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Wrong Site Surgery

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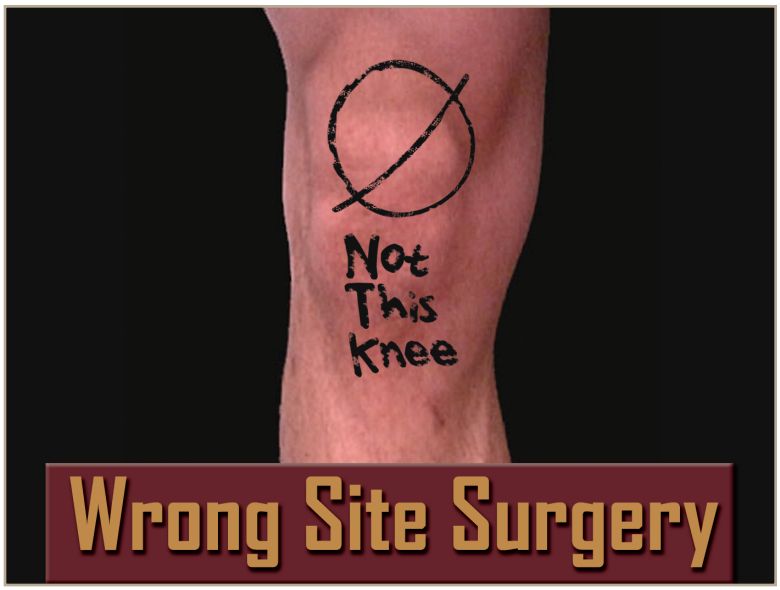


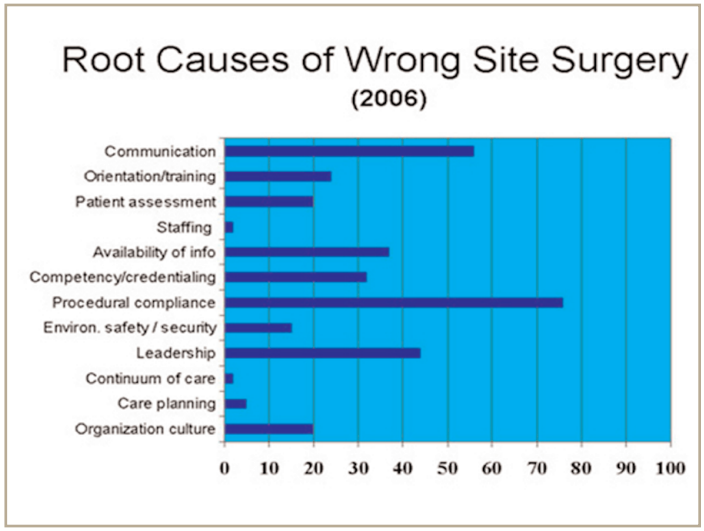
Despite years of patient-safety efforts, an increasing number of healthcare facilities have reported mistakenly removing the wrong limbs or organs, slicing into the wrong side of bodies and performing surgery on the wrong patients. The Joint Commission, in its September 7, 2007 publication of the Sentinel Event Statistics, indicates that wrong site surgery remains the highest reported event. Last year, healthcare facilities reported 94 operations to the commission that involved the wrong body part or the wrong patient. While some states, including New Jersey, require hospitals to report such slip-ups, many hospitals across the nation are not obligated to account for them publicly. Since the introduction of the Joint Commission's Sentinel Event Policy, the Joint Commission has reviewed numerous cases related to surgery and have identified several factors that may contribute to the increased risk of wrong site surgery. These risk factors include:

- more than one surgeon involved in the case, either because more than one surgery is contemplated or the care of the patient required more than one surgeon
- unusual time pressures, related to an unusual start time because of emergent situations or pressure to speed up the pre-operative procedure
- incorrect site preparation by the staff and incorrect interpretation of X-rays
- unusual patient characteristics such as physical deformity or morbid obesity that might alter the usual process for equipment set-up or positioning of the patient

The root causes identified most often are related to the following major themes:

- incomplete or inaccurate communication among members of the surgical team
- inadequate pre-operative assessment of the patient and the procedure or lack of procedure to verify the correct surgical site
- the failure to engage the patient or family member in the procedure of identifying the correct surgery

The following graph published by the Joint Commission shows further breakdown.



Furthermore, the Joint Commission's evaluation of 126 root cause analyses (RCAs) revealed the following specialties were the most commonly involved in the reported wrong site surgeries:

- Orthopedic/podiatric (41%)
- General Surgery (20%)

continued on page 2

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- Neurosurgery (14%)
- Urology (11%)
- Maxillofacial, cardiovascular, otorhinolaryngology, and ophthalmology (14%)

In New Jersey, the New Jersey Healthcare Quality Assessment and Patient Safety Initiative Summary Report does not break down the specialties involved in wrong site surgery; however, the report published in December 2007 indicates the following incidence of surgery-related events in the last two years:

Year	Wrong Body Part	Wrong Patient	Wrong Procedure
2005	10%	3%	3%
2006	20%	2%	4%

The study by Kwaan, Studert, et. al. of 2.8 million operations over a 20-year period, published in *Archives of Surgery*, suggests that the rate of "wrong site" surgery anywhere other than the spine is one in every 112,994 operations. According to the authors, the study excluded the spine because surgical sites on the spine are verified with x-rays. The study, which was funded by the Federal Agency for Health Care Research and Quality, concludes that the rate is "exceedingly rare" but "unacceptable."

The incidence of wrong site surgery has captured national attention, and current patient safety experts say more vigilance is needed. It is clear that the Joint Commission considers this of grave concern – it has convened two summits, one in May 2003 and a second one in February 2007.

After the first summit, the Universal Protocol for preventing wrong site surgery, wrong procedure and wrong person surgery was adapted. It gained wide support from numerous professional organizations such as the American College of Surgeons, the Agency for Healthcare Research and Quality, the American Academy of Orthopedic Surgeons and others who support the initiatives in patient safety. This protocol emphasizes three minimum requirements, namely: pre-operative site verification, marking and time-out.

Preoperative or Pre-procedure Verification
The preoperative or pre-procedural verification process starts at the time the surgery or invasive procedure is scheduled. The Operating Room (OR) schedule must include the exact site, digit, level laterality (including "left" or "right" and "bilateral") without using any abbreviations except in designating spinal levels such as C-Cervical, L-lumbar, S-sacral and T-thoracic - e.g. L-4-5.

Best practice models suggest that the staff responsible for accepting requests to schedule procedures must verify the information provided by the surgeon/physician either by read-back, fax or email as agreed upon by both institution and physician.

At the time of surgery, verification of the correct person, procedure site and side is carried out with the participation of the patient who is awake and aware, if possible. Any inconsistencies or discrepancies/uncertainties about proper site or procedure should be resolved by the surgeon with confirmation agreement by the patient and at least one of the inspecting caregivers. Protocols should explicitly address the manner in which inconsistencies are resolved.

The same procedure of verification is applicable in all clinical settings where invasive procedures are performed, including but not limited to endoscopy, cardiac catheterization and radiology interventional suites, emergency departments, and intensive care units.

Marking the Operative/Procedure Site
The intended site is marked so that the mark is visible after the patient is prepped and draped. The physician either marks the spot for surgery with his/her initials or the word "YES" - never with an "X". The mark must be made using an FDA-approved marker that is sufficiently permanent to remain visible after completion of the skin prep.

The Joint Commission also encourages patients to insist on such a mark. To support this requirement, the Joint Commission published a speak-up brochure for the patients, with tips on how they can help to prevent wrong site surgery.

If a smaller mark is necessary as in the pediatric ophthalmology cases, a dot near the eye may constitute the site marking. Some hospitals have adopted a special purpose wristband as an option.

Time Out
As doctors are required to mark the site, nurses are supposed to call a "time out," A "time out" provides the opportunity to call everyone's attention to a final safety check in an effort to ensure that the right procedure is performed on the right patient.

The New York State Surgical Invasive Protocol published in 2006 suggests that "time out" must be conducted in the location where the procedure will be done, after the patient is prepped and draped. This applies to all invasive procedures performed in all settings and must involve the entire operative/procedure team.

"Time out" using active communication techniques should include the following:

1. Identification of the patient using two identifiers
2. Identification of the correct site and laterality if applicable
3. Procedure to be performed and proper positioning of the patient
4. Availability of special equipment or implants
5. Radiological review, when applicable to the case and confirmation that the images displayed belong to the patient in the correct orientation

Other Protocols:

A vast array of intervention tools exist, and common strategies are evident in these protocols. What is evident in most of these protocols is the use of a standardized checklist to document information related to the site verification and the "time out" process. Monitoring compliance is another common element.

In conclusion, the incidence of wrong-site surgery must be viewed not as the failure of one individual but the failing of a complex system. Dr. Charles Chodroff, senior vice president of WellSpan Health, advises disciplinary action will not prevent systems errors but that "studying the psychology of errors will more effectively identify factors that can improve performance and detect systems breakdowns before they occur; and therefore improve safety."

Below is a list of organizations that have developed resources in doing the "right things to correct wrong site surgery."❖

Resources

1. Joint Commission: www.jcaho.org - Sentinel Event Alert
2. Institute of Healthcare Improvement – through Collaboratives, www.ihi.org
3. American Academy of Orthopedic Surgeons
4. Association of periOperative Registered Nurses: www.aorn.org (for the AORN toolkit)
5. New York State Department of Health: http://www.health.state.ny.us/nysdoh/commish/2001/preop.htm
6. Agency for Healthcare Research and Quality: http://www.ahrq.gov/consumer/20tips.htm
7. The Institute for Clinical Systems Improvement
8. Veterans Administration, Department of Veterans Affairs: “Seven Absolutes to Avoid Surgical Site Errors”
9. National Patient Safety Agency (UK)
10. NASS - National Association of Spinal Surgery, SmaX Campaign (Sign, Mark and X-ray)❖

Questions and/or suggestions are welcome. Call the Healthcare Risk Services Department at 1-866-RX4-RISK