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INSIDE

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Study says wrong-patient procedures underreported: JCAHO gets involved

Agency requires compliance with new patient safety goals by Jan. 1

What do the Challenger space shuttle disaster, Chernobyl nuclear reactor explosion, and the Bhopal chemical factory catastrophe have in common with invasive procedures performed on the wrong patients?

They all involve many individuals converging and interacting with system weaknesses, increasing the likelihood that individual errors will do harm, according to a recent study reported in the *Annals of Internal Medicine*.[1] When you throw short stays and growing caseloads of outpatient surgery patients into the mix, the likelihood of errors doing harm increases, some surgery experts say.

Wrong-patient medical errors are underreported, according to the report. And the problem isn't limited to large organizations such as hospitals, says **Richard Croteau**, MD, executive director of strategic initiatives at the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) in Oakbrook Terrace, IL. "A patient who comes in for a procedure interacts with large number of people and systems within an organization, even in a small freestanding surgery center," Croteau says. "There's still a lot of interaction, and lot of opportunity for checks,

Audio conferences tackle critical compliance issues for sharps safety, pain management

Don't run the risk of fees or losing your accreditation

Health care organizations today are challenged by more than just providing quality patient care. Compliance issues can create headaches for facilities that aren't prepared. How well does your facility meet certain regulations? Is your staff properly armed with the most up-to-date information? To help you prepare, American Health Consultants offers two upcoming audio conferences dealing with current, hot-topic compliance issues: pain management and needle safety.

(Continued on page 118)

EXECUTIVE SUMMARY

A recent study says wrong-patient medical errors are underreported. The Joint Commission on Accreditation of Healthcare Organizations has listed patient safety goals, including one on wrong-patient surgery, that must be met by Jan. 1. Sources suggest:

- Have surgeons conduct informed consent in their offices and involve patients as partners.
- Have standardized procedures for identifying patients, and ensure they are followed. Use a verification checklist, and verify with the patient.
- Before starting the procedure, acknowledge out loud the patient, the procedure, and the site. Have discussions, workshops, and case presentations to address communication barriers among staff.
- When it occurs, frankly discuss wrong-patient surgery with the patient and family, and conduct a root-cause analysis.

but there are also lots of opportunities for breakdown in communication."

Anyone from the admitting clerk to the patient can be responsible for wrong-site or wrong-patient surgery, says **Tom Russell**, MD, executive director of the American College of Surgeons in Chicago. Russell recalls one case in which a hospital employee shaved the wrong side of the patient. "That set up a sequence of events that led to wrong-sided surgery," he says. "Ultimately, the surgeon carries on a procedure on the wrong patient, or on the wrong side. There's a chain of events here. That's why it is a system problem."

Carol Beeler, past president of the Alexandria, VA-based Federated Ambulatory Surgery Association, says, "While we believe the ambulatory surgery center industry provides high-quality care, even one wrong-site surgery occurring is one too many. The Federated Ambulatory Surgery Association's goal is that not a single wrong-site surgery occur in our industry, and we will continue our efforts to make that a reality."

The Joint Commission has announced six patient safety goals, with 11 corresponding recommendations, that accredited facilities must meet by Jan. 1, 2003. Of the six announced, one addresses wrong-patient surgery, and another addresses patient identification, which often is cited as a factor in wrong-patient surgery. The goals will be surveyed in all regular and unannounced surveys, and organizations must meet all 11 recommendations or risk a Type 1 recommendation. New national patient safety goals will be issued each year. The patient safety goals were based on the sentinel events that have been tracked since 1995. The Joint Commission has reported 20 incidents on wrong-patient surgery. They resulted in one death, and six patients suffered major permanent loss of function.[2]

In comparison, New York state, which maintains its own mandatory error-reporting system, reports 27 incorrect patient/invasive procedures from April 1998 through December 2001.[3] Eight were surgical procedures. None resulted in death or permanent loss of function. This disparity is one reason that experts suggest the voluntary Joint Commission database isn't complete.

The old system of checks and balances doesn't operate in a system in which patients come in, are processed and operated on, and go home the same day, Russell emphasizes. The current outpatient surgery system is being strained, he says.

"Having been a practitioner for many years myself, I can tell you it's quite a frenetic pace now," Russell says.

While there are no data on changes in the rates of wrong-patient surgery, "any circumstances that make it more likely that doctors and nurses will be relatively unfamiliar with their patients — and therefore less likely to recognize when plans are deviating from a course that makes sense for a particular patient's condition — are likely to contribute to the problem," says **Elise C. Becher**, MD, MA, assistant professor of pediatrics and health policy at Mount Sinai School of Medicine in New York City. Becher is one of the authors of the *Annals* study. These factors aren't likely to be fixed soon, she says. "That is why it is important to focus on improving systems of communication, teamwork, and patient identity verification, where we can make changes and have a real impact."

Consider these specific areas for improvement:

• **Informed consent.** Informed consent is not a piece of paper to be signed, Croteau emphasizes.

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2003 National Patient Safety Goals and Recommendations

Goal 1: Improve the accuracy of patient identification. Recommendations:
- Use at least two patient identifiers (not the patient's room number) whenever taking blood samples or administering medications or blood products.
- Prior to the start of any surgical or invasive procedure, conduct a final verification process, such as a "timeout," to confirm the correct patient, procedure, and site, using active — not passive — communication techniques.

Goal 2: Improve the effectiveness of communication among caregivers. Recommendations:
- Implement a process for taking verbal or phone orders that requires a verification "read-back" of the complete order by the person receiving the order.
- Standardize the abbreviations, acronyms, and symbols used throughout the organization, including a list of abbreviations, acronyms, and symbols *not* to use.

Goal 3: Improve the safety of using high-alert medications. Recommendations:
- Remove concentrated electrolytes (including, but not limited to, potassium chloride, potassium phosphate, sodium chloride > 0.9%) from patient care units.
- Standardize and limit the number of drug concentrations available in the organization.

Goal 4: Eliminate wrong-site, wrong-patient, and wrong-procedure surgery. Recommendations:
- Create and use a preoperative verification process, such as a checklist, to confirm that appropriate documents (e.g., medical records, imaging studies) are available.
- Implement a process to mark the surgical site and involve the patient in the marking process.

Goal 5: Improve the safety of using infusion pumps. Recommendation:
- Ensure free-flow protection on all general-use and patient-controlled analgesia intravenous infusion pumps used in the organization.

Goal 6: Improve the effectiveness of clinical alarm systems. Recommendations:
- Implement regular preventive maintenance and testing of alarm systems.
- Ensure that alarms are activated with appropriate settings and are sufficiently audible with respect to distances and competing noise within the unit.

Source: Joint Commission on Accreditation of Healthcare Organizations, Oakbrook Terrace, IL.

"It's a process that's involved communicating with the patient," he says.

Becher concurs that patients should be partners in the decision-making process. Obtaining the signature on the consent form should not be merely a "rubber stamp, but rather the final step in a truly collaborative endeavor," she says. Informed consent should not be done immediately prior to the procedure, Becher contends.

You can't do an adequate job of informed consent without spending time with the patient, Russell adds. He says the process should be handled in the surgeon's office, where the surgeon can talk to the patients, offer educational material, and even suggest they talk to other patients.

"You can't do it in 10 seconds, or a minute," Russell says. "You have to explain, re-explain, give reading materials, and maybe have another session."

• **Patient identification.** There should be routine, standardized procedures for verifying patient identify, and managers must ensure that the procedures are adhered to, the *Annals* authors say. Conduct audits periodically to ensure this is happening, they suggest. "Add birth dates or medical record numbers to patients' names in the scheduling system. Have a strict protocol on all units to ensure that only correctly identified patients with written orders in their charts are permitted to leave their floors for procedures."

Engage the patient in identification, or engage the parent if you're operating on a child, Croteau suggests.

Donald J. Palmisano, MD, JD, a surgeon from New Orleans and a member of the Board of Commissioners for the Joint Commission, said he always visits the patient before the procedure. "I do it for two reasons: I want to make sure it's my patient, and second, I want the patient to have the comfort of knowing that I am there before [going] to sleep," he said.[4]

Use a verification checklist to ensure you have all of the documentation, that the documents are consistent with each other and for that patient, and that they all include the same procedure and site, Croteau advises.

• **Communication and teamwork.** Wrong-patient surgery can occur when there are last-minute changes to room assignments in the OR or changes in scheduling, he says. Recently, one surgeon had three patients scheduled, and the second one was canceled by anesthesia. "The

SOURCES

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surgeon went in expecting to do the second case, but the third case was moved up," Croteau says. He was operating on the third patient, but was performing the second procedure, he says.

Wrong-patient surgery almost always has a breakdown in communication among the staff, Croteau says. "In that particular example, there was a breakdown in communication between anesthesia staff and the surgeon."

Before starting the operation, just before the incision is made, pause briefly to check with everyone involved in that operation and acknowledge aloud the patient, the procedure, and the site, he advises. **(See Joint Commission patient safety goals and recommendations for achieving them, p. 111.)**

The problems hindering effective communication among staffs must be addressed, experts say.

"One place to start is to have clinical leaders [physicians and nurses] openly discuss problems of poor communication and teamwork with staff on a regular basis," Becher says.

"Regular workshops or case presentations can facilitate such discussions," she adds.

• **Full and immediate disclosure when an event happens.** Wrong-patient surgery absolutely should be frankly discussed with the patient and family, with no effort to cover it up, Russell advises.

Report such events to the Joint Commission. Always conduct a root-cause analysis to discover the cause, he suggests. "You must change the system to prevent it happening again," Russell says.

References

1. Chassin MR, Becher, EC. *Ann Int Med* 2002; 136: 826-833.
2. Forstneger M. Personal communication, July 31, 2002.
3. Heigel F. Personal communication, Feb. 14, 2002.
4. Joint Commission on Accreditation of Healthcare Organizations. *Teleconference Transcripts: Wrong Site Surgery and Sentinel Event Alert 24 — A Follow-Up Review of Wrong Site Surgery*. Dec. 5, 2001. Accessed at jcaho.org. ■

Possible link of cochlear implant, meningitis

FDA says at least 25 cases discovered worldwide

Meningitis long has been believed to be a rare occurrence with cochlear implants, with no deaths resulting.

However, that belief was shaken in July when the Food and Drug Administration (FDA) issued a web notification, *Cochlear Implant Recipients may be at Greater Risk for Meningitis.* **(See notification, enclosed in this issue.)**

The FDA's Center for Devices and Radiological Health has developed the new form of notification, web notification, to inform the health care community about safety issues related to medical devices.

Web notifications are used when the available information is limited, changing, and/or the agency may not be able to make specific recommendations but would like to provide the information that it has to the health care community.

The FDA reports that at least 25 cases of meningitis have been diagnosed worldwide in children and adults, from age 21 months to 63 years old, who have undergone cochlear implantation for severe to profound deafness. A total of nine deaths have been reported. However, the number of cases may be underreported. A survey being conducted

EXECUTIVE SUMMARY

The Food and Drug Administration (FDA) has notified providers that cochlear implant recipients may be at greater risk for meningitis. The agency reports 25 cases, including nine deaths, in implant patients worldwide.

- Some providers are sending letters to all cochlear implant patients that advise them to be vaccinated against meningitis.
- Urge cochlear implant patients to contact their family physicians with the FDA notification, and consider notifying pediatricians of new cochlear implant patients.

Consider these steps with implant patients

In light of the web notification from the Food and Drug Administration (FDA) regarding a possible connection between meningitis and cochlear implants, consider the following suggestions:

• **Inform patients.** "We sent a mailing to all patients and parents of pediatric patients telling them we're aware of problem, telling them it's infrequent," says **Noel L. Cohen**, MD, Mendic Foundation professor and chairman in the Department of Otolaryngology at New York University School of Medicine in New York City. The letter from Cohen included this information:

1. All patients with cochlear implants are advised to be vaccinated against meningitis. Cohen says this is particularly important in the following groups:

A. All children younger than 5 should receive the pneumococcal conjugate vaccine (Prevnar, Wyeth Pharmaceuticals, Philadelphia). This already is a recommendation of the American Academy of Pediatricians.

B. Implanted patients with abnormal inner ears (e.g. Mondini's deformity, common cavity, large vestibular aqueduct), those who have received a two-component electrode, and those whose immune status is inadequate should be appropriately vaccinated depending on age, by the pediatrician, family physician, or internist.

2. All ear infections in implanted patients should be immediately and vigorously treated by their physician, in consultation with their implant surgeon.

3. No additional surgery is required.

In addition, Cohen's facility has scheduled a forum on the evening of Sept. 18 to inform patients and answer questions.

Consider offering additional sources of information to patients, suggests **Nancy M. Young**, MD, head of the Section of Otology at Children's Memorial Hospital in Chicago. Young sent a letter to all her patients that included a list of web sites that she obtained from the web site for Advanced Bionics Corp. in Sylmar, CA. (Web: www.bionicear.com. Click on "Information on Meningitis and Cochlear Implantation.") Also, Young is drafting a letter for new patients and is going to send a letter that discusses the issue in detail to new patients' pediatricians.

• **Urge patients to share copies of the notification with their family physician.** One of the concerns with the possible connection between cochlear implants and meningitis is that when people have a fever or cold, they go to a family physician, says **Peg Williams**, PhD, executive director of the Cochlear Implant Association in Washington, DC.

"They may not think to call their ear, nose, and throat doctor," Williams says. For that reason, cochlear implant centers may want to ask patients to provide a copy of the FDA notification to their family physicians, she advises. ■

by two physicians who are working with the FDA has uncovered eight additional cases. That survey is being conducted by **Noel L. Cohen**, MD, Mendic Foundation professor and chairman in the Department of Otolaryngology at New York University School of Medicine in New York City, and **Thomas J. Balkany**, MD, chairman of the Department of Otolaryngology, chief, of the Division of Otology, Hotchkiss Professor at University of Miami (FL) School of Medicine.

Two of the three companies that manufacture cochlear implants have reported cases of bacterial meningitis in patients who have implants.

Cochlear Americas in Englewood, CO, has reported four cases, none of which occurred in the last two years. Cochlear manufactures the Nucleus 24 Contour, and it previously manufactured the Nucleus 24 and Nucleus 22. The physicians' survey has found four additional cases involving Cochlear, but none within the last two years, Cohen says.

Anne Cosgriff, MD, medical officer at Cochlear, says, "At this point, we feel pretty confident we've scoured all the clinics, and the incidences we've calculated to this day of post-op meningitis are no higher than incidences of meningitis in general population with or without cochlear implants."

Advanced Bionics Corp. in Sylmar, CA, reported four cases, all of which occurred in the last two years. Advanced Bionics manufactures Clarion implants. The physicians' survey has uncovered four additional cases involving Advanced Bionics implants, three of which occurred in the last two years.

While no one is certain why there have been additional cases in the last two years, higher risk groups, such as young children, the elderly, and multiply handicapped, are now being implanted, according to Advanced Bionics. Also, the overall number of implants has significantly increased in the last couple of years, particularly in the at-risk age groups, the company says.

Med-El in Durham, NC, has no reported cases, according to a company spokesperson. Med-El manufactures Combi40+ Implants.

Cerebrospinal fluid culture results, which are available in 11 of the 25 worldwide cases, indicate that seven have grown *Pneumococcus* and four have grown *Diplococci* (most likely *Pneumococcus*),

SOURCES

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For manufacturers of cochlear implants, contact:

- **Advanced Bionics Corp.**, 12740 San Fernando Road, Sylmar, CA 91342. Telephone: (866) 566-8913 — Voice or Relay. Fax: (818) 362-5069. E-mail: info@advancedbionics.com. Web: www.bionicear.com.
- **Cochlear Americas**, 400 Inverness Drive S., Suite 400, Englewood, CO 80112. Telephone: (800) 523-5798 or (303) 790-9010. Fax: (303) 792-9025. Web: www.cochlear.com.
- **MED-EL Corp.**, 2222 E. NC Highway 54, Suite B-180, Durham, NC 27713. Telephone: (919) 572-2222. Fax: (919) 484-9229. E-mail: implants@medelus.com. Web: www.medel.com.

according to the FDA. Of the five cases in which a vaccination history against *Pneumococcus* was available, none had been vaccinated, the agency reports. One particular concern with meningitis is that the symptoms can appear anytime from fewer than 24 hours after an implant to more than five years later.

"You might not relate the symptoms to the device" because of the amount of time that has passed, says **Nancy M. Young**, MD, head of the Section of Otology at Children's Memorial Hospital in Chicago.

Early symptoms of meningitis include fever, irritability, lethargy, and loss of appetite in infants and young children. Older children and adults also may have a headache, stiff neck, nausea and vomiting, and confusion or alteration in consciousness.

Patients younger than 2 and the elderly are most vulnerable to meningitis, the FDA reports.

Cohen raises several issues with the notification. "What concerns me about the [notification] is, I don't know where they got numbers from, but the [notification] is very worrisome, and it's inaccurate in that it doesn't at all put things into context," he says.

He uses the 25 cases as an example. "I don't know where they got that from," he says. "They switch back and forth with American data and what they say are worldwide data."

Peg Williams, PhD, executive director of the Cochlear Implant Association in Washington, DC, estimates that worldwide, there have been about 33,000 implants.

Also, the notification implies that the problem is industrywide, which Cohen says is "open to question."

Another issue is that of the nine deaths, only two are in the United States, Young points out. Only limited information is available for the European cases, she says. "We don't know if they really were meningitis or what type of meningitis," Young says.

Interestingly, thus far, none of the U.S. cases have been in children who have had the vaccine against pneumococcal meningitis, Young says.

According to the FDA, there are predisposing factors for meningitis, which may include congenital abnormalities of the inner ear, otitis media, immunodeficiency status, prior history of meningitis, or surgical technique.

While the FDA did not respond to requests for interviews, the reference to "surgical technique" may refer to protecting the inner ear following implant by packing some of the patient's tissue around the electrode to prevent leaking of the fluid out of the inner ear and introducing infection into the cochlea, Cohen says.

Also, some devices can cause trauma to the cochlear if they are completely inserted, he says. These "techniques" could cause recipients to be more prone to meningitis, he says.

Improper sterile technique also could be a problem in some cases, Young and Cosgriff state.

The FDA is continuing to investigate this issue and gather new information. The notification (www.fda.gov/cdrh/safety/cochlear.html) will be updated as additional information becomes available. While data are being collected, providers are urged to exercise caution.

"We don't have enough data to say for sure that there's an increased risk, and to what degree," Young says. "We don't know if there's any. But we have to assume there could be a problem, and we have to react, for the safety of our patients." ■

Same-Day Surgery Manager

Surgery volume is booming — Is yours?

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

The volume of surgery, inpatient and outpatient, is booming across the United States. Centers that we developed just three and four years ago already are at capacity, and they are chopping into the adjacent space for more operating rooms.

The fastest growing segment of our company is not what you might think. It is hospitals building ambulatory surgery centers (ASCs) as an extension of their surgical services departments to accommodate the glut of new patients. Don't you just love the job security that brings to us all? However, it is a double-edged sword. Many surgeons are leaving the hospital environment, and it's not necessarily because the hospital is inefficient (a frequent cry). Now they are leaving because they cannot get their cases scheduled in a "reasonable time." Many of our hospital clients are citing weeks out for elective procedures, which infuriates patients and surgeons alike. You really have to be sympathetic to the institutions with this new wrinkle.

We have spent a lot of time working with a couple of dozen hospital clients on this issue alone. While there are some relatively quick fixes for some, the problem is more complex that it might seem. I want to share some solutions that might help you if you are in the predicament that your peers are in.

As we have noted in previous columns, sometimes building new space is not the answer. First, it takes years to develop a new building or surgical wing, and for many, the problem is reaching a critical stage today. Building new facilities that are properly designed (which is another column topic) usually is a long-term solution. You may not have time for that.

First, obtain input from all your staff. Find out what the problems are, and prioritize them. It is rarely a case of too many patients and not enough operating rooms. Identify bottlenecks in your system. If you are losing 15 minutes per patient because of a bottleneck somewhere, and you are performing 8,000 cases per year, that adds up quickly. Assuming your average surgical minutes per case are 60, freeing up that bottleneck could allow you to perform an additional 2,000 cases per year! You would be surprised what bottlenecks we discover.

Expand your hours of operation. Most hospitals only operate seven to eight hours per day. Expanding your surgical hours by one hour per operating room can add another couple of thousand cases. Pay staff to work through their lunch hour. I know, you all hate me, but eating at noon everyday is not a requirement for life. Some staff will say "No way!" However, others will be delighted to pick up extra money to delay lunch or be willing to leave early in lieu of a lunch break.

Pay staff *NOT* to take vacation days. This used to be a bigger option than it is now. I remember many times getting vacation pay and regular pay by working my vacation time. It's not as if I was going anywhere special anyway. Again, I will get lots of hate mail on this, but it is true that not everyone needs to use all their vacation time going away.

Strongly consider Saturday morning elective cases. For hospitals that do it, the staff enjoy it. Avoid making it mandatory. Do not ignore the fact that surgery is going to continue to increase this country, and these are only bandages I am talking about. You still need a long-term plan. The reason? Once you have done all of the above, you really are backed into a corner if you have no other alternatives for the long-term fix.

Your greatest challenge in the implementation of the above will not come from your staff; it will be from anesthesia. Across the country, anesthesia is being stretched thinner and thinner. The fact is that in many areas, anesthetists are in short supply, and most are not going to be willing to expand into their leisure time to accommodate your surgeons. You have to work with them and include them in your solution planning. Make sure that you do not come up with a plan and present it to the surgical staff before discussing it with anesthesia. I made that mistake once years ago. It wasn't pretty. I am still bleeding.

(If you have suggestions for addressing bottlenecks, please contact *Earnhart at 5905 Tree Shadow Place, Suite 1200, Dallas, TX 75252. E-mail: searnhart@*

earnhart.com. Web: www.earnhart.com/benchmarks.htm Earnhart & Associates is an ambulatory surgery consulting firm specializing in all aspects of surgery center development and management.) ■

Is knee arthroscopy helpful for osteoarthritis?

A study just published in the *New England Journal of Medicine* found that arthroscopy was no more effective than placebo surgery for treating osteoarthritis of the knee.[1] The study assigned 180 patients to receive arthroscopic debridement, arthroscopic lavage, or placebo surgery. All of the groups showed improvement, and neither of the surgical groups reported less pain or better function than the placebo group.

The study didn't examine knee arthroscopy for acute injury, such as partial tear of the ligaments.

"We're talking about old people with 'wear-and-tear' arthritis," says **Nelda P. Wray**, MD, MPH, chief of general medicine at the Houston Veteran Affairs Medical Center and one of the authors of the study. Painful knees are one of the most common reasons patients see orthopedists for osteoarthritis of the knees, she says.

Arthroscopic surgery is performed approximately 200,000 times annually on osteoarthritic knees. The results of the study are apparent, Wray says. "We're saying, people who have had the procedure who are better, are better solely because of the placebo effect." Which raises a significant question, she says: Should we continue to do this procedure if it only has placebo effect? Her answer is clear. An emphatic no.

EXECUTIVE SUMMARY

A *New England Journal of Medicine* study of 180 patients with osteoarthritis of the knee found that patients who received arthroscopic surgery fared no better than those with placebo surgery did. Approximately 200,000 of these procedure are performed annually.

- The study results don't apply to patients with acute injury.
- Patients with mild symptoms, misalignment, and mechanical symptoms fared no better with surgery.
- It's uncertain how insurers will react, but Hartford, CT-based Aetna plans to review the results.

Some media have picked up on the report and are labeling the procedure "sham surgery," says **John Bergfeld**, MD, director of the Cleveland Clinic Sports Health. "The surgery itself is not a sham," he maintains. "If surgeons didn't present the possibilities of cure faithfully to the patient, that would be a sham." One strength of the study is that it points out that this surgery is not going to completely relive the pain of arthritis, Bergfeld says. "I say, 'It can be improved, but not cured.'"

One issue that remains is whether the study's finding would be true for women, because the current study was conducted at a Veteran's Affairs facility and included mostly men. Also, can these results of such a small study be applied to the entire population?

Wray contends that they can. She says that the difference between the placebo patients and the surgery patients was so exceedingly small, that even if more and more patients had been entered in the study, there would not have been a benefit found in the surgical patients.

Wray acknowledges that some surgeons are likely to argue with the results. For example, some may say that the procedure is better if patients have mild arthritis. "We've done a subgroups analysis, and our results don't vary by degree of arthritis," she says.

Some surgeons may say that patients who have worse alignment, such as those who have bowed knees or knock-knees, won't do as well with this procedure. "We did a subgroup analysis, and alignment did not determine results," Wray says.

Most surgeons tell potential patients that they can improve their knees, particularly if they have mechanical symptoms, Bergfeld says. "I tell them there's a real possibility that they could get worse [with or without the surgery]," he says. "It's not realistic to tell them that."

Wray says that 176 of the 180 patients in the study had mechanical symptoms, such as locking, popping, catching, or giving way of the knee, and they did no better with surgery. "Our statement is: Our study provides strong evidence in the population of patients who present for this condition, with osteoarthritis of the knee, when it's gradually gotten worse and there's no trauma, these procedures provide no benefit," she says.

Wray isn't going as far as saying that no patients will do well with surgery. But her position is that if the procedure continues to be done, "there should be a placebo-controlled trial."

This is the first such placebo-controlled study on arthroscopy for osteoarthritis, so it isn't certain

SOURCE

For more information on the knee study, contact:
- **Nelda P. Wray**, MD, MPH, Chief of General Medicine, Houston Veteran Affairs Medical Center. E-mail: nwray@bcm.tmc.edu.

how surgeons or insurers will respond. However, Hartford, CT-based Aetna already has indicated in media reports that it plans to have its medical directors review the information.

Wray recommends that the insurers form an expert panel to decide the future of the surgery. "I would hope we would have some policy discussion about how we should discuss surgical procedures before they are allowed to disseminate widely," she says.

Reference

1. Moseley JB, O'Malley K, Petersen NJ, et al. A controlled trial of arthroscopic surgery for osteoarthritis of the knee. *N Engl J Med* 2002; 347:81-88. ■

Specific risks for pain management practices

(Editor's note: In this second part of a two-part series on anesthesia coding billing problems, we discuss pain management billing risks. In last month's issue, we discussed steps to ensure you avoid fraudulent billing.)

While there are several areas within Medicare rules for anesthesia billing that are open to interpretation, treatment of pain management patients often presents the greatest risk for billing errors, says **Karin Bierstein**, JD, assistant director of governmental affairs for the Park Ridge, IL-based American Society of Anesthesiologists.

One common mistake is billing for medical direction at the same time a procedure, such as a nerve block, is performed personally by the anesthesiologist, she says.

"The only times anesthesiologists can bill for services they provide at the same time they bill for medical direction are explained in the *Medicare Carrier Manual*," Bierstein points out.

These six activities include:

- receiving patients entering the operating suite for the next surgery;
- checking or discharging patients in the recovery room;
- handling scheduling matters;
- addressing an emergency of short duration in the immediate area;
- administering a labor epidural;
- periodically monitoring an obstetrics patient.

Know the proper coding

Improper use of evaluation and management codes in billing also is another area in which physicians err, Bierstein says.

"An anesthesiologist may consider it an insult to their professionalism to say that they conduct less than a comprehensive evaluation on any patient, but when billing, there are definitions for a comprehensive evaluation," she explains.

It's important to understand the different levels of office visits and the appropriate use of codes for them, she says. *(Editor's note: To access a list of the varying levels of service for evaluation and management codes typically used in a pain medicine practice, go to www.same-daysurgery.com. Click on "toolbox." The tool is listed under "anesthesia." You'll need your subscriber number from your mailing label, because it is your user name. Your password is your subscriber number plus* sds.)

You also cannot bill evaluation and management codes for established patients when a procedure is performed, says Bierstein.

A history and physical for a scheduled procedure does not normally qualify for a separate billing charge, she explains.

Anesthesiologists who perform their pain management procedures in a hospital or surgery center setting cannot bill as a "freestanding office," Bierstein says.

Even if the physician has an office in the hospital or surgery center, if the anesthesiologist is not paying for the supplies, drugs, and overhead costs related to the procedure, the physician cannot claim the facility fee, she says. It can be claimed only by the hospital or surgery center, Bierstein says.

Another risky area for pain management treatment is failure to document the surgeon's request for acute postoperative pain management, she adds.

Routine postoperative pain control already is included in the surgeon's global fee, so the anesthesiologist must document that the surgeon transferred care of the patient for the purpose of pain management, she says. ■

(Continued from cover)

The first hurdle to overcome in developing a pain management strategy is the misconception that effective pain management is not a problem within your facility or does not need to be a high priority. The audio conference **Complying with JCAHO Pain Management Standards: Is Your Facility at Risk?** is scheduled for Oct. 8, from 2:30-3:30 p.m., ET. Conference speakers Patrice L. Spath, BA, RHIT, and Michelle H. Pelling, MBA, RN, will teach participants how to:

- Comply with the new Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards relating to pain medication range orders and titration.
- Integrate the Joint Commission's "Speak Up" campaign into your patient education initiatives. The groundbreaking program encourages patients to become active, involved, and informed participants on the health care team.
- Develop a performance measurement system to evaluate the effectiveness of pain management and continually monitor and improve outcomes.
- Avoid documentation deficiencies and staff complacency that can derail your pain management program.

"Hospitals must have a systemwide standard of care for pain management that will reduce patient suffering from preventable pain," Spath says. "Failure to meet this standard of care can result in a Type I recommendation from JCAHO. But more important, inadequate pain management will undermine patients' confidence in the quality of care provided by your health care facility." A Type I recommendation would require your health care organization to resolve insufficient or unsatisfactory pain management standards compliance in a specified amount of time to maintain your accreditation.

Federal regulators are turning up the heat on needle safety compliance, increasing inspections and issuing more than a million dollars in fines in less than a year. The Occupational Safety and Health Administration (OSHA) dramatically has stepped up enforcement of needle safety provisions. Between July 2001 and May 2002, OSHA issued 1,876 citations for those who still haven't gotten the message that needle safety is now the law of the land. These facilities were slapped with $1.3 million in fines, and only about 20% of the inspections were prompted by an employee complaint.

With random visits a possibility, you need to know the latest regulatory information to ensure you can pass muster with OSHA while protecting your employees and patients. **Sharps Safety Compliance: How to Avoid OSHA Citations and Costly Fines** is slated for Wednesday, Oct. 23, 2:30-3:30 p.m., ET. Our program will feature practical handouts and guidance along with the answers to some of your most pressing questions. OSHA expert Katherine West, BSN, MSEd, CIC, veteran infection control consultant at Infection Control/Emerging Concepts in Manassas, VA, will review the latest OSHA requirements and give you the inside tips necessary to pass any future inspection with flying colors. Bruce E. Cunha, RN, MS, COHN, manager of health and safety at Marshfield (WI) Clinic, has 24 years working experience on the front lines of occupational health and safety. He will provide vital insight on what practitioners can do to ensure safety for clinical procedures for which there are currently no safety needles available.

Educational programs for hospital staff at all levels can ensure that sound pain management and sharps safety standards are understood and put into practice. To sign up for either conference, call (800) 688-2421 and mention effort code **62751** for pain management and **62761** for sharps safety. The facility fee for each program is $299, which includes free CE for pain management and free CE or CME for sharps safety. Also included with each conference package are program handouts and additional reading, a convenient 48-hour replay, and a conference CD. If you sign up for both audio conferences, your cost is only $500. That's a $100 discount. Don't miss out. Educate your entire facility for one low fee. ■

On-line form extends deadline for HIPAA

Same-day surgery programs and other providers can go on-line to obtain a form for automatic extension of the deadline to comply with the Health Insurance Portability and Accountability Act (HIPAA) of 1996.

Providers originally were required to file a compliance plan by Oct. 16, 2002, but the deadline has been changed to Oct. 16, 2003, if the provider seeks an extension.

To obtain the form, go to the CMS web site at www.cms.hhs.gov. Under "Programs," click on "HIPAA." Then click on "HIPAA Administrative Simplification." Then click on "Electronic Health Care Transactions and Code Sets Standards Model Compliance Plan." According to users, the on-line form has "drop-downs" and is easy to use.

You will be provided with an instant confirmation number that proves you have filed an extension before the deadline. The confirmation is not available by mail. ■

Clinical trials harmed by lack of informed consent

The mention of clinical trials often triggers a silence between physician and patient, usually because neither one knows much about the subject. Nearly 80% of physicians admit they would like to know more about clinical trials so they can help their patients make an informed decision before volunteering to participate.

"Most subjects enrolled in clinical studies have a meager understanding of what they have gotten into," says **Alan Sugar**, MD, chairman of the New England Institutional Review Board and professor of medicine at Boston University School of Medicine.

"Informed consent has largely focused around the signed form and has not practically become the continuous process that it needs to be. As a result, a subject's misunderstandings largely go unchallenged."

Ethical and necessary

Properly informing patients is not only ethically necessary, say clinical trials experts, but it also ensures better trials and data. Last year, more than 17 million people thought seriously about participating, but only a few million actually completed their trials. And even among them, many gave their consent without a thorough knowledge of the facts.

"There's a simple ethical mandate that you don't ordinarily do dangerous things to people without their knowledge and consent," says **Dale E. Hammerschmidt**, MD, FACP, associate professor of medicine and director of Education in Human Subjects' Protection for the University of Minnesota Medical School in Minneapolis.

"From a more pragmatic perspective, a well-informed subject is likely to cooperate better with the trial and is more likely to report potential problems," Hammerschmidt says. "The quality of the data and the safety of the trial are both enhanced when the subjects really know what's going on."

Indeed, patients can be so daunted by questions and lack of information that they simply decide not to volunteer.

A new resource, written for doctors and clinical trial participants, can help answer some of these tough questions.

Boston-based CenterWatch, the leading publisher of clinical trial news and information, now offers *Informed Consent*, a consumer's guide to the risks and benefits of volunteering for clinical trials. The book is a practical guide through the confusing world that patients perceive clinical trials to be.

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Subscription rates: U.S.A., one year (12 issues), $499. Outside U.S.A., add $30 per year, total prepaid in U.S. funds. Two to nine additional copies, $399 per year; 10 to 20 additional copies, $299 per year; for more than 20, call (800) 688-2421. Missing issues will be fulfilled by customer service free of charge when contacted within one month of the missing issue date. **Back issues**, when available, are $83 each. (GST registration number R128870672.)

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Editorial Questions

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

Informed Consent is a step-by-step guide that begins with a history of the clinical trials industry, and it explores the drug development process and how a new drug makes its way to the marketplace.

The book goes into detail about why people decide to participate, how to find clinical trials, how to research clinical trials and evaluate their risks, how to ensure proper informed consent, who the vulnerable populations are, and what to do when things go wrong.

The cost is $16.95, and it can be ordered from CenterWatch at (800) 765-9647 or by faxing your request to (617) 856-5901.

Informed Consent also can be ordered through these web sites: centerwatch.com, Amazon.com, and barnesandnoble.com. ■

CE/CME *questions*

Save your monthly issues with the CE/ CME questions in order to take the two semester tests in June and December. A Scantron form will be inserted in those issues, but the questions will not be repeated.

- Identify the deadline for meeting six patient safety goals from the Joint Commission on Accreditation of Healthcare Organizations.
- Discuss the time period in which symptoms of meningitis can appear after a cochlear implant.
- List which knee arthroscopy patients in a *New England Journal of Medicine* study fared no better than those with placebo surgery.
- Identify the number of patient identifiers recommended by the Joint Commission in 2003 National Patient Safety Goals and Recommendations.

9. What is the deadline for meeting six patient safety goals from the Joint Commission on Accreditation of Healthcare Organizations?
   A. Jan. 1, 2003
   B. June 1, 2003
   C. Jan. 1, 2004
   D. June 1, 2004
   E. none of the above

10. In what time period can symptoms of meningitis appear after a cochlear implant?
   A. within 24 hours
   B. within 7-10 days
   C. within 30-60 days
   D. within 90 days
   E. Anytime from fewer than 24 hours after an implant to more than five years later

11. A *New England Journal of Medicine* study found that ____ patients who received knee arthroscopic surgery fared no better than those with placebo surgery did.
   A. osteoarthritis
   B. traumatic injury
   C. osteoarthritis and traumatic injury

12. According to new patient safety goals and recommendations from the Joint Commission, how many patient identifiers should be used whenever taking blood samples or administering medications or blood products?
   A. one (not including the patient's room number)
   B. two (not including the patient's room number)
   C. three (not including the patient's room number)
   D. four (not including the patient's room number)

FDA Public Health Web Notification: Cochlear Implant Recipients May Be at Greater Risk for Meningitis

July 24, 2002

The FDA has become aware of a possible association between cochlear implants and the occurrence of bacterial meningitis. At least 25 cases of meningitis have been diagnosed worldwide in children and adults ranging in age from 21 months to 63 years who have undergone cochlear implantation for severe to profound deafness. A total of nine known deaths resulted from these cases. At this time, two out of three companies have reported cases of bacterial meningitis in patients who have been implanted. FDA is following up with all the manufacturers of cochlear implants. Surveys of cochlear implant centers currently under way suggest there are additional, unreported cases of meningitis in the cochlear implant population.

Cerebrospinal fluid culture results are available in 11 cases. Seven have grown *Pneumococcus,* and four have grown *Diplococci* (most likely *Pneumococcus*). The vaccination history against *Pneumococcus* was available in five cases and none had been vaccinated. The onset of meningitis symptoms ranged from less than 24 hours to greater than five years from time of implant.

What are cochlear implants?

Cochlear implants are devices containing electrodes which are positioned in the cochlea (inner ear) to activate auditory nerve fibers allowing for transmission of sound signals to the brain. Approximately 60,000 implantations have been performed worldwide to date.

Meningitis

Meningitis is an infection of the lining of the surface of the brain. Early symptoms of meningitis include fever, irritability, lethargy, and loss of appetite in infants and young children. Older children and adults also may manifest headache, stiff neck, nausea and vomiting, and confusion or alteration in consciousness. Physicians are encouraged to consider a diagnosis of meningitis in cochlear implant patients when such symptoms exist and to begin appropriate diagnosis and treatment as soon as possible. The younger patient population (< 2 years) and the elderly are most vulnerable to meningitis.

Predisposition to meningitis

A small percentage of deaf patients may have congenital abnormalities of the inner ear which predispose them to meningitis even prior to implantation. Other predisposing factors may include otitis media, immunodeficiency status, prior history of meningitis, or surgical technique. The cochlear implant, because it is a foreign body, may act as a nidus for infection when patients have bacterial illnesses.

Cochlear implants and otitis media

In some of the reported cases of meningitis in cochlear implant recipients, patients may have had overt or subclinical otitis media prior to surgery or before the meningitis developed. Physicians are encouraged to consider prophylactic antibiotic treatment prior to implantation, as appropriate, and to diagnose and treat otitis media promptly in patients with cochlear implants.

Cochlear implants and vaccination

Cochlear implant candidates, as well as those already implanted, may benefit from vaccinations against organisms that commonly cause bacterial meningitis, particularly *Streptococcus pneumoniae* and *Haemophilus influenzae*. The immunization status should be ascertained for all candidates for cochlear implants prior to surgery as well as for those with an existing implant.

- *Haemophilus influenzae* conjugate vaccines are recommended by the Advisory Committee on Immunization Practices (ACIP) for all children up to age 5.
- Heptavalent pneumococcal conjugate vaccine (Prevnar) is indicated for use in infants and toddlers, and is recommended by the ACIP for all children younger than age 2, and for children up to age 5 who are at high risk of invasive pneumococcal infections.
- The 23-valent pneumococcal polysaccharide vaccines (Pnu-Imune23 and Pneumovax23) are recommended for children older than age 2, adolescents, and adults who are at high risk of invasive pneumococcal disease.
- For children 2 years to 5 years of age who are at high risk of invasive pneumococcal infections, ACIP recommends use of pneumococcal conjugate vaccine followed at least two months later by 23-valent pneumococcal polysaccharide vaccine, in order to provide protection against a broader range of serotypes, although supporting data are limited.[1] See individual product labeling for information on dosing and scheduling of the vaccines.

For additional information regarding immunizations refer to the National Vaccine Program Office of the Centers for Disease Control and Prevention (http://www.cdc.gov/od/nvpo/).

Reporting cases of meningitis in cochlear implant recipients

We encourage you to report cases of meningitis in cochlear implant recipients. You can report these directly to the device manufacturer or you can report them to MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch one of four ways: on-line at http://www.accessdata.fda.gov/scripts/medwatch/; by telephone at (800) FDA-1088; by fax at (800) FDA-0178; or by mail to MedWatch, Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20857.

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Additionally, a voice mail message may be left at (301) 594-0650, and your call will be returned as soon as possible.

Reference

1. *Preventing Pneumococcal Disease Among Infants and Young Children.* Recommendations of the Advisory Committee on Immunization Practices (ACIP) Oct. 6, 2000; 9(RR09):1-38.