A surgeon discusses why retained surgical items occur, and what needs to be done to prevent this problem.

by Amanda Hankel

or the past 10 to 12 years, Verna Gibbs, MD, a general surgeon at San Francisco Veterans Affairs Medical Center and professor of clinical surgery at the University of California-San Francisco, has been pondering the issue of retained surgical items (RSI). Why is it such a persistent problem? And, what do we do to fix it? To answer those questions, Dr. Gibbs began researched-based, investigational work to dig deeper into how to prevent these events. In October 2005, she started NoThing Left Behind®, a national surgical patient safety project to prevent RSIs.

According to the project's website, www.nothingleftbehind.org: "A surgical item is considered to be retained if an item not intended to remain is found to be in any part of the patient's body after the patient has been taken from the operating or procedure room." An estimated 1,500 to 2,000 RSI cases occur each year in the U.S., although reporting systems indicate there is a wide spectrum of occurrence. The most frequent retained surgical item is the cotton gauze surgical sponge, with most reports referring to the 4" x 4" radiopaque textile (raytex) or the 18" x 18" laparotomy pad. Along with sponges, the project classifies instru-

ments, needles and miscellaneous small items as the other forms of surgical items that could be retained.

Gibbs explains NoThing Left Behind® works to design ways to help hospitals - and surgeons, nurses and radiologists - "get this right." It has developed practices, including its own manual sponge management system called Sponge ACCOUNTing, and provides other practice and technological recommendations to help hospitals achieve zero retained items.

"My goal was, by 2010, to have gathered evidence, have 10 hospitals join the project and by the end of that year, get to zero retained sponges [in those facilities]," Dr. Gibbs says.

By 2010, the project didn't have 10 participating hospitals — it had hundreds, including a few large hospital systems with as many as 40 hospitals. It's important to note that the initiative is unfunded, so participant hospitals are private sector facilities looking to improve their processes. Despite tremendous growth and overwhelming participation, the project is still working toward its goal of zero.

"At the end of 2010, 97 percent of the hospitals had no retained sponges," Dr. Gibbs says. "That number translates to one hospital had one 'event.' So, we are waiting to get to zero because our goal was zero."

is apparent in the difference in thinking between a surgeon and a nurse when an RSI event happens.

"It's a lot of finger pointing at each other and not a lot of really productive investigation," Dr. Gibbs says. "The surgeons think it's the nurses' fault because they 'can't count,' and the nurses think it's the surgeons' fault because they don't listen to them.

"When an event occurs in a hospital, the hospital will do a root cause analysis, or a focused review of the event," Dr. Gibbs adds. "The problem is, they get these superficial roots and do not really understand the way to solve a problem."

Dr. Gibbs provides this example. Say a hospital experiences a retained surgical sponge case. They

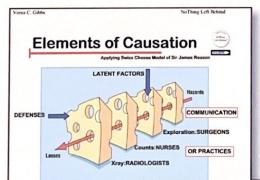
conduct an analysis of the event and diagnose the problem as two-fold: there were distractions in the OR, causing a mistake in the sponge count, and the surgeon did not communicate to the nurses where he/she put the sponge, so

the nurses couldn't account for it.

From that analysis, the hospital develops a new policy stating that there will no longer be distractions in the OR and anytime a surgeon puts anything in the patient, they must tell the nurses and the nurses will write it on the room's white board.

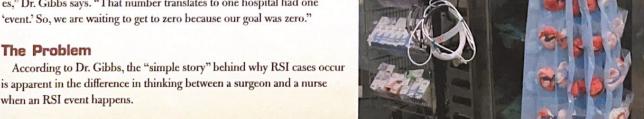
"Now, the nurses must manage all the items they normally count, all the information they

Dr. Gibbs says RSI events are related to unreliable item management practices and communication issues among OR staff.





Verna C. Gibbs MD, Director, NoThing Left **Behind®**



normally write on the white board, plus they're going to write down every time a sponge is put in the patient and they're going to try to eliminate any distractions," Dr. Gibbs says. "That is set up for failure."

Instead, Dr. Gibbs says a deeper root is to say, the nurses were distracted while they were doing their counts, so that must mean there is a problem with the practice of counting.

"If it was a reliable and durable practice, an interruption would not dismantle it," Dr. Gibbs says. "An analogy is pilots flying planes. If the steward-

ess knocks on the door of the cabin, that is a distraction, but the pilot is not completely unable to fly the plane."

Therefore, a key problem contributing to RSI cases is an unreliable management practice.

"The steps that go into the counting practice are highly variable between each hospital and each OR," Dr. Gibbs says. "Hospitals have never standardized the practice."

The second issue contributing to RSI cases is communication problems between staff members in the OR about their role in preventing these events,

Dr. Gibbs says. The nurses are responsible for a reliable management practice. Meanwhile, the surgeons must do a methodical wound exam to confirm nothing unintended is left in the patient.

"The surgeon's first job is to get all the items out of the patient so that the nurses can count and then tell the surgeon whether or not there is something missing," she says. "Traditionally, surgeons do a sweep or a swish and say they're ready to close, but just doing that, they're not engaged in the practice. The surgeon must do a methodical wound exam to determine what they intended to remain. For example, those staples we put in, we intended those to stay there, but we didn't intend for the stapler head to be left there."

The Solution

According to Dr. Gibbs, the key to preventing RSI events is to improve the practice of item management, or change it completely. The key to improving a practice is decreasing the number of steps in the practice to simplify the process and/or increasing the reliability of any individual step. It's on these points that NoThing Left Behind®'s manual Sponge ACCOUNTing practice was developed.

"It's reliable because it fulfills many of the criteria for reliability — it's simple, it's straightforward, it's transparent," Dr. Gibbs says. "It decreases the number of steps and improves individual steps."

The basics of Sponge ACCOUNTing include:

A structured, standardized use for sponge holders. "These sponge holders are often called counters or counter-bags," Dr. Gibbs says, "but we call them holders because they're not counting the sponges and they're not bags, they're individual pockets that you can put the sponges in and it holds them so they can be easily seen."

The plastic sponge holders have 10 pockets, so all the sponges are

managed in units of 10. "This is a major step of simplification, because right now, some sponge types are managed in units of five, others are managed in 10," Dr. Gibbs explains.

Separate sponges during count-in. The important part of counting-in sponges at the beginning of a case is not the counting, it's to make sure that the sponges are separated, Dr. Gibbs says. There are manufacturing errors in the packaging of the sponges, and sometimes, the packages won't have 10 sponges in them, but they have 11 or nine or packs of lap pads

may have four or six instead of five.

"The goal is to start with 10 or multiples of 10," Dr. Gibbs says. "This simplifies the process by making it only multiples of 10 and increases the reliability of at least one step by separating the sponges."

One sponge is placed in each pocket of a holder. As sponges are taken out of the patient, they are put into kick buckets. Then, throughout the cast, they are moved to the holders. Even if not all sponges in a group of 10 are used, at the end of the case, the used and unused sponges still must be placed in the hold-

ers. As sponges are taken out of the patient, they're placed in the holder.

Before closing, the surgeon must perform the methodical wound



The Sponge ACCOUNTing practice works to increase the reliability of manual sponge management in the OR.



Practice Changers For Sponge Management

Gauze products account for approximately 80 percent of all RSI cases, says Jeffrey Port, MD, a cardiothoracic surgeon at New York Presbyterian, associate professor of cardiothoracic surgery at Weill Cornell Medical College and co-founder of RF Surgical, Inc. Dr. Port says in his experience, the problem of RSIs usually presented itself in two ways.

First is a miscount of surgical sponges that often "wreaks havoc" in the OR. "On a daily basis, there was always this mini-crisis of making sure at the end of the procedure that counts are correct," he says of his experience in the OR. If a team has an incorrect count, nurses dig through garbage bins full of blood-soaked sponges to rectify the count, or x-rays are taken of the patient, lengthening the procedure considerably.

The second instance is a 'false negative' in which the OR staff believe the count was correct, when in actuality, it is not. These instances result in an RSI event.

The problems related to the manual counting of surgical sponges have sparked the development of technologies designed to prevent retained surgical sponges. As Dr. Gibbs explains, these technologies are 'practice changers,' forcing all staff to learn sponge management in a standardized, reliable way. On its website, the NoThing Left Behind® project provides recommendations for technology to help change the practice of sponge counting and serve as an adjunct to manual counting. Recommendations include:



Radio-frequency detection technology. The RF Assure Detection System (RF Surgical) consists of gauze products with a tiny radiofrequency tag embedded in the sponge. The first rendition of the system involved a wand that was waved over the patient, and an audible and visual signal alerts the team if a gauze product was still left inside. In its most current form, the technology has been transferred to a gel pad placed underneath the patient. Surgical staff members press a button and the patient

is scanned on the surgical table before leaving the table to ensure nothing is left behind. This adds "another safety layer," Dr. Port says, atop of a manual sponge counting practice to ensure nothing is left behind.

Radio-frequency identification (RFID) technology. The SmartSponge System (ClearCount Medical Solutions) is an RFID platform that both verifies sponge counts and detects sponges if they remain in the patient. Each sponge contains a unique RFID identification chip. The packages

of sponges are scanned in. After use, sponges are placed in a bucket, which contains a detection and counting system to count sponges that have been removed from the patient. A readout takes place on the visible screen showing the number of sponges counted in, the number counted out and any difference. A wand is also available to be used in the event of

hospitals an evidence-based outcome.



a missing sponge or can function independently as a counting and detection device.

Computer-assisted sponge counting. The Safety-Sponge System (Surgicount Medical) is comprised of: (1) a full-line of surgical sponges, each one affixed with a unique data matrix code (Safety-Sponges®), (2) a handheld mobile computer/scanner and (3) a backend data management software application (Citadel™).

According to the company, when used together, the components of the Safety-Sponge® System enable a more accurate intra-operative count by helping eliminate the human error associated with most retained sponge events, false "correct" counts. Additionally, the solution provides a complete post-operative documentation solution, giving

exam. The surgeon must examine all parts of the wound, specifically looking for surgical items, before asking for closing suture.

At the final count, all of the sponges must be in the holders, and the staff must see that every pocket is full. "If you start with 10 sponges or multiples of 10, at the end of the case at the final count, you must have one holder full of sponges for each group of 10," Dr. Gibbs says. Now, instead of "counting" the sponges, the nurses are looking at the holders to make sure there are no empty pockets. Seeing zero empty pockets means a correct sponge count.

A hospital can also change the practice of managing sponges itself using new technology as 'practice changers,' Dr. Gibbs says. For example, sponge counting and detection technology is now available as an adjunct to manual counting by adding counting and detection capability on top of manual counting to ensure a more reliable method for sponge management.

The Future: Getting To Zero

In the future, Dr. Gibbs is confident the issue of retained surgical sponges will be solved, or become very infrequent, but more attention must

be drawn to other forms of RSIs. Miscellaneous small items and device fragments are the second-most common RSI, which she refers to as the 'surgical junkyard.' Dr. Gibbs says this problem can't be fixed as easily with technology, like sponge accounting has been, so other practice improvements and changes must be implemented.

In the end, prevention of RSI events comes down to solving the two problems identified earlier as the root of the problem — creating reliable practices and improving communication.

"What I would like to see is all the stakeholders — surgeons, nurses, radiologists, all the team members — to work together," Dr. Gibbs says. "We need safer, more reliable practices in place, and people need to work together while they're in the OR to make sure there is NoThing left behind."

For more information about the NoThing Left Behind® project, visit www.nothingleftbehind.org

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