Wrong-site surgery is unacceptable. It is also rare, and serious injury from these events is even rarer, a new study finds. A large hospital could expect 1 of these events every 5 to 10 years.

At least one-third of incidents analyzed by the researchers would not have been prevented with current site verification protocols, according to the report in the April Archives of Surgery.

The study also examined hospital protocols and found they require, on average, 12 separate checks per patient.

“Many of the protocols involve considerable complexity without clear added benefit,” say the authors led by Mary R. Kwaan, MD, MPH, of Brigham and Women’s Hospital, Boston.

The study examined 2.8 million operations at institutions covered by one large malpractice insurer. A total of 40 wrong-site operations were identified, an incidence of 1 in 112,994 procedures, roughly equivalent to 1 every 5 to 10 years at a large hospital. Of these, 1 caused permanent, significant harm, and 2 resulted in temporary major harm.

In contrast, retained foreign bodies are 10 times more likely (1 in 8,801 to 1 in 18,760 inpatient operations), and severe injuries are more likely, the authors say.

Cases not prevented

Of the 40 wrong-site operations, 25 did not involve the spine. Of these 25, 12 involved multiple structures or lesions, 1 was on a wrong patient, and 2 happened during emergencies.

Examining medical records for 13 of the nonspine cases, the researchers determined that the Joint Commission on Accreditation of Healthcare Organizations’s Universal Protocol for preventing wrong surgery probably would not have prevented 5 of the 13 (38%). The Universal Protocol requires a preoperative verification process, marking of the operative site, and a time-out before the procedure begins.

Examples of cases the authors think the Universal Protocol would not have prevented:

- An MRI of the knee was printed at a referring hospital for the incorrect patient with the same name as the correct patient.
- The surgeon decided to change the side of the operation in the holding area for a patient who had bilateral disease. The surgeon obtained the informed consent after the patient had sedation, and the patient did not recall consenting to the procedure.
- Two cases involved multiple lesions (lipoma and epidermal inclusion cyst). On the day of surgery, both the patient and surgeon were uncertain about the lesion to be excised.

Protocols vary widely

The authors analyzed 16 site-verification protocols from 25 hospitals and found wide variation. On average, the protocols required 12 separate checks per patient and involved 2 to 4 personnel.

“The point of our analysis was to see how hospitals interpret the Universal Protocol and what level of detail is applied,” Dr Kwaan told OR Manager in an interview. “The question is how you design a patient safety protocol when there is no evidence base to follow. How do you balance smoothness of the process with the safety risk?”

The researchers consulted the safety literature and a human factors expert. They
learned that if a protocol has too many redundant checks, there is the risk, for example, that some personnel may skip steps, seeing them as “busywork.”

Their advice: “Keep it simple. It’s not necessary to involve 4 personnel,” says Dr Kwaan. “We also emphasize that there has to be a clear system to address what to do about inconsistent information. A simple screen and a way to deal with inconsistencies might be the way to catch the clear dangers” of a wrong surgery.

The researchers’ own experience at Brigham & Women’s, though not studied, is that the time-out is the “most easily enforced and implemented step in site verification,” Dr Kwaan says. “Everyone is together. The consensus here is that the time-out has high yield [for preventing errors] and is easy to implement.”

**Suggestions for protocols**

In the article, the authors suggest a protocol with the following elements:

1. **Site marking.** At a minimum, the surgeon or surgeon’s designee marks the site with initials or “yes.” The researchers don’t define “designee,” but Dr Kwaan says it is implied that it is a person who works with the surgeon. In a teaching hospital, the resident is acceptable; in a community hospital, it could be the physician assistant.

2. **Preoperative verification process.** A verification of patient identity, procedure site, side, and vertebral level should be performed by 2 staff members, 1 of whom is the surgeon. Both should compare the OR schedule and informed consent document. A time-out before the procedure should provide final confirmation.

3. **Process to resolve inconsistencies.** Any inconsistencies or uncertainties about the site should be resolved by the surgeon and confirmed by the patient and at least 1 of the inspecting caregivers. The protocol should address how inconsistencies are to be resolved.

4. **Informed consent.** The consent must specify laterality if the site is bilateral. If there are multiple structures or lesions, the consent form must attempt to localize them. The procedure should be booked with the same detail.

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**Reference**