How ORs conduct time-outs varies widely—and facilities tend not to follow their own policies. These findings are part of a statewide project in Pennsylvania to learn how wrong-site surgery happens and how to prevent it. As part of the project, researchers observed one or more steps of 48 procedures at 6 hospitals and 1 ambulatory surgery facility in the state. They also analyzed more than 400 wrong-site reports made to Pennsylvania’s mandatory reporting system. Facilities in that state must report all health care errors, whether or not they resulted in harm to patients.

John Clarke, MD, FACS, who heads the wrong-site surgery project as clinical director for the Pennsylvania Patient Safety Reporting System, discussed the findings with OR Manager.

“We viewed a variety of steps in the process of preparing a patient for the operating room,” he says, adding that it is noteworthy that facilities were willing to let them observe. “It shows a lot of trust and interest on their part in trying to help solve the problem.” Four of the facilities had more than 1 case of wrong surgery but were known to be committed to patient safety, while 2 had no wrong-surgery reports during the reporting period but had reported other problems in the OR.

The findings are described in the December 2007 Patient Safety Advisory from the Pennsylvania Patient Safety Authority. The researchers also reported on their analysis in the September 2007 Annals of Surgery.

Dr Clarke says the errors fall into 2 main categories—misinformation and misperception (sidebar).

No single step is enough

A key point: No single step will prevent wrong surgery. Surgical site verification must be a package of activities that involves the team—the nurse, patient, surgeon, and anesthesia provider—as well as an accurate OR schedule, consent, and review of patient information.

Two overall observations about the Universal Protocol:

• There were many different interpretations of the protocol.
• Facilities tended not to follow their own protocols.

“In almost half of our observations, people did not follow what they said were their own rules,” Dr Clarke says.

Some specific findings:

Preoperative verification

Facilities differ in how they interpret what is an acceptable preoperative verification.

“Some take it very seriously, and everyone who touches the chart has to reconcile all the documents,” Dr Clarke says. “In other cases, it’s a one-time reconciliation by one person.”

In some facilities, all sources of information, including the schedule, the consent, the history and physical (H&P), and the patient’s understanding, must match before the patient is taken to the OR. If they do not match, the surgeon must get involved. In other facilities, a nurse can proceed if 2 pieces of information agree.

Marking the site

The mark on the site serves as the patient’s voice after the patient is sedated or anes-
thetized, Dr Clarke notes. To illustrate, in one report, the patient was awake in the OR and provided useful information: “While the nurse was prepping the left leg, the patient asked if both legs would be shaved. The nurse stopped shaving and reviewed the consent and saw that the right leg was the correct leg.”

**How the site is marked**

There was fair consistency in how the site was marked. Nurses who did the marking typically marked with a “yes” over the site and made no other marks. “We thought that was good technique,” he says. When physicians marked, they usually marked with their initials. Some preferred to mark as close to the incision as possible so the mark would be visible after draping. Others marked in an area that would not involve the incision, presumably because of concern about contamination from the mark.

**When the site is marked**

“We think marking the site while the patient is still awake is the proper way to go,” Dr Clarke says. Patients are the ones who are the most likely to catch an error in the preoperative phase, they learned.

**Who should mark the site?**

Dr Clarke and his team did not come to a conclusion. “This is an open scientific question,” he says.

When nurses marked the site, they “were more compulsive about verifying all of the information before they marked the site. They tended not to make information errors because of the verification process.”

On the other hand, physicians were more accurate in marking so the site would not be hidden by the drapes.

“But doctors were not as compulsive about making sure all of the information lined up,” he says. “We observed people who marked the site without checking any documentation and, in some instances, without even talking to the patient at the time they were marking the site.”

If the preoperative nurse marks the site, the marking should be confirmed by the surgeon, the researchers say.

Though some think the patient should mark the site, Dr Clarke says he does not think that is a good idea because patients are occasionally misinformed and do not know the facility’s protocol for site marking.

If there were concerns that having the surgeon mark the site would cause delays, the most common solution was for the surgeon to visit the first 2 patients before the first operation, then visit the third patient after the first operation, and so forth.

**Conducting the time out**

Time-outs were carried out in a variety of ways and were often done “rather poorly,” he says.

Some facilities did a time-out before an anesthetic block, but others did not. Based on a number of reports of an incorrect block, the researchers suggest there should probably be 2 time-outs when there is an anesthetic block, one before the block and another when the entire team, including the surgeon, is together in the OR.

It’s also a good idea to do a time-out after a patient is reoriented, say from supine to prone, to make sure the entire team understands the correct orientation.

**Who should lead the time-out?**

Who should lead the time-out is an open question. Most commonly, they observed that “the nurse recited something, and the surgeon responded passively,” Dr Clarke says. The nurse might or might not verify documents during the time-out.

In some cases, the surgeon led the time-out. How effective this was depended on whether the surgeon had access to electronic information to use in verification.

What do the researchers suggest?

- Someone, whether nurse or physician, verifies all of the information during the time-out.
• The surgeon gives an active response. For example, the time-out leader says: “What are we doing? Who are we doing it on? What side are we doing?” The respondent would say: “We are doing a total knee replacement. The patient is Mrs Jones. We are doing it on the right side.”
Dr Clarke adds: “My guess is that a situation in which the nurse led the timeout but the doctor had to give an active response would probably be effective. But that is an open question.”

The patient’s role
Patients serve as an important double check against errors—though they aren’t always right. Some tips:
• When verifying information with the patient, ask questions that require an active rather than a passive response, such as: “Before we put you to sleep, which ear are we operating on?” rather than, “Before we put you to sleep, we’re doing your left ear, right?”
• When there are inconsistencies, the surgeon must resolve them because the patient is not correct 100% of the time.
• One facility took the proactive approach of educating patients that they would be asked repeatedly about their name, procedure, and correct site.

Near-misses versus wrong surgery
What keeps a near-miss from becoming a wrong surgery? Based on in-depth analysis of 16 near-misses and 6 actual wrong-site events, the observers noted:
• In all near-miss reports, a checklist was used to document the verification and reconciliation process, while in 1 in 4 actual wrong-site surgery events a checklist was used. A checklist may be valuable in detecting inconsistencies in documents before they lead to wrong-site surgery.
• In all near-miss events, the surgeon responded to a specific concern voiced by a member of the OR team about a possible near-miss event, but this happened in only 1 in 4 actual events. Reluctance to express or acknowledge concerns can contribute to a situation becoming a wrong-site event instead of a near miss.
“Clearly, a surgeon who is going to blow off the nurse is likely to get into trouble,” Dr Clarke says. “If you pay attention to another’s concerns, even if it is not necessarily a valid concern, you are going to pick up errors.”
In the Annals of Surgery report, some factors that resulted in “saves” included:
• correct information from patients and families
• surgeon involvement in reconciliation and verification of information in the preop holding area
• verification against proper consents, the patient’s medical record, or surgeons’ office records
• nurses performing verification and reconciliation in the preop holding area.

Lessons so far
The researchers say opportunities for wrong-site surgery are most likely to be minimized when:
• For elective surgery, reconciliation of all the important information, such as the OR schedule, consent, H&P, and definitive diagnostic studies can occur before the day of surgery.
• All members of the OR team assume a personal responsibility to have firsthand knowledge that the correct patient is getting the correct procedure at the correct location.
• The mark on the operative site is the patient’s voice, continuing to speak after sedation or induction of anesthesia.
• Though the time-out is commonly seen as the opportunity to make sure the correct procedure is being done, it is not—it is the final opportunity of many that began when the surgery was scheduled.
Many steps can lead down the path of wrong-site surgery. Preventing wrong-site surgery may require attention at every step of the process, not just the 3 steps of the Universal Protocol.
Two major types of errors

Wrong surgery usually results from 2 major types of errors:

Misinformation
Misinformation is the main source of errors that start before the patient reaches the OR. This includes failure to identify incorrect information in documents such as the schedule, consent, and history and physical (H&P). “One of the essential elements of being accurate was to make sure all the documents lined up all the time,” says John Clarke, MD, of the Pennsylvania Patient Safety Authority.

Misperception
There is a tendency to interpret new information in a way that confirms preconceptions, despite physical facts.

In one such event, a patient was admitted for left knee surgery. The patient was properly identified, and the site was properly marked. But in the OR, the physician elevated the right leg, and the nurse prepped and draped it. During the time out, no one recognized that the wrong leg had been prepared. The procedure was performed on the wrong leg.

Misperceptions can also arise when patients are repositioned, say, from supine to prone.

“We’ve seen instances where a femoral and sciatic block was performed. When they flipped the patient over, they didn’t move to the other side of the table,” Dr Clarke says.

Misperception was more common than misinformation by a ratio of 2:1 in their analysis.

Actual time-outs

Examples observed in Pennsylvania:

After the nurses completed the time-out, no one acknowledged it. Between 30 and 60 seconds later, the attending surgeon asked, “Are we going to do a time-out?” The nurse said, “We did the time-out. We already did it.” The surgeon then started the operation.

The circulating nurse started the time-out, saying “time-out.” The surgeon turned to the scrub tech and said, “I need a 10 [scalpel with a no. 10 blade].” The circulating nurse said, “We are doing [name of procedure] on [patient’s name].” The surgeon was already making the incision.

Source: Pennsylvania Patient Safety Authority.

How safe is your facility?

Take stock of your program for preventing wrong-site surgery with a 23-point checklist developed by the Pennsylvania Patient Safety Authority.

The checklist is available at www.psa.state.pa.us/psa/site. Look under Advisories and Related Resources.