



Schwartz Communications



A PIAA PUBLICATION FOR THE MEDICAL PROFESSIONAL LIABILITY INSURANCE INDUSTRY • 2011 SECOND QUARTER

physicianinsurer

Toolkit

April 2011

BY JEFFREY PORT, MD

Retained Surgical Items



Retained surgical items (RSI), such as sponges, towels, or gauze, are not typically given a second thought—that is, until one is inadvertently left inside a patient after surgery. According to the American Hospital Association, America’s hospitals perform nearly 30 million surgeries and deliver 4 million babies each year. Perhaps the most alarming statistic, according to recent surgical literature, is that an estimated 1,500 to 2,000 RSI cases occur each year in the United States. In fact, there is growing evidence that these estimates are conservative and that the

actual number of incidents involving retained surgical items may be even greater. RSIs are classified among the growing list of “Never Events” for which the Centers for Medicare and Medicaid Services (CMS) and private insurers will no longer provide reimbursement.

Despite strict counting protocols, surgical sponges are unintentionally left inside patients after wound closure. These types of preventable

events are a potential source of morbidity for patients and a liability for care providers and institutions.

The complications with surgical items left behind are significant—post-procedure infection, pain, bowel perforation, abscess, follow-up surgery, and in some instances death. Patients may also have expenses from additional follow-up visits or medication. In addition to patient safety and care issues, incidents of RSI can also result in re-operative expenses, legal issues, and compromised reputation for providers.

RSI incidents also negatively impact operating room (OR) efficiency, and staff may spend an inordinate amount of time rectifying miscounts if not all surgical items are accounted for. When this happens, nurses may need to be pulled in from other areas in the OR to assist.

Cases with retained surgical items can be often linked to high-risk emergency and trau-

ma situations that lead to unexpected findings and strict time pressure on OR staff, resulting in “no-time-to-count procedures.” However, no type of surgery is “immune” to the risk of a retained surgical item, which can also occur in laparoscopic surgeries, elective cases, and even in procedures performed in ambulatory settings, among others.

One study published in 2008 by the *Journal of the American College of Surgeons*, noted that 62% of retained surgical items were detected after the surgical count was reported as correct. Other surgical literature suggests that up to 88% of cases with retained surgical items are associated with falsely reported correct counts.

In August 2010 the Association of periOperative Registered Nurses (AORN) made public the results of a comprehensive Healthcare Failure Mode and Effect Analysis (HFMEA) titled: “Limitations of the Surgical Count.” The HFMEA found that the top five causes for potential failures involving surgical counts are: distraction, multitasking, not following procedures, time pressure, and emergency cases. These causes account for 91% of all causes yielding to surgical count failures. The presenter, Victoria M. Steelman, PhD, RN, concludes: “Counting is not enough to prevent retained sponges 100% of

One study noted that 62% of retained surgical items were detected after the surgical count was reported as correct.

Jeffrey Port, MD, is an Associate Professor of Cardiothoracic Surgery and an Associate Attending Surgeon within the Division of Thoracic Surgery at New York Presbyterian-Weill Cornell Medical Center. He is also the co-founder of RF Surgical.

the time, and peri-operative nurses should evaluate technology for assistance.” AORN’s recently revised *Recommended Practices for Prevention of Retained Surgical Items* also includes a new recommendation that peri-operative nurses evaluate technology to assist with the surgical count.

The rise of adjunctive technology

Bellevue, Washington-based RF Surgical Systems is looking to eradicate the problem of retained surgical items with a state-of-the-art detection system designed to alert operating room staff automatically if a foreign object is left behind. The company recently released the latest version of its technology platform—the RF Assure Detection System—which features an automatic detection mat that allows for “hands-free” patient scanning. The system safely and accurately reads through deep cavity tissue, fluids, and bone to detect if any radio frequency tagged surgical sponges, gauze, or towels remain in a patient following surgery. With the push of a button, the system can perform a complete scan in 15 seconds, mitigating the risk of a retained sponge, even during emergency situations. Additionally, the system has a dual-detection mode with a wand that is used to perform a quick scan to rectify sponge counts and is useful for extended coverage needs in cardiac, trauma, and bariatric cases.

Besides radio-frequency detection, there are other technologies available on the market to prevent RSI. Radio-frequency identification (RFID) systems utilize a large wand to both detect and count surgical mate-

rials, though users have reported that the wand can be cumbersome, and the system has “blind spots” or areas where accurate detection is difficult to guarantee. Additionally, these systems use high-frequency platforms known to be more susceptible to decreased performance in harsh environments such as fluids and metals and can be costly to implement.

Barcode counting uses uniquely tagged items, which are scanned manually, requiring perfect alignment with the reader. Though the barcode counting system features reporting/performance capabilities and is very portable, this technology is not a detection system and is not capable of locating missing surgical items to rectify a miscount or addressing the risk of a retained surgical item which may still occur when the count is accurate. Additionally, this method can be time-consuming to use, because OR staff must manually scan each item to account for it, often making it an inadequate option in trauma or “no-time-to-count” situations. Barcode scanning also requires the staff to handle soiled sponges, which increases risk for exposure to biohazards.

Sponge counting bags offer hospital staff an easy-to-use, low-cost way to visually account for surgical materials. However, this technology offers no way to locate any missing materials and is subject to human errors, again, due to the manual nature of this method.

Finally, x-rays may be used in cases where a retained item is suspected, though this method does not guarantee detection, and this also involves more time and additional expenses.

Clinical data

Interim results from the largest prospective multi-center study on the effectiveness of radio-frequency detection technology to improve surgical counts and staff wound closure confidence were presented at the American College of Surgeons Clinical Congress meeting in October 2010. Results indicated that the system allows for the early detection of missing items, reducing the number of unnecessary x-rays and associated anesthesia time, demonstrating that the technology is easy to operate and is a valuable check and balance to enhance patient safety in surgery.

Additionally, according to a published study in the *American Journal of Surgery*, the sensitivity and specificity of RF sponge technology are

much higher than published reports of surgical counts or published findings of intra-operative radiographs for retained sponges. The sensitivity and specificity of detection of the RF sponges through the torsos of subjects of varying body habitus were 100%.

The incident of a retained surgical item is an error that is highly preventable. As attention to error and patient safety grows, both with patients/consumers, regulatory bodies and hospitals, healthcare providers will continue to invest in and innovate solutions that mitigate human error. Such technology can improve not only care and patient safety, but also efficiency and workflow in the OR, saving time and cost on a daily, ongoing basis. ✦ PIAA