

System marks new method of preventing wrong-site surgery

By Leigh Page

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Operating rooms can move toward eradicating wrong-site surgery under a universal protocol by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), Oakbrook Terrace, Ill., that requires OR personnel to mark the surgical site with a pen in advance.

But the new protocol, which took effect in July 2004, won't help if personnel forget to carry out the marking task. Now that problem is being addressed with a new reminder device, the CheckSite Medical System. It sends a wireless signal from the patient's ID wristband to an alarm when the surgical site is not marked.

CheckSite Medical, Eureka, Mo., put the product on the market in mid-September. While the company says that in late November half a dozen hospitals were on the verge of ordering the system, only one facility was using it at that point—the outpatient surgery center for 962-bed Barnes-Jewish Hospital, St. Louis.

The center, which has 15 ORs, has a promising eight-month track record with CheckSite, the company reports. It was first installed for beta-testing in March and has been used in all surgeries since mid-September. Several times, the company says, the alarm has stopped patients from being wheeled in for surgery before being marked.

A marked need

Some 4,000 wrong-site surgeries take place in the United States each year, which is a rate of one in 17,000 surgeries, and such mistakes are the third most frequent life-threatening medical error, according to a press release from the Washington University School of Medicine, St. Louis.

"When you do surgery, it's easy to get confused," says CheckSite's inventor, Richard A. Chole, M.D., chairman of otolaryngology at the medical school. In ear surgery, for example, "one ear looks like the other," he says. "So you need to write 'yes' on the ear lobe or next to the mastoid."

Chole has long believed that with a systematic approach, all wrong-site surgeries could be eradicated. The need for a reminder system for marking became clear to him in 2004, when he conducted a survey of all types of surgery and identified several that involved the wrong site. He found that every one of these wrong-site surgeries involved failure to mark the site.

"What was needed," Chole says, "was a fail-safe marking system so that every patient going into the OR was marked."

The solution came to him while waiting in the checkout line at his local Home Depot, viewing an event so mundane it usually goes unnoticed. The clerk swiped his purchase over a plate to deactivate a signal that would have set off an antitheft alarm. It occurred to Chole that the technology to stop a thief could also stop OR staff from taking an unmarked patient into surgery. He then explained his idea to engineers at Washington University and they built a prototype, which involved using a different signal technology and adjusting the signal so that it did not interfere with other wireless systems in the hospital.

Band together

The CheckSite system involves purchasing a supply of the company's specially designed disposable marker pens and wristbands as well as two permanent CheckSite alarms.

The marker pen comes with a peel-off label. Once site marking is completed, the label is affixed to a patient's wristband, blocking a signal that is emitted by a tiny chip in the wristband. A wristband lacking the label will activate one of the alarms, which makes a gentle sound or gives a visual cue. Two alarms are needed because a typical hospital corridor is 7-feet wide

and the chip's signal has a 4-foot range, the company says.

CheckSite reports that each wristband-and-marker set costs \$3.85—about \$2.50 more than what hospitals usually pay for a standard wristband and marker; and the pair of alarms costs \$7,000 to \$8,000. Installing the alarms, which takes two to four hours, is part of the price.

Chole says the extra cost of the CheckSite system is worthwhile, considering the price of liability litigation from wrong-site surgery. The American Association of Orthopedic Surgeons, Rosemont, Ill., reports that 84 percent of legal actions alleging wrong-site orthopedic surgery result in payments to a patient. And a survey of insurance claims at 22 malpractice carriers from 1985 to 1995 by the Physician Insurers Association of America, Rockville, Md., found that 331 cases and almost 1,000 closed claims involved wrong-site surgery.

Denise Murphy, R.N., the chief patient safety and quality officer at Barnes-Jewish Hospital, says she is impressed with the improved patient safety. "This system means we don't have to depend on the memory of staff members."

She adds, "It's a way to get the attention of the whole team," which is one goal of the JCAHO's universal protocol.

One key advantage of CheckSite, Murphy adds, is that it makes verification of site-marking more efficient. Without the wristband, "we need health care workers to take an extra step and write down what they have done," she says. The simpler the process, Murphy says, the greater the likelihood that it will be carried out. "Having to document in writing is one of the biggest reasons for noncompliance in health care," she explains.

Quick adoption

Chole reports that some surgeons at the Barnes-Jewish outpatient center were initially wary, but then they quickly adopted the new system. "At first they saw it as just one more thing to do," he says, "but once they got used to it, they saw it was easy." Several OR nurses liked it immediately, and two of them are scheduled to present CheckSite at upcoming meetings for perioperative nurses.

The company has set up relationships with medical device distributors nationwide and CheckSite reps have been making presentations on the system at institutions around the country.

Chole reports that officials at Barnes-Jewish have not yet given the go-ahead for using CheckSite in the hospital's inpatient ORs, but they are close to doing so, and approval also is expected soon at hospitals in Atlanta, Chicago and suburban New York.

"It's a fairly complicated decision-making process for a hospital," Chole says. Approval usually requires sign-offs by many parties, such as perioperative nursing, OR nursing, surgeons, patient safety officers, the medical director and even registration because it is responsible for the patient wristbands, he says.

Looking beyond site marking, both Chole and Murphy believe the wristband-alarm combination could eventually serve as a reminder for other functions as well. The system could be used to confirm the preoperative checklist, including consent forms, blood tests, anesthesia clearance and discharge medications. "I'm sure this technology could be expanded to other tasks," Murphy agrees. "There is a lot of information that we get from patients and have to document."

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Right site alarm system

Purpose: alerts staff when a surgical site has not been marked.

How it works: after site-marking, a label is affixed to patient's wristband. Wristbands without a label activates an alarm.

Price: \$2.50 for disposable wristband with wireless chip; \$1.35 for disposable marker with label; \$7,000–\$8,000 for two permanent alarms, including installation.

Maker: CheckSite Medical, Eureka, Mo.