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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

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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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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.*

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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

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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.

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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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Cima R R, Kollengode A, Garnatz J, et al. Incidence and characteristics of potential and actual retained surgical object events in surgical patients. *J Am Coll Surg.* 2008;207:80-87.

Gawande A A, Studdert D M, Orav E J, et al. Risk factors for retained instruments and sponges after surgery. *N Engl J Med.* 2003;348:229-235.

Gibbs V C, Coakley F D, Reines H D. Preventable errors in the operating room: Retained foreign bodies after surgery. *Current Problems Surg.* 2007;44:281-337.

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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.

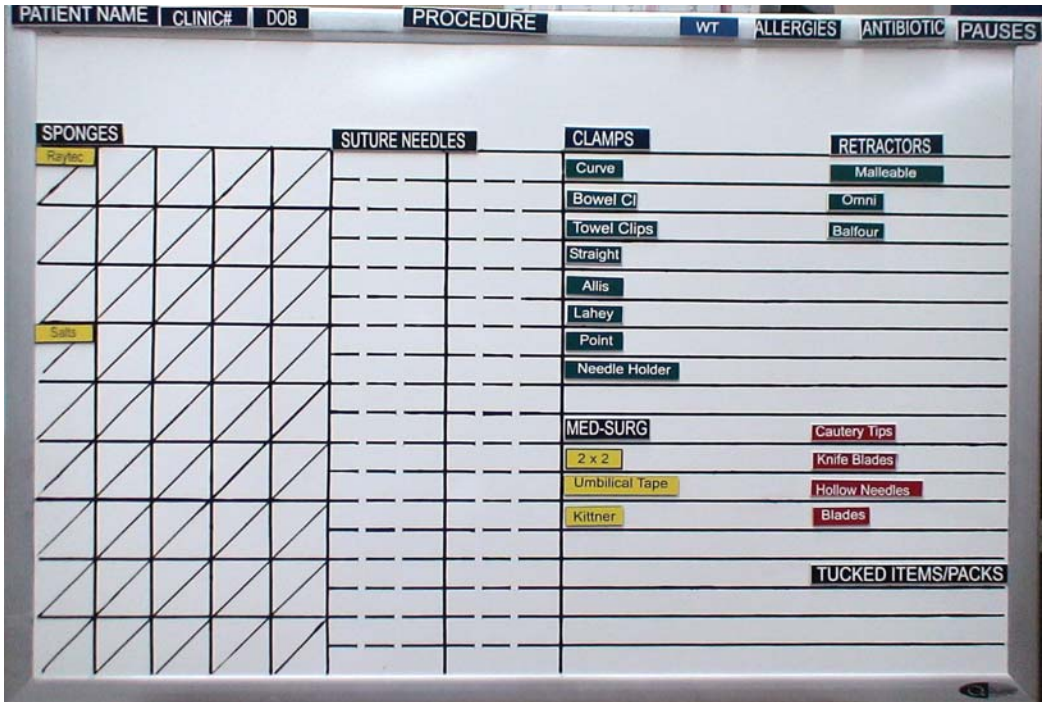
Source: Cima R R, Kollengode A, Storsveen A A, et al. Jt Comm J Qual Patient Saf. *2009;35:123-132.*

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.

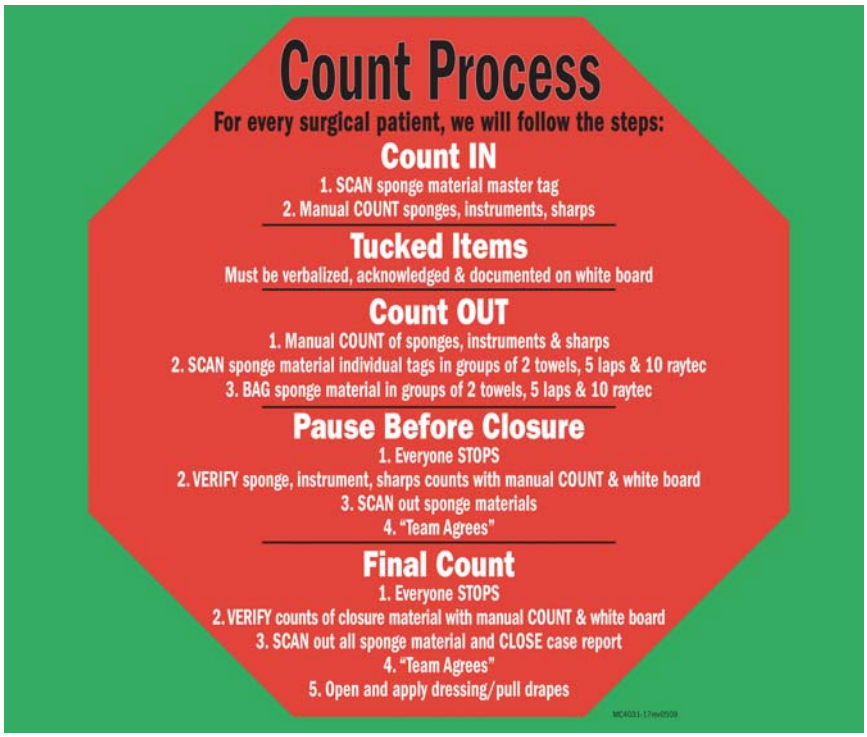
this effort, and had engaged them in trying to improve performance."

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.

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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