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Your patients' worst nightmare, and yours: Awareness despite anesthesia

Device allows 17% to 19% faster discharge, providers say

This summer, a jury awarded a Virginia woman $150,000 after she woke up during surgery and had to endure the 45-minute procedure while paralyzed but able to feel all the sensations of having her ovaries removed. The anesthesiologist acknowledged that, unbeknownst to him, the anesthetic being administered to the patient ran out during the procedure.

And earlier this year, *People* magazine featured a story on Jeanette Tracy, who woke up during a hernia repair. Tracy since has formed a group called Awareness with Anesthesia Research Education, a one-woman help line based in her home in Alexandria, VA.

Patients who have experienced sensations during surgery say it is a horrific experience. Clinicians have given it the term "patient awareness." And same-day surgery managers, those who recognize the legal and public relations implications, label it a disaster.

While providers might be tempted to overmedicate patients in order to avoid any potential problem of awareness, same-day surgery programs also face pressures to discharge patients more quickly. So how do you deal with this dilemma? A new monitor — the first of its

SDS launches 4-part series on new procedures and services

In this year's reader survey, you told us you want to know about new procedures and services being offered in same-day surgery programs. We heard you! Beginning this month, we're starting a four-part series to give you the information you need to bring new patients, and dollars, into your program. This month's feature is pain management. **(See story, p. 152.)** In the next three issues, we'll highlight procedures such as laparoscopic Nissen fundoplication, plastic procedures, and sentinel lymph node biopsy.

Don't miss this special series in *Same-Day Surgery!* ■

EXECUTIVE SUMMARY

Recent publicity about cases of patient awareness during anesthesia is raising provider and patient attention to the problem. Awareness is more likely among patients who are chronic users of alcohol, tranquilizers, sedatives, or narcotics; obese patients; patients who have high metabolic rates; and pediatric patients, among others.

- The Bispectral Index or BIS (pronounced "biz") monitor helps providers avoid problems and helps discharge patients 17% to 19% faster, users report. Some patients are able to bypass phase I recovery. The cost is $9,000 for each monitor and $15 for each disposable sensor.
- Inform patients about the risk of awareness before surgery and reassure them if the problem does occur. Keep the atmosphere professional in the operating room.

type — is now available to measure the effects of anesthesia on consciousness. The Bispectral Index or BIS (pronounced "biz") monitor caused a stir at the October meeting of the American Society of Anesthesiologists, where 35 abstracts and multiple presentations highlighted the device. BIS is manufactured by Aspect Medical Systems in Natick, MA. **(See contact information, p. 151.)**

The BIS works in this way: A sensor is attached to the patient's forehead, and a monitor provides a reading between zero and 100.

"Essentially, it's an EEG machine that monitors brain waves," says **Maureen Witte**, CRNA, staff nurse anesthetist at Presbyterian Hospital in Philadelphia. "At 100, you're completely awake, and at zero, you have total EEG suppression," Witte says.

Providers are instructed to keep patients around the 40 level, which should be an indication they're asleep and unaware, she says. "Maybe we can avoid some lawsuits related to awareness if we keep our patients asleep enough."

Using the BIS monitor prevents providers from overdosing hypnotics or analgesics, she maintains, and other providers concur.

The BIS monitor allows about 30% less anesthetic to be administered, says **Nand Varyani**, MD, medical director of The Surgery Centers, based in Middleburg Heights, OH.

Surgery programs that use the BIS monitor tell *Same-Day Surgery* their patients are being discharged 17% to 19% faster. And some of those patients are able to bypass phase I recovery.

"Anesthesiologists need to know that if they want to be efficient, this is useful for reducing anesthesia cost: one, by saving anesthetics, and two, by quicker discharge time," Varyani explains.

At The Surgery Centers, about 35% of patients are bypassing phase I recovery, compared with 22% of patients who bypassed phase I before the BIS monitor was used. **(For additional information on bypassing phase I recovery, see *SDS*, January 1998, p. 5.)**

44% of patients skip phase I

At Massachusetts General Hospital in Boston, patients are being discharged 17% quicker since the BIS monitor was added, and 44% of patients are bypassing phase I, compared with 23% of patients before the BIS monitor, says **James Mayfield**, MD, associate director of the same-day care unit.

"I don't consider it an awareness monitor. [Patient awareness] is so rare, we hardly we see it," Mayfield says. " I consider it an efficiency monitor."

He can titrate medication to meet specific needs of patients, Mayfield says. "Patients wake up quicker and more satisfied and get out of the hospital quicker," he says. "Patients like that. We've been calling patients after they're bypassed the next day, and we've had very positive response. We haven't had anyone have to revert to phase I PACU [postanesthesia care unit]."

COMING IN FUTURE MONTHS

- Comparison of reimbursement for hospitals and surgery centers
- Using LPNs in same-day surgery
- Addressing competence, privileges, and credentialing
- Update on 23-hour stays
- Joint Commission hot button on patient education

Is there a downside to using the BIS monitor? "Just the cost," Varyani reports, which is $9,000 for each monitor and $15 for each disposable sensor.

While the efficiency benefits of the BIS monitor may get managers' attention, it's the problems with patient awareness they're most anxious to avoid. Each year in the United States, an estimated 40,000 to 200,000 patients experience some degree of intraoperative awareness.[1,2]

Awareness is more likely with:

- patients who are chronic users of alcohol, tranquilizers, sedatives, or narcotics;
- obese patients who may have an altered drug response because of excessive weight or due to intubation difficulties that can result in delay between induction and the time of administration of maintenance agents;
- patients who have high metabolic rates;
- pediatric patients;
- obstetric patients;
- trauma patients.[3]

While patient awareness has always existed, recent publicity of cases has captured providers' attention, Witte says. She is serving on the American Association of Nurse Anesthetists' Council for Public Interest in Anesthesia. This group is educating providers and patients about the possibility of awareness during anesthesia.

Also serving on the board is **Kay Ball**, RN, MSA, CNOR, FAAN, perioperative consultant/educator with K and D Medical in Lewis Center, OH, and part-time consultant with Steris Corp. in Mentor, OH. "We're trying not to scare people but make them aware this possibly could happen," Ball says.

Some tips to follow

To avoid problems with patient awareness, Ball and Witte suggest the following tips:

- Before surgery, tell patients about the risk of awareness. As part of the informed consent procedure, tell them that if awareness occurs, the staff will work to manage and control the problem appropriately, Ball says.
- Check the level of the inhalation agent you're using in the vaporizer to make sure it's adequate, Witte suggests. "If you have a multi-gas monitor, that will usually tell you the percentage of the agent that the patient is getting."
- Use Versad and similar medication that offer an amnesia-like effect, Witte says. "Using it as a premedication may help you to avoid awareness."
- In the operating room, maintain a level of quiet that's respectful and conscious of the fact that patients might be able to hear you, Witte advises. In other words, keep it professional.
- If awareness is detected, stroke the patient's face lightly and offer reassurance, Ball suggests. At that point, more anesthetic agents can be administered.
- If you suspect a patient experienced awareness, educate the patient, Ball suggests. Such patients might have difficulty trying to remember what they experienced, she says. Reassure them that it's OK to ask questions. Consider referring them to an anesthesia provider, as well as a psychologist or social worker, she advises.

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3. Bennett HL. Awareness and learning in anesthesia. *Anesthesia Today* 1991; 3:13. ■

SOURCES

For more information on the BIS monitor, contact:

Aspect Medical Systems, 2 Vision Drive, Natick, MA 01760. Telephone: (508) 653-0603. Fax: (508) 653-6788. World Wide Web: www.aspectms.com.

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SDS, anesthesiologists tackle pain management

Spinal endoscopy, blocks use fluoroscopy

The growing complexity of pain management procedures is creating opportunities for same-day surgery programs, as SDS managers form links with specialized anesthesiologists to treat a new population of patients.

While some pain patients simply can visit their doctor's office or a clinic for steroid injections, others need more sophisticated epidural treatments that require continuous radiologic guidance. And a new procedure, spinal endoscopy, involves threading a tiny fiber optic camera into the epidural space so the anesthesiologist can see the irritated nerve and inject medication at its root.

Spinal endoscopy must be performed in a sterile environment, such as an OR. That requirement has led to a natural bond between pain management anesthesiologists and same-day surgery facilities, says **Robert J. Masone**, MD, director of the Fairfield Pain Management Center in Lancaster, OH. Masone also is the anesthesia director for River View Surgery Center in Lancaster, which opened a year ago and recently began offering pain management procedures.

"This marriage is kind of new," says Masone. "There's a tendency for doctors to have freestanding pain clinics. They will probably try to locate near surgery centers to utilize their resources."

The new procedures offer a new source of case volume at reasonable reimbursement levels, says **Patricia Moore**, RN, CNOR, director of River View Surgery Center. In fact, workers' compensation boards often favor pain management for workers injured on the job, she says. "They see pain management as an opportunity to get the work force back where they need to be in a shorter period of time with less complications or recurrences."

When Moore first began offering pain management at a different surgery center in the 1980s, CPT codes didn't even exist for the procedures. She had to fight for reimbursement and sometimes lost money. That situation has completely turned around now, as pain management grows in acceptance and desirability, she says.

"Pain management offers new procedures for old problems," she says. "In the past, if you had sciatica, then you would be pretty much treated medically with bed rest and oral medications. Now that [researchers] have validated the potential positive outcomes and patients are actually doing better being on a pain management program, payers see the benefit of those and added the procedures to the reimbursement list."

EXECUTIVE SUMMARY

New pain management procedures that require fluoroscopy or a sterile environment offer new opportunities for same-day surgery programs.

- Freestanding pain clinics run by anesthesiologists with a specialization in pain management often prefer to locate near a surgery center.
- Surgery centers can offer nerve blocks in the recovery area with support from post-anesthesia care unit staff.
- Spinal endoscopy allows anesthesiologists to locate the irritated nerve root and directly administer medication.

1,200 patients a year

Surgery centers often offer the same injections and nerve blocks performed in clinics or office settings. For example, Bethesda North Ambulatory Surgery Center in Cincinnati, which is hospital-based, began offering blocks about four years ago and now sees 1,200 pain management patients a year. Bethesda North converted space in its recovery area for pain management, says clinical nurse manager **Carolyn Lekien**, RN, CNOR.

Pain management procedures occur in the OR at River View Surgery Center because of a need for fluoroscopy or the new spinal endoscopy equipment. "One nurse is assigned to the procedure primarily for patient support and positioning," says Moore. Patients wait for about 15 minutes in the recovery area for observation before discharge. Because a patient may need three injections, she keeps a single revolving chart to record each visit.

If patients don't get relief from the injections, they may be candidates for spinal endoscopy, says Masone. The procedure is used to diagnose and treat chronic low back pain and radiculopathy, or pain that radiates to the legs.

Myelotec of Roswell, GA, received approval from the Food and Drug Administration for use of the endoscopic equipment for diagnostic purposes in 1996 and approval as a drug delivery system in 1998.

SOURCES

For more information on spinal endoscopy, contact:
Charles Eichenberg, RN, PhD, Director of Medical Affairs, Myelotec, 4000 Northfield Way, Suite 900, Roswell, GA 30076. Telephone: (800) 574-1633. Fax: (770) 664-4363.
For information on training in spinal endoscopy, contact:
Janice Gore, Office of Postgraduate and Continuing Medical Education, Yale University School of Medicine, New Haven, CT 06520-8052. Telephone: (203) 785-4578. Fax: (203) 785-3083.
For more on pain management programs in same-day surgery facilities, contact:
Patricia R. Moore, Director, River View Surgery Center, 2401 N. Columbus St., Lancaster, OH 43130. Telephone: (740) 681-2700. Fax: (740) 681-2750.

"We actually use a fiberoptic camera and go up the spinal canal from the caudal area, and we can look at each nerve root," says Masone. "You can inject medicine on the nerve root. This is especially helpful for people who have a normal MRI but still have back pain."

The spinal endoscope, which is barely a millimeter in diameter, costs $3,000 and lasts for about 35 procedures. Physicians also need to use an access kit ($60 per case) and video-guided catheter ($375 per case). A conversion unit ($1,350) is available for facilities that already have a video system, or you can purchase a video system from Myelotec (about $18,000; **see sources, above**). The facility fee varies widely by payer and region of the country, with a non-Medicare reimbursement ranging roughly from $900 to $3,000 per case.

Patients are mildly sedated during the hour-long procedure, and they help direct the anesthesiologist to the nerve that is causing their chronic pain.

A non-scientific study of 72 patients who were surveyed before the procedure and six months later showed a reduction in the severity of overall pain and an increase in physical functioning. Yale University researchers have published articles related to the spinal endoscopic technique[1,2] and are analyzing other outcomes data. About 6,000 procedures have been performed nationwide.

Resolving — or significantly improving — a patient's chronic pain ultimately can lead to lower health care costs, says Masone. Pain patients often end up in the emergency department seeking treatment, and they use hundreds of dollars worth of medicines in an effort to control the pain, he says.

"You present that [potential savings] to managed care companies, and they'll weigh the risks and the benefits," he says.

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SDS patients will benefit from new tissue adhesives

Increase hemostasis, expedite wound closure

Two new tissue adhesives, both approved this year by the Food and Drug Administration (FDA), are likely to find their way rapidly into same-day surgery because one product increases hemostasis and the other speeds wound closure.

Fibrin sealant, a tissue adhesive approved in May, increases surgical hemostasis, says **Sandra Burks**, RN, clinical coordinator of the Tissue Health Center at the University of Virginia Health Science Center in Charlottesville. The center, which develops tissue adhesives, is made up of representatives from various specialties.

"Fibrin sealant can be used to control diffuse

EXECUTIVE SUMMARY

The Food and Drug Administration approved two new tissue adhesives this year that will make same-day surgery easier on patients and physicians. The adhesives are fibrin sealant, a biologic glue for internal use, and Dermabond, a topical skin adhesive that can take the place of sutures.

- Fibrin sealant controls diffuse slow bleeding over large surfaces.
- Made of naturally occurring proteins that cause blood to clot, it forms a pliable seal and stops bleeding. Eventually, it is reabsorbed by the body without damaging tissues or leaving scars.
- Although much stronger than fibrin sealant, Dermabond is a chemical glue that contains potentially reactive byproducts. Hence, it should be used to close topical lacerations and incisions, not in place of subcuticular suture.

slow bleeding over large surfaces and to join skin flaps or muscle flaps in procedures such as a mastectomy," Burks says.

The material is a "biologic glue" composed of naturally occurring proteins that causes blood to clot, thus forming a pliable seal and stopping the bleeding. Eventually, it is resorbed by the body without damaging tissues or leaving scars.

"That's why it can be used internally," Burks explains. Although it has just been approved in the United States, it has been used on more than 3 million European patients, she says.

Use Fibrin to control bleeding

For outpatient programs that perform minimally invasive surgical procedures such as laparoscopies, fibrin sealant can be especially useful for patients who are at risk of bleeding.

"As you are removing the instrumentation, for example, you could control bleeding by putting fibrin sealant in places where you would not be able to get traditional sutures in," Burks says.

She explains that the tissue adhesive can be applied in several ways: First, surgeons may use a dual syringe applicator. "There are two proteins that are mixed together, much like you would epoxy glue. Then it can applied using a syringe to drop the sealant onto the bleeding surface," she says." Second, the adhesive can be sprayed.

Finally, the adhesive may be put on a sponge. "You can hold it in place with pressure over the area. That method is very effective in controlling large amounts of bleeding," Burks points out.

However, the product should not be used to close large wounds or used in lieu of sutures under those circumstances, she cautions.

An average patient dose in a 2 ml kit costs about $350, she says.

"In the literature, there is no documented transmission of any viral infection from the tissue adhesives currently on the market," she says. "There's always a risk of viral transmission with any pooled plasma product; however, with fibrin sealant, there's significantly less than a traditional blood transfusion."

Fibrin sealant is currently available in the United States through two companies: Baxter Healthcare Corp. in Deerfield, IL, distributes the product under the name of Tisseel. Haemacure Corp. in Sarasota, FL, distributes Hemaseel APR. **(See sources, at right.)**

The other tissue adhesive that has significant implications for same day surgery is Dermabond, which the FDA approved in August.

Unlike fibrin sealant, Dermabond is intended for topical use only — not for deep wounds under the skin, says **Dean Toriumi**, MD, associate professor in the division of facial plastic and reconstructive surgery in the department of otolaryngology, head and neck surgery at the University of Illinois at Chicago.

"It is much stronger than fibrin sealant, so it can be used to close lacerations and incisions that otherwise would require sutures, staples, or skin strips," says Toriumi, who participated in the clinical trials. However, because it contains some potentially reactive byproducts [such as cyanocrylate and formaldehyde], Dermabond shouldn't be used internally, he adds.

"For deeper wounds, physicians would need to use small sutures beneath the skin surface, but then use Dermabond to hold the top layers of skin together," he explains. "It may be used in place of topical sutures or staple and in conjunction with, but not in place of, subcuticular sutures."

Dermabond also can be used to hold together skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, says Toriumi. However, it should not be used for wounds across areas of high skin tension, such as knuckles, knees, or elbows, unless the joint will be immobilized during the healing process, he says.

"In areas where the skin is tight, such as the palm of the hand, sutures would be better," he says. "It also shouldn't be used for decubitus

SOURCES

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Baxter Healthcare Corp., Hyland Division, 1627 Lake Cook Road, Deerfield, IL 60015. Telephone: (800) 423-2090. Fax: (800) 756-4952.

Haemacure Corp., 2 N. Tamiami Trail, Suite 802, Sarasota, FL 35236. Telephone: (877) 872-4236 or (941) 364-3700. Web: http://www.haemacure.com.

For more information on Dermabond, contact:

Ethicon, P.O. Box 151, Somerville, NJ 08376. Telephone: (877) 384-4266. Web: http://www.ethiconinc.com.

ulcers, infected wounds, or in situations where there is a complex crush injury."

Other contraindications include a potential hypersensitivity to cyanocrylate or formaldehyde.

The product, which comes in a single-use applicator packaged in a blister pouch, costs the hospital $24.95 for each vial — enough to treat one patient. "That's about the cost of high-end sutures," Toriumi says.

However, the product reduces the need for suture kits, wound dressings, anesthetic injections, syringes, and other instruments, he points out. Because it also eliminates the need for a follow-up visit for suture removal, it can reduce overall treatment costs.

Dermabond is a trademark of Ethicon, a Johnson and Johnson company, and manufactured by Closure Medical Corp. in Raleigh, NC. ■

Follow these tips to apply Dermabond

Dean Toriumi, MD, offers these tips for applying Dermabond, a tissue adhesive approved by the Food and Drug Administration in August. Toriumi is an associate professor in the division of facial plastic and reconstructive surgery in the department of otolaryngology, head and neck surgery at the University of Illinois at Chicago.

To apply, crush the inner glass ampule contained within a plastic vial that has an attached applicator tip. Then hold the edges of the wound together and "paint" on the sterile liquid, which is slightly more viscous than water.

"It looks simple; however, it does take a little practice," Toriumi says. "On occasion it does run, so you need to use the surface tension of the applicator to keep the adhesive at the surgical site. Also, make sure the surgical surface is flat so the adhesive won't run off the side of the surgical field."

Toriumi also recommends using multiple, thin layers rather than one thick application. "This gives you more control," he says.

Allow about 30 seconds between each application for the adhesive to dry and form a strong yet flexible waterproof coating. This coating protects the wound during the normal healing process and sloughs off gradually and painlessly, which eliminates the need for suture removal. ■

Same-Day Surgery Manager

Does your facility need to hire a consultant?

Take this self-assessment quiz to find out

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

Everyone hates consultants. I hate them too, and I am one! However, hospitals and other health care providers are relying on them in greater numbers than ever before.

Why? Let me give you a perfect example: We get called in to do a lot of "benchmarking" on everything from cost per case to turnaround time to admissions. Hospitals and ambulatory surgery centers (ASCs) are always looking for the "norm" and want to know where they fall. It's like when we were in school and took exams to see where we as individuals fit in with our peers. Personally, I like knowing where I am and how I compare to others. It gives me a sense of accomplishment or impending doom — or somewhere in the middle, I hope.

So benchmarking is a good thing. Hospitals always want to know how they compare with the freestanding centers in cost, efficiency, and other issues. But why do they think they need a consultant? They don't! Read on, and save some money.

When we meet with managers or administrators, we are impressed with their level of knowledge on the issues. So why are we there? What is it we are going to discover — at your facility — that you don't already know? Probably not much.

So why doesn't your CEO just ask *you* for the data? So many of you have told me (in a kind way, of course), "Why does the hospital need a consultant? I know the answers to what they are looking for in this." For many managers out there, you are right. But for others . . . well, that's not always the case. Here's a quick quiz that you as the administrator or manager should be able to complete within five minutes. You'll see why your CEO doesn't ask you. The questions with

asterisks are those that 80% of managers / administrators could not answer or find the answer to within five minutes! Here goes:

- What is your average supply cost per case?*
- What is your payer mix?*
- Define the "start time" you use to calculate turnaround time.
- Who is the busiest surgeon in your facility?
- Who is the most productive?*
- How many full-time equivalents (FTEs) do you employ?*
- Where are you on your staffing budget year-to-date (YTD)?*
- Can you produce your budget within five minutes?*
- When was the last time your preference cards were updated?*
- When was the last time you had a staff member audit a procedure for supply usage?*
- When was the last time you did a lunch relief?
- Who is your most expensive surgeon in the area of supply usage?*
- When did you review / audit the above surgeon's supply usage?*
- How many payer groups are in the proposed ambulatory payment classifications (APCs)?*
- What is your turnaround time between cases?*
- What is your "same store growth" percentage this YTD vs. the previous YTD?*
- What are you paying for your intraocular lenses?*
- What is the average pharmacy cost per patient in anesthesia supplies?*
- What is your most profitable (in money!) procedure?*
- When was the last time you reviewed your surgical volume by physician?*

A silly exercise perhaps, but revealing. That is why consultants are called in! You should know or at least have access to this type of information. So many people say, "They don't share that with me!" Or I'll hear, "We have other people who handle that — my job is to take care of the patients."

I'm sorry, but in health care today, it is our job to know these answers. You need to know this stuff and then make sure your boss knows you know it! It does you no good to keep your light under a bushel.

If you could answer all of the above questions or know who to call *and get an answer* within five minutes, please call me. I have a job for you. If you couldn't answer the questions marked by asterisks, unfortunately you have a great deal of company. Health care is changing. More hospitals are developing their own ASCs and going off campus in partnership with the surgeons. If you can't answer these questions, don't be surprised when you aren't invited to participate.

For what it's worth: Before I start a consulting assignment, I usually discuss the project with the hospital CEO. I cannot tell you the number of times the conversation starts with, "My staff was unable to tell me . . ." Thank you.

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Will HCFA bar women from certain procedures?

HCFA tables proposal until mid-2000

The prospective payment system proposed by the Baltimore-based Health Care Financing Administration (HCFA) for outpatient procedures in surgery centers and hospital outpatient surgery departments may prevent many Medicare women from being able to choose some of the most advanced surgical procedures.

Three breast diagnostic procedures will be reimbursed at a lower rate under the proposed surgery center ambulatory payment classifications (APCs). And some new minimally invasive procedures essentially will be unavailable to elderly women because their higher equipment

EXECUTIVE SUMMARY

The Health Care Financing Administration (HCFA) has two fee schedule proposals that would directly impact the financial health of surgery centers and hospitals performing breast procedures and other women-specific surgeries.

- Industry experts criticize what they say is HCFA's outdated methodology, which relied on old cost information.
- Critics also have pointed to the exclusion of new technology such as stereotactic breast biopsy.
- Implementation of the surgery center and hospital proposals has been delayed until mid-2000.

costs are not recognized in the proposed APCs, according to directors at several surgery centers. Two of the three breast diagnostic procedures will see a lower reimbursement rate for hospital outpatients, with the third procedure receiving a slightly higher reimbursement than previous reimbursements to hospitals.

"The APCs might prevent women from having biopsies done with new instruments, and these new instruments are an improvement," says **Beth A. Boyd**, RN, clinical director and educational coordinator for The Breast Center in Marietta, GA. The Breast Center is a private surgical practice that specializes in breast procedures, including ultrasound, stereotactic biopsy, and mammography.

"Overall, to me it's unfortunate," says **Maxine Brinkman**, MHA, director of women's health services for Mercy Health Network in Mason City, IA. Brinkman also is the president of the National Association of Professionals in Women's Health in Chicago.

"It's a step backward and is subjecting women to less technically good procedures," she says.

Y2K concerns halt final rule

In September 1998, after months of heated outcry from surgery centers, HCFA tabled proposals for fee schedules for both outpatient surgery centers and hospital outpatient surgery departments. A major reason for the delay in completing these schedules is the need for HCFA to concentrate on the potential year 2000 (Y2K) problems that could delay Medicare payments to patients and to providers. The delay also has been extended to the controversial reimbursement system for surgery centers that was proposed in June 1998.

Both the proposed system for hospital outpatient services, which was published in the *Federal Register* Sept. 8, and surgery centers, published June 12, rely on APCs. APCs are groups of procedures that are reimbursed at the same rate because they are similar clinically and in terms of resource costs. **(For information on how to access the original documents, see box, p. 158.)** The same classification system, with different rates, is proposed for surgery centers and hospital outpatient services.

Because HCFA tabled both projects so soon after the hospital-based outpatient rates were proposed, hospital-based financial managers are holding off on analyzing the reimbursement levels in detail.

"We are not conducting an in-depth analysis at this time because the rates will probably change when HCFA reissues them after the beginning of the year 2000," says **Tracie Holyfield**, product line specialist for women's services at Moses Cones Health System in Greensboro, NC.

Although reimbursement for outpatient services will continue as usual for the next 13 months or longer, it is important to understand the reasons for the heated debate generated by the APCs specific to women's surgeries and the

Prostate surgery reimbursement rises

Some other surgeries are hurt by new APCs

Critics of the proposed ambulatory payment classifications (APCs) suggest the Health Care Financing Administration (HCFA) could have updated the APC proposal and allowed for new technologies.

HCFA did update data for three new procedures for men with prostate problems. For example, one of those procedures is currently reimbursed at $595 and listed under CPT code 52601: transurethral electrosurgical resection of the prostate, including control of postoperative bleeding, complete. The proposed APC code of 524 defines it as a level IV cystourethroscopy and other genitourinary procedures, with a reimbursement payment of $1,131, a $536 increase.

However, HCFA's proposed APCs likely will have a negative effect on many more surgical procedures, two surgery center executives say. The proposed APCs may harm ophthalmology surgery centers because of large decreases in reimbursement for cataract and other procedures, says **Mark Mayo**, executive director of the Illinois Freestanding Surgery Center Association and director of Valley Ambulatory Surgery Center in St. Charles, IL.

Ken McDonald, president and chief executive officer of AmSurg Corp. of Nashville, TN, says two of the field's most affected specialties are gastroenterology and ophthalmology. AmSurg is a publicly traded outpatient surgery center company that specializes in single-specialty surgery centers.

The solution to all reimbursement problems with APCs would be for HCFA to make changes in its methodology, McDonald says. "The real key is to see if we can get HCFA to work with the industry to come up with viable methodology to use correct data in making the right change." ■

potential impact of the lower reimbursements.

A frightening possibility if HCFA proposes similar rates in 2000 is that commercial payers will follow suit, as they usually do, and base their payment structures on Medicare's APCs, says **Jerry Henderson**, executive director of SurgiCenter of Baltimore in Owings Mills, MD. The multispecialty center performs about 11,000 procedures a year, including breast procedures.

Proposed rates are disappointing

At the center of the controversy are the proposed reimbursement rates for breast biopsy diagnostic procedures. Currently these are reimbursed under these three CPT codes:

❒ **19100: Breast biopsy; core** — $314 for surgery centers; $224 for hospitals.

(Editor's note: Hospital outpatient rates are based on national averages and do not take into account the wage index for each urban or rural area. A cost-to-charge ratio of 45% was assumed. The source for this information is the Healthcare Financial Management Association in Washington, DC.)

❒ **19101: Breast biopsy; incisional** — $422 for surgery centers; $699 for hospitals.

❒ **19125: Excision of breast lesion identified by preoperative placement of radiological marker** — $482 for surgery centers; $699 for hospitals.

The new APC group definition lists CPT 19100 as APC 122, defined as a Level II needle biopsy, aspiration; and the proposed reimbursement rate is $186, a decrease of $128 from the current payment rate. Hospital reimbursement for APC 122 is $258, an increase of $34.

The CPT codes 19101 and 19125 are grouped under the APC 197 as an incision / excision breast procedure, and the proposed reimbursement for this APC is $411, an $11 decrease from CPT 19101 and a $71 decrease from CPT 19125. Hospital reimbursement for APC 197 is $642, which represents a $58 decrease.

The reduction in reimbursement is only part of the problem. The bigger issue, directors say, is that the proposed codes do not address new breast biopsy procedures.

Until 1994, for example, most stereotactic breast biopsies in outpatient settings involved using a core needle biopsy. And the gold standard was an open excisional biopsy performed in a hospital operating room. The latter procedure requires a general anesthesia, and the woman needs longer recovery time. Plus it leaves some

How to Access HCFA's Proposal

For a copy of the Sept. 8, 1998, *Federal Register* containing the Medicare Program; Prospective Payment System for Hospital Outpatient Services; Proposed Rules, and the June 12, 1998, *Federal Register* containing the Medicare Program: Update of Ratesetting Methodology, Payment Rates, Payment Policies and the List of Covered Surgical Procedures for Ambulatory Surgical Center Effective Oct. 1, 1998, send your request to:

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- **The *Federal Register*** is available for viewing at many libraries or in an on-line database through GPO Access, a service of the U.S. Government Printing Office. Internet users may access the data base by using the Web: http://www.access.gpo.gov/su_docs/.

SOURCES

For more on how the proposed APCs will affect Medicare patients, contact:

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internal and external scarring, Boyd says.

Then manufacturers introduced the stereotactic biopsy procedure with the vacuum-assisted biopsy device. The new stereotactic technology allows digital imaging on a computer during the biopsy. The new technique is minimally invasive, so it doesn't cause as much scarring, and the woman does not need general anesthesia. The woman can drive herself to and from the outpatient facility, and the whole procedure and recovery may take two hours, she says.

"It's a very big difference," Boyd explains. "You don't have operating room time, pre-operative laboratory time to pay for, so it benefits the insurance companies to work with this too."

Stereotactic biopsy is better diagnostic tool

Although the stereotactic biopsy, using a vacuum-assisted biopsy device, costs more than the traditional stereotactic core needle biopsy, it is a much better diagnostic tool because it allows the surgeon to remove larger tissue samples and an entire area of abnormality in the breast, instead of only a small tissue sample, she adds.

The Biopsys Mammotome Breast Biopsy System, manufactured in 1994, is now marketed by Ethicon Endo-Surgery Inc. in Cincinnati. It was the first vacuum-assisted biopsy device, Boyd says. Norwalk, CT-based United States Surgical Corp. recently introduced the MIBB (minimally invasive breast biopsy), which also is a vacuum-assisted breast biopsy device used with stereotactic imaging.

Both devices use new technology that allows larger tissue samples and removal of the lesion through a 4 mm incision, Boyd says.

United States Surgical Corp. also manufactures the ABBI (advanced breast biopsy instrumentation), another new stereotactic breast biopsy technology that would be adversely affected by the APCs, says **Kathryn Barry**, senior director of health policy and reimbursement for United States Surgical Corp.

The MIBB was introduced this year, and the ABBI was introduced in 1996, which means they were not included in cost data HCFA collected in its 1994 ASC survey, Barry says.

"We are concerned they are using an outdated methodology that doesn't keep pace with advancements of technology that are piloting a shift to ambulatory care," Barry says.

The ABBI, which uses a disposable product, costs more than the proposed APC surgery center reimbursement of $411, Barry says. Add in the cost of the surgeon, facility, and staff time, and the cost of the new stereotactic breast biopsy will exceed Medicare's reimbursement rate.

"So this creates two perverse incentives: There are ASCs with this technology, but they won't schedule Medicare patients for the procedure, so Medicare women will be denied access to the technology," she says.

"Or physicians will be motivated to send their patients to a hospital because the procedure is reimbursed more there." While the hospital reimbursement of $642 is more generous, hospital outpatient departments still are facing higher overhead costs than surgery centers, and those costs will not be covered by the reimbursement level, Barry says.

Ironically, while Medicare's low reimbursement level might deny older women stereotactic technology, other government agencies are paying for it, Brinkman notes. The Atlanta-based Centers for Disease Control and Prevention (CDC) has included stereotactic procedures for low-income women in its Breast and Cervical Cancer Early Detection Program, which is funded by the National Institutes of Health in Washington, DC.

Hysteroscopy rate also falls short

Henderson points out that women also are being shortchanged with HCFA's proposed reimbursement for surgical hysteroscopy, which is under APC code 550 and corresponds to CPT code 56356, which is for hysteroscopy, surgical, with endometrial ablation. The procedure allows a surgeon to destroy the endometrial lining of a woman's uterus, which can be done in place of a hysterectomy.

The procedure traditionally has been done in a hospital setting, where the reimbursement rate is more than $1,000 in many states, Henderson says. The proposed hospital reimbursement for APC 550 is $893.

The proposed APC code 550 would reimburse the procedure in an outpatient surgery center setting at $610. Surgeons now have the option of new technology that uses a heated balloon to destroy the endometrial lining, which is safer and quicker but involves a disposable instrument that costs about $650, Henderson says.

"So before you have the first minute of surgery, the first staff person, and the first suture, you're already behind," he says. ■

True consent: Study says it doesn't exist

Put your emphasis on process, not forms

Most informed consent forms used for surgical procedures don't really inform the patient or obtain true consent, according to a new study. But while the study should be disconcerting for managers, it's important to remember that true informed consent comes from a process, not a piece of paper.

The research was done by **Kenneth Hopper**, MD, and colleagues at Penn State University in Hershey, PA.[1] They reported their findings in a recent issue of *Surgery*. The researchers concluded that "the majority of surgical / procedural informed consent forms used by U.S. hospitals are complex and are not easily understood by the average patient. In addition, the majority of reviewed consent forms do not list specific benefits or potential complications of the planned surgery / procedure."

That should make every risk manager question the effectiveness of the consent forms at their own facilities, says **Malcolm Parsons**, ARM, vice president for risk management at Doctors Hospital in Columbus, OH.

"After reading this study, I pulled out our informed consent form and looked to see if we need to revisit how that form is worded and designed," Parsons says. "That's probably a good idea for everyone to do."

Study examines 616 forms

Hopper conducted the study by requesting copies of informed consent forms from 10% of all U.S. hospitals. The forms were digitized and then assessed for readability, and each form was assessed for completeness and applicability of the content. The researchers received 616 consent forms to study.

They found that the average grade level of education required to understand the forms was 12.6 — very high in terms of the average person's reading ability. The bed size, which could be related to the hospital location or population served, had no effect on the reading level required by the forms. People reading at less than an eighth-grade reading level could understand only 5% of the 616 forms. Those reading at an eighth-grade level could understand 23%; those reading at a 10th-grade level could understand 56%; and those reading at a 12th-grade level could understand 75% of the forms. A surprising 21% of the forms required the reading level of college sophomore to understand them, and 9% required a reading level of a college graduate.

The content of the forms also varied a great deal. Almost all required the names of the patient, physician, and procedure, and most stated in general terms a description of the procedure, its benefits, risks, and alternatives. But only a small number of the consent forms provided specific details for each of those items. Only 6.2% listed specific benefits of the planned procedure, and only 5.4% listed specific alternatives.

2.3% list risks of not having procedure

A larger percentage, 30.1%, listed specific risks. A minority of the forms, 21.7%, stated there were risks of not having the procedure at all, and only 2.3% listed specific risks of not having the procedure.

One finding may seem particularly troubling. Though the forms were intended for surgery or other procedures, 87.4% also obtained consent for the anesthesia to be used during the procedure. But less than half of the forms, 47.7%, stated there were additional risks from the anesthesia itself, and only 14.9% provided any specific risks of anesthesia. Parsons says he would be troubled by a surgeon obtaining anesthesia consent. That clearly is the role of the anesthesiologist, he says.

"Is the surgeon really appropriate for explaining the risks of anesthesia, a well-recognized subspecialty of medicine?" he asks. "My understanding is that most do it separately, even though the article suggests it is very common for the surgeon to do both. That would not be appropriate in our organization."

Here are some of the study's other findings:

- 28.2% of the forms requested permission to transfuse blood if necessary.
- 86.3% asked permission to dispose of tissue removed in the procedure.
- 95.2% asked for consent to perform other procedures if the surgeon decided they were necessary.
- 99% stated that the patient authorized the procedure.

• Only 50.9% stated that the patient understood the procedure.

• Only 27.1% stated that the patient's questions had been answered.

• 87.4% noted that there was no guarantee of success.

• 60.1% included the name of the individual obtaining the consent.

• Though almost all forms included the patient's signature and date, the physician's signature was required on only 43.2%.

Forms don't educate

The researchers say the findings are disturbing because they suggest that hospitals use informed consent forms just to cover themselves and head off legal liabilities, rather than to truly educate patients about upcoming procedures. They note that only 28% of Americans have attended any college and that 72 million people are marginally or functionally illiterate, putting most of the informed consent forms beyond their level of understanding. Using data on literacy and American reading skills, the researchers estimate that only 3% to 20% of American adults can understand most informed consent forms.

A short consent form isn't necessarily easier to read, Hopper says. One of the briefest forms in the study had only 82 words, but they were difficult words requiring a 12th-grade reading level. Another form contained only 209 words but required at least 19 years of education to understand it. That form consisted of only three sentences — a final 19-word sentence preceded by two whoppers of 99 and 91 words each. Factor in the inevitable stress faced by a surgery patient and the desire to trust the doctor, and it's likely that most patients sign the forms without a true understanding of the information.

Hopper also points out that a complex, difficult-to-read form doesn't necessarily convey more information, even if the patient can read it. Some of the most difficult-to-read forms actually left out a great deal of what the researchers considered important content such as specific risks and alternatives. The better, more readable forms used a lot of blanks where the physician could fill in specific information about the patient's situation, Hopper says. While the content of a form is crucial to its value, the researchers also caution that it's possible to overload patients with information. That often is done in hopes of eliminating all potential liability, he says.

"A consent form that contains every detail of every eventuality would likely be unread, not understood, and self-defeating," he says.

While the study is important in revealing the readability problems of informed consent forms, Parsons says it's important to keep the results in perspective. They don't necessarily reflect the facilities' ability to provide informed consent to patients, he says. The form doesn't represent the entire informed consent process but instead is the final step documenting that the process took place. If you're depending on the form to educate the patient, that's a mistake.

"If you don't read it carefully, the study might [seem to] suggest that the surgeon walks down the hall, hands a form to the patient, asks him to sign, and that's all the patient knows about the procedure," Parsons says. "I don't think that's what's happening in medicine today. There's much more to the process."

"A consent form that contains every detail of every eventuality would likely be unread, not understood, and self-defeating."

Parsons suggests the researchers may have overreached when they concluded that patients are ill-informed about procedures they undergo simply because the informed consent forms seem inadequate when studied as stand-alone items. In reality, the conversations that make up the informed consent *process* usually are documented throughout the progress notes and medical record.

In his own facility, the medical staff have settled on a fairly simple informed consent form with several blanks, which is meant to finalize the conversations that have taken place up to that point. **(For a copy of the form, see *Same-Day Surgery*, September 1998, p. 120.)** Hospital policy requires physicians to take full responsibility for informing their patients. "We do not allow nurses or interns or residents to participate in this dialogue," he says. "They may witness it, but they are not going to be the informant."

Reference

1. Hopper KD, TenHave TR, Tully DA, et al. The readability of currently used surgical / procedure consent forms in the United States. *Surgery* 1998; 123:496-503. ■

ACCREDITATION TIP

Physicians and nurses must be involved

Leaders of same-day surgery programs should be involved in the design and any redesign of their facilities in order to meet the leadership standards from the Joint Commission on Accreditation of Healthcare Organizations, says **Ann Kobs**, sentinel event specialist for the department of standards at the Joint Commission.

"The physicians need input. The nursing staff needs input. Why? Because you're the ones who are going to work there," Kobs says.

Managers know patients' needs and patient flow, which are critical, she says. "It becomes a very different kind of unit that's been designed by the collaborative caregivers than one designed by an architect who's guessing at what you'd like," Kobs says.

Who are the leaders?

According to the Joint Commission, leaders include the chairman of the governing body, the chief of the medical staff, the CEO, the chief of nursing, the director of quality, other elected and appointed leaders in those categories, department heads, and anyone who directs patient care. "We say to all of you who are leaders that you participate in policy decisions, communicate the hospital's vision, mission, values, priorities, and you collaborate to design services," Kobs says.

It's particularly important for nurse leaders and top administrators to be involved in the operation and business of the program, says **Marshall M. Baker**, FACMPE, president of Physician Advisory Services, a Boise, ID-based health care services firm providing transitional management and consultation to physician practices and health systems. Baker has been a surveyor for the Accreditation Association of Ambulatory Health Care since 1978.

For example, nurse leaders and administrators should attend meetings of the governing board when their areas of responsibility are being evaluated, discussed, or debated, he says.

"They don't have to be at the table when the vote is taken, but they certainly should participate in the process," he says. "The governing body should govern, and managers should manage. That should be documented and demonstrated."

And don't forget your physicians, he emphasizes. Physicians should be professionally invested in the same-day surgery program, regardless of whether they are invested financially, Baker says.

> **"Leaders have a responsibility to facilitate regular attendance at their medical staff meetings by all providers who use the facility. And it must be documented."**

"As I walk down the hall and ask a surgeon a question, I don't want the answer, 'I just come here to operate. I don't know what's going on,'" he says. "Leaders have a responsibility to facilitate regular attendance at their medical staff meetings by all providers who use the facility. And it must be documented." **(For tips on getting your physicians to attend meetings, see *Same-Day Surgery*, June 1998, p. 78.)**

Joint Commission leadership standards LD.2 through LD2.7 basically constitute the job description of the leader, Kobs says. "It says you need to have your department integrated with the hospital, coordinate with other departments, implement policies and procedures, recommend sufficient staff, determine the staff competence, and maintain quality control programs," she explains.

As part of ensuring you have competent, qualified staff, expect surveyors to ask to see the dollars budgeted for education, Kobs says.

Another tip: As part of quality control, quit obsessing over the temperature of the refrigerator, she advises. The bottom line is how you know if the refrigerator is the right temperature, Kobs says.

"Do you have to take it every shift? No. Do you have to check it every day? No. But you need to check it with some regularity," she says.

Consider buying a digital clock at a hardware store that will flash if the power goes out, Kobs suggests.

"How simple," she says. "Then you don't have to worry about all the crazy checking." ■

NEWS BRIEF

JCAHO 'hot button' on patient education

Health care systems undergoing a survey by the Oakbrook Terrace, IL-based Joint Commission on Accreditation of Healthcare Organizations must have consistent education standards throughout their organizations, warns **Janette Helm**, MA, RN, CHES. Helm is director of education and training for Johnson Memorial Hospital in Franklin, IN.

Helm, who recently participated in a survey at her institution, says information and materials must be consistent. That policy includes parts of your health care system that are off-site, such as physician practices and rural clinics.

You don't have to have the exact same materials or documentation forms as long as the content is the same, she explains. "They want to know that off-site locations are using the same education standards and guidelines as the main hospital site."

[Editor's note: For additional information, contact: Janette Helm, MA, RN, CHES, Director of Education and Training, 1125 West Jefferson St., P.O. Box 549, Franklin, IN 46131. Phone: (317) 736-3239. Fax: (317) 736-2692. E-mail: jlhelmches@aol.com.] ■

• **Bridging the Centuries through Collaborative Leadership** — Jan. 22-24, Orlando. Sponsored by American Association of Nurse Anesthetists and Association of Operating Room Nurses. For additional information, contact: Association of Operating Room Nurses, Customer Service/Registration, 2170 S. Parker Road, Suite 300, Denver, CO 80231-5711. Telephone: (800) 755-2676 or (303) 751-0337. Fax: (303) 750-3212.

• **ASC Update 1999** — March 4-6, San Diego. Sponsored by the American Association of Ambulatory Surgery Centers (AAASC). For more information, contact: AAASC, 401 N. Michigan Ave., Chicago, IL 60611-4267. Telephone: (800) 237-3768. Fax: (312) 321-5150. E-mail: aaasc@sba.com.

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2. Identify how long patients wait for observation after pain management procedures.
3. List the use for a tissue adhesive approved by the Food and Drug Administration.
4. Identify one demand of the Joint Commission on Accreditation of Healthcare Organizations related to its leadership standards.