PAPER

Incidence, Patterns, and Prevention of Wrong-Site Surgery

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Hypothesis: We hypothesized that wrong-site surgery is infrequent and that a substantial proportion of such incidents are not preventable by current site-verification protocols.

Design: Case series and survey of site-verification protocols.

Setting: Hospitals and a malpractice liability insurer.

Patients and Other Participants: All wrong-site surgery cases reported to a large malpractice insurer between 1985 and 2004.

Main Outcome Measures: Incidence, characteristics, and causes of wrong-site surgery and characteristics of site-verification protocols.

Results: Among 2 826 367 operations at insured institutions during the study period, 25 nonspine wrong-site operations were identified, producing an incidence of 1 in 112 994 operations (95% confidence interval, 1 in 76 336 to 1 in 174 825). Medical records were available for review in 13 cases. Among reviewed claims, patient injury was permanent-significant in 1, temporary-major in 2, and temporary-minor or temporary-insignificant in 10. Under optimal conditions, the Joint Commission on Accreditation of Healthcare Organizations Universal Protocol might have prevented 8 (62%) of 13 cases. Hospital protocol design varied significantly. The protocols mandated 2 to 4 personnel to perform 12 separate operative-site checks on average (range, 5-20). Five protocols required site marking in cases that involved nonmidline organs or structures; 6 required it in all cases.

Conclusions: Wrong-site surgery is unacceptable but exceedingly rare, and major injury from wrong-site surgery is even rarer. Current site-verification protocols could have prevented only two thirds of the examined cases. Many protocols involve considerable complexity without clear added benefit.

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Cases of wrong-site surgery have captured national attention and prompted mounting efforts to prevent these mishaps.[1-3] The term *wrong-site surgery* typically encompasses surgery on the wrong person, the wrong organ or limb, or the wrong vertebral level. Although the problem appears to be rare, the incidence of these errors has been difficult to measure and study. In a 1999 mail survey of hand surgeons, 21% reported performing wrong-site surgery at least once during their career, with wrong-finger surgery accounting for 63% of the 242 incidents reported. The estimated incidence of wrong-site surgery was 1 in 27 686 hand procedures.[4] An analysis of data from 22 medical malpractice insurers, representing 110 000 physicians, identified 331 claims for wrong-site surgery throughout 10 years. These claims comprised 1.8% of orthopedic surgical claims.[5] The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) also performed a root cause analysis of 126 cases reported to them.[6] Surgery on the wrong patient occurred in 13% of cases, using the wrong procedure in 11%, and on the wrong body part or site in 76%. Possible risk factors identified included emergency operations, unusual time pressures to start or complete the procedure, and involvement of multiple surgeons or multiple procedures in a single surgical visit.

In 2003, the JCAHO convened a national summit to review the problem. Based on the summit's recommendations, it promulgated the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery.[7] The Universal Protocol emphasizes 3 minimum requirements: preoperative verification, site marking, and a "time out" in the operating room. The Association for Operating Room Nurses has distributed guidelines for adherence to the JCAHO protocol. As of July 2004, all accredited hospitals are required to implement it. However, how the protocol has been implemented in practice and how effective the protocol will be in preventing patient harm remain un-

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	Preadmitting Office/Pretest Nurse	Preoperative Nurse	Anesthesia	Circulating Nurse	Surgeon
Informed Consent					
History and Physical Examination					
OR Booking Form					
OR Schedule	NA				
Patient Verbal					
Site Marking or Visualization of Marked Site	NA				
Patient Marks Site					
Time Out					
Total Score (Maximum, 30)					

Figure 1. Potential checkpoints in preoperative site verification. Column headings indicate the providers who can participate in the checks listed in the rows. Each box in the grid represents a separate check for conformity in the preoperative process. NA indicates not applicable; OR, operating room.

clear. This study aimed to provide data to help answer these questions.

METHODS

WRONG-SITE SURGERY: CASE IDENTIFICATION, REVIEW, AND ANALYSIS

As part of a larger study of medical error among malpractice claims, we sought to identify all cases of wrong-site surgery reported to the Controlled Risk Insurance Corporation during a 20-year period. The Controlled Risk Insurance Corporation provides liability insurance to one third of Massachusetts physicians and approximately 30 hospitals. The Human Subjects Committee at the Harvard School of Public Health approved the study.

To construct the study sample, we searched the insurer's administrative database for all malpractice claims filed between 1985 and 2003 and all loss observations reported between 1994 and 2004 that included a surgeon as a named party. A loss observation is a report from a hospital to the malpractice insurer that alerts the insurer to incidents with recognized potential to trigger litigation. We reviewed text abstracts of the claims and loss observations to identify those involving wrong-site surgical procedures (cases), defined as operations conducted on a different organ or body part than intended by the surgeon and patient. Cases that occurred outside an operating room were excluded.

To calculate an incidence rate for wrong-site surgery, we obtained surgical procedure volume at the covered hospitals from the American Hospital Association. The calculations used the number of cases as the numerator and aggregate procedure volume as the denominator. This incidence rate assumed that claims and loss observations captured all wrong-site surgery cases at the covered hospitals during the study period.

We designed a data collection instrument for abstraction from the malpractice claim file and medical record associated with each case in our sample. Information collected included patient characteristics, procedure type, circumstances surrounding the procedure, and the injury outcome. Injuries were scored according to the National Association of Insurance Commissioners' 9-point severity scale, which ranges from emotional injury only to death. The instrument also included queries about errors in the preoperative process that may have led to the wrong-site surgery; the candidate errors were based on the previous studies and reports. A single surgeon (M.R.K.) conducted all reviews. Summaries of each case were then analyzed by 2 surgeons (M.R.K. and A.A.G.) to assess their potential for prevention had the Universal Protocol been followed.

SITE-VERIFICATION PROTOCOLS

We collected site-verification protocols on file in 2004 from 28 hospitals covered by 4 malpractice insurers in New England and Texas that had participated in our larger medical error study. The protocols were classified and systematically examined in 5 areas: (1) methods of marking the operative site, (2) operations excluded from site marking, (3) number of patient and procedure checks in the preoperative process, (4) strategy for verification of patient identity, and (5) prevention of procedures at the wrong vertebral level in spine surgery.

Thirty separate checkpoints were identified as opportunities for an intervention to ensure the correct patient or site (**Figure 1**). Each hospital's protocol was scored for the number of checkpoints involved. We also recorded the number of health care professionals involved in the process. The following details of the site-marking procedure were enumerated: (1) whether site marking is required, (2) which cases require site marking, (3) who marks the site, and (4) when during the preoperative process the site is marked.

The protocols were also examined for the presence of guidelines relating to spine surgery. If present, we determined whether these guidelines directed (1) intraoperative imaging of the spine and/or (2) radiopaque marker placement before intraoperative imaging.

RESULTS

CASE CHARACTERISTICS

Forty cases of wrong-site surgery were identified among 1153 malpractice claims and 259 loss observations relating to surgical care. Twenty-five (62%) of the cases were nonspine wrong-site surgical procedures; the remainder involved surgery at the wrong vertebral level or wrong-side laminectomy of the spine. From 1985 to 2004, the covered hospitals performed 1 426 901 inpatient and 1 399 466 outpatient surgical procedures. Therefore, the estimated incidence rate for nonspine wrong-site surgery was 1 in 112 994 operations (95% confidence interval, 1 in 76 336 to 1 in 174 825).

Among the 25 nonspine cases, 12 were wrong-side cases, 12 were wrong-site cases that did not involve laterality (8 involving multiple structures and 4 involving multiple lesions), and 1 was a wrong patient. Two cases (8%) occurred during emergency operations.

The mean patient age was 38.4 years, and half were female. **Table 1** describes the setting of care in which cases occurred and the specialties of surgeons involved in nonspine cases. **Table 2** enumerates the planned procedures.

Medical records were available for detailed review in 23 cases (all among the 30 malpractice cases). Thirteen of these cases were nonspine, and the rest involved spine surgery. Most injuries sustained by patients in the reviewed nonspine cases were temporary and minor (**Table 3**). The median indemnity payment for all 18

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Table 1. Procedure Characteristics for 40 Wrong-Site Surgery Cases

Characteristics	No. (%) of Cases
Specialty (nonspine cases only; n = 25)	
Orthopedic surgery	11 (44)
General surgery	5 (20)
Plastic surgery	4 (16)
Other specialties	5 (20)
Specialty (spine cases; n = 15)	
Neurosurgery	12 (80)
Orthopedic surgery	3 (20)
Setting of care (all cases; n = 40)	
Inpatient	27 (68)
Ambulatory center on day of surgery	13 (32)
Adult	35 (88)
Pediatric	5 (13)

Table 2. Procedures Planned for 25 Nonspine Wrong-Site Malpractice Cases

Wrong Side	Wrong Structure or Lesion	Wrong Person
Arthroscopy of the knee (n = 4)	Arthroplasty of the second toe	Arthroscopy of the knee
Lower extremity bypass	Osteotomy of metatarsal	
Inguinal hernia repair (n = 2)	Repair of hammer toe	
Adrenalectomy	Excision of phalangeal tumor	
Osteotomy of the humerus	Excision of facial nevi	
Internal fixation of the femur	Excision of flank lipoma	
Excision of thumb lesion	Excision of ear lesion	
Ureteral stent	First rib resection	
	Epigastric hernia repair	
	Release of trigger finger (n = 2)	
	Coronary artery bypass graft	

nonspine wrong-site malpractice cases in our cohort was $12 000. The median administrative costs associated with defending these cases was $1528. Among the reviewed spine cases, 7 of 10 involved the lumbar spine and 5 involved aberrant anatomy (eg, transitional vertebrae); in 3 cases, no intraoperative imaging was used.

CONTRIBUTING FACTORS AND PREVENTABILITY

Of the 13 nonspine cases reviewed, 9 involved ambiguity or error that preceded the arrival of the patient at the operating room area on the day of surgery (**Figure 2**). Specifically, 4 cases involved errors in operating room scheduling; 3 involved multiple lesions that were not identified, clarified, or documented in the clinic visit; 1 involved an incorrectly printed magnetic resonance image; and 1 involved a clinic note and consent form that specified the incorrect side. Site and/or side was not specified in 6 of the 9 consent forms available for review. Four of the 13 cases were judged to have been preventable by review of radiologic films or reports; in 2 of these cases, radiologic findings were not available in the operating room.

Table 3. Injury Severity of 13 Reviewed Nonspine Wrong-Site Cases

Injury Severity	No. (%) of Cases
Temporary-insignificant (scar only)	6 (46)
Temporary-minor (minimally delayed recovery)	4 (31)
Temporary-major (moderately to severely delayed recovery)	2 (15)
Permanent-significant	1 (8)

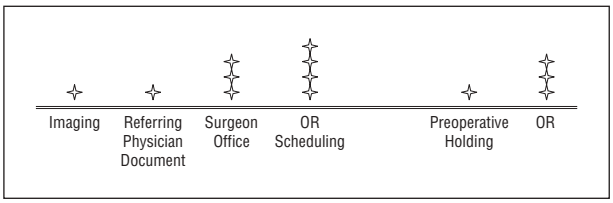

Figure 2. Setting of first error in site localization among 13 nonspine wrong-site surgical procedures. OR indicates operating room.

For 5 (38%) of the 13 cases, we judged it unlikely that the Universal Protocol would have prevented them. In one case, a magnetic resonance image of the knee was printed at a referring hospital for the incorrect patient with the same name as the correct patient. In another case, the surgeon decided to change the side of the scheduled procedure for a patient with bilateral disease in the preoperative holding area. The surgeon obtained updated informed consent after the patient had received sedatives, and the patient did not later recall consenting to the procedure performed. Another case involved resection of the second rib instead of the first rib during an operation to treat thoracic outlet syndrome. Two cases involved multiple lesions (lipoma and epidermal inclusion cyst); when these patients presented on the day of surgery, there was uncertainty on the part of both patient and surgeon regarding which lesion was to be excised. Site marking would not have prevented these errors.

Under optimal conditions, the other 8 nonspine cases (62%) we reviewed might have been prevented by the Universal Protocol. In 2 cases, a clear contradiction might have been detected between the site described on the consent form and the site described on the operating room schedule. In another case, discussion with the patient might have revealed an error in the operating room schedule. In 2 cases, a requirement to specify the site of the procedure on the consent form and the operating room schedule would likely have prevented the error (wrong-side hip surgery and umbilical instead of epigastric hernia repair). In one case, a specification of side on the radiologic report would likely have prevented wrong-site surgery from occurring.

Two cases might have been prevented by site marking. In a wrong-toe case, the correct foot was marked, but the toe intended for surgery was not. In another case, site marking might have prevented the surgeon from making a herniorrhaphy incision on the opposite side of the defect.

SITE-VERIFICATION PROTOCOL ANALYSIS

We obtained 16 site-verification protocols covering 25 of the 28 hospitals. The number of redundant checks in

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Table 4. Features of the Site-Marking Process in 16 Cases

Feature	No. (%) of Cases
Which cases are marked	
All	6 (38)
As required by JCAHO*	4 (25)
Cases involving laterality only	5 (31)
Extremity procedures only	1 (6)
Marked by whom	
Surgeon	9 (56)
Surgeon and nurse	3 (19)
Patient	1 (6)
Surgeon or patient	2 (12)
Surgeon, patient, or nurse	1 (6)
How to mark	
Initials	6 (38)
Initials or "yes"	2 (12)
"Yes"	2 (12)
Not described	3 (19)
Other	3 (19)
Marked by a designee	
Yes	5 (31)
No	11 (69)
When the site is marked	
Preoperative holding	13 (81)
Operating room	1 (6)
Preoperative within 30 days	1 (6)
Not specified	1 (6)

Abbreviation: JCAHO, Joint Commission on Accreditation of Healthcare Organizations.
*All cases involving laterality, multiple structures, or multiple levels.

each protocol averaged 12 and ranged from 5 to 20. The number of personnel involved ranged from 2 to 4. The personnel included the preadmission testing nurse, preoperative nurse, perioperative (circulating) nurse, anesthesiologist or nurse anesthetist, and surgeon.

The features of the protocols' site-marking processes are given in **Table 4**. Significant variability occurred in which cases required site marking, who should perform the marking, and how the marking should be performed. Six of 16 protocols, for example, did not require marking in cases that involved multiple structures (eg, excision of 1 of several skin lesions). The surgeon was directed to mark the patient's operative site in 12 of 16 protocols. At one hospital, the patient rather than the surgeon was supposed to mark the operative site when possible. One hospital had the surgeon mark a drawing of the body on the consent form and not the patient's skin (although the next year, this protocol was changed to require skin marking). Five of 16 hospitals allowed a resident or other surgeon's designee to mark the site. Ten protocols implicitly or explicitly specified that the marked area must be visible after the patient had been prepared and draped for surgery in the operating room. At one hospital, an alert placard was not to be removed from the patient's bed until his or her site had been marked.

Fourteen of the protocols explicitly required a pause or time out, all but 1 of which called for documentation of this pause in the medical record. Eleven protocols made no explicit mention of site identification for spine surgery. Among the 5 that did, 4 mandated intraoperative fluoroscopy or radiographs to confirm that the correct level was exposed once in the operating room. One protocol allowed the surgeon to decide whether intraoperative imaging was necessary. One protocol did not require intraoperative films but required that preoperative films be used to verify the level before the procedure. Only 2 protocols required the use of radiopaque markers at the intended level before performing the x-ray examination.

COMMENT

Wrong-site surgery is unacceptable but rare, and serious injury attributable to it is even rarer. At the rate detected in this study, a wrong-site surgery serious enough to result in a report to risk managers or a lawsuit would occur at a single large hospital about once every 5 to 10 years. By comparison, retained foreign bodies after surgery are 10 times more likely to occur than wrong-site surgery (1 in 8801 to 1 in 18 760 inpatient operations), and severe injuries are more likely when they do occur.[8] Publicized cases of wrong-site surgery may exaggerate perceived incidence and harm.

Site-verification protocols vary across hospitals, and many require significant personnel time for multiple redundant checks. No published evidence offers guidance on the effectiveness of site-verification interventions. Enforced redundancy is the key feature of site-verification protocols. In the design of patient safety–oriented protocols, there is a natural tendency to maximize redundancy in checks. Our survey indicates that up to 20 checks per patient are required. Industry safety expert James Reason[9] has identified several concerns with this approach.

First, written checklists, although designed for easy use, are prone to several types of error: skipped steps due to interruptions and distractions and stating that an item has been completed (checking the box) when in fact it has not.[10] Second, redundant checks can achieve an exponential decrease in risk of error but only if each checkpoint is independent. Third, increasing the number of involved caregivers can foster routine violations because the multiple checks begin to seem like "busy work." Finally, efforts to keep up with the pace of patient flow may lead to viewing violations of protocol as acceptable or necessary.[10] Simplification of protocols would improve adherence and efficiency and allow surgical teams to focus their limited time and energy on prevention of more common or harmful errors.

A model for a site-verification protocol would include the following provisions:

1. Site marking: At minimum, the surgeon or surgeon's designee marks the site with initials or "yes."
2. Preoperative verification process: Preoperative verification of patient identity, procedure, site, side, and vertebral level should be performed by 2 health care staff members, one of whom should be the surgeon. The operating room schedule and informed consent document should be compared by both staff members. A time out before the incision should then provide a final confirmation.
3. Inconsistencies: Any inconsistencies or uncertainties about the proper site should be resolved by the surgeon with confirmation and agreement by the patient and at least 1 of the inspecting caregivers. Protocols should

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explicitly address the manner in which inconsistencies are resolved.

4. Informed consent must specify laterality if the site is bilateral. If there are multiple structures or lesions present, the consent form must attempt to localize them. The procedures should be booked for the operating room with equivalent detail.

Our findings show that current site-verification protocols would not have prevented at least one third of the wrong-site surgery cases analyzed. Initial errors begin before the patient's arrival at the hospital on the day of surgery. Surgeons need to ensure in the clinic that the correct site is identified, especially when dealing with multiple lesions or lesions seen only on a single imaging study.

Our study has several limitations. First, the incidence rate reported may underestimate the true rate of wrong-site surgical procedures, since only those cases that prompted claims or reports to the malpractice insurer were identified. However, wrong-site surgical procedures that cause serious injuries are unlikely to be missed because claims are much more likely in such cases and hospitals are under considerable pressure to report such events to the insurer. Second, the incidence rate spans all operations. Rates likely differ among specific procedures, potentially explaining why a study of hand surgeons showed wrong-site surgery to be 4 times more common than our generic rate.[4] Third, the incidence rate is averaged over a 20-year period and does not provide information on whether wrong-site surgery is more or less common after the implementation of site-verification protocols. Fourth, our review of site-verification protocols found variability among 25 hospitals in 3 states. It is unclear how representative these hospitals are or how closely personnel followed the protocols. There is undoubtedly even greater variability in hospital practices nationwide.

Wrong-site surgery is rare but shocking to the public. This mandates an approach that balances safety, simplicity, and efficiency. No protocol will prevent all cases. Therefore, it will ultimately remain the surgeon's responsibility to ensure the correct site of operation in every case.

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DISCUSSION

Neil Yeston, MD, Hartford, Conn: Notwithstanding that wrong-site surgery is rare, I'd like not to be the individual who has the wrong-site surgical problem. The question is, if you were in charge of a national program to eliminate this problem with a zero-tolerance result, how would you fix it?

Dr Kwaan: I think it would be a good idea to implement a Universal Protocol, meaning something that is done for every patient prior to going to the operating room, but since this is a very rare occurrence, we shouldn't be spending a lot of time and effort on a very cumbersome protocol, especially when we have no data to support the efficacy of such protocols. So I would implement a protocol that involves, at most, 2 personnel checking a limited number of documents. The surgeon should take responsibility in the clinic to ensure the specification of the correct site when booking the case.

Pardon Kenney, MD, Boston, Mass: The protocols you referred to came into existence in the mid-1990s, largely at the instigation of the American Academy of Orthopaedic Surgery, and were adopted nationally around that time. I may have missed it but did you point out the incidence; that is, how many of these wrong-site procedures happened before these protocols were instituted? We might get some idea how well they actually work.

Dr Kwaan: The majority of our cases occurred prior to the implementation of those protocols. I don't have the exact numbers for you in terms of the dates. With the information available in claims files, few or none involved a site-verification process.

Erwin Hirsch, MD, Boston: Thank you very much for something that confronts us every day, either a pink, green, or orange piece of paper. None of us when all this was implemented a few years ago were very happy that another piece of paper had to be signed. I know the process that you described. However, I think we still need to do it. The data that you showed are the data that are being reported. I can tell there are many more cases that are not being reported. In our own institution we've gone through this process, and it is welcomed because we have recognized that there were times when we were close

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to a disaster that we were able to avoid, specifically, the right or wrong side or right or wrong organ.

This process has opened another interesting issue. There are other issues that pertain to perioperative management of patients, and I'll just bring up one, which is the adequacy and timeliness of perioperative antibiotic therapy. We've included that in this little checklist; since we did this, we have improved the management of perioperative antibiotic therapy, for which I'm sure every hospital has its own problems.

So I recognize what you are saying, but I would not encourage people to abandon this cumbersome or perhaps sometimes less-than-happy process because, in the long run, it is going to be beneficial in more ways than we currently know.

Dr Kwaan: I appreciate your comments. There are 2 points I'd like to make. One is that bundling patient safety issues so that you can accomplish multiple things with a couple of simple steps is a great approach to simplifying patient safety protocols. Number two, I consider trying to design studies to show what sort of site-verification protocols would be more likely to pick up either near misses or true events. We need a little more data on how to design these protocols so that they do not get in the way of operating room efficiency and yet are effective in preventing near misses or true events.

Announcement

In concert with the International Committee of Medical Journal Editors (ICMJE), *Archives of Surgery* will require, as a condition of consideration for publication, registration of all trials in a public trials registry (such as http://ClinicalTrials.gov). Trials must be registered at or before the onset of patient enrollment. This policy applies to any clinical trial starting enrollment after March 1, 2005. For trials that began enrollment before this date, registration will be required by June 1, 2005, before considering the trial for publication. The trial registration number should be supplied at the time of submission.

For details about this new policy, and for information on how the ICMJE defines a clinical trial, see the editorials by DeAngelis et al in the September 8, 2004 (2004; 292:1363-1364) and June 15, 2005 (2005;293:2927-2929) issues of *JAMA*. Also see the Instructions to Authors on our Web site: www.archsurg.com.

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