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INSIDE

Enclosed in this issue:

- *SDS Accreditation Update*

AHC Media

New problems mean new solutions for retained surgical items

(In this first part of a two-part series, we discuss some new challenges and solutions for retained surgical items. In next month's issue, we discuss how to resolve count discrepancies, the importance of standardization, and how to address needles.)

The OR staff at one California hospital didn't even realize that a blue towel had gone into the patient during his abdominal surgery. But there it was, three months later. Towels had never been counted in the hospital. As a result of this retained item, the hospital was fined more than $86,000. It has changed its policy and now counts blue towels. *(To read more about this case, go to lat.ms/1nAkzmz.)*

You know you're supposed to count sponges and other similar items at your facility, but what about miscellaneous items, including small microneedles, trocars, guidewires, and sheaths?

Verna C. Gibbs, MD, director of San Francisco-based NoThing Left Behind, a national surgical patient safety project to prevent retained surgical items, recently reviewed a case in which the intraoperative record had no place for the staff to document a count of miscellaneous items. For that reason, the staff members didn't think they had to keep track of them, Gibbs said. Progress has been made with retained sponges, so now there are increased reports of other items, including devices and unretrieved device fragments. "These include intact but separated parts of surgical items, some of which are not radiopaque, broken pieces of instruments, small microneedles, trocars, guidewires, and sheaths," according to NoThingLeftBehind.org.

Those findings are backed up by data collected by the Oregon Patient Safety Commission, according to **Bethany Walmsley**, executive director. "Generally, in Oregon we are seeing a smaller percentage of retained sponges and an increase in other objects such as supply parts, IV or IV parts, needles, towels, and tips of cannulas, drains, electrodes, tubing, etc.," Walmsley says.

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The problem is mentioned in a recently updated guideline for prevention of retained surgical items from the Association of periOperative Registered Nurses (AORN), which says that staff must account for all needles, guidewires, as well as surgical soft goods, instruments, and other items used during procedures.[1] *(For information on ordering the updated guideline, see Resource at end of this article.)*

Surgery isn't performed only in the OR anymore, Gibbs points out. "There are lots of 'ORs' all over the hospital, and they need to adopt safer practices," she says. Gibbs says the "other ORs" include areas such as cath labs, interventional radiology suites, and hybrid ORs. Walmsley concurs and says, "Interestingly, our data shows that there is a correlation between incidence of URFOs [unintended retained foreign objects] and when a surgery occurs outside of the operating or procedure room, such as in labor and delivery or emergency situations."

The problem of retained items seems to be growing. URFOs were the most frequent sentinel event reported to The Joint Commission's (TJC's) Sentinel Event database for 2015 (115 reported) and 2014 (112 reported), according to a *Quick Safety* article just published by TJC to update its 2013 "*Sentinel Event Alert*."[2] However, according to NoThingLeftBehind.org, there are between 2,000 and 4,000 retained surgical items each year in the United States. Some of those retained items are leading to lawsuits. The Doctors Company in Napa, CA, examined 19,000 surgery claims over an eight-year period. Less than 5% involved a retained foreign body, according to **Robin Diamond**, MSN, JD, RN, senior vice president, patient safety and risk management at The Doctors Company.

According to the TJC, the most common root causes of URFOs continue to be:

- failure to comply with existing policies and procedures;
- problems with hierarchy and intimidation;
- failure in communication with physicians;
- failure of staff to communicate relevant patient information;
- inadequate or incomplete education of staff;
- the absence of policies and procedures.[2]

Diamond says, "The department must have unambiguous policies/guidelines that allow for zero variation in sponge counts as well as tracking and accounting for tools and parts of devices."

The policies should guide all perioperative care personnel, not just nursing and facility staff, according to NoThingLeftBehind.org. (A MultiStakeholder Prevention of

EXECUTIVE SUMMARY

New challenges are emerging for retained surgical items, including retained miscellaneous items and surgery performed outside of the OR.

- Staff members need to be educated about communication, so they are comfortable speaking up, and about new instruments, so they will recognize if parts are broken or missing.
- A "no-distractions zone" can help ensure that the count is correct.
- Ensure retained items are reported to the facility and to the patient.

Retained Surgical Items Policy *has been revised and is available at bit.ly/1Sm54dw.)*

Consider these additional solutions for addressing URFOs:

• Incorporate formal training programs to support open communication among team members.

According to the updated guidance from AORN, there should be team training that teaches communication and teamwork. TeamSTEPPS is one example mentioned by AORN. It is an evidence-based system that aims to optimize patient care by improving communication and teamwork among healthcare professionals. It includes ready-to-use materials and a training curriculum. *(More information is available at 1.usa.gov/1Sm5BMz. Also see "TeamSTEPPS offers help with distractions," S*ame-Day Surgery, *July 2014, at bit.ly/1UhvIY2.*)

Walmsley says that communication is one of the most frequent URFO contributing factors (62%) reported to her organization, and it is second only to policy and procedure factors (65%). "The AORN guideline recommendation to support communication among staff with programs like TeamSTEPPS is absolutely critical to preventing adverse events, including URFOs," she says.

There are many new instruments in the ORs, and training should include information about the devices for nurses and surgical technologists, Gibbs says.

Anyone passing instruments back and forth needs to be familiar with the multiple parts of instruments so they will notice if a part is missing or broken, she says. "The assumption that the surgeon will recognize if it's broken is wrong," Gibbs says, because the instrument might have been functioning correctly when the surgeon was holding it. If the problem with the instrument isn't identified in the OR, "the patient is long gone from the OR with whatever part is missing inside of them," she says.

• Monitor compliance with tool use, and hold staff accountable for using tools consistently.

According to the TJC, tools to avoid retaining objects include white boards, sponge trees, radio-frequency identification (RFID) technology, radiopaque supplies, and count documentation methodology.[2] When selecting which one to use, consider your facility's priorities, such as cost and whether the device is easy to use.[2]

Diamond says their effectiveness is clear. "Assistive technologies have decreased the frequency of retained sponges," she says.

One caveat: Sometimes count documentation doesn't identify missing or broken parts, just that the item is accounted for, says **Mark Mayo**, CASC, executive director of Golf Surgical Center in Des Plaines, IL. "So a count policy must not only say the item is accounted for, but that it is whole, not missing parts, and not broken," Mayo says.

• Limit distractions to ensure accurate counting.

AORN's updated guideline says to perform the initial count before the patient is brought into the OR to reduce distractions that can cause errors. When the count can't be completed before the patient is in the OR, a second RN circulator can help the primary RN circulator with the count or with patient care, AORN says.

Create a "no-interruption zone" that doesn't allow nonessential activities and conversations and that stops the count from being rushed, AORN says.

• Use a systems approach to quality improvement.

Have a system approach to your quality assurance/performance improvement interventions, AORN's updated guidance says. In addition to having a no-interruption zone, this approach can include standardized reconciliation procedures, methodical wound exploration, radiological confirmation of a retained surgical item, team training, and enhanced communication.

Regarding team communication, the TJC says your policies should clearly state your expectations.[2] For example, the policy might say that the physician will affirm the count before closing the wound, the organization says. Also, the physician might be expected to say when an instrument is placed in the body and not removed immediately, so the circulator can track that instrument.

When the policy isn't followed, staff members need to be educated that they should speak up.[1] Staff members should be educated about stopping the case and going up the chain of command as needed. Spell out the escalation process in your policy, TJC advises. If one member of the OR team thinks the count should be repeated, that action should be supported and taken, it says.

"Each team member should be empowered to call a 'time out' prior to the initial closing count to allow for no interruptions until the count is complete," Diamond says. "Documentation in the medical record and on all tracking reports must be done and monitored for compliance in quality meetings."

• Report discovered retained items.

A retained item that is found should be reported regardless of where the item was retained, the TJC says.[2] It gives the example of a retained

item found in a physician's office that should be reported to the facility where the surgery occurred.

Have a nonpunitive system when retained items are reported, the TJC says.

Also, disclose the retained item to patients, Diamond urges. She shares that one surgeon was performing spinal surgery on a patient when the catheter broke off. The fact that the item had been retained in the patient was discovered after surgery. "The surgeon did not think the wound should be opened up, as there was no emergent need," Diamond says.

The surgeon documented what happened, Diamond says. The surgeon also informed the patient and told the patient which signs and symptoms to look for. The patient had no pain for a week. After a week, the surgeon called the patient to follow up, and the patient said the pain was back and he was going to another surgeon. The first surgeon offered remedial surgery, but the patient refused.

"The patient sued, but the case was dismissed after the expert testified that the surgeon took appropriate action," Diamond says. "Keeping patients engaged in their healthcare and disclosing information when something goes wrong are two strategies that strengthen the physician-patient relationship."

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- *Same-Day Surgery*. See "Sentinel Event Alert issued on retained surgical items," December 2013, bit.ly/1P0EfXI; "Sponges retained in patients during surgery are reduced by 93% in study," February 2015, bit.ly/1P0EpOT, "Surgery staff reduces count problems by 50%," July 2012, bit.ly/1Set6cc; and "Procedures, technology can prevent retained items," September 2010, bit.ly/1PlP22z. ■

Antibiotics over surgery for peds appendicitis? Proceed with caution, experts say

Several recent studies suggesting that appendicitis could be treated with antibiotics alone have generated serious buzz among clinicians and parents.

The antibiotics-only approach has been used in adults for several decades, but in children, it remains new, is still deemed experimental, and does not preclude disease recurrence down the road, say pediatric surgeons at Ann & Robert H. Lurie Children's Hospital of Chicago.

Appendicitis is responsible for more than 300,000 surgeries a year in the United States. It occurs most commonly in children and teens ages 10-19. One in five pediatric surgeries is performed for appendicitis.

Experts have flagged several concerns with the medication-only approach. These include longer stays, possibility for disease recurrence, and side effects such as antibiotic-induced diarrhea. For these reasons, the decision to treat a child with antibiotics rather than surgery should not be made lightly, Lurie Children's surgeons say. Clinicians and parents must carefully weigh such concerns against other factors, including a child's overall health, the severity of symptoms, and the degree of appendix inflammation.

Lurie Children's Hospital is part of a multi-center national trial to compare the long-term outcomes of children treated with antibiotics with those undergoing surgery. The findings will help answer some of the lingering questions surrounding antibiotic-only therapy for a condition that has been treated with surgery for more than a century, researchers say.

"No matter how straightforward, no operation is completely risk-free, so the notion of avoiding surgery is decidedly tantalizing," says **Julia Grabowsk**i, MD, an attending physician at Lurie Children's Division of Pediatric Surgery and assistant professor of surgery at Northwestern University Feinberg School of Medicine. "Antibiotics are a legitimate therapeutic choice in a small number of children with appendicitis, but it's important to remember it's surgery that remains the standard of care for most kids."

Even if antibiotics quell the initial infection and a child gets better, appendicitis can recur,

necessitating a surgery down the road, Lurie Children's specialists say. In addition, any child with a history of antibiotic-treated appendicitis who later develops abdominal pain may require repeat visits to the emergency department and imaging tests to rule out disease recurrence.

Catherine Hunter, MD, an attending physician in the Division of Pediatric Surgery at Lurie Children's and assistant professor of surgery at Northwestern University Feinberg School of Medicine, says, "As surgeons we should always consider non-surgical alternatives to clinical problems. While non-operative treatment may be appealing in the short run, we must bear in mind that not having surgery can create its own set of challenges down the road."

Stopping recurrence

One of the most critical questions in the drugs-versus-surgery conundrum remains whether antibiotics provide a truly permanent solution, Hunter notes.

Most studies comparing treatment outcomes followed patients for a year or less, so it remains unclear whether those treated with antibiotics had a recurrence and required surgery past the one-year mark. A small study among Swedish children revealed that 62% of those treated with antibiotics did not need a surgery within a year of antibiotic treatment.

One of the largest clinical trials to date was a study conducted in Finland among more than 500 adult patients and published in *The Journal of the American Medical Association* in 2015. In that study, more than a quarter of patients treated with antibiotics ended up undergoing surgery within a year of treatment. Most of those who required surgery had the procedure within three months of initial diagnosis.

In addition, Hunter says, it remains uncertain precisely which patients might benefit the most from antibiotics and holding off surgery.

Another vexing concern is that even if a child gets better, any subsequent abdominal pain may signal recurrent appendicitis, Hunter and colleagues say. That possibility alone will result in repeat visits to the doctor, more imaging tests, and, in some cases, an eventual surgery. "Every time a child with history of antibiotic-treated appendicitis develops belly pain, the question of another episode will loom large," Hunter says.

Appendicitis is a spectrum disorder ranging from simple to complicated, the latter of which can lead to a serious widespread infection of the entire abdomen. Disease severity is determined by a physical exam as well as blood and imaging tests.

If a child has been diagnosed with uncomplicated appendicitis, antibiotics might be a reasonable approach, but aren't necessarily the first choice. The decision must be made on a case-by-case basis, depending on test results, the degree of organ inflammation, and the severity of symptoms, says Grabowski. ■

New standards for children's surgery verification

New document paves the way for centers to apply online for verification

The Children's Surgery Verification Quality Improvement Program, a quality program of the American College of Surgeons, has released its latest standards document, *Optimal Resources for Children's Surgical Care*. The standards set forth in this document are the nation's first multispecialty standards for children's surgical care.

"This is the first time ever that there has been a formal delineation of resource standards that relate specifically to children's surgical care across all relevant disciplines," said **Keith T. Oldham**, MD, FACS, chair of the Children's Surgery Verification Program and the surgeon in chief at Children's Hospital of Wisconsin, Milwaukee. "The vision is to see that every child receiving surgical care receives quality care in an environment with resources matched to his or her individual needs."

The standards were developed by the American College of Surgeons with the Task Force for Children's Surgical Care. They seek to improve surgical care for pediatric surgical patients.

The new document includes revisions to the 2014 standards document and updates from lessons learned during the pilot phase of the program, such as the need for alternative training pathways for anesthesiology, emergency medicine, and radiology. The new standards also clearly state the safety data elements required for all level designations.

In what Oldham describes as a "major, long-term, ongoing commitment" by healthcare facilities, the process starts with an application to the American College of Surgeons.

The online application is expected to launch later this year. Next, the facility submits a prereview questionnaire, which Oldham describes as a "fairly complicated data collection form" with information regarding the character of the institution, the background and training of the providers who care for children, and the quality programs in place.

"The standards presented in this document are the basis for the Children's Surgery Verification Program, for which the American College of Surgeons will visit centers periodically and verify that relevant standards are met and related quality improvement mechanisms are in place," said Oldham. The site visit will result in a report that is reviewed by a committee. The process is rigorous and is, in many ways, more quantitative than what The Joint Commission requires, Oldham says.

To access these standards, visit bit.ly/1K9gPCE. If your organization is interested in becoming verified or has questions, email childrenssurgery@facs.org. ■

SDS Manager

Two of your pressing issues: Over-regulation and cost of cataract supplies

By ***Stephen W. Earnhart****, MS*
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In *USA Today*, there was an article on a recent survey of 1,400 CEOs from around the world. They were asked what they perceived as key threats to business. The no. 1 threat (79%) was "over-regulation." We in healthcare understand. Another interesting result was that 72% listed lack of "key skills." Tried to hire any quality, experienced staff lately?

It made me wonder what we, as healthcare providers and workers, can do to reduce meaningless, bureaucratic, paper-shuffling, just-burden-them-with-useless-waste-of-time-busywork so we can eliminate some of the mind-numbing nightmare of taking care of our patients. Much of this work is passed down to us from above, but that doesn't necessarily make it right. I work with some of those people at the top, and most are clueless as to how to deal with it, so they just keep shuffling it down the tube to us to make sure it is properly dealt with.

Let's see if we can't make a difference. Send me an email and let me know what you think is the biggest waste of time we deal with in our surgical departments, and let's try to eliminate it. I will research it and get back to everyone with a potential solution!

Question on IOL costs

Someone asked me last month what is the ideal supply cost per case for cataract extraction with an intraocular lens (IOL) implant. Great question.

I did some research and found, what I think, is among the lowest in the country. Depending upon the CMS wage index for your part of the country, Medicare reimbursement is about $980 for the procedure, which includes the patient co-payment of $196 (collect it before surgery!) and the cost of the IOL. Ugh! Can you make a profit anymore? Yes, but you have to work hard for it. The key to success resides in your supply cost and a high number of cases.

Surgeons can choose the lens that they think is right for their patients (of course), and they have several vendors to choose from: Abbott Medical Optics, Alcon, Bausch + Lomb, and perhaps others. The prices also vary enormously among these vendors. Good luck trying to get your doc to choose the lowest price lens — it just makes them mad, I know — but at least you can anonymously slip the price of each lens into their lockers. It helped me once.

What price should you strive for? If you are not around $200 per case — yes, that includes the IOL — you are missing an opportunity to improve your bottom line. It can and is being accomplished!

Now, many facilities doing cataracts have several surgeons doing them. In one facility, we have seen some docs supply cost around $200 and others around $500. Why? Old habits. That, and the fact that there is not enough physician education going on at your hospital or ASC on cost control.

Most staff members, except possibly your docs, are willing to be educated on lowering their supply cost; they just have not been willing to learn new ways and techniques. Peer pressure always works best, so try doc on doc first. A facility doing 3,000 cataracts per year that can save $150 per case in supplies adds up to $450,000. It's worth the effort.

Speaking of "effort," do send me your paperwork pet peeve. Let's see what we can do! *[Earnhart & Associates is a consulting firm specializing in all aspects of outpatient surgery development and management. Earnhart & Associates, 5114 Balcones Woods Drive, Suite 307-203, Austin, TX 78759. Phone: (512) 297-7575. Fax: (512) 233-2979. E-mail: searnhart@earnhart.com. Web: www.earnhart.com.]* ■

New duodenoscope, recalls, and revised reprocessing instructions

The Food and Drug Administration has given marketing clearance to a newly redesigned duodenoscope that is expected to improve patient safety.

The manufacturer of the device, Olympus Corporation of the Americas in Center Valley, PA, is voluntarily recalling duodenoscopes already on the market that have been linked to life-threatening, antibiotic-resistant infections among patients in several facilities, including Virginia Mason Medical Center in Washington state. *(For more information, see "FDA says to inform patients about risk of endoscopy linked to CRE infections,"* Same-Day Surgery*, April 2015, at bit.ly/1VvCxBv.)* Olympus will repair the recalled devices and is replacing the parts of the closed-channel tip of the duodenoscope to reduce the risk of bacterial infections.

The actions follow a report released by Sen. Patty Murray (D-WA) showing that the manufacturer knew the scopes could not be reliably cleaned and could present a threat to patients' lives. *(To access the report, go to 1.usa.gov/1SisZfg.)* "These devices exposed far too many patients and their families to unacceptable risks, and I am pleased to see that the FDA and manufacturers have taken additional actions to protect patients in the future," said Murray. "The steps taken today are important, but there is much more we need to do to make sure the FDA can respond quickly and appropriately when problems with medical devices occur."

The report recommends legislative and regulatory changes, including:

• requiring that unique device identifiers be included in medical data to allow the FDA to more quickly identify risks associated with a given device;

• strengthening FDA guidance regarding clearance of modified medical devices by manufacturers.

In other news, Fuji has issued revised manual reprocessing instructions for its ED-530XT duodenoscope to replace those provided in the original device labeling, the FDA reported.

Facilities using the duodenoscope should train staff on the new validated instructions and implement them as soon as possible. The FDA also encourages facilities to apply the revised instructions to Fuji's 250 and 450 duodenoscope models.

"While formal validation testing with the revised reprocessing instructions is ongoing for Fuji's 250 and 450 duodenoscope models, FDA … believes that the revised reprocessing instructions for the ED-530XT duodenoscope are more robust because of additional pre-cleaning, cleaning and high-level disinfection steps and, for that reason, should increase the safety margin of the 250 and 450 duodenoscope models," the agency said. *(For more information, go to 1.usa.gov/1kLDKId.* Same-Day Surgery *tweeted about Fuji on Jan. 6 @SameDaySurgery.)* ■

New perioperative guideline released for geriatric surgical patients

A new collaborative best practices guideline has been released for care of older adults immediately before, during, and after surgical operations.

The new consensus-based guideline was developed by the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) and the American Geriatrics Society's (AGS) Geriatrics-for-Specialists Initiative (GSI), with support from The John A. Hartford Foundation.

Optimal perioperative management of the geriatric patient: A best practices guideline is available for download at bit.ly/1OHl6ZW. It also has been

published online on the *Journal of the American College of Surgeons (JACS)* website and will appear in print edition of *JACS* and the *Journal of the American Geriatrics Society* this year.

Building on a 2012 collaboration on joint guidelines addressing the preoperative care of older patients, the groups again partnered for the new best practices guideline. *(For more information on the 2012 guidelines, see "Preop guidelines published for geriatric surgery patients,"* Same-Day Surgery*, December 2012. The story can be accessed at the AHCMedia.com page at bit.ly/1P6q1rU.)*

The new guideline addresses the perioperative care of all surgical patients 65 years old and older as defined by Medicare regulations. The guideline provides a framework for thinking about the complex issues these patients face because they are more prone to experience postoperative complications and prolonged recovery with advanced age.

The ACS Geriatric Surgery Task Force developed the guideline with a multidisciplinary panel, which evaluated current evidence and best practices in the medical literature to arrive at a set of recommendations targeting surgeons, anesthesiologists, and allied healthcare professionals. While this consensus-based guideline is "not a substitute for clinical judgment and experience," it can do much to support tailored, comprehensive geriatrics evaluations, the authors explain.

"This new interdisciplinary guideline provides us with another meaningful tool for improving geriatric surgical care," said guideline coauthor **Clifford Y. Ko**, MD, MSHS, FACS, director of ACS NSQIP and principal investigator of the Coalition for Quality in Geriatrics Surgery (CQGS) Project. "We now have expert recommendations in place for older patients that range from preoperative assessment to perioperative management."

The perioperative guideline is organized into three sections:

• Immediate preoperative management.

This section addresses patient goals, preferences, and advance directives; preoperative fasting; antibiotic prophylaxis; venous thromboembolism prevention; and medication management.

• Intraoperative management.

This section provides a management checklist for the intraoperative period. It addresses the use of anesthesia in older adults, perioperative analgesia in older adults, perioperative nausea and vomiting, patient safety, strategies to prevent postoperative complications and hypothermia, fluid management, and the targeting of physiologic parameters.

• Postoperative management.

This section provides a postoperative rounding checklist. It covers postoperative delirium, methods for preventing pulmonary complications, fall risk assessment and prevention, postoperative nutrition, ways to prevent urinary tract infections, functional decline, and pressure ulcer prevention and treatment.

A final section of the document guides clinicians in managing transition to care following surgery. It provides helpful appendices on a wide range of issues, from advance directive position statements to perioperative risk factors for delirium.

Guideline coauthor **Sanjay Mohanty**, MD, a general surgery resident at Henry Ford Hospital, and an ACS/AGS James C. Thompson Geriatrics Surgical Fellow, said, "As a start, this guideline functions as an unprecedented educational resource, one that organizes all of the components of perioperative care of the older adult in one place. Moving forward, perhaps it will one day play an important role in informing us about process and providing us with insightful metrics on outcomes for geriatric surgical patients." *(For more information on caring for geriatric patients, see these stories in the December 2015 issue of* Same-Day Surgery *bit.ly/1YgJCID: "4 steps to avoid hospital admissions that are unanticipated with elderly patients" and "What makes seniors more likely to have unanticipated admissions?")* ■

Ambulatory surgery centers are in OIG's sights

Ambulatory surgical centers (ASCs) are among the many healthcare operations targeted for close oversight in the 2016 Work Plan from the Office of Inspector General (OIG) of the Department of Health and Human Services.

The focus on ASCs is new to the Work Plan this year, notes **Bart Walker**, JD, a partner with McGuireWoods in Charlotte, NC. The Work Plan indicates that OIG will focus on oversight of the state agencies that handle Medicare surveys and ASC accreditation organizations, with the agency expressing concern with the infrequency of Medicare certification surveys of ASC facilities. Although most private accreditation organizations traditionally required unannounced surveys every three

years, OIG has found that many ASCs have gone for five years, and some for even longer, between surveys. The Work Plan also expresses concern about the lack of public information on the quality of ASCs, Walker notes.

Among the most noteworthy parts of the plan is the OIG's emphasis on the Health Insurance Portability and Accountability Act (HIPAA) at all facilities, Walker says. This year OIG will have a heightened focus on the HIPAA Security Rule (45 CFR Part 160 and Subparts A and C of Part 164), which delineates how covered entities must protect data.

The HIPAA material is actionable for managers, "particularly where it concerns secure devices and network with those devices," Walker says. Contingency planning is another focus that managers should examine, he says. "There are some specific requirements in the rule that require providers to have contingency plans in place and conduct audits of their security system," Walker says.

Walker explains that the Work Plan calls for increased scrutiny of protections of electronic protected health information (ePHI) with respect to "networked medical devices." The Work Plan also calls for regulators to determine the "extent to which hospitals comply with contingency planning requirements" of HIPAA regarding their use of electronic health records (EHR) systems. More specifically, OIG will examine whether the Food and Drug Administration (FDA) is providing sufficient oversight of networked medical devices in hospitals, Walker says. *(The Work Plan is available online at http://tinyurl.com/ohc962j.)*

The Work Plan also notes a focus on HIPAA EHR contingency plans. It emphasizes that "the HIPAA Security Rule requires covered entities to have a contingency plan that establishes policies and procedures for responding to an emergency or other occurrence that damages systems that contain protected health information." Walker expects that will lead to OIG using government- and industry-recommended practices to gauge a healthcare organization's performance with regard to contingency plans.

Provider-based clinics

"Provider-based facilities" also are targeted in the Work Plan. Those are facilities that are operated and reimbursed as if they were part of the affiliated hospital.

The provider-based facilities increase Medicare beneficiary coinsurance liability and increase costs to the program, the Work Plan notes. "That has long been a bone of contention between hospitals and other providers, because those facilities are able to collect a higher rate from Medicare, and that makes them stronger economically when it comes to competing with other facilities," Walker says. "Increasingly in recent years, hospitals have been accumulating other assets that are not within the hospital but treating them as provider-based. They're not doing anything wrong because the rules are there, and if you comply with the provider-based rules, you're eligible for provider-based reimbursement."

OIG has scrutinized these provider-based arrangements for at least two years because of this discrepancy in reimbursement based only on who owns the facility, Walker says. That scrutiny will increase this year as a result of the Bipartisan Budget Act of 2015, which, with some exceptions, excludes off-campus facilities from receiving enhanced reimbursement starting Jan. 1, 2017. As provider-based facilities prepare for the loss of revenue and competitive edge, OIG plans to closely monitor how they try to compensate.

Walker cautions that the OIG's interest in compliance will not wane this year just because the enhanced reimbursement will end soon. Hospitals operating provider-based facilities should ensure that they comply with provider-based rules and not let their guard down, he says.

"A lot of hospitals and health systems will have a look at their strategies and determine whether those facilities remain economically viable," Walker says. "This change had been considered in past budget legislation, but actually ending the enhanced reimbursement this soon was not on anyone's radar. It pretty much came out of the blue. Now hospitals are suddenly faced with a loss of revenue or lobbying for some other way to bill for these services that is site-neutral. That's always been the holy grail of Medicare reform." ■

Safety checklist boosts perceived periop safety

An initiative to implement surgical safety checklists at 13 South Carolina hospitals was linked with improved staff perceptions of mutual respect, clinical leadership, assertiveness on behalf of safety, team coordination and communication, safe practice, and perceived checklist outcomes, according to a just-published study.

The objective of this study was to evaluate the impact of a large-scale

implementation of surgical safety checklists on staff perceptions of perioperative safety in the operating room, according to the study results in press for the *Journal of the American College of Surgeons.*

As part of the Safe Surgery 2015 initiative to implement the checklists in South Carolina hospitals, the members of the research team administered a validated survey designed to measure perception of multiple areas of perioperative safety among membes of the clinical operating room staff before and after implementation of a surgical safety checklist.

Thirteen hospitals administered baseline and follow-up surveys, separated by one to two years. Results suggest improvement in five of the five dimensions of teamwork. The relative percent improvement ranged from +2.9% for coordination to +11.9% for communication. These statistics were significant after adjusting for respondent characteristics, hospital fixed-effects, and multiple comparisons, and clustering robust standard errors by hospital, the researchers said.

More than half of respondents (54.1%) said their surgical teams always used checklists effectively; 73.6% said checklists had averted problems or complications. *(To access the abstract, go to bit.ly/1m1Qlrq. To access an award-winning safety checklist, see "Defective instrument probe and safety checklist lead to award,"* Same-Day Surgery, *July 2015, at bit.ly/1WSiFtG.)* ■

Patients can safely shower 48 hours after surgery

Forty-eight hours after surgery, wounds that are clean and clean-contaminated can be safely showered, according to the results of a study just published in the *Annals of Surgery*.

Such postoperative showering doesn't increase the risk of surgical site infections, according to the research. It might increase patient satisfaction and lower the cost of wound care, the authors say.

Jin-Shing Chen, MD, PhD, attending physician at National Taiwan University Hospital in Taipei City and associate professor at National Taiwan University in Taipei, and his colleagues focused on patients with clean or contaminated wounds who had one of the following surgeries: thyroid, lung, inguinal hernia, and face and extremity. The 444 patients were randomized to allow showering or to keep the wound dry starting 48 hours after the surgery. The study looked at the rate of surgical wound infection, wound pain score, satisfaction with wound care, and the cost of wound care.

The researchers reported four superficial site infections in the group that showered and six in the group that didn't shower (4/220, 1.8% vs 6/220, 2.7%, p = 0.751). The pain scores were comparable between the groups. Patients who showered were more satisfied with their method of wound care, and their wound care costs were lower compared to the nonshowering group, the researchers reported.

To access the study results, go to bit.ly/1NXvvRH. ■

Colonoscopy quality varies among facilities

Researchers have found important variation in quality of colonoscopies among outpatient facilities.

The researchers at the Center for Outcomes Research and Evaluation (CORE) at Yale–New Haven Hospital, New Haven, CT, developed an outcome measure by estimating risk-standardized rates of unplanned hospital visits within seven days of colonoscopy. The research was published in the January 2016 issue of *Gastroenterology.*

They used a 20% sample of 2010 Medicare outpatient colonoscopy claims (331,880 colonoscopies performed at 8,140 facilities) from patients 65 years of age or older. They estimated the risk of unplanned hospital visits (for example, emergency department visits, observation stays, and inpatient admissions) within seven days of colonoscopies. They estimated facility rates of risk-standardized unplanned hospital visits using data from the Healthcare Cost and Utilization Project (325,811 colonoscopies

COMING IN FUTURE MONTHS

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at 992 facilities), from four states containing 100% of colonoscopies per facility.

Outpatient colonoscopies were followed by 5,412 unplanned hospital visits within seven days (16.3/1,000 colonoscopies). Hemorrhage, abdominal pain, and perforation were the most common causes of unplanned hospital visits, the researchers said. A history of fluid and electrolyte imbalance, psychiatric disorders, and, in the absence of prior arrhythmia, increasing age past 65 year were most strongly linked with unplanned hospital visits.

The facility risk-standardized unplanned hospital visits calculated using Healthcare Cost and Utilization Project data showed significant variation. Median risk-standardized unplanned hospital visits were comparable between ambulatory surgery centers and hospital outpatient departments (each was 10.2/1000), and ranged from 16.1/1000 in the Northeast to 17.2/1000 in the Midwest. *(To see a copy of the study, go to bit.ly/1ntjHA4.)* ■

No link found between anesthesia after age 40 and mild cognitive impairment

A study of people who received anesthesia for surgery after age 40 found no association between the anesthesia and development of mild cognitive impairment later in life. The study was conducted by the Mayo Clinic in Rochester, MN.

The findings are published in the February issue of *Mayo Clinic Proceedings*.

"We looked at a group of patients who have been followed here in Olmsted County, where we have detailed information about their cognitive function as they age. The bottom line of our study is that we did not find an association between exposure to anesthesia for surgery and the development of mild cognitive impairment in these patients," says senior author **David O. Warner,** MD, a Mayo Clinic anesthesiologist.

A previous Mayo study found that older patients who receive anesthesia are no more likely than others to develop dementia. (*For more information on that study, go to mayocl.in/1PYZgSv.)* In the current study, researchers analyzed detailed patient information from the Mayo Clinic Study of Aging and the Rochester Epidemiology Project. The study included people who were ages 70-89 and cognitively normal as of October 2004. Their mean age was 79, and there were almost equal numbers of men and women.

They were evaluated every 15 months. Of 1,731 people studied, 85% had at least one surgery requiring general anesthesia after age 40. Thirty-one percent developed mild cognitive impairment during the study period, but it was not found to be linked to their anesthesia exposure.

The researchers noted that while exposure to anesthesia for surgery after age 40 wasn't linked to mild cognitive impairment, they couldn't exclude the possibility that surgical anesthesia after age 60 might be, particularly in vascular surgery patients. "That may not be surprising, because there is increasing evidence that some of the problems that we see with cognition in the elderly may be caused by vascular problems that cause stroke and other sorts of problems like that," says Warner.

Mayo researchers also are studying the effects of anesthesia in young children. At that age, they are seeing associations between surgical anesthesia exposures and problems with learning and memory later in life, Warner says. "That by no means is established yet. Right now it's just associations, and we and many other people are doing a lot of work to try to see if this really is a problem in children or not," he says. "Because of the associations that we've seen, there is more concern in the young than the old, and it will require quite a bit more research to find out what is happening with the children, and if there is a problem, how we can best address it. But for the moment, there is little clinical evidence that anesthesia itself leads to cognitive decline in the elderly, although more research is needed." *(For the abstract, go to bit.ly/1PFncKh.)* ■

CNE/CME OBJECTIVES

After reading *Same-Day Surgery,* the participant will be able to:

- identify clinical, managerial, regulatory, or social issues relating to ambulatory surgery care;
- identifiy how current issues in ambulatory surgery affect clinical and management practices;
- incorporate practical solutions to ambulatory surgery issues and concerns into daily practices.

SAME-DAY SURGERY

CNE/CME INSTRUCTIONS

To earn credit for this activity, please follow these instructions:

1. Read and study the activity, using the provided references for further research.

2. Scan the QR code to the right or log on to AHCMedia.com then select "My Account" to take a post-test. *First-time users must register on the site.*

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CNE/CME QUESTIONS

1. What do newly updated guidelines on retained items from the Association of periOperative Registered Nurses say that staff must account for?

A. All needles
B. All guidewires
C. A and B
D. Neither A nor B

2. What is the standard of care for children with appendicitis, according to Julia Grabowski, MD, an attending physician at Lurie Children's Division of Pediatric Surgery and assistant professor of surgery at Northwestern University Feinberg School of Medicine, both in Chicago?

A. Antibiotics
B. Surgery

3. Which of the following was done by Olympus Corporation of the Americas in Center Valley, PA?

A. It submitted a newly redesigned duodenoscope to the Food and Drug Administration, which gave marketing clearance to the device.
B. It voluntarily recalled duodenoscopes already on the market.
C. A and B
D. Neither A nor B

4. The Office of Inspector General, in its 2016 Work Plan, indicated that it will focus on which of the following?

A. Ambulatory surgery centers
B. The Health Insurance Portability and Accountability Act
C. Provider-based clinics
D. All of the above

SDS ACCREDITATION UPDATE

Covering Compliance with TJC, AAAHC, AAAASF, and Medicare Standards

Staying survey-ready is critical in current accreditation environment

Outpatient surgery leaders offer tools and tips to be ready when surveyor arrives

A cautionary note: Those days of knowing when surveyors or government regulators are coming and having time to prepare? They're long past, say accreditation experts interviewed by *Same-Day Surgery*.

Surveyors and regulators can decide to do a survey for risk management reasons, to examine your adherence to life safety regulations, or to conduct a more focused inspection, cautions **David Shapiro**, MD, CASC, CHC, CHCQM, FABQAURP, FAIHQ, LHRM, a board member for the Accreditation Association for Ambulatory Health Care (AAAHC). For that reason, don't wait for your accreditation cycle to approach its expiration date, Shapiro says.

"Those folks have the ability … to show up any day of the week you're open," he says. "You want to be ready when they get there."

"THESE FOLKS HAVE THE ABILITY … TO SHOW UP ANY DAY OF THE WEEK YOU'RE OPEN. YOU WANT TO BE READY WHEN THEY GET THERE."

The preparation is particularly important because the Office of Inspector General (OIG) of the Department of Health and Human Services has added ambulatory surgery centers to its Work Plan for this year. OIG has expressed concern about the infrequency of Medicare certification surveys for ASCs. *(See more information in this month's issue of* Same-Day Surgery*.)*

Consider these suggestions for being survey-ready:

• Have a solid education program.

The reason for most survey deficiencies is that employees either aren't aware of the requirements or they skip steps in the process because they aren't focused, says **Jan Allison**, RN, CHSP, director of accreditation and survey readiness at Deerfield, IL-based Surgical Care Affiliates.

"Educate teammates in understanding their responsibilities, including their role before, during, and after survey," Allison says. "They need to be aware of current standards and common survey citations." *(See list of AAAHC most common deficiencies in this issue of* SDS Accreditation Update. *The Joint Commission's most common deficiencies are available at bit.ly/1lW8cjv.)* She points out that during a survey, surveyors follow a tracer methodology by selecting a patient and assessing the patient's experience from check-in to discharge.

"Teammates from various departments within a facility are involved in sharing with surveyors how they fulfill the standards through their day-to-day responsibilities," Allison says. "Each teammate needs to be knowledgeable of the important issues and have a clear understanding of the regulations/standards that apply to their job and department."

Surgical Care Affiliates records webinars about survey readiness and posts them on its eLearning system. Employees who watch webinars earn continuing

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EXECUTIVE SUMMARY

Surveyed organizations need to be ready at any time for accreditation surveyors or government regulators to visit.

- Educate employees on what to expect, including the tracer methodology. Delegate responsibilities for compliance.
- Cross-reference standards to your policies.
- Ensure documentation is up to date by using templates for meeting minutes that are preprinted with topics, as well as spreadsheets or software with prompts.
- Tools include regular self-assessments, audit checklists, mock surveys, and "tickler" programs.

education credit. *(AHC Media, publisher of* Same-Day Surgery, *also offers webinars on accreditation topics. See list of webinars at bit.ly/1JCREbM.)*

"Monthly newsletters or posters addressing updates work to keep teammates current," Allison says.

• Delegate responsibility.

Accreditation is a lot of work, so spread it around among employees, Shapiro advises.

"All of them should have skin in the game," he says. "If you divide up the work, it's a much less daunting task, instead of putting on one person's shoulders who has other responsibilities and may be taking care of patients 12 hours a day."

Allison concurs that accreditation needs teamwork. "One person alone cannot effectively drive compliance," she says.

• Be familiar with the standards, and cross-reference them to your policies.

On site, you should have current state-specific regulations, the Centers for Medicare and Medicaid Services *State Operations Manual,* and the most current version of the accreditation manual, Allison says. "Be familiar with their contents," she says.

Shapiro concurs. "It's an open-book test," he says. "You will not be surveyed against anything that you shouldn't have easy access to and more than passing familiarity."

Many organizations have found it helpful to index their policies or cross-reference them to specific standards, Shapiro says. When a surveyor asks about a specific standard, a cross-referenced document will allow you to search for the specific standard, he points out.

• Use tools and processes to ensure compliance.

Many outpatient surgery programs struggle with documentation that shows required activities took place, Allison says. "This may be in the form of missing elements in the governing body meeting minutes or in the reports from vendors that conduct maintenance and testing," she says. "We have to remember that documentation tells the story of the activities taking place in the facility and, in a number of situations, that is all the surveyor has to look at."

Surgical Care Affiliates uses meeting minute templates that are preprinted with topics, in bulleted form, that will be discussed, Allison says. "Spreadsheets or software is implemented that prompts for a required activity to take place just prior to being due," she says.

Shapiro says that monthly, or at least quarterly, you should perform self-assessment of accreditation problem areas, such as credentialing and personnel records, "those mountains of paperwork that surveyors go through, such as peer review files." Ensure they are current on an ongoing basis, he advises.

Allison says compliance audits "ensure teammates are knowledgeable over basic standards and are performing processes appropriately, that facility policies reflect current best practices, the environment is safely maintained, and documentation is current and complete. Audit checklists contain key observations used to determine the extent to which standards are being followed in designated areas."

Your QA/PI program should be robust, she says. "This is where audit results are initially reported and analyzed and corrective actions are developed and implemented for improvement," Allison says.

Use a "tickler" program for yourself or the staff members who handle survey responsibilities as reminders of deadlines, Shapiro says. "If physician credentialing files are up for recredentialing, start six months ahead, not two months after, when you have to hold up bookings," he says.

Accountability is key, Allison says. "Vendor contracts need to reflect the required inspections, maintenance, and testing and the frequency with which they occur," Allison says.

Conduct mock surveys on a regular basis by acting in the role of surveyor and looking at protocols as a surveyor would, Shapiro advises. Mock surveys can be held on just a few regulations or standards, such as patient handoff protocols or the fire safety system. Use the surveyor worksheets, Allison adds.

By following these steps, Shapiro says, you "keep your facility up to date in every regard that pertains to a survey so you're never playing catchup."

When the surveyor walks in the door, you want to be ready and up to date, "not behind the eight ball, not scrambling around," he says. "Everything is polished and ready to go." ■

AAAHC's Most Common Deficiencies for ASCs

• Safe injection practices

Standard 7.1.C.2 Subchapter I Infection Prevention and Control: An accreditable organization maintains an active and ongoing infection prevention and control program as evidenced by the following characteristics: C. The infection control and prevention program reduces the risk of health care-acquired infection as evidenced by education and active surveillance, consistent with: 2. CDC or other nationally-recognized guidelines for safe injection practices.

• Credentialing, Privileging and Peer Review

Standard 2.11.D Privileges to carry out specified procedures are granted by the organization to the health care professional to practice for a specified period of time. The health care professional must be legally and professionally qualified for the privileges granted. These privileges are granted based on an applicant's qualifications within the services provided by the organization and recommendations from qualified medical personnel.

Standard 2.11.H The results of peer review are used as part of the process for granting continuation of clinical privileges, as described in Chapter 2.II.

Standard 2.11.B.5. Medical staff must apply for reappointment every three years, or more frequently if state law or organizational policies so stipulate. At reappointment, the organization requires completion of a reappointment application and verifies items listed in Standards 2.II.B.3.c-g and peer review activities as described in Chapter 2.III.

• Quality Management and Improvement Standards

Standard 5.1.C and Standard 5.1.C.2 The organization demonstrates that ongoing improvement is occurring by conducting quality improvement studies when the data collection processes described in Standard 5.I.B indicate that improvement is or may be warranted. Written descriptions of QI studies document that each study includes the following elements as applicable: 2. Identification of the measurable goal against which the oganization will compare its current perfomance in the area of study.

• Documentation

Standard 6.F. The presence or absence of allergies and untoward reactions to drugs and materials is recorded in a prominent and consistently defined location in all clinical records. This is verified at each patient encounter and updated whenever new allergies or sensitivities are identified.

Source: Accreditation Association for Ambulatory Health Care, Skokie, IL.

AAAHC has new standard requiring written risk assessment for infection control

Beginning this year, the Accreditation Association for Ambulatory Health Care (AAAHC) has a new standard (7.I.B.) requiring a written risk assessment in infection control. The risk assessment becomes the basis for the infection control program for the facility, according to **Marcia Patrick**, MSN, RN, CIC, surveyor for ambulatory care at AAAHC.

The Joint Commission already requires a written infection control plan based on a risk assessment for hospitals, ambulatory centers, and office-based surgery.

AAAHC now requires its accredited facilities to identify risks and rank them. The accrediting group doesn't specify how the risk assessment must be done, but it says that a tool will make the process easier.[1]

AAAHC says that if your facility already has a tool that is working well, you can continue to use it, as long as you rank your risks.[1]

Factors to consider

When determining risks, facilities should consider their facility type and community risk, Patrick says. For example, are you a facility that processes scopes and related instruments? Are you in a community with a high number of tuberculosis cases? Other considerations are: your staff and providers; your environment of care; your care practices; your medication practices; disinfection and sterilization of medical equipment, surgical instruments, and endoscopes; surveillance; and your emergency management plan.[1]

"What we want to see is facilities that identify their risk based on their patient population, their geographic

EXECUTIVE SUMMARY

The Accreditation Association for Ambulatory Health Care now requires a written risk assessment in infection control (Standard is 7.I.B).

- You must identify risks and rank them.
- When ranking risks, consider the probability of the event occurring; the degree of risk; the potential impact on care, treatment, or services; and how prepared the organization is to respond to the problem.

location, conditions in the community — even socioeconomic factors can play a role in terms of education level and education they may or may not need following intervention or diagnostic testing at your facility," Patrick says.

She says AAAHC would like to see the following issues high on the list of priorities: transmission of bloodbone pathogens, surveillance for healthcare-associated infections, lack of compliance with standards for disinfection of instruments, and environmental cleaning. For example, many facilities have a janitorial service that comes after business hours, but those services need to be monitored, Patrick says. Ensure that janitorial service is using the correct products and that the germicide wet contact time is being met.

Use these criteria for ranking

The risks you identify should be ranked in the order that they will be dealt with. AAAHC says that issues should be prioritized (ranked 0 to 4) based on four criteria:

- What is the probability of the event occurring?
- What is the degree of risk?
- What is the potential impact on care, treatment, or services?
- How prepared is your organization to respond to the problem?[1]

The issues with the highest numbers have more risk and should be a higher priority, AAAHC says.

The ranking should take into consideration that some large items might requires budget allocations. For example, the flow of the utility room might be cramped. However the facility might be in office space that has been converted for healthcare purposes, so addressing that issue might require major changes such as tearing down walls. "But we can't do that tomorrow morning," Patrick says. "We will have to budget for it."

What is the goal?

Each risk should have a goal, which is an over-arching direction of where you want to go, she says.

Improving hand hygiene compliance should be on every organization's list, Patrick says. Managers should write a measurable objective. For example, the leaders might want to reach 90% to 95% compliance.

"But if you're at 40% to start, and you say, 'next month, we'll be at 95% compliance,' that's not realistic," Patrick says.

Instead, your goal might be to reach 75% by the end of the quarter. Compliance could be measured by secret shoppers, patient query, observations by the supervisor, or another method. If the organization has reach 75% by the end of the quarter, leaders could set a goal for the next quarter of 80-85%. Your goals and objectives become the evaluation of your program, Patrick says.

The written risk assessment is a living document that changes over time, Patrick says. "New issues crop up," she says. "Old ones sometimes disappear or reoccur."

REFERENCE

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TJC, CDC collaborate on infection prevention project

The Joint Commission and the Centers for Disease Control and Prevention (CDC) are collaborating on an initiative to disseminate CDC guidance related to infection prevention and control in ambulatory settings.

The goal is to create model infection control plans and expand the adoption of these and other infection prevention and control guidance materials to prevent infections in outpatient settings.

The project will focus on a variety of freestanding ambulatory settings and services. In collaboration with the CDC, The Joint Commission will select and work with 12 outpatient-focused professional organizations and 10 ambulatory health care systems. The Joint Commission and CDC also will engage with local chapters of professional organizations and state health departments.

For more information, contact Cheryl Richards at crichards@jointcommission.org or Barbara Braun, PhD, atbbraun@jointcommission.org. ■