OR Manager

The monthly publication for OR decision makers

November 2009 Vol 25, No 11

Ambulatory Surgery Centers

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In this issue

Patient safety

Preventing retained surgical items: What role does technology play?

A patient needs major surgery to remove 5 laparotomy sponges left behind during a previous case. The investigation finds that during an exploratory laparotomy, the circulating nurse introduced a 5-pack of sponges into the sterile field but did not enter the count on the worksheet or white board. Relief staff were not aware of the extra 5 sponges, and the count later appeared correct. The incident is 1 of 6 retained-item cases that resulted in $25,000 fines for California hospitals in September 2009.

What does it take to eliminate the rare but stubborn problem of retained items?

Though the incidence is unknown, estimates are that an item is left behind in from 1 in 1,000 to 1,500 abdominal operations and 1 in every 8,000 to 18,000 inpatient operations.

Medicare has a policy to no longer pay an additional amount for treatment associated with retained surgical items. Insurance companies have followed suit.

Could technology such as barcoded or radiofrequency tagged sponges help prevent retained

Continued on page 8

Performance improvement

New Joint Commission center to take on wrong-site surgery

A lot of effort has gone into preventing wrong surgery through the Joint Commission's Universal Protocol and other measures.

Still, the data suggest the incidence hasn't changed very much. The Joint Commission estimates about 40 wrong surgery cases happen every week in this country. The numbers are projected from Minnesota and Pennsylvania, 2 states that have mandatory reporting.

A new Joint Commission initiative is aiming for breakthroughs on this and other persistent problems like hand-washing failure and communication breakdowns during hand-offs, failures that harm thousands of patients and cost billions of dollars a year.

The Joint Commission's new Center for Transforming Healthcare, rolled out September 10, 2009, teams with groups of hospitals to apply quality improvement methods long used by industry like Lean Six Sigma. The intent is to develop "targeted practical strate-

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Upcoming

Heading off drug diversion

Steps to prevent pilfering by staff and physicians.

New accrediting body

Get to know DNV, a new hospital accrediting organization. What is it like to go through a DNV survey?

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OR Manager is a monthly publication for personnel in decision-making positions in the operating room.

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Editorial

Every year, we honor an OR Manager of the Year. Last month, we introduced you to this year's honoree, Elena Canacari, RN, CNOR, director of perioperative services at Beth Israel Deaconess Medical Center in Boston.

The award, in honoring an individual manager, also honors all OR managers and their important contributions.

Candidates are nominated by their colleagues. This year's nominating letters portray leaders who mentor and support their staffs, advocate for patients and professionalism, and do their utmost to run their departments in a safe and cost-effective manner.

We'd like to introduce you to a few of them.

Guillermo Abogado

"He takes on patient care at every level," a colleague wrote of Guillermo Abogado, RN, director of nurses at the Center for Special Surgery at the Texas Center for Athletes in San Antonio. Known as "G," Abogado led the move to a new surgery center and shepherded it through accreditation, working with 15 physician partners. He can also be found at the bedside caring for patients.

"'G' has won my respect over and over again,'" wrote Sharon Waite, RN, BSN.

Janet Dauphinee Quigley

"Janet is one of the most passionate and successful leaders we have had the honor of working with; she has a clear vision and a devoted staff," wrote 5 RN colleagues in nominating Janet Dauphinee Quigley, RN, MSN, nurse director of the Same Day Surgery Unit at Massachusetts General Hospital in Boston.

Among her achievements, Quigley led the development of a regional block program in collaboration with the anesthesia team, bringing together all disciplines.

> **"The award honors all OR managers."**

"She guides the staff with patience and a quiet wisdom that inspires dedication," her colleagues said.

Regina Znosko

Nurse and physician colleagues lauded Regina Znosko, RN, BSN, CNOR, for the high standards she upholds as surgical services leader at Gwinnett Medical Center in Lawrenceville, Georgia.

Surgeon Don W. Penney, MD, wrote that Znosko has seen her workload expand beyond the OR to encompass outpatient surgery, the recovery room, and preop care, as well as construction projects.

"Regina has the capacity and will to rally her employees and peers to a common purpose, that being excellence in patient care and safety, growth and self-improvement both individually and collectively."

We would like to thank the many OR professionals who wrote on behalf of their leaders. It's a wonderful reminder of the service our readers and their colleagues give every day. ❖

—Pat Patterson

The OR Manager of the Year is honored at the annual Managing Today's OR Suite Conference and receives an expense-paid trip to the meeting.

Do you know someone who should be honored? Watch for the announcement for 2010 nominations in coming issues of OR Manager.

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Scrub tech pleads guilty in hepatitis case

A former surgical technician who apparently infected more than a dozen patients with hepatitis C by stealing fentanyl and placing used syringes back on anesthesia carts pleaded guilty September 25, 2009, to federal charges of tampering and theft, the *Denver Post* reported.

Kristen Diane Parker, 26, faces sentencing in December for 10 of the 38 counts against her. The recommended sentence is 20 years in prison. Remaining counts were dismissed. Parker agreed to further blood testing and other steps needed to address victim issues.

Parker admitted she stole the fentanyl while employed at Rose Medical Center in Denver between October 2008 and April 2009 and at Audubon Surgery Center in Colorado Springs in May and June 2009, according to the plea agreement. About 6,000 patients had surgery at the facilities during the time Parker worked there.

> **"The recommended sentence is 20 years."**

As of September 25, 26 patients from Rose had positive HCV tests epidemiologically linked to Parker, and 15 had been positively linked to the case by more definitive viral sequencing analysis, the Colorado health department reported. One patient who tested positive at Audubon was initially linked to Parker, but the link was not borne out by viral sequencing.

Contaminated syringes

According to the plea agreement, Parker, who was infected with hepatitis C, while employed as a scrub tech at the 2 facilities stole fentanyl syringes from ORs, injected herself with the drug, and replaced the syringes on the anesthesia carts with used saline-filled syringes, which were then used on patients.

Parker acknowledged she was positive for hepatitis C when she started working at Rose, according to the plea agreement. In March 2009, a Rose employee reported she was stuck by a needle in Parker's scrub top pocket, and she had found Parker in an OR to which she was not assigned. Parker was questioned but denied use of narcotics, and a drug test was negative for narcotics.

A few weeks later, Parker was again found in an OR to which she was not assigned. She claimed to be setting up for the next surgery. She was immediately screened for drugs. The test came back positive for fentanyl, and she was fired. Rose reported the incident to the health department and Drug Enforcement Administration. Meanwhile, Parker sought employment at Audubon, asking that Rose not be contacted as a reference.

Health departrment investigates

About the same time, the health department received 9 positive HCV tests from patients who had had surgery at Rose. The department says its investigation suggested the infections were caused by exposures during surgery and coincided with Parker's employment there. Parker was originally charged in July 2009 with tampering and other drug-related charges.

Rose notified about 4,700 patients who had surgery during the time of Parker's employment, and Audubon notified about 1,200. ❖

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gies," Joint Commission President Mark Chassin, MD, MPP, MPH, said at a press conference.

The Joint Commission says it will share the strategies, such as assessment tools and packages of interventions, with accredited facilities at no extra cost.

The program is separate from accreditation today. But Dr Chassin said over time the commission will consider building elements that work into accreditation requirements.

Beyond easy fixes

The center will start by tackling 3 issues:

- hand hygiene
- preventing wrong surgery
- hand-off communication.

Eight hospitals volunteered for the hand hygiene initiative, among them Cedars-Sinai Health System in Los Angeles and Johns Hopkins Hospital in Baltimore.

As the group began digging into the issue, Dr Chassin said they found the problems were "beyond easy fixes." Among barriers they discovered were not having soap and hand-rub dispensers in convenient places and faulty data that led the hospitals to think hand-cleaning rates are better than they are. On average, caregivers actually were cleaning their hands less than 50% of the time.

Targeted solutions are now being tested, such as holding everyone accountable and responsible—physicians, nurses, technicians, therapists, housekeepers, and others and using a reliable way to measure performance.

Wrong-surgery initiative

Two hospitals will work on preventing wrong surgery, Rhode Island Hospital, a large teaching center, and Newport Hospital, a community facility, both part of the LifeSpan system based in Providence, Rhode Island. Hospitals in the state have had several widely reported wrong-surgery incidents.

"What can this initiative add?"

Given the effort already spent on prevention, what can this initiative add? Rhode Island hospitals spent 2 years developing a statewide surgical safety protocol introduced in July 2009 (September 2008 *OR Manager*).

Mary Cooper, MD, JD, LifeSpan's chief quality officer, told *OR Manager* she and other leaders see an opportunity to introduce tools like Lean Six Sigma, which the hospitals do not currently have experience with.

The heart of the matter

"We wanted to do something about preventing wrong surgery that gets to the heart of the matter," she says. The Joint Commission center is providing LifeSpan with 2 Six Sigma Black Belts, one of whom is a surgeon, and a "master change agent" for the wrong-site surgery project. They are working with front-line staff as well as physicians. The project started in July 2009, with results expected by next spring or summer.

Focus on variation

The wrong-site project is focusing on 2 areas, Dr Cooper explains.

Newport Hospital will look at standardizing surgical site marking. Though site marking has been an expectation for a long time, she notes, there is variation. For example, even if everyone in a hospital signs, "yes," there still are differences in the distance from the mark to the incision site and in the size of the mark.

At Rhode Island Hospital, the focus will be on situations where there are inherent variations, making it difficult to mark the site. Examples are procedures where there will be 2 incisions on the same side or where a laparoscope will be inserted in a different location than the intended procedure.

"As we talk to colleagues around the country, we have found that procedures that are done incorrectly and are near misses tend to be ones where people scratch their heads and say, 'I've never come up against this before,'" Dr Cooper says. "It is not the routine procedures where people are making mistakes."

The hospital will also look at surgical site verification in emergencies, when care is rushed.

Stepping forward

"It was very important to us to step forward and tackle this problem, in large part because we have had wrong-site procedures about which we and the state have been very vocal," she says.

"It was important for us to say, not only are we going to be open, but we want to be out there looking for innovative approaches to make sure this doesn't happen to the next patient."

The Joint Commission said the center has received support from the American Hospital Association, the Federation of American Hospitals, and companies including BD, Ecolab, GE Healthcare, and Johnson & Johnson. ❖

Learn more about the Joint Commission Center for Transforming Healthcare at www.centerfortransforminghealthcare.org/

Hernia, total joint volumes down

Three elective surgical procedures saw declines in early 2009 for a group of facilities participating in the OR Benchmarks Collaborative.

Hernia repair and total hip and total knee replacement volumes were down in January through July compared with the same period the year before. Declines were:

- Hernia repair: minus 7%
- Knee replacements: minus 11%.
- Hip replacements: minus 6%.

The data are from 12 months of data submitted to the collaborative by 130 US hospitals and 14 ambulatory surgery centers (ASCs). Of the hospitals, 88% were community facilities, and 12% were academic centers.

Geographic distribution was:

- North Atlantic: 32%
- South Atlantic: 28%
- Midwest: 16%
- West: 24%.

The recession and elective surgery

The impact of the recession on elective surgery has been hard to gauge.

As the downturn hit in late 2008, press reports quoted hospital execs as saying volumes of elective cases were falling, as people postponed care because of the loss of jobs and insurance.

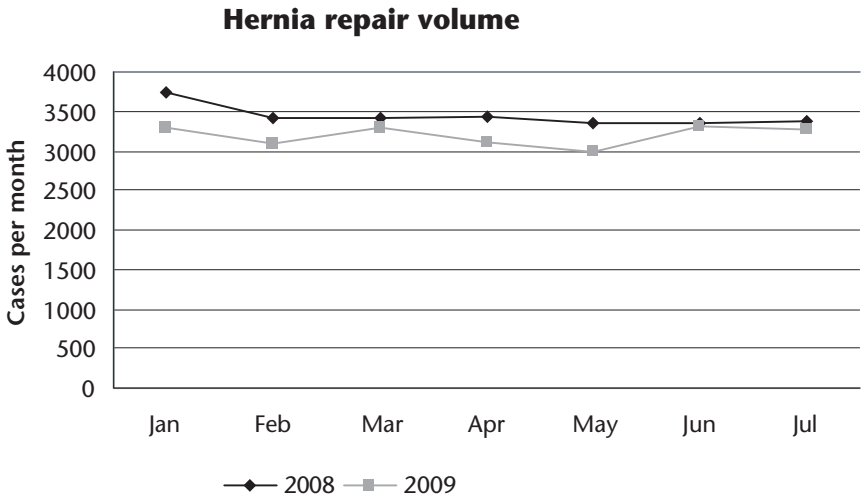
In a survey by the American Hospital Association in March 2009, 59% of members had seen a moderate to significant decline in elective procedures.

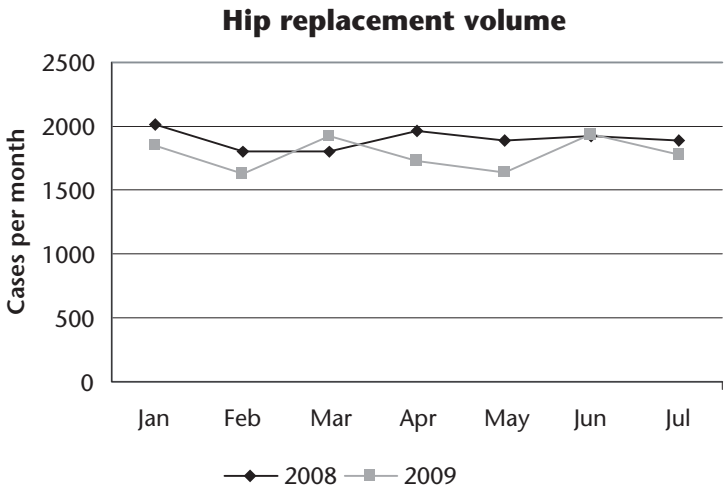
OR directors interviewed by *OR Manager* in February 2009 reported uneven effects—for some, volume was down, but for others it was even or a little ahead.

In the 2009 *OR Manager* Salary/Career Survey, 30% of respondents from hospital ORs reported a decrease in surgical volume, compared with 24% in 2008. For ASCs, 90% had seen a decrease in elective surgery (October 2009 *OR Manager*). (The hospital OR survey did not ask specifically about elective volume.)

In August 2009, Thomson Reuters reported hospital finances recovered somewhat in the first quarter of the year, based on benchmarking data from 522 hospitals. The report does not include elective surgery.

Other Thomson Reuters databases had not shown much change in elective surgery. Only in June and July did the company see a downward trend for elective procedures such as screening colonoscopy and knee arthroscopy, but the trend was not strong, according to a spokesman. ❖





The OR Benchmarks Collaborative is a partnership of OR Manager, Inc, and McKesson that offers benchmarking on key performance indicators.
More information is at www.orbenchmrking.com

Retained items: Fast facts

Estimates are that a foreign body is retained:

- in 1 in every 1,000 to 1,500 abdominal operations
- in 1 in every 8,000 to 18,000 inpatient operations.

—*Gawande A A, Studdert D M, Orav E J, et al.* N Engl J Med. *2003;348:229-235.*

—*Gonzales-Ojeda A, Rodrigues-Alcantar D A, Arenas-Marquez H, et al.* Hepatogastroenterology. *1999:46:808-812.*

In a study at the Mayo Clinic in Rochester, Minnesota, the actual rate of retained items was 1 in 5,500 operations. Postoperative x-rays are routinely performed for open-cavity cases.

—*Cima R R, Kollengode A, Garnatz, J et al.* J Am Coll Surg. *2008;207:80-87.*

The weak link in preventing retained foreign bodies is the deceptively correct count—72% to 88% of retained items happen in operations with "correct counts."

—*Regenbogen S E, Greenberg C C, Resch S C, et al.* Surgery. *2009;145:527-535. (References 9-12)*

Standard sponge counting alone is predicted to prevent about 82% of retained sponges, or a rate of 12 retained sponges per 100,000 operations.

With use of bar-coded sponges, the estimated rate of retained objects is 1 in 60,000 operations, or 1.7 per 100,000.

—*Regenbogen S E, Greenberg C C, Resch S C, et al.* Surgery. *2009;145:527-535.*

Continued from page 1

items? Three technologies are available (sidebar, p 9).

OR leaders whose facilities have adopted technology caution that it is not a substitute for manual counting and other preventive measures.

"This is a big change in OR culture, and it cannot just be thrown into the OR without preparation for everyone," says Robert Cima, MD, MA, chair of the surgical quality committee at the Mayo Clinic in Rochester, Minnesota. The Clinic has introduced scanning of bar-coded sponges as part of a 4-year project to prevent retained items (related article, p 12). How the technology is implemented and the culture into which it is introduced are more important than the technology itself, he notes.

Common themes

Leaders in organizations that have adopted sponge-tracking technology stress these common themes:

- Staff and physicians must be involved in planning and implementing any solution to prevent retained items.
- Implementation needs to be carefully planned and include thorough communication and education.
- Team communication and collaboration are essential to prevention.

'You have to communicate'

A recent study Dr Cima led at Mayo found communication breakdowns were the most common root cause of retained items.

"The technology is great, but it doesn't take the place of counting—and you have to communicate with each other," stresses Cheryl Weisbrod, RN, MS, nurse administrator of surgical services at the Mayo Clinic in Rochester.

The real work is "to change the behavior of the nurses and surgeons to have them work together," adds Verna Gibbs, MD, a surgeon who developed the No-Thing Left Behind campaign to prevent retained items (sidebar, p 10). She is a professor of clinical surgery at the University of California, San Francisco (UCSF) and a surgeon at the San Francisco Veterans Affairs Medical Center.

Low-tech and high-tech

The UCSF Medical Center adopted the bar-coded sponge technology (SurgiCount Medical) more than 2 years ago as part of a multidisciplinary effort.

Perioperative nurses at UCSF also worked with Dr Gibbs in developing a standardized low-tech method for verifying that all sponges are accounted for. The method, called the Sponge ACCOUNTing system, uses inexpensive plastic hanging sponge holders and dry erase boards to keep track of sponges. (See September 2008 *OR Manager.*)

The use of the hanging sponge holders adds about 30 cents per holder to total case costs, Dr Gibbs says.

Sandra Wienholz, RN, MSN, patient care manager in the Moffitt Long ORs at UCSF, says, "Nurses have to be very confident in their practice before you add technology. As our technical and patient care responsibilities increase, our sponge counting practice has to be strong." (At the time UCSF adopted bar-coded sponges, technologies using radiofrequency energy had not yet

Technologies for sponge accounting and detection

SmartSponge System

ClearCount Medical Solutions

www.clearcount.com

The system, which combines sponge accounting and detection, consists of a bucket with scanner, RFID-tagged sponges, and scanning wand. Sponges are scanned in and out of the case. If there is a discrepancy, the patient is scanned with the wand to detect any remaining sponges. The system is cleared by the Food and Drug Administration (FDA).

Costs: ClearCount estimates the cost per case at $25 to $35, including hardware and disposables. The hardware is offered as a rental. Disposable costs include a sterile sheath for the reusable wand plus the RFID-tagged sponges.

Installations: ClearCount announced its first installation in June 2009 at Memorial Sloan-Kettering Cancer Center in New York City.

RF Surgical Detection System

RF Surgical Systems, Inc

www.rfsurg.com

The system has 3 components: A handheld scanning wand connected to a console and micro radiofrequency (RF) tags embedded in gauze, sponges, and towels. When the wand is passed over a patient, an alarm signals the presence of any retained RF-tagged item. The system can be used to locate missing sponges elsewhere in the OR. The system was cleared by the FDA in 2006.

Costs: Costs include $50 for the wand, now marketed for 24-hour use in each OR. On average, a wand is used for about 3 cases per day, the company says. RF-tagged sponges cost about 20 cents more than conventional sponges. A sterile wand sleeve is also needed. The consoles are provided on loan.

The company estimates the cost at about $15 per case if averaged across all of a hospital's surgical cases.

Installations: About 75.

Safety-Sponge System

SurgiCount Medical, Inc

www.surgicountmedical.com

The system includes bar-coded sponges and towels, a scanner, and software for documenting counts and generating reports.

Sponges and towels have unique bar codes. Sponges are scanned and recorded during initial and final counts. The system was cleared by the FDA in 2006.

Costs: The incremental cost per procedure is estimated at $12 per procedure by the company. The only incremental cost is the bar-coded sponges, according to Cardinal Health, the distributor. The hardware (scanner/computer, mount for IV pole, charger, and extra battery) is available at no charge.

A cost-effectiveness model developed by Harvard researchers found bar-coded sponges were the only technology with a cost-per-event prevented in a range acceptable to most institutions (Regenbogen S E, Greenberg C C, Resch S C, et al. *Surgery.* 2009;145:527-35). Marketing models for the RF systems have been modified since the study was conducted.

Installations: Number of installations not disclosed.

been cleared by the Food and Drug Administration.)

Empowering nurses

One benefit of the bar-coded sponge system is that it has empowered the nurses, Wienholz says. When there is a count discrepancy, nurses can be more confident that a missing sponge might still be in the patient.

A recent example was an early-morning case. At the end of the case, the bar-coding system showed a missing sponge. After a thorough inspection by the staff of the back table, floor, and garbage, the sponge was not recovered.

"They were pretty adamant with the surgeon that it still had to be in the patient," Wienholz says. The surgeon called for an x-ray and conducted a manual wound exploration, locating the sponge.

Cohesive teamwork, aided by technology, averted a retained sponge, she says.

Since introducing bar-coded sponges, Wienholz says OR nurses at UCSF have been able to predict with 100% accuracy items that would have been retained.

She estimates the system's costs at about $10 to $15 a case. "That may seem like a lot if you do a large number of cases, but if you can avert one retained item, you pay for it," she says.

The hanging sponge holder bags have also been useful, she notes. "Now a relief nurse can walk into a room, and it is clear where you are in your counts."

Collaborate with physicians

Collaborating with surgeons and the radiology department is crucial to a successful implementation, Wienholz comments.

"If the physicians don't see the importance of counts and aren't

Continued on page 11

NoThing Left Behind

Steps to prevent retained items

Hanging sponge holders.

NoThing Left Behind campaign

Surgeons

1. Use only x-ray detectable sponges or towels. Don't alter them.
2. Perform a methodical wound exam while the nurses perform the closing count. Take a "pause for the gauze." Call out, "All sponges are out." Then ask for the closing suture.
3. At the end of the case before leaving the OR, look at the hanging sponge holders and say, "Show me that all of the sponges are there." Dictate, "A methodical wound exploration was performed, and I saw that all sponges were accounted for."

Nurses

1. In-count: Use a standardized and transparent process. Record the count for all personnel to see.
2. Closing count: While the surgeon does the wound exam, perform a focused 2-person count, using hanging sponge holders to get the sponges in one place. Check back: "We think the count is correct."
3. Final count: Performed before the patient leaves the OR. Verify that all sponges (used and unused) are in the hanging sponge holders.

Radiologists

1. X-ray the complete operative field with proper technique; consider oblique/lateral views.
2. Know what is being looked for; eg, the kind of sponge, the size of needle.
3. Report the findings directly to the surgeon of record.

Source: Verna C. Gibbs, MD.

Sponge ACCOUNTing system

Checklist

Audit at the end of ***every*** case.

- ❑ **A**ll plastic bags in the OR used for sponge accounting are clear.
- ❑ **B**lue-backed sponge holders are on a rack, mounted to an IV pole that doesn't tip.
- ❑ **C**ount is recorded in standardized format on dry erase board as a running total.
- ❑ **D**uring in-count, the scrub person and circulating nurse "separate, see, and say" 10 sponges.
- ❑ **E**very closing count has a surgeon perform a methodical wound exam.
- ❑ **F**ull sponge holder(s) (all sponges) at final count have a visual team verification.

Source: NoThing Left Behind, Verna Gibbs, MD. Used with permission.

Continued from page 9

willing to allow the nurses to get the technology up and running, the staff will be forced to find shortcuts," she says. "It really comes down to the nursing staff feeling they have a sense of ownership of their practice and the technology."

Collaborating with the radiology department is also important. Because the bar-coding system can alert nurses to miscounts, intraoperative x-rays to rule out a retained item may be more common.

Rolling out RF technology

The ORs at the Hospital of the University of Pennsylvania in Philadelphia have been using the RF Surgical Detection System since 2007. The system consists of a handheld scanning wand and radiofrequency-tagged gauze, sponges, and towels.

The technology is an additional patient safety feature. Nurses count as usual. The wand is used for all open cavity cases or when there is a count discrepancy.

If a sponge is not detected in the body cavity, the wand can be swept over the trash and linen carts, notes Marianne Saunders, RN, BSN, CNOR, nurse manager of perioperative services.

In one example, the wand helped locate a sponge in an unlikely spot during an orthopedic case. Normally, wanding isn't necessary during orthopedic cases, but the staff nurse had counted multiple times and not found the sponge. As the wand passed over the area, the system alarmed, and the sponge was found under the bed in the foot pedal of a drill.

Dr Gibbs comments that she views the wand as an adjunct to the methodical wound exam, adding that the "wand should be used by the surgeon in all cases if you are not going to use a standardized manual counting system."

> **"The real work is to change behavior."**

Working through the implementation

The University of Pennsylvania was one of the first to implement the RF Surgical Detection System. Initially, there were some frustrations, says Saunders, which she and her team worked through with the company's engineers. At first, wands alarmed if they touched metal on the back table or got too close to staff members' RF-tagged ID badges. The engineers adjusted the signal and replaced the consoles that control the wands, which fixed the problem.

Gary Blackbourn, RF Surgical's vice president for sales and marketing, explains that the RF tags on the sponges and on ID badges emit signals that are similar but not the same. The problem was fixed by tightening the signal in the RF Surgical software. He says the company has not had issues with the RF system reacting to ID badges for about 1 to 1½ years.

The wand is now marketed for 24-hour use. Saunders explains that when the staff turns on the console and opens the wand, they label the wand, and it is good for 24 hours. The staff must be educated not to unplug the console between cases. If the console is unplugged for more than 2 minutes, use of the wand is lost, and a new one must be opened.

Have an education plan

Saunders says education was also needed for the physicians on the new RF system. According to policy, wanding is performed for open cavity cases or when there is a count discrepancy. Though wanding takes less than a minute, some physicians perceive it as a delay.

Extensive education is needed before the system is implemented, Saunders advises.

"We rolled it out to everyone beforehand," she says. Stations were set up so all personnel could participate in demos. "We did demos for weeks." In addition, mass e-mails were sent to attending physicians, fellows, and residents. The chief of surgery sent a memo supporting the initiative, which was also supported by the senior administration. ❖

—Pat Patterson

The California violation reports were posted September 3, 2009, by the California Department of Public Health website at www.cdph.ca.gov. Look under News Room.

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A 4-year effort to prevent retained items

The Mayo Clinic in Rochester, Minnesota, added bar-coded sponge technology in February 2009 as part of a comprehensive 4-year effort to improve prevention of retained foreign objects (RFOs).

The Mayo Clinic in Rochester has 98 ORs, 3 obstetrical ORs, and 8 labor and delivery birthing rooms in 2 hospitals and performs about 50,000 procedures a year. The project was described in the *Joint Commission Journal on Quality and Patient Safety*. The Clinic reported its data on retained objects and near miss reports in the *Journal of the American College of Surgeons* (sidebars).

The result of the project was to improve from an average of 1 retained object or near miss every 16 days to an average of 1 every 69 days, a level that had been maintained for over 2 years. The Sigma performance level rose from 5.6 to 6.0, and remains essentially unchanged. (A process is considered to be at Six Sigma when there are 3.4 defects per 1 million opportunities.)

Careful planning needed

Adding technology is a step that must be carefully analyzed and planned, says Robert Cima, MD, MA, associate professor in the Department of Surgery and vice chairman of quality and safety.

"I would not even consider looking at any technology for this problem without an assessment of the need in an individual operating room environment," he told *OR Manager* in an e-mail.

"We spent 3 years preparing our staff so they understood the issues, saw the value leadership placed on

Mayo Clinic's project phases

Phase 1: Defect analysis and policy review

Researchers analyzed all retained objects and near misses reported over 4 years. A major finding—in 62% of 34 retained-object events, counts at the end of the case were considered correct. The most common root cause was a communication failure.

A multidisciplinary team then reviewed and revised all policies and procedures for retained objects and counting. Many policies had changed over time but had not been completely revised or reconciled with other policies.

Phase 2: Awareness and communication

A communication and education campaign was conducted for all physicians, nurses, and allied health personnel. The primary goal was to ensure all team members understood the problem and the need to improve communication.

A Conscientious Count Campaign was conducted to educate nurses, surgical technologists, and surgical assistants on proper counting and revised count policies.

Phase 3: Monitoring and control

The Surgical Event Team responds to any near miss or actual retained object. Within 12 to 24 hours, the team meets with all OR personnel involved to debrief team members about the event.

This process does not replace a root cause analysis nor seek to assign responsibility for the event. The purpose is to determine any potential system weaknesses. Within 24 to 48 hours, the team prepares a memo and shares it with all OR personnel.

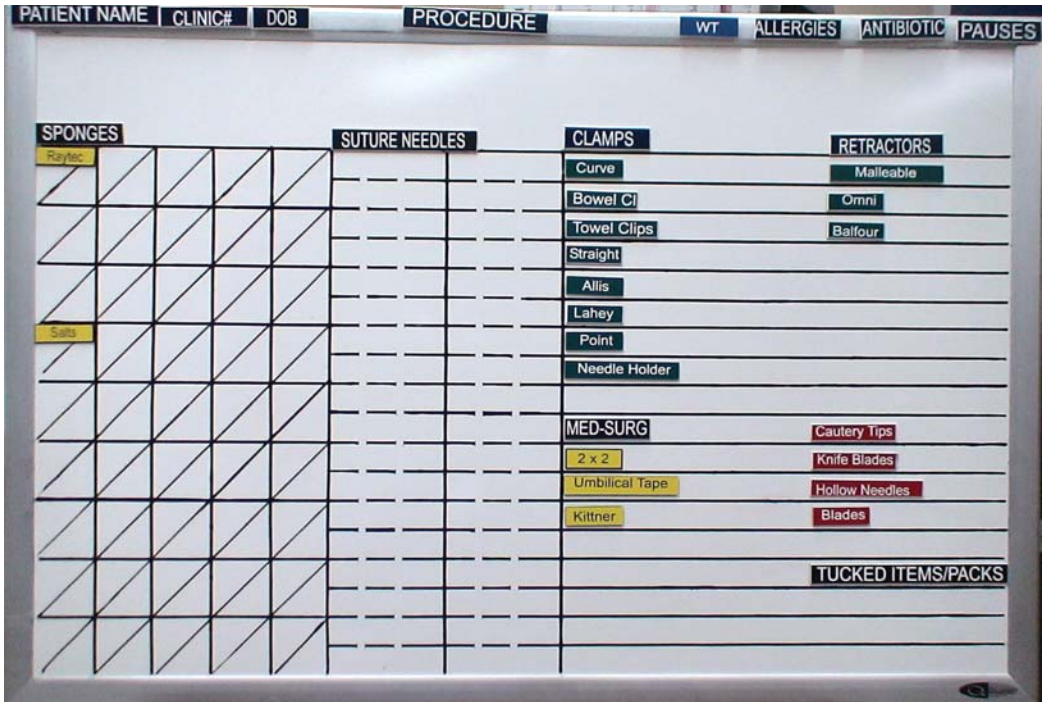
Source: Cima R R, Kollengode A, Storsveen A A, et al. Jt Comm J Qual Patient Saf. *2009;35:123-132.*

Retained items at the Mayo Clinic

Reviewing reports of retained objects at their institution over 4 years and 191,168 operations, researchers at the Mayo Clinic in Rochester found:

- 34 actual retained objects, a rate of 1 in 5,500 operations. Of these, 23 (68%) were sponges.
- For 21 events (62%), the count was recorded as correct.
- 59% of the retained objects were found unexpectedly through the Clinic's routine use of postoperative x-rays—in all, the counts were reported as correct.
- None of the retained objects happened during emergencies or high blood-loss procedures. Objects were retained most commonly in routine operations.
- The most common contributing factor was a breakdown in communication, such as failing to communicate with other team members when an item was placed in a body cavity.

Source: Cima R R, Kollengode A, Garnatz J, et al. J Am Coll Surg. *2008;207:80-87.*



Every OR at the Mayo Clinic in Rochester has a standardized white board for recording counts plus a wall-size poster that lists the "red rules" for counting.

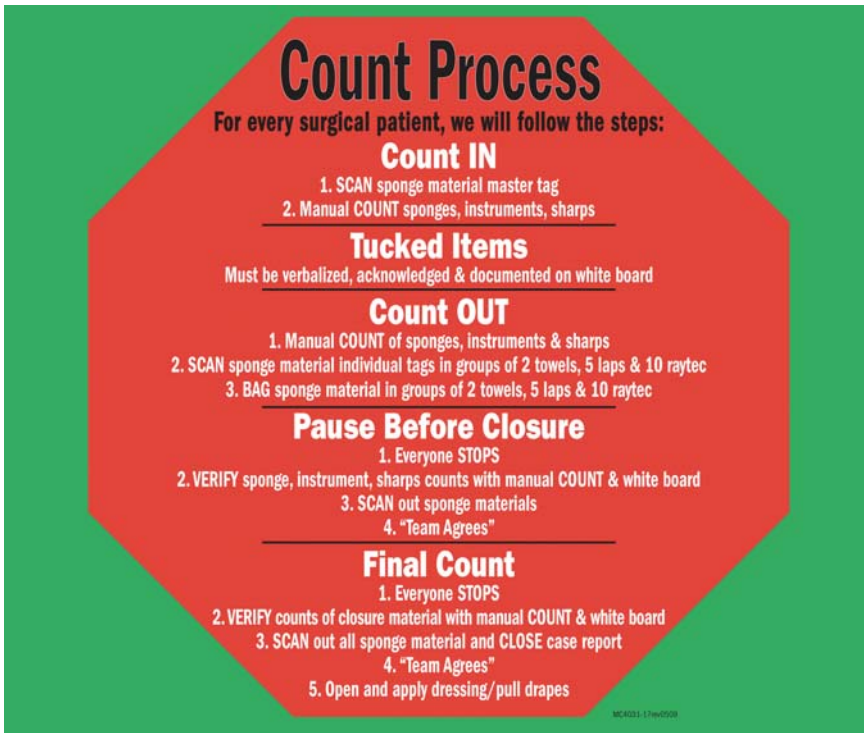
this effort, and had engaged them in trying to improve performance."

Why add technology?

Traditionally, RFO prevention at the Mayo Clinic in Rochester has included manual counts as well as routine screening x-rays for open-cavity cases. The x-rays are performed in dedicated imaging rooms after patients leave the OR.

X-rays do not take the place of manual counts, stresses Cheryl Weisbrod, RN, MS, nurse administrator of surgical services, noting she has fielded many questions about this.

The decision to add bar-coding technology was made for several reasons. First, definitions of retained objects by the Joint Commission and State of Minnesota have become more precise in recent years, Dr Cima notes. Under these definitions, objects are considered retained if not detected before the incision is closed. If there is no wound being closed, the defining point is when the procedural team withdraws from the patient.



"Clearly, our x-rays did not allow us to meet these definitions," he said.

The problem of accounting

The second reason was that the Clinic's analysis showed 50% of its retained objects were sponges.

"Our main problem was one of 'accounting,'" Dr Cima notes. Bar coding is an "accounting" technology. In addition, he said, bar coding is an established technology, is well understood by staff, and made sense economically.

Continued on page 15

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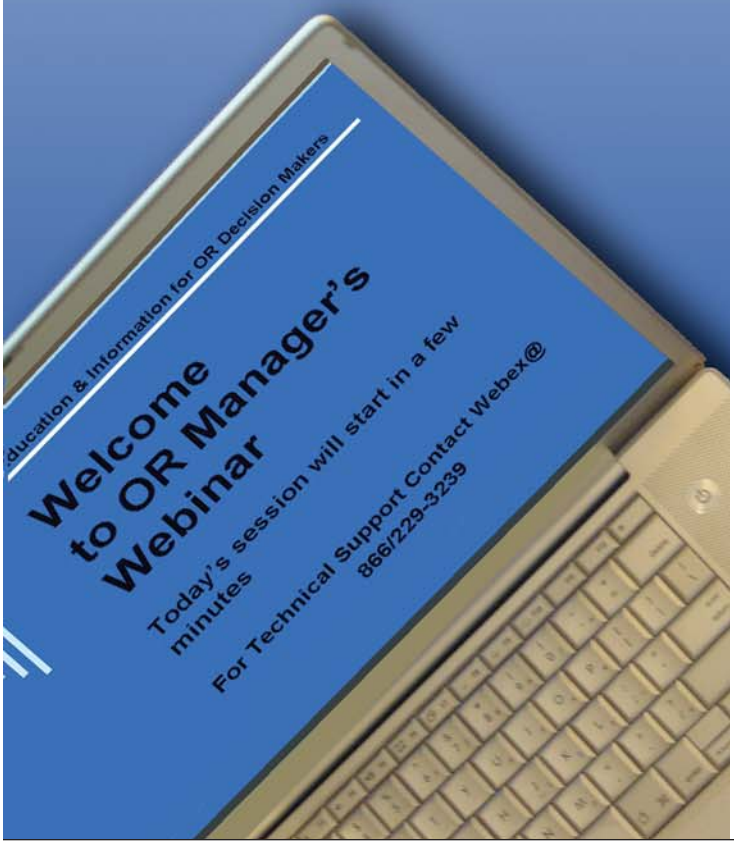

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Continued from page 13

Even with bar coding, he noted, "We continue to obtain postop survey films to make sure needles or instruments are not in the patient, even though we would still consider them RFOs because they would be found outside the OR."

Adopting bar coding

A key to implementing the bar-coding system was to understand in detail how the system would work in the OR. A perioperative nurse educator guided the process, walking through the steps with the staff and gathering feedback.

The team learned, for example, that the bar-code scanner did not work as well when it was held in the hand as when it was left in its holder on the IV pole. But nurses said it was easier to use when held.

"The scanner is not held at the same angle as when it is in the holder," Weisbrod explains. As a result, some staff thought the scanner didn't work. The solution was to leave the scanners in the holders, at least until more experience is gained.

Other key steps were to educate the department's 15 nurse managers and to develop a group of "super-users" who could mentor others.

White boards, red rules

To make sure counts are performed in a standardized manner, the Mayo Clinic has adopted "red rules" and standardized white boards (illustrations, p 13).

Every OR has a wall-sized poster with the "red rules" for counts. Red rules are clear, simple directives intended to foster patient safety that are supported by the entire organization. Any deviation causes activity to cease until the situation is addressed.

The red rules now state that the final count includes, in addition to the usual steps, scanning out of all sponge material and closing of the bar-coding report.

> **"Every OR has 'red rules' for counts."**

Every OR has a standardized white board for recording counts.

"We have had erasable boards for years, but we found different people wrote the information in different ways," Weisbrod notes. The boards make the count visible to the entire team.

"Before the end of the procedure, everyone looks at the white board and says, 'Are the counts correct?'" she says.

In addition to sponge, needle, and instrument counts, the white boards have space to record tucked items. If a tucked item has not been erased and is not accounted for, the team knows to conduct a wound exploration and possibly have an x-ray taken.

An ongoing effort

OR personnel are updated regularly on how the surgical service is performing on quality measures, including preventing retained objects. An analyst collects data daily on these and other measures, which are reported on control charts posted throughout the department and on a surgical services scorecard.

The staff is encouraged to report any concern or near miss to the surgical services leadership. A Surgical Event Team reviews these reports and debriefs team members involved. The process does not take the place of root cause analysis nor does it seek to place responsibility. The focus is on what can be learned to improve the process.

But regardless of the technology and other interventions, Weisbrod says, "it comes down to the fact that we are human beings, and we need to talk to each other. I have been in the OR a long time, and we used to have more time to talk with the surgeons and residents. Now, with more technology to manage, there seems to be less time for those face-to-face discussions."

The ORs are introducing briefings and debriefings to encourage communication. The department has provided education in Crucial Conversations, a program by VitalSmarts (www.vitalsmarts.com) that teaches people how to bring up and discuss difficult issues effectively.

"There are events that will occur," she says. "We tell the staff, 'Be respectful. But don't be afraid to speak up.' We are here. We will support you." ❖

—Pat Patterson

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OR business manager gains ground

The OR business manager position has gained ground in the past 5 years. Well over one-third (37%) of ORs responding to the *OR Manager* Salary/Career survey have business managers, compared with 24% in 2004. For the second year, the survey included specific questions about the OR business manager.

The *OR Manager* Salary/Career Survey was mailed in April 2009 to 800 *OR Manager* subscribers who are directors or managers of hospital ORs; 323 were returned for a response rate of 40%.

Over half (54%) of teaching hospitals and a third (31%) of community hospitals have OR business managers. In contrast, 5 years ago only 44% of teaching institutions and 18% of community hospitals had the position.

The average salary is $78,600, up from $73,000 in 2008, the first year this question was asked. Salaries range from more than $100,000 to less than $60,000. Salary information was provided by 71 of the 109 respondents who have an OR business manager.

Reporting structure

Most business managers (70%) report to the OR director or director of surgical services, with the remainder reporting to a senior administrator such as the nurse executive or chief financial officer.

More than half (51%) have staffs of 4 or more direct reports; 19% do not have direct reports.

Responsibilities

The 5 leading areas of responsibility are financial analysis and reporting, the annual budget, billing and reimbursement, value analysis/product selection, and materials management.

Qualifications

More respondents this year (78%) say a specific degree is required for the OR business manager position, compared with 73% in 2008. For those that require a de-

Continued on page 19

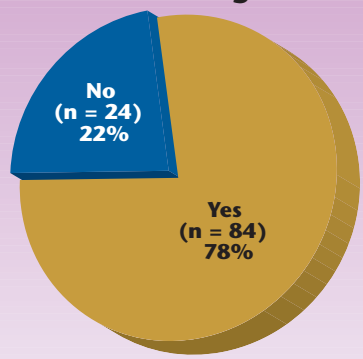
OR business manager salaries

(n = 71)

Mean = $78,600
Median = $75,000

$100K	11%
$90K-$99,999	11%
$80K-$89,999	12%
$70K-$79,999	16%
$60K-$69,999	13%
<$60K	8%
Don't know	29%

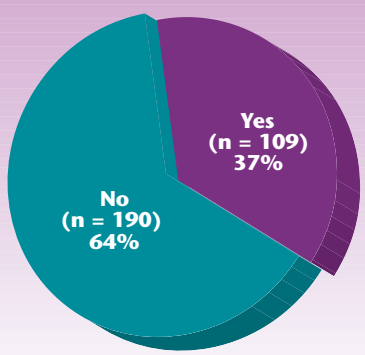
Is a specific degree required for the OR business manager?



Degree required

Bachelor's	50%
Master's (any)	19%
MBA	31%

Does your OR have a business manager?



By facility type

Community	Teaching
(n=66)	(n=39)
31%	54%

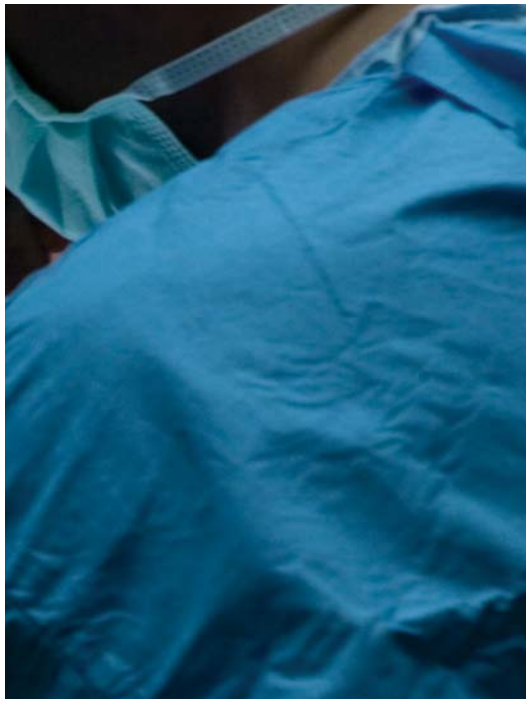
By number of ORs

1-4	5-9	10+
(n=5)	(n=17)	(n=84)
8%	21%	56%

To whom does the business manager report?

(n = 109)

OR director	70%
Chief financial officer	6%
Nursing executive	6%
Chief operating officer	6%
Other (such as VP)	12%



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*Based on calculation of 10.9 minutes per case at Beaufort Memorial Hospital. Individual results may vary.

Salary/Career Survey

Continued from page 17

gree, the split is 50-50 between those that call for a bachelor's or a master's degree. Most that specify a master's degree, 26 out of 42, require a master's in business administration. Perhaps not surprisingly, teaching hospitals (87%) are more likely to require a specific degree than community hospitals (70%).

One-third (33%) require the business manager to have a clinical background, similar to 2008. Community hospitals are more likely to require a clinical background for business managers than teaching institutions (41% vs 21%). ❖

The OR Manager *Salary/Career Survey results on staffing were in the September 2009* OR Manager. *Results on salaries and benefits were in the October issue.*

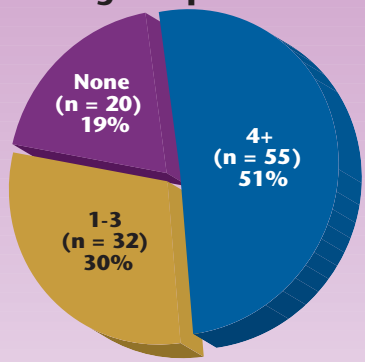
Thank you

OR Manager thanks the respondents who took time to complete this year's survey. We appreciate your part in gathering this information, which will be useful to your colleagues around the country.

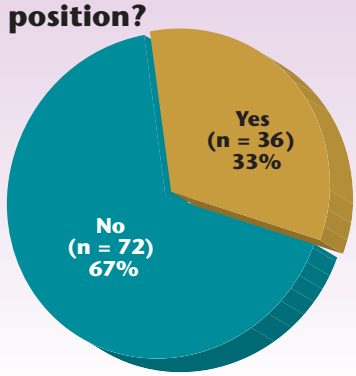
What are the OR business manager's responsibilities?
(n = 108)

Financial analysis/ reporting	92%
Annual budget	74%
Billing/reimbursement	71%
Value analysis/product selection process	60%
Materials management	57%
Purchasing	52%
Surgical information system	44%
Strategic planning	42%
OR scheduling	35%
Quality improvement	17%
Other	6%

How many direct reports does the OR business manager supervise?



Is a clinical background required for the OR business manager position?



Failure to rescue drives postoperative mortality

A new study debunks assumptions about the role of complications in distinguishing low- and high-mortality hospitals. The report in the Oct 1 *New England Journal of Medicine* confirms that serious complications are common after major surgery—about 1 in 6 patients—but the study shows failure to rescue is what drives hospital mortality.

Heading off complications

Low-mortality hospitals have teams with the ability to rescue patients by recognizing and heading off potentially catastrophic complications such as deep wound infections, pneumonia, kidney failure, blood clots, and strokes. Despite similar patterns of complications, patients at high-mortality hospitals are nearly twice as likely to die after developing a serious postop complication.

"The general assumption has been that high-mortality hospitals simply have higher complication rates. We were quite surprised to find that's not true," says study author John D. Birkmeyer, MD, of the University of Michigan, Ann Arbor.

The study used data from 84,730 patients having general and vascular surgery at 186 hospitals participating in the American College of Surgeons National Surgical Quality Improvement Program (NSQIP).

The hospitals' mortality rate varied dramatically from 3.5% to 6.9%. But there was not much difference in the complication rates, 18.2% versus 16.2%.

Dr Birkmeyer says the findings give a better sense of what to look for in reducing mortality rates from surgery.

"Rather than focusing on what the surgeon does in the operating room, we need to focus on what's happening on the wards and in the intensive care unit afterward."❖

Reference

Ghaferi A A, Birkmeyer J D, Dimick J B. Variation in hospital mortality associated with inpatient surgery. *N Engl J Med.* 2009;361:1368-1375.

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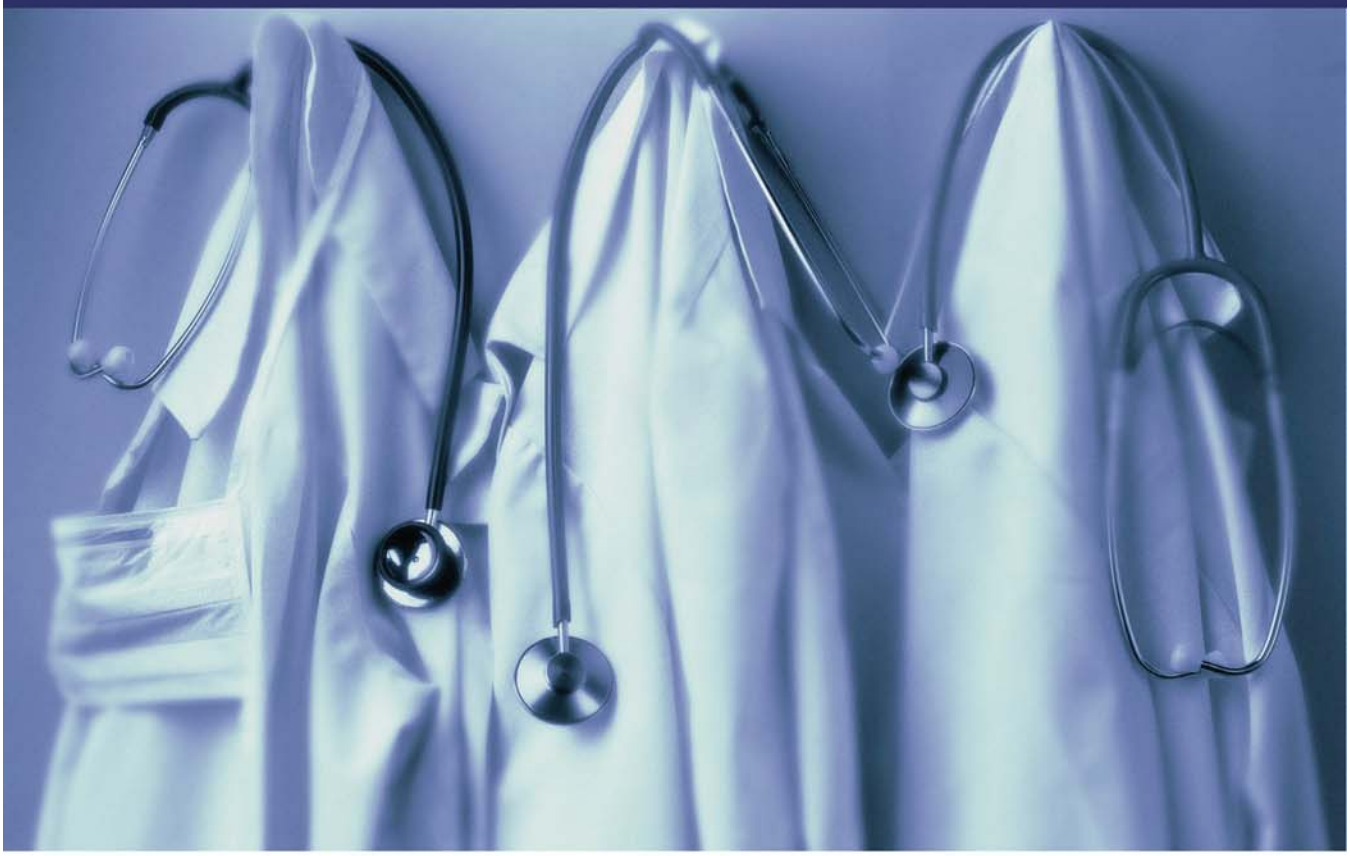

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Tackling an outbreak of MRSA SSIs

In late 2007 and early 2008, an Arizona hospital saw an alarming increase in surgical site infections (SSI) with methicillin-resistant *Staphylococcus aureus* (MRSA).

For the first quarter in 2008, the infection rate for total hip replacements and revisions averaged 3.73%, well above the national average of 1.6%, with most involving MRSA. Some MRSA infections had also occurred after total knee procedures, cholecystectomies, and hernia repairs with mesh.

A multidisciplinary team at the hospital, Banner Baywood Medical Center in Mesa, which has 10 ORs, began a top-to-bottom review of the OR environment and practices.

By the end of October 2008, MRSA SSIs fell to zero, and none were reported through early May 2009.

MRSA can be devastating. Patients who develop an MRSA SSI have a 3.4 times higher risk of death than patients with methicillin-susceptible *Staph aureus*, and their median hospital costs are almost twice as high, according to Engemann, et al.

These are steps the hospital took to reach zero for MRSA SSIs. Two OR issues the team found needed particular attention—OR ventilation (positive pressure) and terminal cleaning.

Team goes to work

In May 2008, the infection preventionist, Julie Peters, RN, gathered a multidisciplinary team to begin a review and make recommendations. Included were representatives from the OR as well as infection control, sterile processing, and quality management. They used as their guide the Centers for Disease Control and Prevention Guideline for Prevention of Surgical Site Infection, 1999.

> **"Terminal cleaning wasn't up to par."**

The group reviewed sterilization practices. Flash sterilization was already minimal. Among steps they took:

- All prevacuum cycles were standardized, and 1 minute was added to drying time.
- Autoclave settings were set so the staff cannot change them.
- The team changed to thicker sterilization wrap, sent letters to vendors reminding them to check and replace trays with spurs and sharp edges, and placed plastic trays under consigned orthopedic trays to reduce tearing of wrap.
- A new process was employed for cleaning all instrument containers.

Hand hygiene compliance in perioperative services averaged 75%, higher than in other units. To aid compliance with contact precautions, the hospital uses color coding to identify patients who are and who are not on contact precautions.

Informing the surgeons

Peters presented information on the outbreak to the Surgery Committee, which discussed practices such as ensuring that the antibiotic for total knee procedures was given before the tourniquet was applied and the antibiotic was administered within 1 hour of incision for all cases.

Compendium has advice on infection

A comprehensive review of strategies for preventing health care-associated infection is available from the Society for Healthcare Epidemiology of America. Included are strategies for:

- surgical site infection
- central line-associated bloodstream infection
- catheter-associated urinary tract infection
- ventilator-associated pneumonia
- *Clostridium difficile*
- Methicillin-resistant *Staphylococcus aureus.*

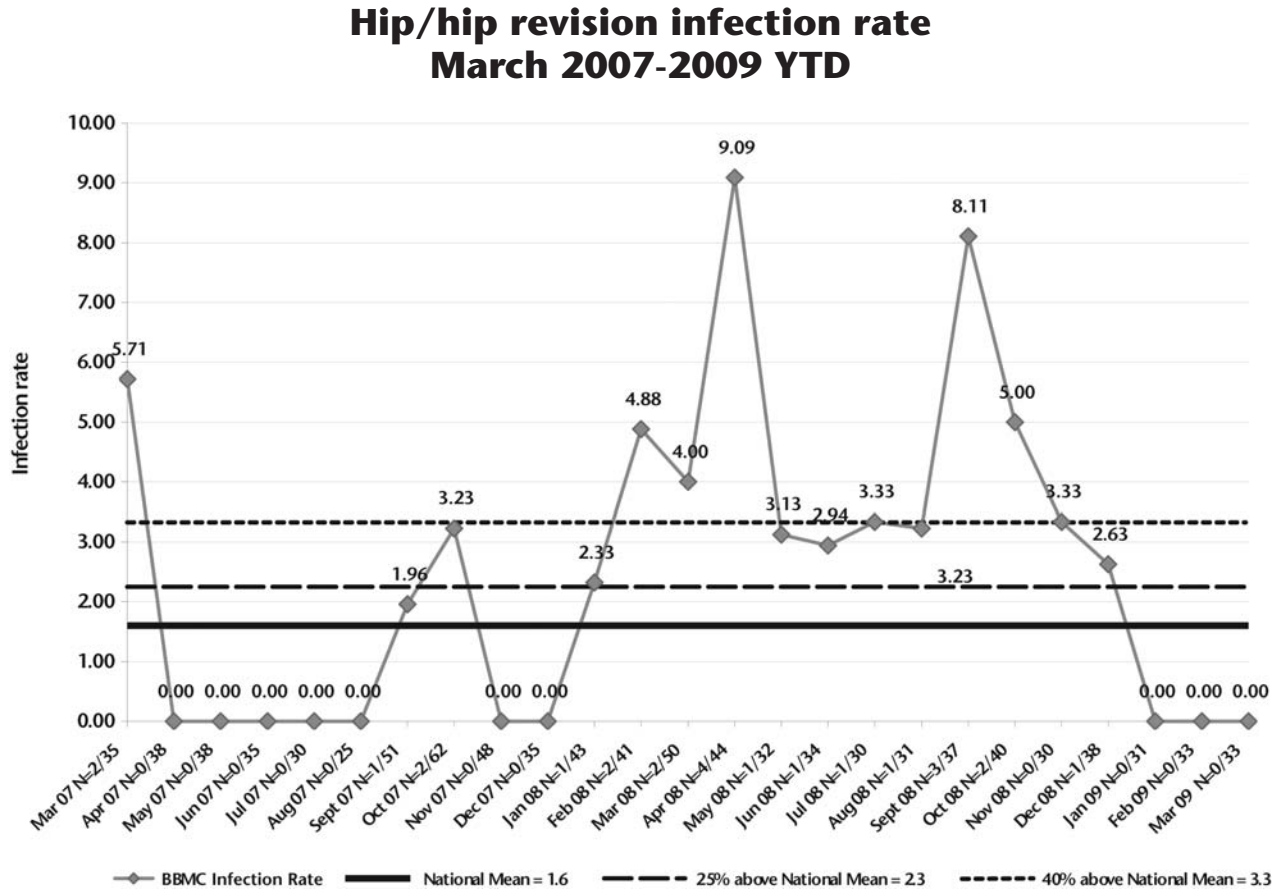
— www.shea-online.org/about/compendium.cfm

Compliance with the antibiotic measures from the Surgical Care Improvement Project (SCIP) for total joint procedures in the second half of 2008 was 94% or above. These include giving the antibiotic on time and selecting the right antibiotic. Appropriate hair removal was at 100% overall.

The surgeons discussed whether to introduce active surveillance testing for patients at high risk for MRSA, but have not gone ahead with that at present.

The effectiveness of active surveillance testing in preventing MRSA transmission is controversial, and optimal strategies for testing have not been resolved, according to a review of strategies for preventing MRSA transmission by Calfee and colleagues, part of the compendium on preventing health care-associated infections (HAI)

Continued on page 22



Source: Banner Baywood Medical Center.

Continued from page 21

from the Society for Healthcare Epidemiology of America (SHEA) and other organizations (sidebar, p 21).

Education reinforced

The team began reinforcing education for the staff on sterile technique and the SCIP measures. A review was conducted for the OR assistants and environmental services staff on decontamination and sterilization techniques. The need to control traffic in and out of the ORs was reinforced. ORs where implants are performed have signs on the doors instructing personnel to enter only through the sterile core.

A surprise discovery

Though reports showed all OR ventilation parameters were within guidelines, the team discovered to its surprise that 5 of the 10 ORs were actually under negative air pressure rather than positive pressure as recommended, says Chris Halowell, RN, MS-HSA, CNOR, director of perioperative services. In a positive pressure room, air flows outward to the corridor, sweeping out contaminants. Under negative pressure, air currents flow into the room.

The discovery was made on a weekend when the team came in to investigate an unrelated incident. A technician performed a "tissue test," using a facial tissue to see the flow of air currents in the ORs and found air was actually flowing into 5 rooms.

"I didn't believe him at first. But he showed me he was correct," Halowell says.

The team immediately contacted the facilities department to make sure OR ventilation was brought within the correct parameters. (A table with the recommended parameters for OR heating, ventilation, and air conditioning is in the AORN *2009 Perioperative Standards and Recommended Practices*, p 421.)

Terminal cleaning gaps

The team also learned terminal cleaning in the ORs wasn't up to par. Environmental cleaning is important because patients infected or colonized with MRSA contaminate their environment, which can in turn contaminate health care workers' hands, clothing, and equipment.

When Georgie Elias, RN, BS, CNOR, CPN, senior clinical manager for surgical services, and another clinical manager spent a week each with the terminal cleaners, they found lapses.

"We found they weren't making a connection between invisible bugs and the dust they could see," Halowell notes.

Some creative ways were used to reinforce the cleaners' education. Elias seeded an area with a harmless powder called Go Germ, which is invisible under normal conditions but glows under a black light (www.glogerm.com).

She had the cleaners perform their routine cleaning and used the black light to check their work.

As a further check, Elias used a luminometer, a device that detects low levels of light from ATP (adenosine triphosphate) in the cells of biological material to check on the effectiveness of cleaning.

"We found they still were missing important parts of the room like the high-touch surfaces," Elias says.

When the cleaners' performance didn't improve after these efforts, they were let go.

Preoperative wash for patients

As an additional measure, surgical patients are now given a bottle of 4% chlorhexidine gluconate, or CHG (Hibiclens), at their preoperative appointment and instructed to shower with it the day of surgery. Also, in the preoperative area, patients' surgical areas are cleaned with 2% CHG wipes. CHG provides persistent activity against microorganisms. For the skin prep, most of the orthopedic surgeons prefer an iodophor, Halowell notes.

Preoperative bathing with CHG is considered an unresolved issue in the strategies to prevent surgical site infections by Anderson and colleagues, part of the HAI compendium. Though showering with CHG before surgery has been shown to reduce bacterial colonization of the skin, studies have not shown clear evidence of a benefit, the article notes. AORN recommends that patients having Class 1 surgical procedures below the chin have 2 preoperative showers with CHG when appropriate.

> **"Staff learned about speaking up."**

Reinforcing sterile conscience

The team also looked for ways to reinforce aseptic technique and sterile conscience.

"Everyone is trained in that. But I think as time goes on, people start getting lax," Elias says.

An in-service on the study Silence Kills provided an eye-opening reminder. The study, released in 2005, found fewer than 10% of health care workers speak up when they see a colleague break rules, make mistakes, or appear clinically incompetent (www.silencekills.com).

Banner Baywood had already introduced Crucial Conversations, a training program that teaches skills for addressing difficult issues with colleagues (www.vitalsmarts.com).

The training is also being provided to the nonclinical staff. Halowell has found it is helpful to work with them in small groups.

"We have said, 'It is OK to call the nurses and doctors on their practice if you think it is harming your patient,'" Halowell says. "The patient is the center of focus."

Team Safe

A hospitalwide program called Team Safe is being introduced to develop a culture of safety and accountability.

"We are trying to create accountability so a person is not afraid to confront a coworker in the OR or anywhere," says Peters. Personnel learn to watch for and speak up about safety lapses, such as medication that is lying around or failure to observe hand hygiene or isolation precautions.

Halowell says that as a result of the training, she observes more staff intervening when they see a lapse, and she believes most staff would now speak up about a practice breach.

Targeting zero

Halowell admits to feeling "a little complacent" prior to 2008. She says the effort to address the outbreak raised awareness at all levels of the organization.

"Now I've learned you don't take a piece of paper for granted. You have to do your own testing," she says, referring to the OR ventilation reports.

She adds that the experience and Crucial Conversations training helped get the staff involved and fueled the department's shared leadership team.

"It's been a team effort to fix it," she says.

For Peters, the situation reinforced the value of the CDC SSI guideline.

"Now I think targeting zero is possible," she says. "It's like a diet—there is no immediate fix. It requires a change in habits that

Continued on page 24

Continued from page 23

must be followed for life. You have to tighten up on the basics."❖

—Pat Patterson

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Facilities Guidelines Institute. *Guidelines for Design and Construction of Health Care Facilities.* Washington, DC: American Institute of Architects, 2006. Includes ventilation guidelines. www.fgiguidelines.org

Six hospitals settle with feds over Medicare claims for kyphoplasty

Six hospitals in Indiana and Alabama agreed to pay the government more than $8 million to settle allegations that they submitted false claims to Medicare, the US Department of Justice announced September 29, 2009.

The settlements resolve allegations that from 2002 to 2008, the hospitals overbilled Medicare for kyphoplasty, a minimally invasive procedure used to treat spinal fractures due to osteoporosis.

The government contends the hospitals performed the procedure on an inpatient basis to increase their Medicare billings even though kyphoplasty in many cases can be performed safely as outpatient surgery.

The Indiana hospitals include St Francis Hospital in Beech Grove ($3.2 million), Deaconess Hospital in Evansville ($2.1 million), and St John's Health System in Anderson ($826,000).

The Alabama hospitals are St Vincent's East Hospital ($1.5 million) and St Vincent's Birmingham Hospital ($423,000), both in Birmingham, and Providence Hospital in Mobile ($382,000).

Some 100 hospitals are said to be under investigation.

The settlements follow the government's $2.3 million settlement with 3 Minnesota hospitals in May 2009 for allegedly fraudulent kyphoplasty claims.

In 2008, the government reached a $75 million settlement with Medtronic Spine LLC, which now owns Kyphon, the company that developed the procedure. The company did not admit wrongdoing.

St Francis said in a statement that it cooperated fully with the government. It said the focus of the investigation was on "the lack of documentation to support the treatment in an inpatient setting."

St Vincent's Health System also said it had cooperated in the investigation, admitted no liability, and settled to avoid further litigation costs. It said the investigation focused on documentation, and "there were no concerns about the medical necessity of the kyphoplasty itself for any patients."

St John's Health System issued a similar statement.

Whistleblower lawsuit

The settlements stem from a whistleblower lawsuit filed in 2006 by 2 former Kyphon employees, Craig Patrick, a former reimbursement manager, and Charles M. Bates, a former regional sales manager.

The suit alleged that Kyphon conducted a fraudulent marketing campaign that induced hospitals to bill Medicare for kyphoplasty as an inpatient procedure.

Billings for unnecessary inpatient admissions are considered false claims under the False Claims Act.

Among allegations were that Kyphon representatives met with hospital personnel to explain how to code and bill charges to ensure payment under the DRGs.

Court documents also said sales reps would be present in the OR during kyphoplasty and were taught how to prompt staff and physicians to order inpatient admissions (July 2009 *OR Manager*).

The whistleblowers will receive about $1.4 million as their share of the settlements. ❖

Avoiding inpatient-only claims pitfalls

Understanding how Medicare pays for inpatient and outpatient surgery is critical to your hospital's revenue. Medicare stipulates that certain procedures will be paid only if performed on an inpatient basis. How can you avoid pitfalls of billing for these inpatient-only procedures?

OR Manager asked Keith Siddel, MBA, an expert on health care business operations, to respond to frequent questions. He is CEO of HRM Consulting, Creede, Colorado.

Q What qualifies as an inpatient-only procedure? How should we handle a change from an outpatient to an inpatient procedure that occurs during surgery?

Siddel: To explain the background on this issue, Medicare designates that for safety reasons, particular procedures should be performed only on an inpatient basis. The thinking is that it is not safe to send patients home the same day.

For procedures on the inpatient-only list, Medicare says, "If you don't do this as an inpatient procedure, we won't pay." Not only do you not get paid for the surgery but also for any other services associated with that episode of care, such as the IV line inserted before the patient went to the OR.

The inpatient-only list is updated every year by the Centers for Medicare and Medicaid Services (CMS) as part of the Medicare Outpatient Prospective Payment System (OPPS) rule. This year, the proposed OPPS rule was released early on July 1, 2009. A final rule is expected this fall. The rule is effective for discharges taking place after January 1, 2010. The HCPCS codes paid only as inpatient procedures are found in Addendum E.

In the final rule, CMS will list all of the comments it received and discuss its decisions for updating the inpatient-only list. Once the final rule is published, all of the inpatient-only procedures must be done on an inpatient basis.

Be alert to procedure changes

Most hospitals do a good job of screening for these inpatient-only procedures. For example, the scheduling software usually notes if a patient is scheduled for such a procedure.

If a hospital loses reimbursement for this reason, 90% of the time it is because the physician makes a decision that changes the original procedure. For example, the physician might say, "This looks more complicated than I thought. Let's expand it." That may move the case into an inpatient-only mode.

When that happens, someone in the OR needs to alert the appropriate person and say, "By the way, we not only did the scheduled procedure. We also did B or C procedure." Then someone needs to check the procedure against the inpatient-only list. If the procedure is inpatient only, a manager needs to go to the physician and say, "This is inpatient only. Will you write an order to admit this patient overnight?"

Avoiding denials

The real problem occurs when the change isn't caught. The patient remains an outpatient and goes home the same day rather than being admitted. The record is coded and billed, and the claim is denied. There is really not an appeal process, even if the procedure was done as an emergency.

CMS has declined to authorize an appeal process or to provide a modifier to address an unscheduled inpatient-only procedure. CMS has also said no to a process that would at least pay a hospital for ancillary services associated with an unscheduled inpatient-only case. This is what CMS said in the final 2009 OPPS rule: "We understand hospitals' dilemma when a decision is made intraoperatively to perform an unscheduled procedure. However, we continue to believe it is important for hospitals to educate physicians on Medicare services paid under the outpatient prospective payments system to avoid inadvertently providing services in a hospital setting that would be paid only during an inpatient stay, because we believe that the hospital outpatient department is not an appropriate site of service for these procedures."

Basically, CMS said it is the hospital's problem, and the hospital has to educate the physicians. ❖

The Medicare 2010 OPPS final rule will be posted at www.cms.hhs.gov/center/hospital.asp

Have a question on the OR revenue cycle?

Keith Siddel will respond to questions in a regular column. Send your questions to Pat Patterson, Editor, at ppatterson@ormanager.com. You can also reach Siddel at ksiddel@hrmlc.com.

ASCs weigh impact of Medicare pay

Is it time to stop performing colonoscopies and go full steam ahead with knee surgery? Maybe. According to the proposed Medicare Outpatient Prospective Payment System (OPPS) rule released July 1, 2009, colonoscopy reimbursement rates for ambulatory surgery centers (ASCs) will decline by 5.6% in 2010, compared with an increase of 15% for knee arthroscopy with repair of medial meniscus.

On the other hand, Medicare is proposing to reimburse 2 additional gastrointestinal procedures next year, providing an increase in potential business at some surgery centers.

Expect final rule in November

That is a small example of factors ASCs must weigh as they adjust their strategic planning. It is not all about Medicare payments, of course; the local market, staff specialties and preferences, and demographic projections play a role as well.

For ASCs serving a large elderly patient population, however, it will pay to keep an eye on the trends as the Centers for Medicare and Medicaid Services (CMS) issues its final rule in November. The rule will be effective January 1, 2010.

> **"Trend is toward lower payments."**

"You will need to review payment changes at the procedure level to determine the impact of the proposed changes on your particular ASC," the Ambulatory Surgery Center Association reminds members in its summary of the proposed 2010 rates.

As an example, CMS plans to add 28 procedures to the list of those it will reimburse ASCs for next year. They include surgery to repair the tibia, at $1,775.48; repairing arterial or venous blockage, $1,990.24; and partial thyroid excision, at $1,926.01. For the complete list, visit the ASC Association's website www.ascassociation.org.

'Aligning payments'

On the down side, reimbursement for some of the most common outpatient procedures will decrease. The most dramatic example is injection of anesthesia into the spine to manage back pain (HCPCS code 64476), for which the proposed payment would decrease by 25.6%.

The rule covers both ASCs and hospital outpatient departments (HOPDs) but at different payment levels.

According to CMS, the aim of the 4-year transition period to the new ASC payment system, of which 2010 will be the third year, is to align rates for similar services for both types of outpatient facilities.

However, rates will be aligned at different levels, with ASCs getting a smaller share because of economic advantages ASCs are perceived to enjoy.

A complex system of weights and legislative compromises has resulted in proposed rates that give ASCs on average 57.7% of HOPD payments for similar procedures, plus a hard-won inflation update of 0.6%. HOPDs would receive 2.1% toward inflation under the proposal. Under an earlier version of the rule, ASCs would have received no update for inflation.

According to CMS projections, total Medicare payments to HOPDs in 2010 will be $31.5 billion, while ASCs will receive just $3.4 billion. CMS estimates about 5,000 ASCs participate in Medicare.

An unfair system?

Is the new system unfair? ASCs maintain it is. In a recent presentation, ASC Association President Kathy Bryant asked, "How do we stop the bleeding?" She called on Congress at least to equalize inflation updates for ASCs and HOPDs.

Caryl Serbin, RN, BSN, LHRM, explains that based on a Government Accountability Office (GAO) review, the typical ASC cost for a procedure was 84% of that of an HOPD. Despite that, CMS originally planned to give ASCs 75% of the HOPD rates. In 2008, that was reduced to 65%. In 2009, the rate declined again to 59%, and in 2010, it is due to drop to 57.7%.

"If it costs ASCs 84% of what it costs HOPDs to perform a procedure," Serbin says, "and ASCs get reimbursed 57.7% of what HOPDs get reimbursed, it sounds like the ASCs are losing money."

Serbin is the owner of Serbin Surgery Center Billing, Fort Myers, Florida, a provider of outsourced coding, claims submission, and collections services.

Proposed ASC payment changes for device-intensive procedures

HCPCS code	Name	Proposed 2010 rate	2009 rate	% change
24361	Reconstruct elbow joint	6,079.17	6,085.62	-0.10%
24363	Replace elbow joint	6,145.30	6,221.16	-1.20%
24366	Reconstruct head of radius	6,079.17	6,085.62	-0.10%
25446	Wrist replacement	6,145.30	6,221.16	-1.20%
27446	Revision of knee joint	6,401.02	10,921.17	-41.40%
29881	Knee arthroscopy	1,036.94	901.24	15.10%
33206	Insert cardiac pacemaker	6,939.30	6,938.76	0.00%
33224	Insert pacing lead and connect	12,694.82	8,123.29	56.30%
62361	Implant spine infusion pump	11,849.33	10,941.40	8.30%
64476	Paravertebral injection	158.13	212.55	-25.60%

Source: Centers for Medicare and Medicaid Services.

> **"Pain management and GI are vulnerable."**

The device factor

In one way, the Medicare payment rules recognize that ASCs, like their hospital counterparts, have become increasingly dependent on expensive, high-tech products they must purchase to treat patients, from orthopedic implants to laparoscopic instruments to cardiac catheters.

So while the new ASC payment rate for a service is a fraction of the HOPD rate, when devices represent more than 50% of the cost of a procedure, payments are equal.

The bad news is, once again, most payments are decreasing. A big exception is cardiology, where inserting a pacemaker lead will bring in more than 50% more (chart).

Specific rates could change in the final rule, but the trend represents little change from previous years and is unlikely to vary drastically.

In addition, though CMS plans to increase by 28 the number of procedures it will pay ASCs for, it also proposed to designate 6 other procedures as payable only at the lower rate applied to office-based procedures.

Another indication of the trend toward lower payments is the fact that the highest-volume ASC procedures will be paid less in the future. After-cataract laser surgery will drop by 8.6%; upper GI endoscopy with biopsy will decline by 7%.

Tighter constraints

According to Serbin, overall ASCs are facing tighter economic constraints. This is true, she says,

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ASCs can benchmark quality data

First in a series on quality improvement for ambulatory surgery centers.

Ambulatory surgery centers (ASC) have a new source for benchmarking data. The national ASC Quality Collaboration is now posting quarterly data on 6 quality and safety measures (sidebar). The measures, which are in the public domain, were developed by ASC leaders specifically for surgery centers.

"These are consensus standards developed by the ASC Quality Collaboration and endorsed by the National Quality Forum," explains Donna Slosburg, RN, BSN, LHRM, CASC, the Collaboration's executive director. NQF, a nonprofit organization, endorses consensus health care quality measures. The data are posted at www.ascquality.org.

Depending on the measure, the data represent from 423 to 1,294 surgical facilities and from 433,000 to 1.5 million patient admissions. The latest results include figures from the ASC Association's Outcomes Monitoring Project, with about 600 ASCs enrolled.

The measures with the most data to date are patient falls in the ASC and patient burns. There is less data on the 2 process measures, on-time administration of prophylactic antibiotics and appropriate hair removal.

Quality reporting

Quality measurement is becoming increasingly important to ensure quality as well as to meet regulatory requirements.

The Centers for Medicare and Medicaid Services (CMS) refers to 5 of the ASC Quality Collaboration measures as examples of ones surgery centers can use in its interpretative guidelines for state surveyors. The interpretive guidelines support the revised Medicare Conditions for Coverage (CfCs), which require ASCs to have a quality assessment and performance improvement (QAPI) program. According to the interpretive guidelines, ASCs may choose to use these measures but are also free to use different measures as long as they meet regulatory criteria.

How can ASCs use the data?

ASCs can use the ASC Quality Collaboration's data to compare their own results with other facilities across the country, Slosburg suggests.

For example, for patient burns, an ASC could compare its experience to the national rate. If that ASC's rate of burns is significantly higher, "I would look to see if there were any trends. Then I would see what changes are needed to correct that," she advises.

There are a couple of caveats about using the data.

First, ASCs need to make sure they are "comparing apples to apples" by using the same definitions, Slosburg notes. (The definitions are on the Collaboration's website.)

For instance, the Collaboration defines patient falls as those that occur "within the confines of the ASC." To compare its results, an ASC would need to use the same definition; that is, exclude falls that happen outside the ASC, such as in the parking lot or after the patient goes home.

In a second caveat, 4 of the measures are reported as the rate per 1,000 patient admissions. An "admis-

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ASC quality measures

Measures endorsed by the National Quality Forum.
Data for second quarter of 2009.

	Rate
Patient falls in the ASC	0.183 per 1,000 admissions
Patient burns	0.042 per 1,000 admissions
Hospital transfer/admission	0.997 per 1,000 admissions
Wrong site, side, patient, procedure, implant	0.032 per 1,000 admissions
Prophylactic antibiotic given on time	96%
Appropriate surgical site hair removal	98%

Source: ASC Quality Collaboration. www.ascquality.org

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sion" is defined as a patient who has completed registration to the facility.

ASCs often use a percentage to measure their rates. To compare to the Collaboration data, they would need to divide by 10. For example, taking the patient fall rate of 0.183 per 1,000 admissions and dividing by 10, the rate would be 0.0183 falls per 100 patient admissions, or about 2/100th of 1%.

Many ASCs track their data on a quarterly basis. Now they can use the Collaboration's data for comparison, Slosburg notes.

Medicare's quality reporting plans

Surgery centers have been expecting Medicare to start requiring ASCs to report quality data, as hospitals now do. But CMS proposed not requiring ASC reporting for 2010. Still it would be wise to be ready. Though CMS is postponing reporting for now, the agency says in the proposed 2010 outpatient payment rule, "It is our clear intention to implement quality reporting in the future."

The Collaboration "strongly advocates quality reporting for ASCs," Slosburg says.

In its comment to CMS on the proposed rule, the Collaboration expressed disappointment in the agency's lack of progress and encouraged CMS to move ahead quickly with ASC quality reporting. ❖

The ASC Quality Collaboration data are at www.ascquality.org/qualityreport.html

Medicare pay

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not only because of lower payments but because the cuts are coming at a time when volume is down.

"Like all types of businesses in these economic times, we have already seen ASCs working reduced hours and laying off staff. There have also been reports of ASCs closing completely, doing joint ventures, or converting to HOPDs."

Two specialties Serbin sees as especially vulnerable are pain management and GI procedures.

"In order to be profitable with single-specialty pain management or GI endoscopy centers, the volume must be exceptionally large and the costs well contained," she says.

Medicare still rules

For some surgery centers, it may be tempting to withdraw from Medicare altogether.

But Serbin does not expect that to happen, especially in large multispecialty ASCs, "because some specialties are increasing in reimbursement." Instead, centers are likely to drop lower-paid procedures. One might be pain management, because patients tend to be younger victims of workplace or sports injuries and not covered by Medicare.

On the other hand, Serbin notes, "a lot of private payers require Medicare certification or accreditation, which also may require Medicare certification, in order to participate in their networks."

For facilities specializing in GI endoscopy, there is even greater incentive to remain with Medicare because the majority of their patients are elderly.

A slightly different perspective comes from a study by KNG Health Consulting, published in June 2009 for the ASC Coalition, now part of the ASC Association. KNG found business shifting from hospitals to surgery centers in the past decade due to preferences of both physicians and patients. Ophthalmology, the largest-volume specialty for ASCs, the researchers found, has had the slowest growth since 2000. Meanwhile, the number of colonoscopies increased by 15% per year during that period.

At the same time, they note, the Medicare population has remained relatively stable. Increases in Medicare spending for ASC services were almost entirely due to additional services for current beneficiaries.

While the comment period for the proposed rule has ended, Bryant advises ASCs to continue communicating with their legislators in an effort to soften the impact of future cuts.

Pending legislation

Pending legislation is intended to help. US Representatives Kendrick Meek (D-FL) and Wally Herger (R-CA) have introduced the ASC Access Act of 2009 (HR 2049). One provision would freeze ASC Medicare payments at 50% of the HOPD rate, avoiding the downward trend that would otherwise continue in 2011. The bill was sent to the House Ways and Means Committee. The ASC Association supports the measure, but spokeswoman Kay Tucker says lawmakers are unlikely to take action before the wider issue of health care reform is resolved. ❖

—Paula DeJohn

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At a Glance

Full moon, timing not linked to CABG outcomes

There is no bad time or phase of the moon to have elective coronary bypass graft surgery, finds a new study.

Sleep deficits, body rhythm disturbances, and prolonged duty have been shown to reduce performance of drivers and pilots. Researchers tested whether the same effects might occur with OR personnel who work off-hours and long shifts. The researchers examined the phase of the moon because of the belief that accidents and emergency department visits increase at full moon.

They also looked at the month of July when new residents start working. None of the factors significantly affected outcomes.

—Tan P J, Xu M, Sessler D I, et al. Anesthesiology. *2009;111:785-789.*

DuraPrep associated with lower SSI rate in study

In a study comparing effects of 3 skin preparations on surgical site infection (SSI), an iodophor-based prep solution (DuraPrep, 3M) was associated with a lower infection rate than chlorhexidine-isopropyl alcohol (ChloraPrep, Cardinal Health). No differences were seen between DuraPrep and povidone-iodine (Betadine).

The 18-month study examined 3,209 general surgery operations performed at one academic medical center.

The main findings were somewhat unexpected, said one of the authors Robert G. Sawyer, MD. "Based on data derived from central venous catheter insertions, we had thought the infection rates would be lowest in the period where chlorhexidine was the preferred agent for skin preparation. This was not the case." He added that the findings need to be reproduced in a multicenter study. The study was funded by an unrestricted educational grant from 3M.

—Swenson B R, Hedrick T L, Metzger R, et al. Infect Control Hosp Epidemiol. *2009;30:964-971.*

Companies in race for first percutaneous heart valve

Two companies are in a race to get Food and Drug Administration approval for the first percutaneous aortic valve, according to the September 30 *New York Times.* Leaders are Edwards Lifesciences Corp and Medtronic Inc. Edwards has a head start, recently enrolling the last of 1,000 patients in a major trial. The Edwards valve could be on the US market in 2 years if the study is successful, and the device is approved by the FDA. Medtronic entered the race in April when it purchased CoreValve, a privately owned company. Medtronic hopes to start a trial next summer.

The new valves, available in Europe for 18 months, sell for about $30,000. Presently, the valves are used in patients who are not candidates for conventional surgery.

—nytimes.com

Urologic surgeons call for robotic surgery standards

The Society of Urologic Robotic Surgeons is calling for guidelines and proctoring recommendations for robotic-assisted radical prostatectomy. Currently, there are no standards for evaluating a surgeon's competency with the robot. Recommendations, published in the September *Journal of Urology,* were to be discussed at an international meeting in October. ❖

—Zom K C, Gautam G, Shalhav A L, et al. J Urol. *2009:182:828-829.*