



Same-Day Surgery®

Covering Hospitals, Surgery Centers, and Offices for More than 35 Years

April 2013: Vol. 37, No. 4
Pages 37-48

IN THIS ISSUE

- Advice on how to handle aging surgeons. cover
- Chronically infected surgeon transmits HBV to as many as 8 patients 41
- Should you be concerned about off-label use of devices? 43
- **Same-Day Surgery Manager:** Are your policies and procedures antiquated? . . . 44
- Symptoms that should prompt colorectal patients to call the surgeon 46

Enclosed in this issue:

- Same-Day Surgery Accreditation Update: How to avoid adverse events; AAAHC standards updated

Financial Disclosure:

Executive Editor **Joy Dickinson**, Board Member and Nurse Planner **Kay Ball**, and Board Member and Columnist **Stephen W. Earnhart** report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study. **Mark Mayo**, Consulting Editor, reports that he is director of ambulatory services, Ambulatory Surgical Care Facility, Aurora, IL. **Stephen Punzak**, MD, physician reviewer, discloses that he is CEO, founder, and stockholder with Medical Web Technologies.

As surgeons age, are they putting your program at risk?

Leaders offer advice on how to handle this sensitive issue

By Joy Daughtery Dickinson, Executive Editor

An 82-year-old surgeon had a career spanning 50 years in a large, prestigious suburban hospital and had an excellent reputation. Over the previous two years his surgical complication rate, especially the length of time of procedures and the infection rate, began to climb and was greater than that of his colleagues. His colleagues volunteered more often to “assist” him with surgery and help him with difficult cases.

His problems culminated one weekend when he left on vacation with several seriously ill postoperative patients in the hospital, one of whom subsequently died. He did not sign out to a covering surgeon, and no one in his department was aware of his plans for vacation. When he returned, he was horrified, and he admitted that he had forgotten to obtain coverage during his vacation.

The surgeon was referred to a physician assessment and clinical education (PACE) program. These programs perform intensive competency evaluations of doctors referred by state medical boards or healthcare facilities. The PACE program determined he had a markedly poor performance on the screening exam for cognitive functioning, which triggered a neuropsychological examination that revealed major deficits in memory; the ability to assimilate new information; executive function, including the ability to deal with novel or unexpected situations; and visuospatial processing. When presented with the results, the sur-

EXECUTIVE SUMMARY

Be ready to address the quality of care given by aging surgeons.

- A policy should address when surgeons will be tested, who will test, and what tests will be done.
- Elderly surgeons can consider limiting their practice, having other surgeons assist, or moving into mentoring roles when they feel their skills or cognitive abilities are declining.
- Physicians can be evaluated by an independent family medicine physician or a Physician Assessment and Clinical Education (PACE) program.



NOW AVAILABLE ONLINE! Go to www.same-daysurgery.com
Call (800) 688-2421 for details.

Follow us on Twitter @SameDaySurgery

geon voluntarily surrendered his medical license. The real-life scenario was shared by **William A. Norcross, MD**, clinical professor of family medicine and director of the University of California, San Diego (UCSD) PACE Education Program, in the Department of Family and Preventive Medicine, UCSD School of Medicine.

“Same-day surgery managers should respond to older physicians with impairment in the same manner they should respond to physicians who are impaired for any other reason: substance abuse, general incom-

petence, etc.,” Norcross says. “The same-day surgery manager should be guided by the following concern: What is best for the patient?” Norcross evaluates 100-150 physicians annually. He estimates, based on accepted prevalence data, that about 8,000 currently practicing physicians suffer from significant cognitive deficits, including various types of dementia.

Often, staff members have a “code of silence,” sources say. While commercial airline pilots have to undergo regular health screenings at age 40 and retire at age 65, such rules don’t exist for physicians. Unfortunately, it sometimes takes a catastrophic event with a patient before the surgeon’s impairment is addressed, sources say. Such an event can bring liability or loss of the physician’s license, however. There is some research supporting declining abilities among older surgeons, including a 2006 study that found surgeons older than age 60 had more patient mortality in complex operations than their younger colleagues did.¹

Some hospitals are implementing policies that require doctors over a specific age, such as 70 or 75, to have periodic physical and cognitive exams before they can renew their privileges.²

The issue is not going to go away. According to the American Medical Association, one in five licensed physicians in the United States is older than age 65.³ Additionally, the recession has changed physicians’ retirement plans, about 52% reported this change in one recent survey by Jackson & Coker, a physician staffing agency in Alpharetta, GA.³

In some cases, medical malpractice insurance companies limit what an aging physician can do, says **Stephen Trosty, JD, MHA, CPHRM, ARM**, president of Risk Management Consulting Corp., in Haslett, MI. “Some won’t write a policy after a certain age, such as 75 or 80,” Trosty says. Others limit a physician’s work, especially as it pertains to certain physical skills such as outpatient surgery or minor procedures, he says. “Some insurance companies will require a test both in terms of physical ability and sometimes even mental acuity,” Trosty says.

Are surgeons up to date with technology?

Outpatient surgery managers must address this issue, particularly considering how much technology and methods are changing in the field, sources say.

“Every decade or two, there are entirely new operations to learn,” says **Marty Makary, MD, MPH**, a Johns Hopkins Medicine surgeon and author of The New York Times bestseller “Unaccountable: What Hospitals Won’t Tell You and How Transparency Can Revolutionize Health

Same-Day Surgery® (ISSN 0190-5066) is published monthly by AHC Media, a division of Thompson Media Group LLC, 3525 Piedmont Road, NE, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals Postage Paid at Atlanta, GA 30304 and at additional mailing offices.

POSTMASTER: Send address changes to Same-Day Surgery®, P.O. Box 105109, Atlanta, GA 30348.

SUBSCRIBER INFORMATION

Customer Service: (800) 688-2421 or fax (800) 284-3291, (customerservice@ahcmedia.com). Hours of operation: 8:30 a.m. to 6 p.m. Monday-Thursday; 8:30 a.m.-4:30 p.m. Friday. Subscription rates: U.S.A., one year (12 issues), \$499. Add \$17.95 for shipping & handling. Outside U.S.A., add \$30 per year, total prepaid in U.S. funds. Discounts are available for group subscriptions, multiple copies, site-licenses or electronic distribution. For pricing information, call Tria Kreuzer at 404-262-5482. 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.)

Photocopying: No part of this newsletter may be reproduced in any form or incorporated into any information retrieval system without the written permission of the copyright owner. For reprint permission, please contact AHC Media. Address: P.O. Box 105109, Atlanta, GA 30348. Telephone: (800) 688-2421, ext. 5491. Fax: (800) 284-3291 Web: <http://www.ahcmedia.com>.

AHC Media is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center’s Commission on Accreditation.

This activity has been approved for 16.5 nursing contact hours using a 60-minute contact hour.

Provider approved by the California Board of Registered Nursing, Provider #14749, for 16.5 Contact Hours.

AHC Media is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

AHC Media designates this enduring material for a maximum of 20 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

This activity is intended for outpatient surgeons, surgery center managers, and other clinicians. It is in effect for 24 months after the date of publication.

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

Executive Editor: **Joy Daughtery Dickinson** (404) 262-5410 (joy.dickinson@ahcmedia.com).

Production Editor: **Kristen Ramsey**.

Senior Vice President/Group Publisher: **Donald R. Johnston**.

Copyright © 2013 by AHC Media. Same-Day Surgery® is a registered trademark of AHC Media. The trademark Same-Day Surgery® is used herein under license. All rights reserved.

AHC Media

Editorial Questions

Questions or comments?
Call Joy Daughtery Dickinson
at (229) 551-9195.

Care.” The doctors need retraining on these procedures, Makary says. “There are older doctors who nicely keep up and up to date, and there are others that have not,” he says. That issue is “poorly tracked and measured,” Makary says.

The focus should not on the surgeon’s age solely, says **Ray Grundman**, MSN, FNP-BC, CASC, senior director of external relations and surveyor, Accreditation Association of Ambulatory Health Care (AAAHC). “Aging per se is not the issue,” Grundman says. “It’s maintaining competence.” (*See more on accreditation and Medicare requirements, p. 40.*)

Ralph Blasier, MD, JD, orthopedic surgeon at OSF Saint Francis, Escanaba, MI, says physical and cognition tests are available, “but no one agrees who should administer them or how.”

So what’s an outpatient surgery manager to do? Consider these tips:

- **Establish a policy.**

“Ideally, there should be a policy, process, and protocol in place that allows for immediate intervention in cases where patients are at immediate risk,” Norcross says.

If the physician’s perform is in a “gray area,” the policy should allow reporting the physician confidentially “and subsequently assessing his competence to perform surgeries and provide quality of care in the privileges that he/she has requested,” he says. “Physicians should be referred for competency evaluations whenever there is a reasonable concern that a competency issue exists”

Healthcare facilities increasing are having requirements to determine if their elderly physicians are still coherent and physical capable, Makary says. “That way if someone is strong and capable, providing good care, even into their 80s, there is validation that there is safety,” he says. Many of these centers have said that an evaluation is mandatory when a physician turns 70, and the annual physical examinations are used to support their credentialing or privileges, Makary says.

- **Consider the alternatives.**

One alternative is for aging physicians to limit their practice. Blasier, age 62, took this step himself. “I gave up doing total hip, total knees, knee arthroscopy, and I limited the shoulder arthroscopy I do — the more difficult ones,” he says. “I’m trying to make sure I’m not persisting in doing things when I think I’m OK, but I’m old.” Blasier plans to give up practicing medicine at age 65, or sooner if he has problems.

Blasier suggest physicians ask a trusted colleague younger than themselves to tell them when it’s time

to quit, and not argue.

Makary says other alternatives include suggesting a second surgeon to assist with operations, along with physical and cognitive examinations for certain competencies for memory loss, vision, hearing and tremors, “rather than dealing with this issue by being draconian.”

Small instruments often need fine motor coordination, Grundman says. “When that starts to go, they still have the ability to help others do procedures,” he says. Also, a mentoring role “can be an important role in the final years of their careers,” Grundman says.

- **Have physician evaluated.**

One option is that limited competency evaluations can be performed by a hospital’s chief of staff or the Physician Wellbeing Committee, Norcross says. “However, when a larger scale, detailed and objective assessment is required, I would recommend a referral to one of the member organizations of the Coalition for Physician Enhancement,” he says. The UC San Diego PACE Program evaluates physicians and surgeons of all specialties, Norcross says. (*For more information on these programs, see Resources at end of this article.*)

“I do support age-based medical staff screening policies, but of course, the devil is in the details,” Norcross says.

A number of diseases can impair physicians’ abilities to provide quality care, and they increase with age, he says. In general, a screening process should have these criteria, he says:

- **It should be confidential.**

- **It should be evidence-based and reliable in detecting deficiencies in competence.**

- **Ideally, it should be local, quick, and inexpensive.**

- **Most importantly, the goal of this process at all times should be optimal, safe, and high-quality patient care.** (*See Norcross’ recommendation for screening, p. 40.*)

Because of the nature of surgery, in terms of it being a referral-based business, avoid the appearance of age discrimination by having elderly physicians undergo independent examinations, such as ones by independent primary care physicians, Makary says.

“Having independent examinations makes the process objective and less subject to the bias of local politics,” he says.

REFERENCES

1. Waljee JF, Greenfield LJ, Dimick JB, et al. Surgeon age and operative mortality in the United States. *Ann Surg* 2006;

- 244(3): 353–362. Accessed at <http://1.usa.gov/Zpxhqp>.
2. Boodman SG. Aging doctors face greater scrutiny. Kaiser Health News. Dec. 10, 2012. Accessed at <http://bit.ly/RZVa4V>.
3. O'Reilly KB. Physician quality: What's age got to do with it? July 30, 2012. Accessed at <http://bit.ly/MNWUf8>.

RESOURCES

- Coalition for Physician Enhancement. Web: <http://www.physicianenhancement.org>.
- The University of California, San Diego Physician Assessment and Clinical Education (PACE) Program evaluates physicians and surgeons of all specialties. Web: <http://www.paceprogram.ucsd.edu>. ■

Recommendations for optimal screening

There are many factors to consider when setting up a screening process for aging surgeons. William A. Norcross, MD, clinical professor of family medicine and director of the University of California, San Diego (UCSD) Physician Assessment and Clinical Education (PACE) Education Program, in the Department of Family and Preventive Medicine, UCSD School of Medicine, says his “best vision” for a screening process would include the following:

- Screening would begin at age 65 for male physicians and age 70 for female physicians. It also might be triggered by certain serious events such as stroke, myocardial infarction, or hospitalization for any serious illness, including mental illness.
- The interval for repeat assessment would be in the range of 3-5 years, depending on clinical circumstances.
- The initial assessment would include the following:
 - o a complete history and physical examination, and appropriate lab and imaging tests as indicated, performed by an independent physician (i.e., not a friend or colleague of the physician);
 - o neurocognitive screening via the MicroCog created originally at Harvard but now owned by PsychCorp. It is a reliable and quick, computer-based cognitive screening test that is relatively inexpensive, Norcross says. (*For more information, go to <http://bit.ly/VtKkUv>*);
 - o screening for depression, substance abuse, and perhaps other psychiatric diseases using simple, inexpensive, yet objectively studied, paper-and-pencil screening instruments. “I would

specifically not recommend routine urine drug screening, although I have colleagues who would dispute this,” Norcross says;

o results of a confidential 360 degree assessment that would also be done at routine intervals for all of the physician and staff members of the clinical unit. “We use the PULSE Program in Florida, but many instruments can be used,” Norcross says. (*For more information, go to <http://physiciansdevelopmentprogram.com>*.) ■

Accreditation and Medicare requirements

When it comes to aging physicians, the Accreditation Association for Ambulatory Health Care (AAAHC) trusts healthcare practitioners will assess their skills or others will assess their skills to ensure they’re maintaining their competence, says Ray Grundman, MSN, FNP-BC, CASC, senior director of external relations and surveyor.

In terms of credentialing, AAAHC expected facilities to have the medical staff go through complete recredentialing and reprivileging at least every three years, but some states require that process more frequently.

Peer review is an important part of the process, Grundman says. “We ask organization to have an active, ongoing process for evaluating significantly the competence of the care they deliver,” he says.

The process should go beyond generic peer review criteria, such as looking at 10 charts every quarter to see if physicians signed the operative report and orders, Grundman says. “That’s stuff they’re expected to do,” he says. “But what we’re looking for: What are the key outcomes for the care they provide?”

For example, with cataract surgery, there is about a 2% rate among the best surgeons for a capsule tear. If your surgeons’ rate goes above 2%, examine what is happening, Grundman advises. “It may be symptom of someone not able to physically keep up,” he says. Managers might need to curtail or remove privileges if physicians can’t maintain that level of proficiency, Grundman says.

“The way we guard patient safety is with credentialing and privileges that goes on every 2-3 years and an ongoing process of peer view to evaluate each other and hold each other to highest level of performance,” Grundman says.

Medicare rules for hospitals and ambulatory surgery centers (ASCs) require facilities to review

and periodically re-review the qualifications of the medical staff, including records of any performance duties. A spokesperson for the Centers for Medicare and Medicaid Services (CMS), who spoke on condition of anonymity under department policy, says, “In the case of any ASC that is owned by a surgeon who is the only person performing surgery, this is a more challenging process, but the ASC is still expected to document the evidence that supports the privileging decision.”

Joint Commission addresses aging

The Joint Commission has several standards that address concerns related to the provision of safe quality care, practitioner performance, or practitioner health or behavior, for which investigation might determine that age has impacted the practitioner’s ability to perform the privileges or the practitioner’s behavior. These include:

- MS.08.01.01 EP 2: The organized medical staff develops criteria to be used for evaluating the performance of practitioners when issues affecting the provision of safe, high quality patient care are identified.

- MS.09.01.01: The organized medical staff, pursuant to the medical staff bylaws, evaluates and acts on reported concerns regarding a privileged practitioner’s clinical practice and/or competence.

- MS.11.01.01: The medical staff implements a process to identify and manage matters of individual health for licensed independent practitioners which is separate from actions taken for disciplinary purposes.

- LD.03.01.01 EP 4: Leaders develop a code of conduct that defines acceptable behavior and behaviors that undermine a culture of safety.

- LD.03.01.01 EP 5: Leaders create and implement a process for managing behaviors that undermine a culture of safety. ■

Transmission of HBV raises issues about staff

CDC updates guidelines for facilities

By Gary Evans, Executive Editor of *Hospital Infection Control*

A recently reported case of hepatitis B virus transmission from a chronically infected surgeon to as

many as eight patients underscores the need for providers to know their HBV status and seek the counsel of an expert review panel if they perform invasive or so called “exposure-prone” procedures, public health officials emphasize.

“Hospitals can try, but the obligation really is on the healthcare providers who are doing the work,” says David Henderson, MD, hospital epidemiologist at the National Institutes of Health Clinical Center in Bethesda, MD. “This is one of those unfortunate circumstances where he may not have thought of [his HBV status], but he should have thought of it. It is the responsibility of the healthcare provider, especially those that are doing these kinds of procedures.”

A leading expert on the issue of provider-to-patient infections, Henderson wrote an accompanying editorial commentary to the case report, which does not disclose the location of incident or the identity of the surgeon.^{1,2} The case has several unusual features, including the fact that the surgeon had asymptomatic chronic HBV infection acquired at birth in a country with high endemic levels of HBV.

In light of the case and increasing reports of endemic HBV infections in foreign medical and dental students from Asia and other areas, the Centers for Disease Control and Prevention (CDC) has issued new guidelines on the issue.³ The CDC guidelines also emphasize that medical providers have a professional and ethical obligation to know their HBV status, to protect patients and because circulating HBV can be reduced dramatically by current therapies.

“Responsible medical professionals of any ilk should know their hepatitis B status, but you have a particular responsibility if you are a surgeon or an oral surgeon,” says Scott Holmberg, MD, chief of epidemiology and surveillance at the CDC’s viral hepatitis branch. “If they are infected and they have a high viral load, we think that should be managed and they can get treatment to get that viral load down.”

The surgeon in this case had an extremely high viral load, with an HBV DNA concentration of >17.9 million IU/mL. However, that was not known until

EXECUTIVE SUMMARY

A chronically infected surgeon was reported to have transmitted the hepatitis B virus to as many as eight patients.

- Providers need to know their HBV status and seek counsel from experts if they perform “exposure-prone” procedures.
- The most recent guidelines recommend using HBV DNA serum levels to monitor potential infectivity of a provider.
- Facilities should have written policies and procedures for the identification and management of HBV-infected providers.

a workup investigation began following a needlestick injury to the surgeon. The injury occurred when a needle, passed by an assisting surgeon during suturing, punctured the surgeon's index finger. The surgeon immediately reported the incident to occupational health for evaluation as the assisting surgeon completed the operation. The occupational health evaluation concluded that there was no suggestion of surgeon-to-patient exposure during the event. However, as the subsequent investigation revealed the high titer of HBV in his blood, the surgeon was ordered to halt his orthopedic practice, which mainly consisted of knee and hip replacements. The surgeon was not aware of any risk factors for HBV infection and did not recall any prior instances of needlestick injury during his career, the investigators reported.

A retrospective cohort study of all patients who underwent surgery by the surgeon was conducted. A total of 232 (70.7%) of potentially exposed patients consented to testing. Of those, two were found to have acute infection, and six had "possible transmission — evidence of past exposure without risk factors," investigators reported. Genome sequence analysis of HBV DNA from the infected surgeon and patients with acute infection revealed genetically related virus (>99.9% nucleotide identity). (*For information on lack of follow-up to HBV vaccine status, see story, this page.*)

Transmission route a mystery

Ultimately no clear method of transmission could be determined, which led investigators to theorize "that unknown or microperforation of the glove might have occurred."

Glove microperforation has been shown to occur with a high frequency. Bacterial transmission through microperforations has been estimated to occur at a rate of 5%; however, the rate of viral transmission is unknown. In addition to microperforation, glove laceration during arthroscopic shoulder surgery occurs in 51% of outer gloves and 17% of inner gloves," according to studies cited by the investigators.

The surgeon apparently has returned to practice after his viral titer was diminished through treatment. Improved HBV medications now make it possible to lower circulating virus to near undetectable levels, which makes it possible for infected providers to continue their medical practice with appropriate oversight.

Costi Sifri, MD, one of the authors of the report and an epidemiologist in the division of infectious diseases at the University of Virginia Health System in Charlottesville, says, "It is my understanding that the

institution referred to a panel of experts in hepatitis and infectious diseases, and that is the process that was used to determine future work practices."

The most recent CDC guidelines recommend using HBV DNA serum levels, rather than the hepatitis B e-antigen status, to monitor potential infectivity of a provider. For healthcare professionals requiring oversight, the serum HBV DNA considered "safe" for practice is <1,000 IU/ml. The Society for Healthcare Epidemiology of America (SHEA) has also issued guidelines allowing medical practice by an HBV-infected provider if viral load and other factors are monitored by an expert review panel.⁴

REFERENCES

1. Henderson, DK. Exceptions That Prove the Rule. *Clin Infect Dis* 2013; 56:225-227.
2. Enfield KB, Sharapov U, Hall KK, et al. Transmission of hepatitis B virus from an orthopedic surgeon with a high viral load. *Clin Infect Dis* 2012; 56:218-24.
3. Holmberg SD, Suryaprasad A, Ward JW. Updated CDC recommendations for the management of hepatitis B virus-infected health-care providers and students. *MMWR* 2012;61(RR-3):1-12. Accessed at <http://1.usa.gov/N0zXmH>.
4. Henderson DK, Dembry L, Fishman NO, et al. SHEA guideline for management of healthcare workers who are infected with hepatitis B virus, hepatitis C virus, and/or human immunodeficiency virus. *Infect Control Hosp Epidemiol* 2010; 31:203-32 ■

There was no follow-up on HBV vaccine failure

A critical element in the case of a surgeon infected with the hepatitis B virus (HBV) is that the surgeon had not previously responded to two series of HBV vaccinations, but it appears no further action was taken, say the authors of a case report on the incident.¹⁻²

No additional evaluation of this non-responder status (i.e., testing for the presence of HbsAg, the surface antigen of the hepatitis B virus) was performed prior to the needlestick injury, the authors noted.

Costi Sifri, MD, one of the authors of the report and an epidemiologist in the division of infectious diseases at the University of Virginia Health System in Charlottesville, says, "The hospital in question doesn't have a policy requiring people to know their [HBV] status. I know that in the state of Virginia and other states, it is something that is not a requirement, but there are some questions regarding state licensure

that include whether one knows if they have a chronic viral infection.”

Failure to respond to HBV vaccine — not once but twice — should have raised a red flag, suggesting the possibility the surgeon had chronic HBV infection, says **David Henderson, MD**, hospital epidemiologist at the National Institutes of Health Clinical Center in Bethesda, MD. “That information should have been passed on to the director of the occupational medicine service, who should have called the surgeon up and said, ‘You are from an area where these kinds of HBV infections are endemic, and you did not respond to the vaccine twice. Is it possible that you are a chronic carrier and would you like for us to look into that for you?’”

Such an intervention might have prevented the infections, but the fact that the surgeon reported his needlestick injury suggests he was not trying to conceal his HBV status, Henderson says.

Transmission of bloodborne pathogens from providers to patients has become exceedingly rare, with this incident thought to be the first documented case of provider to patient HBV transmission since 1994. The case also reflects the trend of medical providers coming into the United States from areas in the world such as China where the prevalence of HBV infection is high. In such countries, many people acquire the virus at birth and go to become asymptomatic chronic carriers.

Interviews conducted with the surgeon’s coworkers attested to his excellent technique and use of barrier precautions during operations.

REFERENCES

1. Henderson, DK. Exceptions That Prove the Rule. *Clin Infect Dis* 2013; 56:225-227.
2. Enfield KB, Sharapov U, Hall KK, et al. Transmission of hepatitis B virus from an orthopedic surgeon with a high viral load. *Clin Infect Dis* 2012; 56:218-24. ■

Off-label use might be the standard of care

Concerns about cases involving provider liability should not deter clinicians from off-label prescribing, says **Samantha L. Prokop, Esq.**, an attorney with Brennan, Manna & Diamond, in Akron, OH.

“In fact, failure to use a drug or product off-label could also be considered malpractice, if the standard of care required off-label use,” she says.

Off-label use is permitted if it meets the standard

of care, explains Prokop, and in some cases, it might constitute the standard of care.

Madelyn S. Quattrone, Esq., senior risk management analyst at ECRI Institute in Plymouth Meeting, PA, says, “To succeed in court on a claim of negligence, the plaintiff must prove that the off-label prescribing breached the standard of care, and that the drug, as prescribed, [or device] caused harm to the patient, or it was a substantial factor in causing harm to the patient.”

The use of a device or drug “off-label” does not imply that the physician has acted below an accepted standard of care, and for some conditions, off-label use has become the standard of care, says Quattrone. “But when there is lack of valid clinical evidence and published peer-reviewed literature to support off-label use” of a particular drug or device, the use involves “some degree of uncertainty and risk about safety and efficacy.”

Battle of experts

If a claim involving off-label use goes to trial, the jury will hear opposing expert opinion on whether the physician breached the standard of care and whether the use of the device or drug was the proximate cause of harm to the patient, says Quattrone.

In one claim, a plaintiff alleged that the risk of the off-label use of a YAG laser had not been fully explained to him. **Janice M. Ginley**, assistant claims manager for MIEC, an Oakland, CA-based malpractice carrier, says “Corrective surgery went well, but the patient claimed impairment to near and intermediate distance vision, clouding in the center of the eye and general reduced vision quality.”

The physician’s documentation of the risks and alternatives to treatment was poor. “Despite review by multiple ophthalmic surgeons, we could not find any support on the standard of care for the use of YAG laser ablation in the treatment of vitreous floaters,” adds Ginley.

In fact, several ophthalmologic surgery consultants explained that a YAG laser is too dangerous for treatment of vitreous floaters because there is too much risk of injury to the lens in this off-label application of the device, she explains.

“Although an independent medical examination demonstrated that the patient had a near-full recovery within months of the incident, because of the intentional acts, personal exposure and lack of expert support, the case was mediated and settled in the mid-six figure range,” says Ginley.

A plaintiff’s theory of liability against a physician using a medical device in an off-label manner might

be shaped by the rules of evidence in the jurisdiction in which the litigation is filed, Quattrone says. Although the Food and Drug Administration (FDA) doesn't regulate the practice of medicine, the rules of evidence may permit a manufacturer's package insert (indicating FDA-approved uses) to be admitted into evidence, she says. As a result, the jury might consider that information as "some evidence of the standard of care" regarding the use of the device, she says.

"In other jurisdictions, the device package insert may be admitted into evidence to establish a prima facie standard of care for the use of the product, which, along with expert testimony concerning the standard of care, the defendant clinician must refute in order to prevail against a claim of negligence," Quattrone says.

Know evidence base

A patient given a medication or device "off-label" might allege that he or she was harmed by the prescribing physician as a result of negligent prescribing, says Quattrone.

In 2008, several lawsuits were brought for the off-label use of pain pumps, which were being placed directly in a patient's joint following orthopedic surgery. The plaintiffs argued the off-label use of the pumps destroyed the cartilage in their joints, which necessitated joint replacement and caused permanent damage.

Off-label use isn't unlawful, and it doesn't necessarily constitute malpractice, says Quattrone. "The FDA does not regulate the practice of medicine. That function is reserved for state boards of medicine," she says.

Develop a policy and procedure for innovative off-label use of devices or medications, with a multidisciplinary task force including medical staff, pharmacists, risk management, and the ethics committee, says Quattrone. "A facility might take several approaches to off-label use," she says. For example, it might not permit off-label prescribing at all, it might restrict off-label use to clinical research approved by an institutional review board, it might permit off-label use only if the use falls within the institution's therapeutic guidelines, or it might approve off-label use based on clinical judgment of the provider that adequate evidence supports its use.

Institutions should encourage clinicians to discuss risks and benefits and alternatives related to the proposed off-label use with their patients, and document the discussion in the patient's medical record, Quattrone says. *(See related story on obtaining informed consent, this page.)*

Physicians must obtain consent for off-label use

Patients may successfully sue if you fail to properly obtain their consent when a drug or device is used in a manner that deviates from the purpose for which it was approved, warns **Claudia Dobbs**, loss prevention manager at MIEC, an Oakland, CA-based malpractice carrier. When there is a potential for serious side effects due to off-label use of medications or devices, Dobbs recommends considering these practices to reduce legal risks:

- Have a firm understanding that the "off-label" use is clinically indicated.
- Have an in-depth informed consent discussion with patients and authorized family members or friends.
- Explain how the off-label use of drug or device will work better than other drugs or devices normally approved for treatment of the condition.
- Know whether or not the patient's health insurance will cover the cost of the off-label drug or device.

"Don't make your patients angry by failing to ensure that there is coverage," Dobbs says. Should the patient experience an unexpected injury from the drug, anger over the uncovered medication or medical device will add to the patient's desire to seek the services from an attorney, she says. ■

Same-Day Surgery Manager



Updating your policies & procedures – 3 suggestions

By **Stephen W. Earnhart, MS**
CEO
Earnhart & Associates
Houston, TX

When was the last time you updated your antiquated policies and unimaginable procedures? Do you even have a policy that address "tweets?" No, you don't.

What about “blogging?” You don’t have that either do you? But, I bet you have a policy on “personal phone calls in the workplace” don’t you? Who even uses a phone with a wire sticking out of it anymore?

If you are like most of us — hey, I am just as guilty! — you haven’t gotten around to updating your P&Ps with what is “vogue” and “current.” Let me help you on some, since we just updated all of ours. How about a policy on “romantic relationships?” Got one!

- **Romantic relationships.**

In order to avoid complaints of favoritism, misunderstandings, possible claims of sexual harassment, employee morale and dissension, and the actual or potential conflicts of interest and problems that can potentially result from romantic relationships involving employees in the facility and certain other employees in the facility, the facility would like to discourage these relationships.

Staff are discouraged from becoming romantically involved with one another. Additionally, all employees, both managerial and non-managerial, are discouraged from becoming romantically involved with other employees, when, in the opinion of the facility, their personal relationships may create a conflict of interest, cause disruption, create a negative or unprofessional work environment, or present concerns regarding supervision, safety, security, or morale.

Let’s get back to blogging and tweeting all over each other:

- **Use of social networking communications.**

Blogging, tweeting, e-mail, texting, and other social media such as MySpace and Facebook are subject to restrictions. You may not use company property to create, maintain, amend, view, access, download, contribute to, or store a blog, tweet, or post entries on the Internet (whether through a social network such as MySpace or Facebook, or using another method).

You may not blog, tweet, or post entries on the Internet (whether through a social network such as MySpace or Facebook, or using another method) while you are on duty. The facility has access to all company-provided electronic equipment and property and may, from time to time and without notice, inspect the condition of that equipment and the communications, content, data, and imagery stored on it.

This policy applies to all blogs and other sites, without regard to whether it is accessible by the public or requires a password. The exception would be using social media for professional mar-

keting of the facility with oversight by the governing body of the pre-approved posts or pictures.

Remember, you are personally responsible for any posting that you make. You can be held personally liable for any statements deemed to be defamatory, obscene, harassing, discriminating, retaliatory, violate privacy rights, or include confidential or copyrighted information (e.g., music, videos, or text that belongs to someone else). The facility is not responsible for protecting you from the consequences of any information that you post.

What? They can’t do that! Can they? What about gossip? Come on now! We all do that, like when that employee had to leave town suddenly. New job? I don’t think so!

- **Gossip policy.**

Gossip is an activity that can distract, drain, and reduce employee job satisfaction.

Gossip is defined as a rumor or talk of personal, sensational, or intimate nature. Someone who spreads intimate or private rumors or facts engages in trivial, chatty talk or writing and is engaging in gossip.

- o Gossip always involves a person who is not involved in the discussion.

- o Gossip is an unwelcome and negative discussion involved criticizing another person.

- o Gossip is often about conjecture that can injure another person’s credibility, reputation, or the perception of that individual.

In order to have a more respectful, professional, gossip-free workplace, we ask that each employee make the following pledge. I will:

1. Not speak or insinuate another person’s name when that person is not present unless it is to compliment or in reference to work matters.

2. Refuse to participate when another individual mentions a person in a negative light who is not present. I will change the subject or tell them I have agreed not to talk about another person in a derogatory manner.

3. Choose not to respond to negative e-mail by email or use e-mail to pass on private or derogatory information about any person within the company.

4. Not speak to another co-worker about other employees in a derogatory light while not at work.

5. Follow the proper chain of command if another person in the company does something unethical, incorrect, against procedures, or disruptive, and I will report this to the appropriate person in authority to take corrective action.

6. Mind my own business, work hard, be a professional, and expect the same from others.

In other words, be a good “do-be.” Well, now

that all the fun has been taken out of it, let's get back to work!

7. Discuss with my supervisor or another member of the management team if I have concerns or issues about company policies or procedures, but not discuss these issues with my co-workers.

Making negative comments and badmouthing other employees is detrimental to the productivity of the workplace. Malicious gossip and/or the spreading of rumors will not be tolerated. Any violations of this policy will result in corrective action. This action might involve but is not limited to a written warning for the first offense, and a significant violation of this policy may result in immediate termination. [Earnhart & Associates is a consulting firm specializing in all aspects of outpatient surgery development and management. Earnhart & Associates' address is 238 S. Egret Bay Blvd., Suite 285, Houston, TX 77573-2682. Phone: (512) 297.7575. Fax: (512) 233.2979. E-mail: searnhart@earnhart.com. Web: www.earnhart.com.] ■

Signs of complications after colorectal surgery

Colorectal surgical patients often are discharged from the hospital with vague guidance on how to recognize complications, but researchers at the Michael E. DeBakey Veterans Administration (VA) Medical Center and Baylor College of Medicine, both in Houston, aim to change that scenario.

A research team convened surgical experts to develop a list of postoperative complication signs that should prompt colorectal surgical patients to call their surgeons or go to an emergency department. The study on the development of this early patient-centered warning system appears in the February 2013 issue of *Journal of the American College of Surgeons*.¹

Research has shown that 11.4% of all colorectal surgical patients are back in the hospital 30 days later.

The Patient Protection and Affordable Care Act (ACA) allows the Centers for Medicare & Medicaid Services (CMS) to decline payment to hospitals for some patients who are readmitted after being discharged. "Many hospitals are looking at ACA and readmissions," said study author Linda T. Li, MD, research fellow at the Houston VA Health Services Research Center of Excellence and surgical resident at Baylor. "We're trying to see if the discharge

process has anything to do with readmissions. Everything is under scrutiny."

The panel of surgeons came up with symptoms that should prompt patients to contact their surgeons:

- wound drainage, opening, or redness;
- no bowel movement or lack of gas/stool from any ostomy for more than 24 hours;
- increasing abdominal pain;
- vomiting;
- abdominal swelling;
- high ostomy output and/or dark urine or no urine;
- fever greater than 101.5;
- not being able to take anything by mouth for more than 24 hours.

The panel also identified two symptoms that are serious enough to warrant a trip to the nearest emergency department:

- chest pain;
- shortness of breath.

REFERENCE

1. Li LT, Mills WL, Gutierrez AM, et al. Patient-centered early warning system to prevent readmission after colorectal surgery: a national consensus using the Delphi method. *JACS* 2013; 216(2): 210-216.e6. ■

FDA adds boxed warning on codeine after surgery

Tonsillectomy and adenoidectomy targeted

The Food and Drug Administration (FDA) is adding a boxed warning to the drug label of codeine-containing products to address a known safety concern with codeine use in certain children after tonsillectomy and/or adenoidectomy. Deaths have occurred postoperatively in children with obstructive sleep apnea who received codeine for pain relief following a tonsillectomy and/or adenoidectomy.

Codeine is converted to morphine by the liver. These children had evidence of being ultra-rapid metabolizers of codeine, which is an inherited (genetic) ability that causes the liver to convert codeine into life-threatening or fatal amounts of morphine in the body.

The new boxed warning is FDA's strongest warning. A contraindication, which is a formal means

for FDA to make a strong recommendation against use of a drug in certain patients, will be added to restrict codeine from being used in this setting. The “Warnings/Precautions,” “Pediatric Use,” and “Patient Counseling Information” sections of the drug label also will be updated.

In August 2012, FDA announced it was reviewing the safety of codeine due to cases of deaths and serious adverse events in children who took the drug after a tonsillectomy and/or adenoidectomy and had evidence of being ultra-rapid metabolizers of codeine. FDA conducted a comprehensive safety review to identify additional cases of overdose or death in children taking codeine and to determine if these adverse events occurred in any other treatment settings. Many of the cases of serious adverse events or death occurred in children with obstructive sleep apnea who received codeine after a tonsillectomy and/or adenoidectomy. Because these children already had underlying breathing problems, they might have been particularly sensitive to the breathing difficulties that can result when codeine is converted in the body to high levels of morphine. However, this contraindication applies to all children undergoing tonsillectomy and/or adenoidectomy because it is not easy to determine which children might be ultra-rapid metabolizers of codeine.

Healthcare professionals should prescribe an alternate analgesic for postoperative pain control in children who are undergoing tonsillectomy and/or adenoidectomy. Codeine should not be used for pain in children following these procedures. For management of other types of pain in children, codeine should only be used if the benefits are anticipated to outweigh the risks.

Parents and caregivers who observe unusual sleepiness, confusion, or difficult or noisy breathing in their child should stop giving codeine and seek medical attention immediately, as these are signs of overdose. (To view the entire FDA drug safety communication, go to <http://1.usa.gov/YcZ9to>.) ■

Entertaining game enhances staff training

New way to present privacy and security info

Tedious and boring are often the kindest adjectives used by healthcare employees to describe privacy and security training required in every orga-

nization. However, a new, free training program offered by the Department of Health and Human Services’ Office of the National Coordinator for Health Information Technology can make some of the training more enjoyable.

“Cybersecure: Your Medical Practice” simulates a game environment to provide insights into privacy and security issues by having the employees play a game in which they face scenarios they might encounter in their physician practice, a freestanding center, or a department within a hospital. As the game is played, the employee learns about proper procedures as questions are asked and feedback given. Scenarios include game characters asking if they can take their laptop home to work on billing, if records can be loaded onto a personal USB drive, and how to send patient information to a physician at a conference, without sharing passwords.

While the game is not intended to replace comprehensive privacy and security training, it does provide a no-cost solution for periodic refresher courses. To access the training module, go to www.healthit.gov and search for the title of the game. ■

CNE/CME INSTRUCTIONS

Physicians and nurses participate in this CNE/CME program and earn credit for this activity by following these instructions.

1. Read and study the activity, using the provided references for further research.
2. Log on to www.cmecity.com to take a post-test; tests can be taken after each issue or collectively at the end of the semester. *First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice or renewal notice.*
3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.
4. After successfully completing the last test of the semester, your browser will be automatically directed to the activity evaluation form, which you will submit online.
5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly. ■

COMING IN FUTURE MONTHS

- Battle growing over billing by outpatient surgery centers
- If a “high risk” surgical device is FDA-approved, is it safe?
- How to reduce surgical site infections
- Top technologies to put on your watch list

EDITORIAL ADVISORY BOARD

Consulting Editor: **Mark Mayo**
Executive Director, ASC Association of Illinois
Principal, Mark Mayo Health Care Consultants
Round Lake, IL

Kay Ball

RN, PhD, CNOR, FAAN
Perioperative Consultant/
Educator, K&D Medical
Lewis Center, OH

Stephen W. Earnhart, MS
President and CEO
Earnhart & Associates
Austin, TX
searnhart@earnhart.com

Ann Geier, RN, MS, CNOR CASC
Vice President of Operations
Ambulatory Surgical Centers
of America
Norwood, MA

John J. Goehle, MBA,
CASC, CPA
Chief Operating Officer
Ambulatory Healthcare
Strategies
Rochester, NY

Jane Kusler-Jensen
BSN, MBA, CNOR
Specialist master
Service operations/healthcare
providers/strategy and operations
Deloitte
Chicago, IL

Kate Moses,
RN, CNOR, CPHQ
Chair, Ambulatory Surgery
Specialty Assembly
Association of periOperative

Registered Nurses, Denver
Quality Management Coordinator,
Medical Arts Surgery Centers
Miami

Roger Pence

President
FWI Healthcare
Edgerton, OH
roger@fwihealthcare.com

Stephen Punzak, MD, CEO
Medical Web Technologies
Willington, CT

David Shapiro, MD, CHCQM,
CHC, CPHRM, LHRM
Partner, Ambulatory Surgery
Company, LLC
Tallahassee, FL

Sheldon S. Sones, RPh, FASCP
President, Sheldon S. Sones &
Associates
Newington, CT

Rebecca S. Twersky, MD
Medical Director
Ambulatory Surgery Unit
Long Island College Hospital
Brooklyn, NY
twersky@pipeline.com

To reproduce any part of this newsletter for promotional purposes, please contact:

Stephen Vance

Phone: (800) 688-2421, ext. 5511

Fax: (800) 284-3291

Email: stephen.vance@ahcmedia.com

To obtain information and pricing on group discounts, multiple copies, site-licenses, or electronic distribution please contact:

Tria Kreutzer

Phone: (800) 688-2421, ext. 5482

Fax: (800) 284-3291

Email: tria.kreutzer@ahcmedia.com

Address: AHC Media
3525 Piedmont Road, Bldg. 6, Ste. 400
Atlanta, GA 30305 USA

To reproduce any part of AHC newsletters for educational purposes, please contact:

The Copyright Clearance Center for permission

Email: info@copyright.com

Website: www.copyright.com

Phone: (978) 750-8400

Fax: (978) 646-8600

Address: Copyright Clearance Center
222 Rosewood Drive
Danvers, MA 01923 USA

CNE/CME OBJECTIVES

- **Identify** clinical, managerial, regulatory, or social issues relating to ambulatory surgery care.
- **Describe** how current issues in ambulatory surgery affect clinical and management practices.
- **Incorporate** practical solutions to ambulatory surgery issues and concerns into daily practices.

CNE/CME QUESTIONS

1. What is the issue with surgeons as they get older, according to Ray Grundman, MSN, FNP-BC, CASC, senior director of external relations and surveyor, Accreditation Association of Ambulatory Health Care (AAAHC).
A. Their age.
B. Their endurance.
C. Maintaining competence.
2. What type of physician screening is recommended by William A. Norcross, MD, clinical professor of family medicine and director of the University of California, San Diego (UCSD) Physician Assessment and Clinical Education (PACE) Education Program, in the Department of Family and Preventive Medicine, UCSD School of Medicine?
A. Screening would begin at age 65 for male physicians
B. Screening would begin at age 70 for female physicians.
C. Screening might be triggered by certain serious events such as stroke, myocardial infarction, or hospitalization for any serious illness, including mental illness.
D. All of the above.
E. None of the above.
3. According to Stephen W. Earnhart, MS, CEO of Earnhart & Associates, your policies and procedures should be updated to address which of the following?
A. Romantic relationships
B. Use of social networking communications
C. Gossip
D. All of the above
E. None of the above.
4. Researchers at the Michael E. DeBakey Veterans Administration (VA) Medical Center and Baylor College of Medicine identified what symptom(s) that is/are serious enough to warrant a trip to the nearest emergency department?
A. Chest pain
B. Shortness of breath
C. A and B
D. Neither A nor B



ACCREDITATION UPDATE

Covering Compliance with The Joint Commission, AAAHC, and Medicare Standards

Digging deeper: How can you stop adverse events from happening?

Wrong patient/site/procedures, unintended retentions examined

The same adverse events seem to show up every year on national and state lists, and providers might be asking why, with all the emphasis on patient safety, these problems persist.

Part of the answer might be that providers are focused on the immediate, critical needs of the patient, such as the operation itself, says **Teo Forcht Dag**, MD, DMedSc, FAANS, FACS, SAAANS, FCCM, chair of the American College of Surgeon's Committee on Perioperative Care and a neurosurgeon. Dag is a visiting professor at Harvard Medical School in Boston and professor at Queens University Belfast, Northern Ireland, UK.

"People were taught to do all kinds of things to prevent complications," Forcht Dag says. "As practical matter, we need a team to do that." The team must not only take measures to care for the patient, but to protect the patient, he says.

Consider The Joint Commission's no. 1 sentinel event for 2004-2012: "Wrong-patient,

wrong-site, wrong-procedure." There have been 928 cases reported since 2004, with 109 occurring in 2012 alone. In Minnesota, wrong-site surgeries/invasive procedures have been among the most commonly reported event in the nine years the state had been collecting data.

As surgery grows in complexity, these events continue to occur, says **Rachel Blake Jokela**, RRT, RCP, director of the Adverse Health Events Program in the Division of Health Policy, Minnesota Department of Health in St. Paul. "Fortunately we are catching these events earlier in the process," Blake Jokela says. "For example, more often we are seeing wrong regional blocks prior to the actual surgical procedure, versus a wrong-sided knee arthroplasty for example."

She says that when Minnesota Department of Health (MDH) officials looked at the root causes for wrong site/patient procedure in 2012, they found the following:

- laterality (left vs. right) or other critical information missing from informed consent documents;
- lack of site marking and/or lack of policy for correct site marking;
- lack of consistent and well-known time-out process;
- lack of verification of implant type prior to

EXECUTIVE SUMMARY

Two of the most common adverse events are wrong-patient/site/procedure and unintended retention of foreign objects.

- Ensure staff feel comfortable speaking up. This process starts with introducing every member of the surgical team.
- Double check the patient's name and procedure with the patient, surgeon, and medical record.
- List every item going in to the patient, and check them off as they come out. Have another person double check.

Financial Disclosure:

Executive Editor **Joy Dickinson** and Board Member and Nurse Planner **Kay Ball** report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study. Consulting Editor **Mark Mayo** reports that he is an Administrative Consultant to USPI Chicago Market. **Stephen Punzak**, MD, physician reviewer, discloses that he is CEO, founder, and stockholder with Medical Web Technologies.

insertion.

“MDH and its partners will provide ongoing support to facilities to hardwire the time-out process, implement a standardized scheduling and verification process, and engage leaders to support their staff in speaking up for patient safety when concerns arise,” Blake Jokela says.

Teach staff to speak up

Speaking up is a key step, according to Forcht Dagi.

“People need to be able to express opinions or doubts,” he says. This starts with an introduction of everyone on the surgical team, Forcht Dagi says. “It is a lot easier to talk when you know what someone’s name is,” he says.

This communication allows everyone to agree on who the patient is and what the procedure is, so there are no surprises, Forcht Dagi says. “First and foremost, make sure communication among team is smooth, is open, and is adequate,” he says.

One of the root causes that shows up for wrong site/patient is barriers to communication, says **Stephen Trosty**, JD, MHA, CPHRM, ARM, president of Risk Management Consulting Corp. in Haslett, MI. These issues can include low English proficiency, literacy, and lack of ability to comprehend, which might be due to being upset over having surgery or being under the impact of anesthesia, Trosty says. “You may want to make sure you have patients repeat back to you to make sure they understand,” he says.

When an adverse event does occur, a root cause analysis is essential, Trosty says. Look at whether your processes allow the patient’s name and identifying number to be double-checked before they go in for surgery and once they are in the OR. Also, ensure your processes require having the actual site marked, then verified with the patient and medical record that the marked site is correct. The procedure also should be verified with the patient, physician, and medical record. “... [B]asically do a root cause analysis of what in the system may have gone wrong so you can, hopefully, prevent it from happening again,” Trosty says.

Also common: retention of a foreign body

The Joint Commission’s no. 3 sentinel event

for 2004-2012 is “Unintended retention of a foreign body.” There have been 773 cases since 2004, with 115 reported in 2012.

In Minnesota, retained foreign objects declined by 16%, which was the first decline in this category in five years. “Many of the retained foreign objects for this past year were broken/fragments of items,” Blake Jokela says.

Forcht Dagi says that in terms of procedures to prevent retention of foreign objects, there have been procedures in place “for a hundred years.”

“The thing is, what we’ve done in the past seems very good, the surgery is essentially very safe, but it’s not good enough,” he says. “We may need to do things even better.”

Count and list all instruments and supplies ahead of time, Trosty says. “I even mean cotton swabs,” he says.

Check ahead of time to be sure everything on the list that is going in the patient is present on the tray, Forcht Dagi says. Technology can be as simple as a paper list of every instrument that is used and every device that might be put in. “As it’s removed, it’s checked against the list,” Forcht Dagi says.

There are technologies that allow labeling and automatic counting of instruments and devices, he says. Frequency-tracking devices can be useful. “What we ask is that the right combination of safety measures, safety education for the OR team, the right people are made accountable within the operating room, things are double checked, so that the retention of foreign bodies is prevented,” Forcht Dagi says.

After the procedure, count and list every object that is removed from the body and the tray, Trosty says. “There should be a double checking” by a separate staff member, he says.

If there is a discrepancy in the count, go in the patient and try to find the missing item, Trosty says.

Minnesota lists root causes of retentions

In Minnesota, root causes of retained items included the following:

- Staff didn’t realize that a device had broken. “This was often related to unfamiliarity with the device,” Blake Jokela says. “Either the team did not know what an intact device should look like, or they did not know that there was

a risk for breakage with the particular device being used.”

- The retained device piece was so small that it wasn't detected during inspections of the surgical field. “Over the years, this is most common with broken pieces of wire,” Blake Jokela says.

- The postoperative X-ray didn't show the device fragment or piece due to its size.

Minnesota officials also commonly saw retention of “packed” items such as sponges during gynecological procedures. “These items are tucked by the surgical staff and intended to be removed prior to the end of the procedure,” Blake Jokela says. “The most common root cause for these types of events is an ineffective/incomplete count process or lack of communication between staff regarding ‘tucked items.’”

If you have an unintended retention, review your processes and procedure, Trosty advises. Determine if the problem is with your system or with an individual who counted wrong, he says.

Communication is often a factor, Blake Jokela says. “As facilities continue to be challenged by packed items, it is clear that communication barriers can and do impact patient safety and lead to retained foreign objects,” she says. *(To see an examination of falls as an adverse event, see story, below.)*

RESOURCES

The Agency for Healthcare Research and Quality has a new online toolkit, “**Preventing Falls in Hospitals: A Toolkit for Improving Quality of Care.**” Web: www.ahrq.gov/research/ltc/fallpxtoolkit/index.html.

The Minnesota Hospital Association is conducting “**SAFE SITE,**” a statewide campaign to prevent wrong-site surgeries. To see information that hospitals and clinics are sharing, go to <http://bit.ly/15v4ktJsee>. ■

How can you prevent falls?

Falls in healthcare settings are “very common and sometimes difficult to prevent,” says Rachel Blake Jokela, RRT, RCP, director of the Adverse Health Events Program in the Division of Health Policy, Minnesota Department of Health in St. Paul.

In Minnesota in 2012, the type of event most likely to lead to serious patient harm or death was falls. Eighty cases of harm or death were a result of falls. And the problem is widespread. The Joint Commission's no. 6 sentinel event for 2004-2012 is falls.

There are a million reasons patient can fall, says Teo Forcht Dagi, MD, DMedSc, FAANS, FACS, SAAANS, FCCM, chair of the American College of Surgeon's Committee on Perioperative Care and a neurosurgeon. Dagi is a visiting professor at Harvard Medical School in Boston and professor at Queens University Belfast, Northern Ireland, UK. “They can be as prosaic as rails down on a bed, to the patient who seems fine but faints as soon as she gets out of bed, to someone under the effects of medication, especially in the outpatient surgery arena, who hasn't quite recovered from anesthesia,” Forcht Dagi says.

Patients must be watched and monitored to make sure nothing untoward happens, he says. In outpatient surgery, patients must be carefully monitored because they sometimes walk into the OR, says Stephen Trosty, JD, MHA, CPHRM, ARM, president of Risk Management Consulting Corp., in Haslett, MI. “You want to make sure when they're recovering ... someone is checking on them to make sure they don't try to get off the table while still under the effects of sedation,” Trosty says. “From my experience, that's when falls tend to occur: when you're not paying enough attention to patient, not providing that assistance.”

And when falls occur, staff should protect patients against injuries, Blake Jokela says. Many falls can be attributed to breakdowns in the communications process in the fall risk assessment or the appropriateness of the interventions that are chosen, she says. “The fall risk was not adequately documented or communicated among team members or units,” Blake Jokela says. “The risk reduction interventions weren't matched to the patient's individual risk factors or weren't consistently applied.”

This year, Minnesota facilities are focusing on linking risk assessment/injury assessment with individualized risk factors and proper interventions. “The hope is that this will help to decrease overall falls and significantly decrease fall-related injury,” Blake Jokela says. ■

Are you ready for AAAHC changes?

Organization announces new standards

Facilities accredited by the Accreditation Association for Ambulatory Health Care (AAAHC) have new requirements as of March 1, 2013, including one to document all outcomes related to adverse reactions to drugs and materials.

As part of an organization's definition of an adverse event, a new element requires that it include all events involving reactions to drugs and materials. The expectation is to include unanticipated or unintended responses to drugs or materials. "This requirement enhances a facility's risk management program," says Michon Villanueva, MHA, the director of accreditation services at AAAHC.

Another change is encouragement to report near misses, she says. "I think it actually enhances a facility's risk management program," Villanueva says.

As part of the governing body responsibilities, an organization's representation of accreditation to the public must accurately reflect the accredited entity. The governing body should ensure not only are they ensuring marketing and advertising is not misleading, but they also must ensure the accredited entity is accurately portrayed. "For example, an organization may have multiple locations, but chooses only to accredit a portion of those," Villanueva says. "Those that are not part of the accredited facilities should not be reflected as accredited."

A new standard (5.I.B) in the quality improvement (QI) subchapter requires a clear distinction between auditing and monitoring activities and actual QI studies.

In the clinical records and health information chapter, a new responsibility of the person in charge of clinical records is the security of the clinical record. That security includes a method of tracking who accesses the record, to block unauthorized access. There is possibility of multiple accesses from several individuals. The facility needs to have a method of tracking who accesses the record to be sure use is appropriate. A current standard regarding written clinical records policies now includes the need to address accountability for editing, deleting and accessing

medical record content. The organization has to define access in terms of who is able to enter or change charts.

There are two new standards in the Infection Control subchapter. The first was an element and has been raised to standard level and now requires the organization to adhere to professionally accepted standards of practice, manufacturer's recommendations, and state and federal guidelines, including but not limited to the cleaning, disinfection, and sterilization of instruments, equipment, supplies, and implants. The second is a new standard which requires that medical devices for use with multiple patients are cleaned and disinfected between patients, following the manufacturer's instructions or nationally recognized guidelines, whichever are more stringent.

A new standard in the surgical and related services chapter requires a written policy for the risk assessment and prevention practices relating to deep vein thrombosis, when appropriate. ■

Helping you understand anesthesia standards

Do you have time to sort through the interpretive guidelines from the Centers for Medicare and Medicaid Services (CMS) for the Conditions of Participation (CoPs) regarding anesthesia and sedation? The manual is hundreds of pages. Do you know what documents surveyors are looking for when they come to your facility, and do you know what questions they will ask? Most of the most recent changes are effective immediately.

Help is on the way. AHC Media, publisher of *Same-Day Surgery*, has published "Cracking the Code: Understanding the CMS Hospital CoP Standards on Anesthesia," which explains the anesthesia standards and PACU standards. The chapters are organized in the order in which the anesthesia standards are contained in the hospital CoP manual.

Our book covers anesthesia services, organization and staffing, preanesthesia evaluations, the intraoperative anesthesia record and required policies and procedures, and post-anesthesia assessments. We include hundreds of pages of policies and procedures and other informative practical material you can start using immediately. For more information on this book, go to <http://bit.ly/118jCoT>. ■