to make incisions on the surface of the eye, the statement could be misleading to consumers by suggesting that PRK is a noninvasive procedure. It is not appropriate to claim or suggest, expressly or through use of euphemisms such as "treatment," "therapy," or "vision correction," or "enhancement," that RK or PRK are anything other than invasive surgical procedures.

While differentiation between refractive procedures may be appropriate in order to inform consumers, it should done in a way so as not to be misleading; both RK and PRK are surgical procedures, and this should be made clear to the reader of the ad.

Example 3: An ad states: "The Food and Drug Administration has Determined that the Excimer Laser We Use Is Safe and Effective for PRK Laser Surgery." Such an ad is not acceptable. The Federal Food, Drug and Cosmetic Act forbids references to the FDA-approval status of any medical device in advertisements.

Permanence and Predictability Claims

Example 1: An ad states: "Achieve permanent vision correction with refractive surgery!" A reasonable consumer may assume "permanent" to mean that their post-surgical refractive result will remain stable throughout their lifetime. FTC staff have raised questions with issues of the possibility of regression, drift, and possible instability long-term, and have objected to permanency claims because of their belief that studies of modern refractive surgery techniques available at the time of their review did not adequately substantiate such claims. At this time, physicians considering making claims of permanency or predictability should be aware that this advertising will be carefully scrutinized by the FTC. Accordingly, physicians should avoid permanency claims unless they are able to substantiate the claims on the basis of their own surgical outcomes alone or in combination with current scientific evidence.

Example 2: "Visit the Smith Laser Center and leave with 20/20 vision!" This ad is problematic. A reasonable consumer could interpret this advertisement to mean that the surgeon can guarantee, preoperatively, exactly what the patient's surgical outcome will be, i.e. that refractive surgery results are predictable. To advertise surgical predictability, physicians must be able to substantiate that surgical outcomes are predictable in virtually all of their cases.

The use of ranges, e.g. "80% of our patients have 20/20 vision following surgery," is acceptable if the surgeon can substantiate the claim.

Success Rate Claims

Example 1: "90% of RK (or PRK) patients achieve 20/40 vision or better." If this claim is based on a clinical study, the surgeon making the claim will need to assure that the study is scientifically reliable and that he or she is performing the same procedure using the same protocol as that involved in the study. If these criteria are met, the claim would be acceptable as long as the surgeon's own outcomes did not vary significantly from the reported results.

'Painless' Claims

Example 1: An ad states: "PRK surgery is a safe and painless procedure." A reasonable consumer could understand this statement to mean that the entire experience — preparation, surgery, and recovery — is painless. Patients undergoing refractive surgery typically experience some pain and discomfort for a short time following surgery. Patients are often given prescriptions to deal with pain or discomfort. In these circumstances, "painless" claims are almost certain to be considered false or deceptive.

As with any other surgical procedure, new information and technology in refractive surgery can be expected to evolve over time. Accordingly, these guidelines are subject to periodic review and revision to ensure that they reflect the latest information and technology in refractive surgery.

These guidelines were developed and endorsed by: American Academy of Ophthalmology, San Francisco (Approved, Board of Trustees, February 1997); American Society of Cataract and Refractive Surgery, Fairfax, VA (Approved, Executive Committee, February 1997); International Society of Refractive Surgery in Altamonte Springs, FL (Approved, Board of Trustees, March 1997); Outpatient Ophthalmic Surgical Society, San Luis Obispo, CA (Approved, Board of Trustees, February 1997); and Society for Excellence in Eyecare in Washington, DC (Approved, Board of Trustees, February 1997).

SHARPS INJURY LOG

Date & time of injury	Job classification/ Department	Location of incident	Body part injured	Device brand & type; *protective mechanism?*	How injury occurred[1]	Employee's opinion[2]

[1] Include a) procedure being used b) body part involved in exposure, and c) whether injury occurred before, during or after activation of mechanism.

[2] If sharp had no protection, include: a) employee's opinion as to whether protection would have prevented injury, and b) whether any other engineering, administrative, or work practice control could have prevented the injury.

NOTE: *This sample log was developed by Peggy Baumann, RN, Infection Control Practitioner, and Martha Magdaleno-Hernandez, LVN, from the San Gabriel Valley Medical Center. Reprinted with permission.*

16 States Pass Needlestick Legislation

- **Alaska**. Safer needles bill passed during the past year.

- **California.** In 1998, Service Employees International Union locals in California succeeded in passing the first safer needle law in the country. This historic legislation requires the use of safer needles in all hospitals and other health care facilities and has become a model for legislation in other states. The state of California estimates its safer needle law will save over $100 million a year by reducing the need to test and treat injured and infected workers.

- **Connecticut.** Safer needles bill passed during the past year.

- **Georgia.** The state's Senate and House unanimously approved Georgia's safer needle bill before sending it to the governor's desk. Signed on April 20, 2000, the bill requires the state's Department of Public Health to come up with a safer needle standard by Jan. 1, 2001.

- **Maine.** Safer needles bill passed during the past year.

- **Maryland.** Safer needles bill passed during the past year. A second safer needle bill that would amend the state's bloodborne pathogens standard was signed by the governor this year.

- **Massachusetts.** Rules enacted in August 2000 require hospitals to establish rules for the use of devices that will minimize the risk of injury from needlestick and sharps. Hospitals must also set up effective procedures to identify and select new devices, and maintain sharps injury logs that identify devices involved in any incident.

- **Minnesota.** After it passed the state senate with a vote of 61-1, Gov. Jesse Ventura signed Minnesota's safer needle law on April 10, 2000.

- **New Hampshire.** Gov. Jeanne Shaheen signed a safer needle law on May 26, 2000, after a mentally ill, HIV-positive patient stabbed an emergency department technician with a needle containing the patient's own blood at a Manchester hospital on April 4.

- **New Jersey.** Signed into law by Gov. Christine Todd Whitman on Jan. 4, 2000, New Jersey's safer needle legislation requires health care facilities to begin using safer needle systems within 12 months.

- **New York.** The governor signed a bill on Nov. 1, 2000, that requires the use of safer sharps and needles in all health care settings.

- **Oklahoma.** Safer needles bill passed during the past year.

- **Ohio.** Safer needles bill passed during the past year.

- **Tennessee.** Safer needles bill passed over the past year.

- **Texas.** Safer needles bill passed during the past year.

- **West Virginia.** Legislation signed in April 2000 requires the creation of a needlestick injury prevention program, including the recording of every "sharps" injury, in all public and private health care facilities. In addition, the division of health was required to propose new rules by July 1, 2000, that would require facilities, as a condition of licensure, to use needleless systems or other engineering controls to prevent needlestick injuries.

There is action on this issue pending in the following 10 areas: **Illinois**, **Pennsylvania**, **Florida**, **Washington**, **Rhode Island**, **Michigan**, **Indiana**, **Vermont**, **Iowa**, and the **District of Columbia**.

Source: Service Employees International Union, Washington, DC.