Wrong-site surgery

By Lola Butcher

Hospitals have proven how to end this tragic problem. Now it's time to make it happen

Sometimes the problems that you expect to be the easiest to fix turn out to be the most vexing. Since the Joint Commission first highlighted the problem of wrong-site surgery in 1998, the issue has been the subject of summits, protocols, checklists and process-improvement projects across the country.

And yet, surgeries on the wrong side of the body, the wrong site or even the wrong patient continue to occur an estimated 40 times every week, according to Joint Commission President Mark Chassin. "Awareness about the problem has increased, but we clearly have to do more to get a lot closer to zero," he said at a Joint Commission Center for Transforming Healthcare event earlier this year.

Several initiatives showed the problem is not intractable. Eight hospitals and ambulatory surgery centers participating in the pilot phase of a CTH project significantly reduced the risk of a wrong-site surgery.

Earlier this year, the Minnesota Safe Surgery Coalition started a campaign to eliminate wrong-site procedures in that state within three years — and early results look promising.

"Before this campaign, we were having a wrong-site procedure about every 12 or 13 days, and since we kicked off the campaign, the average over the last six months has been about every 30
days or so," says Diane Rydrych, assistant director of the health policy division at the Minnesota Department of Health.

Two Pennsylvania Patient Safety Authority initiatives also have proven successful, says John Clarke, M.D., its clinical director.

In the first, 30 hospitals and ambulatory surgery centers were able to reduce wrong-site surgeries from an average of 15 a year to 4 a year. In another program, 20 facilities in the UPMC system avoided wrong-site surgeries altogether for more than a year.

But Clarke says many hospitals have yet to make wrong-site surgeries a priority. "When you subtract out the 50 facilities that have been in those collaborations, we don't see any change at all in the remaining facilities," Clarke says. "We do think we have made a difference, but it's only when hospitals actually make a commitment to change their systems."

The Challenges

Wrong-site procedures differ from most other patient-safety challenges in two ways.

Unlike pressure ulcers or health care-acquired infections, the term "never event" really can be applied to wrong-site surgery. "We are never going to eliminate every bed sore, but wrong-site procedures feel like something that we can eliminate," Rydrych says.

Because incidents are relatively rare and many hospitals never experience them, the issue may not get as much attention as safety problems that can be measured more easily.

When they do occur, wrong-site procedures are devastating for patients and can become public relations nightmares, damaging the trust that patients have in their hospitals, says Nancy Foster, vice president of quality and patient safety policy at the American Hospital Association.

The AHA is a key supporter of the Center for Transforming Healthcare, a Joint Commission affiliate that made wrong-site surgery the focus of its third major project. In the initial phase of the project, eight hospitals and outpatient surgery centers studied the processes involved in preparing for and performing a surgery.

In doing so, they documented why wrong-site surgery is such a complex problem to solve. Miscommunication at the time a procedure is scheduled, for example, can lead to a cataclysmic mistake in the operating room.

Many errors are caught before they reach a patient and cause harm. However, unless an organization systematically studies its processes and systems for weaknesses in its ability to stop errors from reaching patients, it is leaving a lot to chance, says Anne Marie Benedicto, the center's vice president of operations and chief of staff for the Joint Commission. "You don't know what you don't know," she says.
Ironically, the practices that reduce the possibility of wrong-site surgery seem so obvious that the issue may not get the attention it warrants, says Bill Berry, M.D., program director for the Safe Surgery 2015 initiative at the Harvard School of Public Health.

That project seeks to have the World Health Organization's Surgical Safety Checklist used in every hospital in the United States by 2015. The checklist includes such items as "surgical procedure to be performed matches the consent" and "the site has been marked."

"Everything on there makes sense, and the standard reaction that I get from lay people is, 'What do you mean, you don't do this already?'" says Berry, a former cardiac surgeon. "And the reality is, no, those kinds of things don't always happen."

AnMed Health Women's and Children's Hospital, a 72-bed facility in Anderson, S.C., participated in the initial nine-month phase of the Center for Transforming Healthcare's wrong-site surgery project, which finished in June. The project team collected and analyzed data about the processes used in four areas: surgery scheduling, surgery assessment center, preoperative holding area and the operating room.

AnMed had never had a wrong-site surgery, so team leader Martha Rush and her colleagues were not sure what they were looking for. They were surprised by what they found: Surgeries scheduled by phone without a written audit trail, illegible information sent by fax, patient consents that did not match the scheduled procedure, consents missing on the day of surgery, inconsistency in the site-marking process and poorly executed OR time-outs.

"We found that we had a lot of opportunities for improvement — that's the way I'm going to put it," Rush says.

One of the most significant improvements has come from implementing the previously unused scheduling module for AnMed's electronic medical record system. Errors in the scheduling office decreased from about 15 per day to fewer than one per day.

"The trickle-down effect that we have seen from this electronic scheduling, the improvements in the assessment center and the pre-op area on the day of surgery have been tremendous," says Martha Stratton, director of surgical services. "It is all from getting that information on the front end as accurate as possible."

The project team created a manual for each surgeon's office when they found that the surgeons' staff did not always understand what information they needed to provide to patients. "We gave them all the information that they need to schedule their cases, we explain who is eligible for phone assessments versus face-to-face assessments, and list the patient education that we need the office to do before the patient gets to the assessment center," Rush says.

To reduce communication problems, the surgery scheduling office was relocated adjacent to the surgery assessment center, and physician office staff were limited to a single fax number to communicate with the hospital's surgery scheduling staff.
Lifespan Corp., owner of a four-hospital system in Rhode Island, initiated the Center for Transforming Healthcare's wrong-site surgery project in 2009 after its flagship Rhode Island Hospital had four incidents in two years.

"We felt that by bringing them in to work with us, we could start to make it public in the health care community that wrong-site surgeries happen much more frequently than expected," said Mary Reich Cooper, M.D., Lifespan's senior vice president and chief quality officer. "We became their learning laboratory."

Two Lifespan hospitals served as the development site for using the Center's Robust Process Improvement, or RPI, in the operating room. RPI applies Lean Six Sigma and change management techniques to quality and safety improvement initiatives.

The following year, the project was expanded to include AnMed and the other pilot facilities. Among other improvements, the hospitals and ambulatory surgery centers decreased defective cases — those at risk for wrong-site surgery because of a preventable error — in the pre-op/holding areas from 52 to 19 percent.

Using the knowledge learned from the pilot, CTH has developed a set of solutions that hospitals can use to help reduce the risk of wrong-site procedures. Information is available at www.centerfortransforminghealthcare.org.

**Safe Surgery 2015**

The Joint Commission already requires accredited hospitals and surgery facilities to use a universal protocol that covers preoperative verification, marking of the surgical site and taking a time-out by all members of the surgical team immediately before the procedure begins. The extent to which the protocol is followed varies widely.

Safe Surgery 2015, which, along with an emphasis on preventing wrong-site errors, aims to reduce surgical infections, major complications and death through the use of surgical safety checklists.

The first statewide push for the program is in South Carolina, where the goal is to have a customized version of the checklist used in every operating room in the state's 67 acute care hospitals by 2013.

Support from the South Carolina Hospital Association is essential to the project's success, Berry says, because hospital administrators can mandate institutional change.

"I recently heard an NFL coach say, 'Just because it's simple doesn't mean it's easy,'" he says. "That's where the CEOs and the CFOs come in on this. Not every surgeon believes in this, and some of them need encouragement. We need help in the operating rooms to make doing this a priority."
Minnesota Time-out

In Minnesota, the state health department in 2008 contracted with the University of Minnesota's Center for Design in Health to observe procedures — from pre-op through the end of the procedure, including the surgical time-out — in eight hospitals across the state. The examiners did not like what they found.

"Time-outs were not consistent; they were chaotic. Sometimes the circulating nurse was standing in the corner and yelling and trying to get people's attention," Rydrych says. "There was at least one time-out where the surgeon wasn't even in the room when it was done."

State officials determined that a more detailed, prescriptive approach was needed to address the problem. The solution: the Minnesota Time-out Process.

The goal, Rydrych says, is for this protocol to become the community standard. "We can't force people to do it, but we set it up so that it is the expectation that you will do a time-out process for every invasive procedure every time," she says.

In the Minnesota Time-out, the surgeon is responsible for initiating the time-out. "The team is more likely to listen to the surgeon than they are to anyone else on the team," Rydrych says. "At the point the surgeon calls for it, all activity ceases — no music, no moving around. Everyone stops."

During the time-out, each member of the team has a specific role. For example, the scrub actually looks for the site mark and says something like, "I'm set up for a right total hip replacement, and I see the site mark on the right hip," so no one can disengage from the process.

The goal of the Minnesota Safe Surgery Coalition, which includes the state hospital and medical associations, the health department and other key players, is to eliminate wrong-site procedures within three years. Since the campaign began earlier this year, more than 100 facilities have signed agreements to do the time-out, Minnesota style. "They have committed they're going to do not just a time-out, but this time-out for every invasive procedure," Rydrych says.

Who's in Charge?

Lifespan's Cooper says preventing wrong-site procedures is not capital-intensive, but it is labor-intensive. "The resources that we put into this were human capital resources — staff support and support from the physicians. It was meetings and observations and everybody had a role in it in order to make this better," she says. "Having leadership stand behind that and make people available to fix the problem are essential."

Clarke says hospital leaders must insist on uniform compliance with evidence-based protocols, even if surgeons balk. He cites a hospital CEO in his state. "At one point when he was trying to implement best practices, a surgeon said, 'I don't want to do it that way,'" Clarke recalls. "The CEO said, 'Look, you can do it however you want, but if you want to do it in my hospital, you're going to have to do it this way.'"
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Why It Happens

The Joint Commission Center for Transforming Healthcare collaborated with eight hospitals, health networks and surgery centers that perform more than 130,000 procedures annually to determine why wrong-site surgery continues to occur. Here are the common root causes identified by the project:

**Operating Room**

- Lack of intraoperative site verification when multiple procedures are performed by the same provider
- Ineffective handoff communication or briefing process
- Primary documentation not used to verify patient, procedure, site and side
- Site mark(s) removed during prep or covered by surgical draping
- Time-out process occurs before all staff are ready or before prep and drape occur
- Time-out performed without full participation
- Time-outs do not occur when there are multiple procedures performed by multiple providers in a single operative care

**Organizational Culture**

- Senior leadership is not actively engaged
- Inconsistent organizational focus on patient safety
- Staff are passive or not empowered to speak up
- Policy changes made with inadequate or inconsistent staff education
- Marketplace competition and pressure to increase surgical volume leads to shortcuts and variation in practice

**Source:** Joint Commission Center for Transforming Healthcare, 2011

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