Doctor Helps Develop Surgical Tracking Technology

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KALISPELL, Mont. (AP) — Dr. William Stewart, a Kalispell urologist, recalls the moment inspiration struck for a life-saving technology now used at Kalispell Regional Medical Center and more than 70 other hospitals.

In the early 1990s in California, he was dealing with a scare over a missing surgical sponge during one of his procedures. It eventually proved to be just an inaccurate count, not a sponge left in a patient.

"I was in a grocery store three days later and it was bothering me," he said. "I realized watching the bar-code technology that the grocery store had much better inventory control than the operating room."

From that germ of an idea, he began working with his investment banker son Brian on developing and securing patents for what became the SurgiCount Safety-Sponge System — a cost-effective method of scanning coded sponges in and out of a patient with equipment and software that tracks and accounts for each sponge.

"What's better about this system: It takes the human aspect out of it," he said. "You know what's counted in and you know what's counted out."

Stewart said it sounds simple to keep track of sponges, but the scope of retained sponges in surgery nationwide proves otherwise.

"Every day in this country 11 sponges are unintentionally left in patients during surgery," he said. "This is after a correct count was thought to have been made." To explain how this happens, Stewart quotes Dr. Robert Cima of the Department of Surgery of the Mayo Clinic, who spent years analyzing problems such as retained sponges in surgery.

"He has said that inaccurate sponge counts occur because we are asking operating staff to exceed the 'human performance barrier,'" Stewart said. "OR people are just asked to do too much."

Cima found doctors, nurses and technicians do a great job but they work in the stressful, chaotic and demanding environment of the operating room. According to Stewart, mistakes often happen on smaller procedures when the staff isn't as intensely focused as during major, stressful operations.

Compounding the problem, he said, is that a sponge saturated with blood in the body cavity looks a lot like other tissue.

"It isn't easy to pick out," he said.

According to Stewart, the sponges left after surgery may cause significant harm to the patient, developing into intestinal obstructions, intra-abdominal abscess, peritonitis and other problems.

"It's a serious complication," he said. "People have died from it."

The math of 11 retained sponges daily adds up to 4,000 patients at risk every year in the United States. Stewart said the general public has little awareness of this danger, yet it's one of the most common surgical errors.

"Even surgeons have no idea the incidence is this high," he said. "When you say 11 a day, they say, 'You've got to be kidding me.'"

Mistakes such as retained sponges have drawn even more attention since 2008 when these statistics became available. In that year, government programs such as Medicare began refusing to pay for procedures or corrective actions for a list of medical errors that should never occur-called "never events."

Retained sponges made the list of surgery-related never events.

Patient safety always served as Stewart's prime motivation since the day of his inspiration in the grocery store.

A resident of the Flathead Valley since 1994, he was still practicing full time while working on the sponge problem. Now semi-retired, Stewart works on call every third weekend at Kalispell Regional and occasionally assists urologists Dr. John Andenaro and Dr. Amy McKerrow on large surgeries.

"I enjoy doing that," he said. "I like staying in touch with it."

With the SurgiCount Safety-Sponge System in use at the medical center, he and the other surgeons now close surgical openings with confidence.

Last July, Velinda Stevens, chief executive officer of the hospital, reviewed the sponge retention figures, the low cost of the system and ease of implementation. By October, Kalispell Regional Medical Center became the first and only hospital in Montana to have the system in place.

"I'm proud of the hospital here — they really are on the forefront of patient safety," Stewart said.

Others institutions with the system include the Cleveland Clinic; University of California San Francisco Medical Center; Brigham and Women's Hospital, Boston; the University of Michigan Hospitals and Health Centers, Ann Arbor; and the Mayo Clinic.

SurgiCount Safety-Sponge System received a major boost in February when the

Journal on Quality and Patient Safety featured the system on its cover. The article reports on the Mayo Clinic's trial using the scanning system.

The article quotes Cima from Mayo reporting no sponges retained after using 1,862,373 in all surgeries over 18 months using the data-matrix-coded system. Stewart makes clear that the Mayo Clinic has not endorsed the system but continues to use it.

"Before, they had a retained sponge on average every 64 days," Stewart said, noting their huge surgical volume as a factor in the number.

This article in the national journal provided a major professional landmark in a long, expensive and arduous journey for the product.

Stewart's son Brian, a business whiz, put together the company and took it public when Stewart exhausted his own financing ability developing the technology and obtaining patents.

"My son has taken back management of the company but it's still publicly traded," he said.

The two tapped a number of experts to help them overcome obstacles, sort through technology and test their system. Dr. Atul Gawande, a cancer surgeon in the forefront of patient safety as well as a Harvard professor, conducted a randomized trial for them.

"Our study found it was readily adopted, was cost-effective and markedly improved detection of sponges that had been misplaced or miscounted in the operating room," Gawande wrote.

Gawande practices at Brigham and Women's Hospital and writes for prestigious publications such as The New Yorker.

Other experts helped overcome obstacles such as finding nontoxic inks and a fail-safe method of attaching the data-matrix code. Heat pressing provided the solution to permanently attaching the code with a unique identifier to preclude double counting.

They chose for their system a high-end scanner with a battery life of about four and half hours and an over-powered beam to read and record the data-matrix code.

"You need less than one-quarter left showing for the scanner to read it," he said. Stewart calls the system, distributed by Cardinal Health, simple and inexpensive with the sponges costing less than $15 a case. At this time, the company provides the scanners at no cost.

Brian, president of Patient Safety Technology, and Stewart, an educator and consultant to the firm, continue to look at other surgery safety issues. Stewart said he feels proud to have played a role in overcoming one hazard.

"At the end of the day, you can with confidence say you don't have to have 11 retained sponges in patients today," he said. "This is going to save lives."

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