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$68,000 proposed OSHA fine for ASC raises concerns: Is the field complying?

Accused of not protecting staff exposed to bloodborne pathogen hazards

Compliance with the bloodborne pathogen standard from the Occupational Safety and Health Administration (OSHA) is an ongoing issue, and now apparent lack of compliance has resulted in a proposed $68,000 fine for a surgery center regarding claims that it failed to protect workers exposed to bloodborne pathogen hazards.

Health East Ambulatory Surgical Center in Englewood, NJ, was cited with 10 "serious" violations of the bloodborne pathogens standard. The serious violations include failing to counsel an employee who was stuck with a contaminated needle, test the employee's blood in a timely manner, and provide the appropriate medicine to the employee to prevent contracting a potential disease, OSHA says. *(See entire list, p. 51.)* A serious citation is issued when there is substantial probability that death or serious physical harm could result and the employer knew, or should have known, of the hazard, OSHA said in a press release. According to a statement from **Anson Moise**, MD, medical director of the center, the violations are disputed, a conference to resolve the dispute was scheduled, and none of the proposed violations arise out of any harm to any employees, patients, or physicians. The center has had "zero instances of infection or contamination to patients, employees or physicians after treating over 8,000 patients," the statement said.

EXECUTIVE SUMMARY

A fine of $68,000 was proposed for a New Jersey surgery center for 10 "serious" violations related to failure to protect workers exposed to bloodborne pathogen hazards.
- To educate staff, share personal stories from your staff or published accounts. *(See story on p. 52 to find these accounts.)*
- Have front-line workers conduct the required yearly evaluation of sharps safety products, and rely on their feedback.
- Have staff use a safe zone where they pass instruments or needles.
- Record all needlesticks, but not all splashes.
- Request a free OSHA consultation without fear of monetary penalties.

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These citations are not an isolated case, according to **Mary Ogg**, MSN, RN, CNOR, perioperative nursing specialist at the Association of periOperative Registered Nurses (AORN). "State and regional OSHA offices have been conducting random, unannounced visits" including surgery centers, Ogg says. At the top of the OSHA list of violations? The bloodborne pathogen standard, Ogg says. Several healthcare facilities have been cited, she warns.

Where workers are occupationally exposed to blood or other potentially infectious materials, OSHA requires engineering controls (e.g., sharps disposal containers, engineered sharps injury protections) and work practice controls such as hands-free passing during surgical procedures and the use of appropriate personal protective equipment (e.g., gloves, garments). *(For tips, see story, p. 52.)* An OSHA spokesperson, who asked not to be identified, said, "Failure to comply can and may result in citations and monetary penalties."

AORN is replacing its guidance statement in the recommended practice (RP) for Sharps Injury Prevention in the Perioperative Setting, which is scheduled for electronic release in June. "This RP is structured on OSHA's hierarchy of controls of eliminating the hazard, engineering controls, work practice controls, administrative controls, and PPE [personal protective equipment]," Ogg says. "The RP goes into great detail in how to implement each of these steps, explains the importance of each step using over 200 evidence-rated references." *(To keep up with the changes, go to http://www.aorn.org/RecommendedPracticesNews.)*

An estimated 80,000 sharps injuries occur in the OR each year. **Stephen Morrison**, BSEH, health compliance officer with the Tennessee Occupational Safety and Health Administration, says, "I have trouble understanding why people who take the Hippocratic Oath are so reluctant to protect themselves, their coworkers, and their patients by following procedures proven to be effective, recommended by various medical professional groups, and mandated by federal and state law."

Providers are exposed to HIV, Hepatitis B and Hepatitis C every day, Ogg says. "Sharps injuries not only harm the healthcare worker," she says. "There have been 132 incidences of healthcare provider to patient transmission of HIV, hepatitis C, etc."

How can lack of compliance be explained? "Change is difficult," Ogg says. Like everyone else, healthcare providers fall into patterns. "If we were initially trained on one device and have used it for years, we don't want to learn a new technique," Ogg says.

Surgeons often are reluctant to change equipment and procedures, Morrison says. "A lot of surgeons refuse to use blunt suture needles when suturing muscle and fascia even though it is recommended by the American College of Surgeons, and numerous studies have shown that the blunt suture needles cause no more trauma than cutting suture needles when suturing muscle and fascia."

Another theory, which Ogg heard from a sur-

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Editorial Questions

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geon colleague, is that surgeons are risk-takers. "If they have had a sharps injury in the past with no consequence, why should they take precautions to prevent one now?" Ogg said, in reporting her colleague's explanation.

Another early problem was the design of the sharps safety devices, she says. "… many of the sharps safety products that were initially produced were difficult to use and did not have the same `feel' of a traditional sharps device," Ogg says. However, that problem has been virtually eliminated, she says. "Manufacturers have responded to feedback and altered the design of sharps safety devices to make it 'feel' like the traditional product and increased ease of use," Ogg says..

Safety measure might take extra effort, and they might not be as comfortable, she acknowledges. "Like wearing a seat belt in your car, it takes an extra few seconds to fasten your seat belt, and movement is restricted," Ogg says. "If you have never been injured in a car accident, do you stop wearing your seat belt?" *(Read about hospital that had a 22% decrease in needlesticks, p. 53.)*

RESOURCES

- **American College of Surgeons Statement on Sharps Safety.** Web: http://bit.ly/14esaLM.
- **Occupational Safety and Health Administration's (OSHA's) Bloodborne Pathogens and Needlestick Prevention page,** which includes frequently asked questions on bloodborne pathogens. Web: http://1.usa.gov/xb9rkm.
- **Safety in Surgery resources from the Global Initiative in Healthcare Worker Safety** at the University of Virginia in Charlottesville. Web: http://bit.ly/102selw. ■

OSHA Citations for Health East Ambulatory Surgical Center

- The employers' exposure control plan did not include a procedure for evaluating the circumstances surrounding exposure incidents. In other words, they did not have a procedure to determine how an exposure incident (i.e. needlestick) occurred, which could hinder them from preventing its reoccurrence.
- The exposure control plan did not document that annually the company considered and implemented the use of safer medical devices designed to eliminate or reduce the potential for injury. In other words – they needed to have a written procedure in their exposure control plan which made them research and consider or implement any new devices that have been made commercially available which are better at preventing needlesticks.
- When the company developed their exposure control plan, they did not solicit input from non-managerial employees responsible for direct patient care in the identification, evaluation, and selection of needles or other devices used that could assist in the prevention of exposure to blood.
- The employer did not determine which of its employees could potentially be exposed to blood or other potentially infections materials.
- The company did not test the source individual's blood as soon as feasible after the needlestick occurred.
- The employer did not make post exposure prophylaxis (HIV-fighting meds) available in a timely manner to an employee stuck by a needle.
- The post exposure evaluation of an employee stuck by a needle did not include counseling.
- The employer did not provide the healthcare professional's written evaluation of an employee stuck by a needle to that employee. This written evaluation contained information regarding medical conditions potentially resulting from exposure to blood.
- The employer did not provide a copy of the OSHA Bloodborne Pathogen standard to the employee's healthcare provider after a needlestick occurred.
- The employer did not provide a description of the exposed employee's duties as they related to the exposure incident (needlestick).
- The employer did not provide documentation of the routes of exposure and circumstances under which the exposure occurred to the employee's healthcare provider.
- The employer did not provide the results of the source individual's blood test results to the exposed employee's healthcare provider.

Source: Occupational Safety and Health Administration, Englewood, NJ. ■

5 steps to compliance with OSHA regulations

What can you, as a manager, do to help ensure members of your staff are complying with sharps safety regulations?

"I believe the key is education and training," says **Stephen Morrison**, BSEH, health compliance officer with the Tennessee Occupational Safety and Health Administration (TOSHA) in Kingsport. "They must be made aware of the consequences of noncompliance such as health risks to themselves, their patients, and their staff, and monetary fines that can be thousands of dollars."

Education is key, agrees **Mary Ogg**, MSN, RN, CNOR, perioperative nursing specialist at the Association of perioperative Registered Nurses in Denver. "Many healthcare providers are unaware of the risks of hepatitis C or HIV from a sharps injury," Ogg says. "Seroconversion to hepatitis C or HIV has career- and life-altering consequences."

Share personal stories from your staff (being cognizant of potential violations of privacy laws) or published accounts, she advises. **Karen Daley**, president of the American Nurses Association, has shared her needlestick injury story and how it changed her career path from clinical practice as an emergency department nurse. *(To read Daley's story, go to http://bit.ly/ZWtls1. Also see one surgeon's story in "Provider-to-patient transmission of HBV raises issues about staff — CDC updates guidelines for facilities,"* Same-Day Surgery*, April 2013, p. 41.)* "Ask your staff how they felt as they awaited results of lab tests to confirm whether they have been exposed," Ogg says.

The hope is that education equals a change in behavior, "but unfortunately this is not always reality," she says, "An OSHA fine is a great motivator to change."

Providers may request an OSHA consultation, which is free and doesn't result in monetary penalties, according to Morrison. Consider these other suggestions:

• Obtain input from your staff on products.

Under the Needlestick Safety and Prevention Act, front-line workers who use sharps safety products are required to conduct an evaluation. "Conduct the yearly evaluation, and select the one that has the best user feedback," Ogg advises. "Acceptance is more likely if the user has input into the decision of what device to use rather than a device showing up one day and being told that they have to use it."

• Don't pass hand to hand.

Where possible, have a safe zone where you pass instruments, says **Teo Forcht Dagi**, MD, DMedSc, FAANS, FACS, SAAANS, FCCM, a neurosurgeon and chair of the American College of Surgeons Committee on Perioperative Care, which created the college's Statement on Sharps Safety. Forcht Dagi also is a visiting professor at Harvard Medical School in Boston and professor at Queens University Belfast, Northern Ireland, UK.

Put sharps in an intermediary tray so there is reduced risk of injury by contact, he says. However, the nature of some procedures makes a sharps safety zone difficult, Forcht Dagi acknowledges. He points to ophthalmology and neurosurgery procedures in which you have micro-techniques using tiny needles. Even in those cases, surgeons and staff can develop systems, such as a magnetic one, to use. "But the principle is the same: The principle is to try to avoid as much as you can passing something that is sharp from one hand to another," Forcht Daggi says.

Also, use blunt needles, when possible, for closure, he says.

• Have staff double glove.

Ogg says, "Double gloving is the easiest sharps injury prevention measure to implement." This one step can reduced sharps injuries by as much as 87%, she says.

"Resistance to arguments that double gloving is uncomfortable or reduced tactility can be overcome by inviting your glove vendor in to help personnel find the proper fit," Ogg says.

Don't assume that the only way to double glove is to wear one size larger glove over the inner glove, she says. "Try different combinations and after a week or two, personnel become used to the slightly different feel, like wearing a seat belt," Ogg says.

• Record all needlesticks, but not all splashes.

"All sharps injuries should be reported," Ogg says. "One can never be certain by outward appearance which patient may be infected with HIV or Hepatitis C."

Any sharps injury that involves a needle or object that was contaminated with a patient's blood or other potentially infectious material must be reported on a sharps log and the OSHA 300 log, even if the patient does not have a

bloodborne pathogen. The OSHA 300 log can serve as the sharps injury log if the sharps injuries can be segregated easily from other injuries. There are privacy cases, so the employee's name should not appear on the log.

A needlestick is considered to be a puncture (injury) unless an infection develops. If an employee develops an infection and receives medical treatment, the log should be updated. Splashes of blood and body fluid do not need to be reported unless the employee develops an infection and requires medical treatment. ■

'High reliability' hospital obsessed with safety

When you walk on an airplane, you expect layers of precautions to prevent any error that could lead to failure and injury. You demand the same or even greater care from the nearby nuclear power plant. And now, you can expect that serious attention to safety from a growing number of healthcare providers.

St. Vincent's Medical Center in Bridgeport, CT, is an example of a "high-reliability organization," a hospital that is "obsessively" focused on safety.

It has welcomed scrutiny from the Occupational Safety and Health Administration (OSHA) to work toward the Voluntary Protection Program. It has attained recognition as a "magnet" hospital from the American Nurses Credentialing Center. And it was profiled by The Joint Commission as a best practice for linking patient safety and worker safety. This focus on safety has translated into savings, in dollars and human terms. For example, the hospital had a 22% decrease in needlesticks and a 30% decrease in serious employee falls in 2012 compared with 2011.

Every day at St. Vincent's starts with safety — even the weekends. The hospital CEO or a vice president leads a hospital-wide "safety huddle," which lasts from 15 to 30 minutes, depending on the issues being discussed. Each huddle begins with a report on how many days it has been since a medical error or worker injury. If there has been an event — for example, a sharps injury in the OR — then there is a short synopsis and discussion of the root cause and what might be done to prevent future similar events.

Anyone in the hospital can come to the huddle and express a concern. "I attend hospital-wide huddle every day, and the room is so full sometimes that there's no standing room," says **Karen J. Nefores**, RN, BSN, MBA, executive director for quality, case management and patient safety. "It goes beyond our 15 minutes sometimes because so many people want to share concerns." Employees who took steps to prevent injury or who identified a potential hazard are recognized with a safety pin. Employees who shared an idea that improved safety or quality can receive a quarterly reward of up to $100.

There are also safety huddles every day in every unit, and monthly "culture of safety" meetings geared toward frontline workers. The safety huddles encompass patient, environmental or worker safety.

"There's always an accountable person who has to come back to the meeting with either a resolution or why there hasn't been a resolution to the problem," says **Kathleen Ventura**, RN, coordinator of employee health.

Serious safety events aren't the only items on the agenda. They also target "precursor safety events," which result in minimal or no harm, and near-misses. Safety coaches on the units help spread information and train other employees to use safety techniques or devices.

The hospital uses "dashboards" to monitor safety metrics, from hand hygiene audits to needlesticks. The dashboards keep people focused on goals, says Ventura. "Our dashboards are a good way to maintain our sustainability," she says.

While injury rates dropped, needlesticks persisted. A needle safety task force met for four months and discovered that some nurses were not activating the retractable devices. The needles and syringes were a single unit, so some nurses had stashed conventional needles that could be removed from the syringe.

St. Vincent's switched to a product that sheathes the needle with a one-handed action. A blunt needle is used to draw medication, and then it is removed and replaced with the safety needle. All other needles have been removed from the hospital, so nurses can't revert to a conventional needle. Needlesticks declined to 25 in the first 11 months of 2012 from 32 in 2011, and St. Vincent's hopes to reduce that number even further.

The cycle of identifying safety concerns and seeking solutions never ends, Nefores says. "[We're] keeping it alive, constantly, every day,

being relentless," she says. "If we have a huddle where it's quiet, the leader will be prompting and encouraging people to speak up and share."

As serious events decline, the hospital will focus on precursor events and near-misses, so there will always be a safety goal, she says. there will always be a safety goal, she says.

The hospital also incorporates patients and family members into its culture of safety. There is an active and successful Patient and Family Advisory Board that was established several years ago, Nefores says. "Former patients and/or family members of patients participate in this committee and also on most of our hospitalwide committees and task forces," she says. "Their voice and perspective is a key component of decision-making at St. Vincent's, especially when it pertains to safety issues." ■

Same-Day Surgery Manager

Tips and tricks for the SDS trade

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

Few ideas I come up with or speak about are original. Sometimes I think they are, but I might have heard them from a doc, nurse, Seinfeld show, or a conference.

I want to share some of my favorite "tips and tricks" this month and, if you like them, I can do them again. (See the last paragraph of this column!)

• Disrobing cataract patients.

I've spoken about and written about this for years, so it could be my idea. Not sure. There is absolutely no reason why our patients having cataract procedures under local or local sedation need to disrobe! It is time-consuming and a stress on our patients. Make sure you advise them in the preop call to wear loose fitting clothes so you can get the chest leads on, and then leave them be. Another thing: Why do you start an IV on these patients? It's a 15-minute case. (I hope!) Save the time, the money, and these poor patients' veins. By the way, the greatest patient complaint from cataract patients is the needlestick for the IV. Let it go.

• Preop testing.

How many of you require routine preop testing for your patients? None, I hope. There is never a situation when your facility should require routine preanesthesia testing. It is a building! Anesthesia might require it. The surgeons might want to get into it, but your building? No way. Find out who actually wanted the tests in the first place (probably anesthesia), and find something to eliminate. Chances are no one has looked at them in forever anyway. *(Editor's note: For more information on eliminating preop testing, and other cost-saving moves, see the special February 2013 issue of* Same-Day Surgery *on your peers' best ideas for saving money.)*

• 45-minute patient arrival time.

It seems as if half of my friends and family are having surgery lately, and I just hate sitting there with them for two hours before their surgery trying to think of something to say while peeking at my emails on my phone. Knock it off! No need for this early arrival anymore. You might not want to reduce that time to 45 minutes right away, but work on it. It could be you having to sit there some day. *(For more on this topic, see my column "13 steps to convert to 45-minute arrivals,"* SDS, *October 2010, p. 115.)*

• Patient privacy.

Forget doing this just because of privacy regulations. Just have your front desk staff members learn to ID patients by where they are sitting in the lobby. Direct the nurse to them from where they are sitting instead of calling out their name as if their table is ready at the local barbecue restaurant. It is starting to irk me that the people at the front desk can't remember that Mrs. Brown in seating in the first row at the end of the bench, or that the pierced and tatted blonde with ear plugs is in the back row. We can do better than this.

• Texting on the job.

We can't do it at the movies (although some jerks do), so why can we do it during Sally's hysterectomy? Really? I can't tell you how many times I have had someone text me "... gotta run, taking the patient off the table." Place phones in a box in the room, and make it a requirement that staff members leave them there until after the case. *(Editor's note: For more on this topic, see "Distracted doctoring' recognized as hazard,"* SDS, *April 2012, p. 42.)*

• Send me home with pay when my room is finished.

If you have full-time staff members who have busted their butts to turn over their rooms and finish their cases early, send them home with pay. Why not? They increased your efficiency, they make the surgeons happy by getting them out early, the patients don't know or care, so everyone wins! Don't make them hang around trying to look busy when they have done their jobs. Set them free! I do not know of any nurse who should be paid by the hour. It is the job and the responsibility that matters. Rise up!

• EMR.

I refuse to spell out what EMR stands for. If you don't know, then just skip this tip. People, it is time! Join the electronic age, and just convert. It is so much better, and it makes all of our lives easier. You can download a movie and watch it on your phone, but you still have a paper chart?

• Theft.

Members of your staff or cleaning crew might be stealing from you. Perhaps you can't stop it, but you can deter it. Go to your local electronics store, and put in a few fake cameras around the place. They cost about $19.85 each. I mounted one in my car, just in case. It might make them think twice. Don't do like the manager who told her staff at a meeting that the cameras were fake. *(For more on this topic, see "Video cameras shine as your best detective,"* SDS*, April 2011, p. 39.)*

I need to hear from every one of you reading this if you want more of these. Send me an email even if it is only "yes!" If you have a phone that can email, just don't do it from the OR. *[Earnhart & Associates is a consulting firm in Houston, TX, specializing in all aspects of outpatient surgery development and management. Phone: (512) 297.7575. Fax: (512) 233.2979. E-mail: searnhart@earnhart.com. Web: www.earnhart.com.]* ■

4-year degree nurses tied to fewer deaths

Patient deaths decrease post-surgery

When hospitals hire more nurses with four-year degrees, patient deaths following common surgeries decrease, according to new research by the Center for Health Outcomes and Policy Research at the University of Pennsylvania School of Nursing in Philadelphia, as reported in the March issue of Health Affairs. Less than half the nation's nurses (45%) have baccalaureate degrees, according to the most recent data available (2008).

If all 134 Pennsylvania hospitals involved in the study had increased the percentage of their nurses with four-year degrees by 10 percentage points, the lives of about 500 patients who had undergone general, vascular, or orthopedic surgery might have been saved, the researchers found.

Specifically, a 10 percentage point increase, say from 30 to 40%, in the overall percentage of BSN-prepared nurses in the hospitals studied between 1999 to 2006 saved about two lives for each 1,000 patients treated on average, according to lead author Penn Nursing professor **Ann Kutney-Lee**, PhD, RN, who is also a senior fellow at the Leonard Davis Institute of Health Economics. The researchers surveyed 42,000 registered nurses (RN) in Pennsylvania in 1999 and 25,000 in 20006.

RNs have obtained a four-year (baccalaureate degree), a two-year (associate's) degree, or graduated from a hospital-based diploma school. Licensed practical nurses (LPN) also practice at the bedside with a one-year degree.

"This adds to the importance of public policies to help direct a substantial shift toward the production of nurses with baccalaureates in nursing," said Kutney-Lee, noting that a recent report from the Institute of Medicine recommends that 80% of nurses hold at least a baccalaureate degree by 2020. "Nursing is both high-touch and high-tech requiring honed critical thinking skills in our complicated healthcare system," she says.

While the study did not pinpoint why more patients survive surgeries, previous work in the center found that better-prepared nurses offer higher levels of surveillance of patients, noticing subtle shifts in their patients' conditions that can lead to death from complications while there was still time to intervene. "As part of their practice, nurses are responsible for the continual assessment and monitoring of a patient's condition, identifying changes that could indicate clinical deterioration, and initiating interventions when necessary," noted Kutney-Lee. *(For more on this topic, see "Growing trend in outpatient surgery: Requirement for nurses to have their BSN,"* Same-Day Surgery*, January 2013,* 2012 Salary Survey Results *supplement, p. 1.)* ■

CDC contacting facilities with high infection rates

While generally citing continued reductions in key health care associated infections (HAIs), a recent Centers for Disease Control and Prevention (CDC) surveillance report also revealed some outliers with high infection rates.

A 17% reduction in surgical site infections (SSIs) was reported since 2008, up from the 7% reduction reported in 2010. This improvement was not evident for all procedure types, and there is still substantial opportunity for improvement across a range of operative procedures, the CDC said.

The report looked at data submitted to the National Healthcare Safety Network (NHSN), the CDC's premiere infection tracking system, which receives data from more than 11,500 healthcare facilities across all 50 states, Washington, DC, and Puerto Rico. Healthcare facilities using NHSN have real-time access to their data for local improvement efforts. The annual report uses a standardized infection ratio (SIR), which represents a red flag for too many infections if a facility exceeds 1.0. Overall, roughly 2% to 9% of the facilities reported SIRs significantly greater than 1.0, or significantly more infections were observed than predicted.

These include:

- 25 facilities that had SIRs significantly higher than 1.0 for SSIs associated with hip arthroplasty;
- 30 facilities who had SIRs significantly higher than 1.0 for SSIs associated with knee arthroplasty;
- 20 facilities that had SIRs significantly higher than 1.0 for SSIs associated with colon surgery;
- 15 facilities that had SIRs significantly higher than 1.0 for SSIs associated with abdominal hysterectomy.

"These are relatively small numbers of facilities compared to the total number of facilities reporting in 2011," such as 2,130 reporting SSIs, the CDC concluded. "However, focusing efforts on these facilities may be one strategy to ensure that prevention resources are utilized most wisely in coming years."

The CDC is contacting the facilities that have significantly high SIRs and connecting them with existing prevention initiatives including:

- state health department collaboratives;
- Partnership for Patients initiative;
- Centers for Medicare and Medicaid Services Quality Improvement Organizations;
- Comprehensive Unit-based Safety Program (CUSP) initiatives funded by the Agency for Healthcare Research and Quality *(For more on CUSP, see, "Pilot program slashes colorectal SSIs by 33% — Hospital saves $168,000-$280,000 in one year," Same-Day Surgery, October 2012. To access the CDC report discussed in this article, go to http://1.usa.gov/V4yL5X. To access the CDC web site on SSIs, go to http://www.cdc.gov/HAI/ssi/ssi.html.)* ■

Your EMR charting might be provably false!

Don't document impossibilities

Entering an overly complete history and examination on a patient presenting with a minor or simple complaint is one danger with electronic medical records (EMRs), especially when time-stamping makes such a lengthy examination unlikely, warns **John Davenport**, MD, JD, physician risk manager of a California-based health maintenance organization.

In a lawsuit, carelessly documented impossibilities can make a physician defendant appear untrustworthy. "In one recent case, a full preoperative clearance exam was entered and documented more than 20 minutes before the patient was documented to have arrived," reports Davenport.

Plaintiff attorneys have several goals in examining the patient's medical record, he explains. "The first is to find documentation that you acted below the standard of care," he says. "The second is to show that you are careless. The third, and one of the most powerful, is that you are not truthful."

EMRs "easy to abuse"

While EMRs are more efficient than paper charting, some of the factors that make them easy to use also make them "easy to abuse," says Davenport. "Such full and automated documentation sometimes leads to discrepancies in the chart."

For example, an automated phrase documenting a patient's pelvic exam with notation of a normal cervix is not credible in a patient who has had a full hysterectomy.

Davenport says he has seen an obviously incorrect finding entered into the chart become an issue many times in medical malpractice litigation, such as a male-specific exam performed on a female patient, and inappropriate responses to clearly abnormal laboratory or X-ray findings. "A plaintiff attorney might ask both the plaintiff and the defense expert if the medical standard of care required accurate charting, followed up by a question if the defendant's charting

was accurate," says Davenport.

Inaccurate charting makes the physician defendant's charting weaker and the case more likely to be settled, he adds.

"When one or two keystrokes can populate a complete and thorough note, there is the risk of accidentally or carelessly entering false documentation into a patient's chart," Davenport says. "Such entries can lead to an attack on the physician's credibility." ■

Top 10 technology issues for healthcare in 2013

Safety and capital expenditures addressed

A new Watch List from ECRI Institute, an independent nonprofit that researches approaches to improving patient care, provides a roadmap to 10 technology issues that healthcare leaders should have on their radar in 2013 and beyond.

"ECRI Institute's Top 10 C-Suite Watch List: Hospital Technology Issues for 2013," available for free, reflects ongoing impacts of healthcare reform initiatives and new technology developments. Some of the technologies represent significant capital investments, such as PET/MR. Others, including mobile health, metabolic surgery, and low-dose computed tomography lung screening, might greatly affect operations and care patterns.

"New demands for information and clinical technology are top issues for executives, and objective perspectives are critical," says **Jeffrey C. Lerner**, PhD, president and chief executive officer, ECRI Institute. Technology issues on this year's watch list include:

1. Electronic health records (EHRs): You've achieved meaningful use, but how safe are your EHRs?
2. Mobile health: What exactly is it, and what can it do for me?
3. Alarm integration technology: Will you be able to reduce alarm fatigue and improve alarm management?
4. Minimally invasive cardiac surgery: Is the transcatheter aortic heart valve (TAVI) ready for liftoff?
5. Imaging and surgery: What imaging won't be done in an OR?
6. PET/MR: The hybrid that everyone has to have?
7. Bariatric surgery: Is it a cure for Type II Diabetes?
8. Supply chain: Will MR-compatible pacemakers explode your supply expenses?
9. Radiation dose safety: CT dose limbo dance — how low can you go?
10. Lung cancer screenings: Enough lung capacity to get in the race?

Robert Maliff, director of applied solutions, ECRI Institute, said, "Hospital leaders should ask if new technology or procedures really improve patient care and make it a less costly patient-care experience."

ECRI Institute's "Top 10 C-Suite Watch List: Hospital Technology Issues for 2013" is available for download at www.ecri.org/2013watchlist. Registration is required. ■

ACOG: Robotic surgery is not the best

President speaks out on hysterectomy options

While many women are hearing about the claimed advantages of robotic surgery for hysterectomy, thanks to widespread marketing and advertising, robotic surgery is not the best minimally invasive approach for hysterectomy, according to **James T. Breeden**, MD, president of the American College of Obstetricians and Gynecologists (ACOG).

"Nor is it the most cost-efficient," Breeden said in a released statement. "It is important to separate the marketing hype from the reality when considering the best surgical approach for hysterectomies."

Studies show there is a learning curve with new surgical technologies, during which there are increased complications, he said. "Expertise with robotic hysterectomy is limited and varies widely among both hospitals and surgeons," Breeden said.

There might be some advantages to using robotics in complex hysterectomies, especially for cancer operations that require extensive surgery and removal of lymph nodes, he said. However, "studies have shown that adding this expensive technology for routine surgical care does not improve patient outcomes," Breeden said. "Consequently, there is no good data proving that robotic hysterectomy is even as good as — let alone better — than existing, and far less costly, minimally invasive alternatives."

For example, he points to vaginal hysterectomy as the least invasive and least expensive option. "Based on its well-documented advantages and low complication rates, this is the procedure of choice whenever technically feasible," Breeden said. "When this approach is not possible, laparoscopic hysterectomy is the second least invasive and costly option for patients."

Robotic hysterectomy generally provides women

with a shorter hospitalization, less discomfort, and a faster return to full recovery compared with the traditional total abdominal hysterectomy (TAH), he said. "However, both vaginal and laparoscopic approaches also require fewer days of hospitalization and a far shorter recovery than TAH," Breeden said. These two methods also have proven track records for outstanding patient outcomes and cost efficiencies, he said.

"At a time when there is a demand for more fiscal responsibility and transparency in healthcare, the use of expensive medical technology should be questioned when less-costly alternatives provide equal or better patient outcomes," Breeden said.

At a price of more than $1.7 million per robot, $125,000 in annual maintenance costs, and up to $2,000 per surgery for the cost of single-use instruments, robotic surgery is the most expensive approach, he said. A recent Journal of the American Medical Association study found that the percentage of hysterectomies performed robotically has jumped from less than 0.5% to nearly 10% over the past three years. A study of over 264,000 hysterectomy patients in 441 hospitals also found that robotics added an average of $2,000 per procedure without any demonstrable benefit.

"If most women undergoing hysterectomy for benign conditions each year chose a vaginal or laparoscopic procedure — rather than TAH or robotic hysterectomy — performed by skilled and experienced surgeons, pain and recovery times would be reduced while providing dramatic savings to our healthcare system," Breeden said.

Aggressive direct-to-consumer marketing of the latest medical technologies might mislead the public into believing that they are the best choice, Breeden said. "Our patients deserve and need factual information about all of their treatment options, including costs, so that they can make truly informed healthcare decisions," he said. "Patients should be advised that robotic hysterectomy is best used for unusual and complex clinical conditions in which improved outcomes over standard minimally invasive approaches have been demonstrated." ■

MedPAC discusses, but doesn't equalize pay rates

In recent discussions, the Medicare Payment Advisory Commission (MedPAC), for the first time, proposed equalization between hospital outpatient departments (HOPDs) and ambulatory surgery centers (ASCs) for certain procedures, according to the ASC Association.

The talk was continued from an earlier discussion on site-neutral payments for similar services provided by Medicare, according to the ASCA.

However, the March report to Congress calls for eliminating the update for ASCs in 2014 and requiring ASCs to submit cost data.

"Once again, we find MedPAC's recommendations frustrating and short-sighted," says Bill Prentice, CEO of ASCA. "The commission is recommending a payment update that fails to take into account the escalating costs that ASCs face in providing care and proposing a burdensome reporting program that will increase costs for both ASCs and the federal government."

MedPAC should support ASCs and the cost savings they offer with an annual ASC update linked to the hospital market basket measure that is used to update HOPDs, Prentice maintains.

The report details fee-for-service payment recommendations for 2014 approved by the commission in January, according to the American Hospital Association (AHA). The recommendations call for a 1% increase in hospital outpatient and inpatient prospective payment system payments, the AHA says. For inpatient services, MedPAC recommends that CMS use the difference between the 2014 statutory update and the recommended 1% increase to offset the costs of changes in hospitals' documentation and coding.

The report can be accessed at http://1.usa.gov/10QsoUh. ■

Preventing unsafe devices from reaching the market

Technological advancements in medicine have allowed patients suffering from musculoskeletal conditions such as hip and knee pain to regain mobility and live relatively pain-free. But some "high-risk" surgical devices that have been approved by the Food and Drug Administration (FDA) are not required to go through clinical trials, where a product is tested to determine its safety and effectiveness.

"This could be potentially very dangerous. Many Americans — patients and even physicians — are not aware of how many devices in this country are on the market without having clinical data of safety and effectiveness," said **Rita F. Redberg**, MD, MSc, professor of medi-

cine and director of the University of California, San Francisco (UCSF) Women's Cardiovascular Services.

UCSF and the Australian Joint Registry published a perspective in *The New England Journal of Medicine* that reveals the complex history of how metal-on-metal hip implants reached the marketplace. *(Access the abstract at http://bit.ly/TLc7P6.)*

The implants are categorized by the FDA as high-risk devices, yet have been allowed into the marketplace without first testing them. They failed at a dangerously high rate, often requiring reparative surgery at least four times as often as traditional hip replacement surgery.

The perspective's authors are calling for changes in how the FDA approves metal-on-metal hip replacement devices and other high-risk devices for the marketplace. "If those hip implants are recalled, besides the problem of having to remove them because they're very painful, they can release chromium ions into the bloodstream, which pose an unknown risk," Redberg said. "Patients would also undergo significant disability having a second, third, or fourth hip operation."

U.S. hospitals perform 48 million medical procedures each year, according to the Centers for Disease Control and Prevention. Of that number, roughly 676,000 patients undergo total knee replacement surgeries and 327,000 undergo total hip replacement surgeries.

"Some patients' mobility will decline to the point of needing walkers or wheelchairs to get around and other serious events up to and including death can occur from subsequent operations," Redberg said. "And that's just for the metal-on-metal implants."

These high-risk metal-on-metal devices avoid going through clinical trials because of FDA loopholes in the 510(k) clearance, which allow them into the marketplace by claiming "substantial equivalence," which means they are similar to already approved devices or "predicate devices."

"All you have to do is show that your device is substantially similar to a number of other devices," Redberg said. "And some of those devices which were originally approved have been recalled or pulled off the market, but their original approval was still allowed for those 'predicate devices' that claimed 'substantial equivalence.'"

Even voluntarily recalled devices can serve as predicates under the 510(k) clearance as long as the FDA did not require their removal from the market or a court did not find they were misbranded or misrepresented in any way.

"High-risk medical devices should go through randomized clinical trials done in people so we can assure patients they are safe and effective," Redberg said. "Even the more stringent pre-market approval [PMA] process doesn't always mean that you actually have gone through randomized clinical trials, so we have to make sure these devices not only go through pre-market approval, but randomized clinical trials as well." ■

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 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

- ■ Is misstatement in the operative report a crime?
- ■ Safely cut staff-to-patient ratio and recovery time, increase OR volume
- ■ New way to measure your employees' exposure to chemicals
- ■ Should surgery techs have more than on-the-job training?

CNE/CME QUESTIONS

1. Which of the following is true of a consultation with the Occupational Safety and Health Administration (OSHA), according to Stephen Morrison, BSEH, health compliance officer with the Tennessee OSHA?
   A. Providers may request the consultations.
   B. They are free.
   C. They don't result in monetary penalties.
   D. A, B, and C

2. What step(s) has St. Vincent's Medical Center used to achieve a 22% decrease in needlesticks and a 30% decrease in serious employee falls in 2012 compared with 2011?
   A. Safety huddles every day, including weekends.
   B. Employees who share an idea that improved safety or quality can receive a quarterly reward of up to $100.
   C. Safety coaches on the units help spread information and train other employees to use safety techniques or devices.
   D. The hospital uses "dashboards" to monitor safety metrics, from hand hygiene audits to needlesticks.
   E. All of the above.

3. What step does Stephen W. Earnhart recommend to deter thefts by your members of your staff or cleaning crew?
   A. Install fake cameras.
   B. Use your own staff to clean.
   C. Have members of the crew agree to drug tests.
   D. None of the above.

4. When hospitals hire more nurses with four-year degrees, what change occurs, according to new research by the Center for Health Outcomes and Policy Research at the University of Pennsylvania School of Nursing?
   A Currently employed nurses also seek a four-year degree.
   B. Patient deaths following common surgeries decrease.
   C. Physician recruitment improves.