

MATERIALS

MANAGEMENT IN HEALTH CARE



Photo by Ken Kauffman

Count on a backup

By John DiConsiglio

QUICK TAKE>>>

About 3,000 times a year, a foreign object is left inside a surgical patient. While hardly an epidemic when compared against the annual number of surgeries in the United States, these situations prove costly in terms of infections, lawsuits and patient outcomes. Technological advancements may hold part of the answer to reducing the risk of retained foreign bodies during surgery, but experts caution that OR teams need to evaluate these systems carefully and take a comprehensive look at their overall practices in this area.

It's the ultimate "oh-no" moment. The OR team is completing its post-op protocols after a long and complex procedure. But a nurse has a sinking feeling in the pit of her stomach—the sponge count is incorrect. Somewhere in the OR—in a waste basket, under a towel or, heaven forbid, in the patient—is the lost surgical sponge.

For OR nurses, a retained sponge is a nightmare scenario, a situation that Marianne Saunders, R.N., at the Hospital of the University of Pennsylvania, calls "terrifying."

"There's no worse feeling than not being able to find a sponge," says Saunders, the hospital's nurse manager for cardio-operative services. "It's devastating. You feel like you let everybody down. You let down the physician, who you

might work with time and again. And, of course, you let down the patient."

Humiliation. Frustration. Panic. The feelings intensify as the surgeon scans the body cavity for the lost sponge. It gets even worse as the X-ray or the portable CT scanner is wheeled in for a detailed search. The surgeon's valuable time is ticking away. The hospital's tight OR schedule is squeezed. And the patient remains in the surgical field, under anesthesia for a longer and possibly more dangerous time than expected.

The retained sponge scenario is infrequent, and many nurses will never experience that hopeless feeling during their careers. But nearly everyone fears it. "It's just terrible," Saunders says. "I've never had it happen to me, knock on wood. But I know several colleagues who've gone through it. Everyone worries about it."

About 3,000 times a year, a foreign object is left inside a surgical patient, estimates research from the federal Agency for Healthcare Research and Quality (AHRQ). The consequences of retained items such as sponges, towels or laparotomy pads are devastating, from infections and perforations to multimillion-dollar lawsuits or even fatal patient outcomes. But to some, the means by which health care professionals protect against retained items seem antiquated. OR staff usually perform manual counts of each item. At the end of the procedure, the staff compare the initial count with the discarded items. If there's a discrepancy, the staff search for the lost items. In some cases, a second operation is needed to recover retained items. Manual sponge counts will likely always play a role in the OR. But clinicians have long wondered if counting alone is a sufficient way to reduce the likelihood of retained items.

Today, health care officials from surgeons and researchers to materials managers and manufacturers are targeting retained items and looking for new ways to prevent them. They've recommended everything from more diligent counting protocols and increased use of X-rays to new products that use radio-frequency technology to find lost sponges.

"Almost all practitioners in the OR are extremely dedicated, hard-working individuals who strive to do their very best," says Caprice C. Greenberg, M.D., from Brigham and Women's Hospital, Boston, and the co-author of a recent study on retained items. "They are, however, faced with a nearly impossible task. ... The majority of items are left behind because of inevitable human error that occurs when you ask someone to keep track of and accurately count so many items. Add to this the other simultaneous tasks that are required during an operation and it is a wonder that it doesn't happen more frequently."

Sponge costs

Experts agree that the statistics, which are based on numbers derived from malpractice claims, aren't reliable. But estimates peg the incidence of retained items at about 1-in-1,000 to 1-in-1,500 intra-abdominal operations.

"It's not a large number, but they certainly have a major impact," says Art Augustine, senior project engineer at the ECRI Institute and the author of a July 2008 study exploring RF-technology items.

Indeed, the consequences can be tragic for a patient, nurse and hospital. Patients are at risk for any number of complications when an item is left behind, from abscesses forming around the sponge to, in rare cases, sepsis. Even a sponge that is misplaced in the OR but not left in the patient poses problems. Any extra time a patient spends on the operating table presents a heightened danger. And, from a monetary standpoint, one tiny retained object can lead to huge costs. OR time is expensive, anywhere from \$150 to as much as \$400 per minute. Each second spent recounting sponges is costly. And the 15 to 30 minutes needed to use an X-ray can rack up exorbitant bills.

An instrument left inside a patient adds an average of four days to a hospital stay and \$36 million a year in added charges, notes the AHRQ survey. The legal costs of retained sponges are just as significant. ECRI estimates the liability for a single incident averages \$52,000 to \$66,000. Worst of all, about 57 people died from these mistakes in 2000.

The financial statistics are likely to get worse with new Centers for Medicare & Medicaid Services policies. As of October, the insurance organization will no longer reimburse for hospital-acquired conditions. That means health care facilities will absorb all costs related to retained surgical items.

“Take all those factors into consideration and it’s clear that this is no small issue for hospitals,” says Curtis Groppe, vice president of sales and marketing for ClearCount Medical Solutions of Pittsburgh, a manufacturer of RF-tagged sponges. “If you do 15,000 procedures a year, statistically that means about two retained sponges. And that doesn’t count near-misses and time spent searching for sponges. All of that obviously adds up.”

About three-quarters of retained sponges occur in cases where the count is thought to be correct, notes a 2008 study. “A lot of this happens despite the best counting efforts. People thought they got it right—that’s the scary part.”

Inside out

Most retained items aren’t the result of carelessness by OR staff, Greenberg insists. Instead, her work suggests other causes for mistakes. The sheer number of tools used in surgeries ranges from 200 to 500. “It is a testament to the hard work and diligence of the OR staff” that more mistakes aren’t made, she says. Other problems include unplanned changes in surgeries that may throw off routines. Obese patients also are at greater risk because their extra girth can make it harder for surgeons to locate lost sponges in the body cavity. More than half of all lost items are left in the abdomen and pelvis.

Greenberg and her colleagues stress that the long-time manual counting protocol, while not foolproof, is still among the most important ways to prevent mistakes. Discrepant counts, where the final count does not agree with the initial count, are 100 times more likely to lead to retained items than correct counts, she says. In most of those cases, surgeons call for X-rays. Sponges, which are twice as likely to be left inside a patient than other items, are tagged with a special strip that can be detected by X-rays. Still the counting protocol shouldn’t be used in all procedures, Greenberg notes. In emergency surgeries or cases requiring an exceptionally large number of sponges, Greenberg says counts should be suspended in place of X-rays, even if no retained items are suspected.

Tech to the rescue?

Greenberg and other health care professionals also are looking at technological advancements to assist clinicians. ClearCount and RF Surgical Systems Inc. of Bellevue, Wash., both market radio frequency items that can be detected in the surgical site. Both products operate on the same principle—each of their sponges, as well as other surgical items such as towels, include penny-sized radio frequency tags. A handheld wand is periodically waved over a patient during procedures. The wand beeps if the system finds a sponge. (Neither company offers radio frequency-tagged surgical instruments.)

The technology, Augustine notes, is far from groundbreaking. It’s the same system used for antitheft devices in retail stores. Hospitals already use radio frequency tags for equipment and in bracelets for newborns. Still, ECRI cautions that the technology hasn’t been fully studied in surgical items. “That’s something hospitals need to consider when going down this path,” Augustine says.

RF Surgical System’s device involves scanning the OR field for sponges. The ClearCount system includes extra features, most notably sponges with unique identification codes that are scanned prior to surgery. After they’ve been used, sponges are dropped into a tableside bucket equipped with antennas. The bucket reader keeps a running tally and matches the number of discarded sponges with the initial count.

ECRI estimates the price of each system at about \$50 to \$60 per procedure. The report noted that ClearCount included an additional \$19,000 for the tag-reading bucket. ClearCount’s Groppe

says that customers who sign a multiyear agreement with the supplier could get the bucket for no added charge. ECRI sees potential in both systems, but cautions hospitals to consider whether the costs—roughly \$50,000 to \$60,000 per 1,000 procedures—is worth the investment.

Augustine says that hospitals shifting to radio frequency systems must be prepared for a complete overhaul. They must throw out old, untagged sponges to prevent mixing products. “This is all or nothing,” he notes.

RF action

Augustine estimates that about 40 hospitals have some form of RF system in their ORs. At University of Pennsylvania, Saunders has used RF Surgical's sponges for 13 months and hasn't had a single retained object. “It's going well,” she says. “We've had some near misses, but the RF system detected the sponges. If someone mistakenly throws one in the trash, it could have taken forever to search for it. But now we can find it right away.”

But the systems come with cautions. From manufacturers to users to researchers, everyone agrees that radio frequency technology should not replace manual counts or become an excuse for sloppy counts.

“These should be thought of as technological adjuncts and used in conjunction with the standard counting protocol, not in place of it,” Greenberg says.

Although the technology is fairly simple, it does have limitations. It can be difficult to locate tags within larger or bariatric patients. And there is some potential for user error. An inexperienced user can hold the wand too far from a patient, scan an insufficiently wide area or perform the scan too early, leading to possible lost sponges after scanning occurs.

Scanning can be done by nurses, but Saunders recommends leaving that task to the surgeons. “The physician is there throughout the whole case. He knows what areas were explored and all the little nuances,” she notes. “That's not the nurse's or the surgical tech's responsibility.” But whomever uses the wand must be trained in the proper techniques. Saunders insists that user training begin early and include the entire staff.

The University of Pennsylvania tabs expertly trained nurses as “floaters” who observe OR techniques. At first, Saunders says, doctors worried that the process might slow the OR workflow. “It took a few months but now everyone loves it, even the doctors who initially balked at it,” she says. Likewise, the technology has hit its share of snags. At first, Saunders says sponges didn't work properly in cardiac cases with balloon pump leads. The leads set off false sponge alarms. But Saunders says RF Surgical immediately sent an engineer to fix the problem. “We haven't had any trouble since,” she says.

ECRI's Augustine stresses that while the RF products appear to have significant promise, the use of the technology in surgical situations is new.

“You have to assume that there are going to be bumps [in the road],” he notes. “The overall technology is sound. But hospitals need to think long and hard before they decide if this is the right move for them.”

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