Chapter 36. Wrong-Site Surgery: A Preventable Medical Error

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Background

Surgery is one area of health care in which preventable medical errors and near misses can occur. However, until the 1999 Institute of Medicine report, *To Err Is Human*,[1] clinicians were unaware of the number of surgery-associated injuries, deaths, and near misses because there was no process for recognizing, reporting, and tracking these events.[2] Of great concern is wrong-site surgery (WSS), which encompasses surgery performed on the wrong side or site of the body, wrong surgical procedure performed, and surgery performed on the wrong patient.[3] This definition also includes "any invasive procedure that exposes patients to more than minimal risk, including procedures performed in settings other than the OR [operating room], such as a special procedures unit, an endoscopy unit, and an interventional radiology suite"[4] (p. 11). WSS is also defined as a sentinel event (i.e., an unexpected occurrence involving death or serious physical or psychological injures, or the risk thereof) by the Joint Commission (formerly called the Joint Commission on Accreditation of Healthcare Organizations), which found WSSs to be the third-highest-ranking event.[5]

Causes and Consequences of Wrong-Site Surgery

WSS can be a devastating experience for the patient and have a negative impact on the surgical team.[6, 7] State licensure boards are imposing penalties on surgeons for WSS,[8] and some insurers have decided to no longer pay providers for WSS or wrong-person surgery, nor for leaving a foreign object in a patient's body after surgery.[9] Surgery performed on the wrong site or wrong person has also often been held compensable under malpractice claims. Indeed, 79 percent of wrong-site eye surgery and 84 percent of wrong-site orthopedic claims resulted in malpractice awards.[10, 11]

WSSs are rare events, but we are learning more about their prevalence. Because reporting of sentinel events to the Joint Commission is voluntary, it could be that only 10 percent of actual WSSs are reported.[12] Researchers have confirmed that the Joint Commission's numbers are low, finding wide variations in the number of WSSs: 1 out of 27,686 cases,[6] or 1 out of every 112,994 surgeries,[13] or 1 in 5 hand surgeons during their career,[7] or 1 out of 4 orthopedic surgeons with 25 years' experience.[14] Regardless of the exact number of WSSs, they are seen as a preventable medical error if certain steps are taken and standardized procedures are implemented in the perioperative setting.[15, 16]

The incidence of reported WSS has increased in recent years. From the inception of the Joint Commission's Sentinel Event program, the number of WSSs reported has increased from 15 cases in 1998, to a total of 592 cases reported by June 30, 2007.[17] Of these, WSSs most commonly occur in orthopedic or podiatric procedures,[5] general surgery, and urological and neurosurgical procedures.[17] In response to the occurrence of these preventable errors, the Joint

Commission issued two National Patient Safety Goals on January 1, 2003 to target wrong-site surgery:

Goal 1—to improve the accuracy of patient identification by using two patient identifiers and a "time-out" procedure before invasive procedures.

Goal 4—to eliminate wrong-site, wrong-patient, and wrong-procedure surgery using a preoperative verification process to confirm documents, and to implement a process to mark the surgical site and involve the patient/family.[40]

Both of these goals continue to be an ongoing priority for the Joint Commission. Yet with many surgical procedures traditionally performed only in acute care settings now being performed in freestanding surgical centers and physician offices—not necessarily all under the purview of the Joint Commission—surgeons, surgical teams, and patients need to be vigilant with all surgeries, particularly when the level of oversight and scrutiny may not be as high as in hospitals.

WSS is generally caused by a lack of a formal system to verify the site of surgery or a breakdown of the system that verifies the correct site of surgery.[18] In using root-cause analysis, a process that determines the underlying organizational causes or factors that contributed to an event, the Joint Commission found the top root causes of WSS to be communication failure (70 percent), procedural noncompliance (64 percent), and leadership (46 percent).[16] Other system and process causes are listed in Table 1. Risk factors associated with WSS were identified as emergency cases, multiple surgeons, multiple procedures, obesity, deformities, time pressures, unusual equipment or setup, and room changes.[17]

Table 1. Causes of Wrong-Site Surgeries[5, 18, 19, 20]

System Factors	Process Factors
♦ Lack of institutional controls/formal system to verify the correct site of surgery ♦ Lack of a checklist to make sure every check was performed ♦ Exclusion of certain surgical team members ♦ Reliance solely on the surgeon for determining the correct surgical site ♦ Unusual time pressures (e.g., unplanned emergencies or large volume of procedures) ♦ Pressures to reduce preoperative preparation time ♦ Procedures requiring unusual equipment or patient positioning ♦ Team competency and credentialing ♦ Availability of information ♦ Organizational culture ♦ Orientation and training ♦ Staffing ♦ Environmental safety/security ♦ Continuum of care ♦ Patient characteristics, such as obesity or unusual anatomy, that require alterations in the usual positioning of the patient	♦ Inadequate patient assessment ♦ Inadequate care planning ♦ Inadequate medical record review ♦ Miscommunication among members of the surgical team and the patient ♦ More than one surgeon involved in the procedure ♦ Multiple procedures on multiple parts of a patient performed during a single operation ♦ Failure to include the patient and family or significant others when identifying the correct site ♦ Failure to mark or clearly mark the correct operation site ♦ Incomplete or inaccurate communication among members of the surgical team ♦ Noncompliance with procedures ♦ Failure to recheck patient information before starting the operation

Universal Protocol for Preventing Wrong-Site Surgery

Early attempts to address the occurrence of WSS started with the American Academy of Orthopedic Surgeons (AAOS) and the North American Spine Society (NASS). After reviewing of 10 years of malpractice claims and polling its members,[21] AAOS developed an awareness campaign to encourage the marking of the right surgical site, called "Sign Your Site."[22] But in practice, adding an additional warning such as "No" on the incorrect site and having the surgical team work together to verify the correct site helped the Sign Your Site program to be effective.[23] The NASS further refined the Sign Your Site process by adding more detail for the appropriate level and site of the spine in its "Sign, Mark, and X-ray" program, calling for marking the exact site and side of the spine with a radiopaque indicator, and put forth a checklist for patient and procedure verification.[24]

In 2003, the Joint Commission convened a summit, including the AAOS and leaders from 23 other organizations, to address the continued escalation of reported WSS cases (i.e., sentinel events reported to the Joint Commission); and the impact of WSS on patients, their families, and health care professionals; and associated health care costs. The summit was specifically designed to bring health care professionals and others together to address and develop strategies to lessen or eliminate WSS.[14] A major outcome of the summit was creation of a protocol, *The Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery* ™ (see Text Box 1).[20] This protocol was designed to be used in all areas where invasive procedures are performed within health care organizations, including nonoperating-room settings. The goal was to drastically reduce or eliminate completely the incidence of WSS by using a standardized routine and acceptable preoperative process of verifying the patient and the correct site, as well as the physician marking the site with his or her initials before the patient is sedated.

The Universal Protocol for WSS is based on prevention theories that drive safety practice in high-risk industries, such as aviation and development of nuclear weapons. The operating room is complex with "tight coupling" of processes that happen very quickly and cannot be turned off once started; failed parts cannot be isolated from other parts—resulting in an unsafe process. A model most often used to demonstrate this is the one described by Reason[25] as the Swiss cheese model, where error defenses breakdown or are not in place, resulting in patient harm. (See the chapter on human factors for more information on Reason's model.)

By implementing a systems change required by the WSS protocol, the possibility of a WSS should be prevented. The three key elements of the Universal Protocol for WSS are (1) preoperative verification process, (2) marking the operative site, and (3) taking a time out. The Universal Protocol is to be used in ambulatory care, hospitals, critical access hospitals, and office-based settings.[20] Implementing and adhering to this protocol should eliminate WSS errors that can be attributable to interruptions, distractions, and too many forms or procedures. On July 1, 2004, the Joint Commission began to include these three key Universal Protocol elements in its accreditation process for health care organizations and also provided further guidance on its implementation (see Text Box 2).

Text Box 1. The Joint Commission Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™

Wrong site, wrong procedure, wrong person surgery can be prevented. This Universal Protocol is intended to achieve that goal. It is based on the consensus of experts from the relevant clinical specialties and professional disciplines and is endorsed by more than 40 professional medical associations and organizations.

In developing this protocol, consensus was reached on the following principles:

- Wrong site, wrong procedure, wrong person surgery can and must be prevented.
- A robust approach—using multiple, complementary strategies—is necessary to achieve the goal of eliminating wrong site, wrong procedure, wrong person surgery.
- Active involvement and effective communication among all members of the surgical team is important for success.
- To the extent possible, the patient (or legally designated representative) should be involved in the process.
- Consistent implementation of a standardized approach using a universal, consensus-based protocol will be most effective.
- The protocol should be flexible enough to allow for implementation with appropriate adaptation when required to meet specific patient needs.
- A requirement for site marking should focus on cases involving right/left distinction, multiple structures (fingers, toes), or levels (spine).
- The Universal Protocol should be applicable or adaptable to all operative and other invasive procedures that expose patients to harm, including procedures done in settings other than the operating room.

In concert with these principles, the following steps, taken together, comprise the Universal Protocol for eliminating wrong site, wrong procedure, wrong person surgery:

- **Preoperative verification process**
  - **Purpose:** To ensure that all of the relevant documents and studies are available prior to the start of the procedure and that they have been reviewed and are consistent with each other and with the patient's expectations and with the team's understanding of the intended patient, procedure, site, and, as applicable, any implants. Missing information or discrepancies must be addressed before starting the procedure.
  - **Process:** An ongoing process of information gathering and verification, beginning with the determination to do the procedure, continuing through all settings and interventions involved in the preoperative preparation of the patient, up to and including the "time out" just before the start of the procedure.

- **Marking the operative site**
  - **Purpose:** To identify unambiguously the intended site of incision or insertion.
  - **Process:** For procedures involving right/left distinction, multiple structures (such as fingers and toes), or multiple levels (as in spinal procedures), the intended site must be marked such that the mark will be visible after the patient has been prepped and draped.

- **"Time out" immediately before starting the procedure**
  - **Purpose:** To conduct a final verification of the correct patient, procedure, site and, as applicable, implants.
  - **Process:** Active communication among all members of the surgical/procedure team, consistently initiated by a designated member of the team, conducted in a "fail-safe" mode, i.e., the procedure is not started until any questions or concerns are resolved.

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Text Box 2. Implementation Expectations for the Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery™

These guidelines provide detailed implementation requirements, exemptions, and adaptations for special situations.

Preoperative verification process

- Verification of the correct person, procedure, and site should occur (as applicable):
  - At the time the surgery/procedure is scheduled.
  - At the time of admission or entry into the facility.
  - Anytime the responsibility for care of the patient is transferred to another caregiver.
  - With the patient involved, awake, and aware, if possible.
  - Before the patient leaves the preoperative area or enters the procedure/surgical room.
- A preoperative verification checklist may be helpful to ensure availability and review of the following, prior to the start of the procedure:
  - Relevant documentation (e.g., history and physical, consent).
  - Relevant images, properly labeled and displayed.
  - Any required implants and special equipment.

Marking the operative site

- Make the mark at or near the incision site. Do NOT mark any nonoperative site(s) unless necessary for some other aspect of care.
- The mark must be unambiguous (e.g., use initials or "YES" or a line representing the proposed incision; consider that "X" may be ambiguous).
- The mark must be positioned to be visible after the patient is prepped and draped.
- The mark must be made using a marker that is sufficiently permanent to remain visible after completion of the skin prep. Adhesive site markers should not be used as the sole means of marking the site.
- The method of marking and type of mark should be consistent throughout the organization.
- At a minimum, mark all cases involving laterality, multiple structures (fingers, toes, lesions), or multiple levels (spine). Note: In addition to preoperative skin marking of the general spinal region, special intraoperative radiographic techniques are used for marking the exact vertebral level.
- The person performing the procedure should do the site marking.
- Marking must take place with the patient involved, awake, and aware, if possible.
- Final verification of the site mark must take place during the "time out."
- A defined procedure must be in place for patients who refuse site marking.

Exemptions

- Single organ cases (e.g., Cesarean section, cardiac surgery).
- Interventional cases for which the catheter/instrument insertion site is not predetermined (e.g., cardiac catheterization).
- Teeth–but, indicate operative tooth name(s) on documentation or mark the operative tooth (teeth) on the dental radiographs or dental diagram.
- Premature infants, for whom the mark may cause a permanent tattoo.

"Time out" immediately before starting the procedure
Must be conducted in the location where the procedure will be done, just before starting the procedure. It must involve the entire operative team, use active communication, be briefly documented, such as in a checklist (the organization should determine the type and amount of documentation), and must, at the least, include:

- Correct patient identity.
- Correct side and site.
- Agreement on the procedure to be done.
- Correct patient position.
- Availability of correct implants and any special equipment or special requirements.

The organization should have processes and systems in place for reconciling differences in staff responses during the "time out."

Procedures for non-OR settings, including bedside procedures

- Site marking must be done for any procedure that involves laterality, multiple structures, or levels (even if the procedure takes place outside of an OR).
- Verification, site marking, and "time out" procedures should be as consistent as possible throughout the organization, including the OR and other locations where invasive procedures are done.
- **Exception:** Cases in which the individual doing the procedure is in continuous attendance with the patient from the time of decision to do the procedure and consent from the patient through to the conduct of the procedure may be exempted from the site marking requirement. The requirement for a "time out" final verification still applies.

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The Association of periOperative Registered Nurses (AORN), realizing the importance of the Universal Protocol for WSS, worked collaboratively with the Joint Commission to develop a Correct Site Surgery Tool Kit. The tool kit, designed to assist health care providers to implement the Universal Protocol for WSS in their facilities, was endorsed by the American College of Surgeons, American Society of Anesthesiologists, American Society for Healthcare Risk Management, American Hospital Association, and the American Association of Ambulatory Surgery Centers.

The AORN Correct Site Surgery Tool Kit contains a variety of resources to educate health care providers about the Universal Protocol for WSS and to assist them with its implementation. The resources include (1) an educational program on CD-ROM; (2) a pocket reference card outlining the steps necessary to promote patient identification, site marking, and the time out; (3) a template to facilitate development of a facility policy to implement the Universal Protocol for WSS; (4) a copy of the Universal Protocol for WSS and Guidelines for Implementing the Universal Protocol; (5) frequently asked questions of the Joint Commission and AORN; (6) letters to nurses, physicians, facility chief executive officers, and health care risk managers encouraging standard implementation of the Universal Protocol across all facilities; and (7) information for patients about the Universal Protocol for WSS and health care safety. This tool kit is available from AORN at http://www.aorn.org/PracticeResources/ToolKits/CorrectSiteSurgeryToolKit. In addition, AORN Standards, Recommended Practices, and Guidelines has a position statement on Correct Site Surgery that has additional information on preventing wrong site surgery.[39]

Several other organizations have set forth tools and policies to prevent WSS. The Veterans Affairs National Center for Patient Safety put forth the Ensuring Correct Surgery and Invasive Procedures directive, based on root-cause analysis, that adds two steps to the Joint Commission's

Universal Protocol: ensuring the consent form is administered and used properly, and having two members of the surgical team review patient information and radiological images prior to the start of the surgery.[26] The OR briefing tool used at Johns Hopkins Hospital expands the time-out part of the Universal Protocol by prompting additional dialogue between the anesthesia care team, nursing, and the surgical team.[27] Additionally, the British National Patient Safety Agency has introduced a risk management tool, setting forth a process for double-checking and identifying who is accountable at each stage for ensuring surgical markings on the right site to avoid WSS.[28]

Research Evidence

There is limited research on wrong-site surgery. The majority of studies have been retrospective, chart reviews, case studies, and surveys of various professional organizations. The evidence table summarizes the most recent evidence related to WSS, specifically the three components of the Universal Protocol.

In two of the retrospective studies that investigated WSS broadly, Meinberg and Stern,[7] in a study relating to the Universal Protocol, found that nearly half of surgeons changed their preoperative practices in response to the Sign Your Site campaign. Since the campaign targeted orthopedic surgeons, they were more knowledgeable about the campaign and were more likely to have changed their practices. Kwaan and colleagues[6] identified 62 percent of WSS cases that could have been prevented had providers adhered to the Universal Protocol. In this study, the authors concluded that the Universal Protocol would not have prevented the remaining one-third of WSS documented cases because of errors initiated in weeks before surgery (e.g., wrong documentation, inaccurate labeling of radiological reports). In an analysis of quality improvement efforts, similar findings also indicated implementation challenges associated with staff nonadherence because the issue of laterality was not addressed in the policy and the process was vulnerable to communication failures during handoffs.[29]

Preoperative Verification

In verifying that the right patient is to have the right surgery in the right location, one study found that when discrepancies occurred among clinicians, a review of the patient's information could resolve the discrepancy.[30] Published guidelines assert the need for a checklist to itemize exactly what should be checked, but do not specify what should happen if a discrepancy occurs.[31]

Marking the Site

Three different studies and one quality improvement project assessed aspects of site marking, included two different approaches in who actually marks the right site. All found challenges in ensuring that each surgical patient had the right site marked, therefore exposing patients to possible WSS. One study that surveyed a small number of surgeons on their site-marking practices following the establishment of national guidelines, found that their practices ranged from no marking to marking every patient, with some relationship to the type of surgery.[32] In approaching site marking from the point of view that it is the patient's responsibility, instead of the surgeon having complete responsibility, DiGiovanni and colleagues[33] sought to have patients

mark the right site after being given a set of instructions. They found that when patients (instead of someone from the surgical team) were asked preoperatively to mark "no" on the wrong foot or ankle, 60 percent of patients marked the site correctly.

The last study and quality improvement project assessed whether marking would cause other errors, because of the permanence of the ink, thereby discouraging site marking. The study found that marking the surgical site with a pen marker did not affect sterility or place a patient at a higher risk for infection.[34] The quality improvement project found that staff were not marking the right site because the ink upset breast cancer patients and was indelible on premature infants, and the policy did not address laterality.[29]

Time Out

Two studies found that the time out component can prevent the majority of WSS, but not all.[6, 13, 35] Another study found that when surgeons, anesthesiologists, and nurses were trained in doing a standardized 2-minute briefing prior to surgery, there were specific improvements in communication on the surgical site and side operated on.[36]

Evidence-Based Practice Implications

In response to continued WSS sentinel event reports, one of the Joint Commission's National Patient Safety Goals continues to be to eliminate wrong-site, wrong-patient, and wrong-procedure surgery. Eliminating WSS errors requires a systems approach, institutionalizing robust systems to verify the correct site that adequately addresses potential causes of breakdowns in the system. Hospital and surgery center leaders and managers should evaluate their policies and procedures regarding WSS and marking the right site to ensure that no WSSs occur under any circumstances.

Adoption of the Universal Protocol standardizes preoperative preparations, improves function of the health care team, and should avert any potential for WSS. All health care personnel must be knowledgeable about the Universal Protocol and consistently adhere to the three key elements—patient identification, site mark, and time out—as outlined in the Universal Protocol to reduce the number of WSSs occurring in the United States.

The Universal Protocol for WSS should be adhered to on all applicable cases, as the operating room and procedural areas are highly coupled and complex areas that would be unlikely to be completely error proof. Measures should be taken that require less reliance on memory. For example, a surgical site mark is a measure to prevent reliance on memory. However, when involving patients in marking the surgical site, one needs to assess their physical, cognitive, and emotional ability.[31]

All health care professionals have an obligation to comply with the Universal Protocol and to speak up if they feel patient safety is being compromised in any way.[37] Nurses, specifically perianesthesia nurses, should function as the patient's advocate and foster procedures that ensure right-site surgery.[38]

Research Implications

There is little empirical evidence regarding prevention of WSS or quantitative evaluation of implementation of strategies to prevent WSS. Part of the problem with research in this area has

been that the medical-error data are not easy to extract, and error data are often transferred to medical claims data and medical liability, further preventing the sharing of such data. Mandatory reporting of these data has just recently been required in some States. Consequently, there are gaps in the current evidence on wrong-site surgery. For example, there were no randomized controlled studies to evaluate the effect of the Universal Protocol on WSS. Research is needed to determine whether the patient's risk for WSS is associated with the organization following the Joint Commission's Universal Protocol or other standardized process, or with the effectiveness of the surgical team in communicating with each other. It is unknown how effective surgical teams are in complying with the protocol on a daily basis, and it is unknown what factors or barriers exist to implementing the Universal Protocol for WSS in facilities across the country.

Conclusion

The reported number of WSS cases continues to increase as health care organizations become more transparent to medical error. Many health care organizations, drawing on error-prevention theories and the experience of the aviation industry, recognize that through such transparencies, systems can change and result in better patient outcomes. However, it is unlikely that WSS will fully be reported because of industrywide report cards, fear of litigation, and difference of opinions. Although absolute numbers of WSS may not be striking, the consequences to the patient on whom it occurs are dire.

Search Strategy

Both PUBMED® and CINAHL® databases between 1990 and March 2007 were searched, using wrong site surgery[keyword] OR wrong site surgery[subject heading]. This identified 239 citations. Citations were excluded for the following reasons: non-English, dealt only with disclosing errors or patient preferences, opinion/editorial pieces, news articles, or announcements. This left 68 articles for consideration in this review, 10 of which were considered as evidence.

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Evidence Table. Summary of Evidence Related to Wrong-Site Surgery

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Cronen 2005[34]	Sterility of surgical site marking	Nonrandomized control study	Test the sterility of the site mark after using a surgical marking pen	20 volunteers. The right forearm was used as the experimental (marked) arm, and the left forearm as the control arm. The experimental forearms were marked with a surgical marker as described by the protocol.	Both upper extremities were sterilized from the antecubital fossa to the phalanges with a 7.5% povidone-iodine scrub followed by the application of a 10% povidone-iodine paint. Swabs were used to obtain samples from the experimental and control arms, as well as from the marker. Swabs were sent for microbiological culture and analysis.	No growth was seen in the cultures of the swabs used on the experimental or control arms or on the marking pens. Preoperative marking of surgical sites in accordance with the Universal Protocol did not affect the sterility of the surgical field, a finding that provides support for the safety of surgical site marking.
DiGiovanni 2003[33]	Surgical site marking	Pretest and post-test study	Evaluated the responses of 100 elective patients undergoing foot and ankle surgery to participating in marking the surgical site. (Level 3)	Prospective study. 100 consecutive patients in a private foot-and-ankle practice followed the explicit preoperative instruction, before they underwent elective orthopedic surgery, to mark "NO" on the extremity that was not to be operated on.	Patients were instructed on how to mark the site	59 patients correctly marked the surgical site, 27 made no mark, 4 were considered partially marked, as the mark was different from the “NO” they were instructed to do. 70% of noncompliant patients had a worker compensation claim.
Giles 2006[32]	Surgical site marking	Noncomparative study	Retrospective qualitative semi-structured surveys. (Level 4)	In person or telephone interview of 38 surgeons in 14 hospitals in the U.K.		Surgeon’s practices and methods of site marking varied, as did their value of the need for marking.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
JCAHO 2003[20]	Surgical site identification protocol	Published guidelines based on a consensus report		Universal Protocol is applicable to all JCAHO accredited facilities commencing on July 1, 2004.	Preoperative strategy to verify the correct patient, type of procedure, and site of intervention	3-step Universal Protocol: • Preoperative verification process • Marking the operative site • Time out immediately before starting the procedure
Kwaan 2006[6]	Wrong-site surgery	Case series	Incidence, characteristics, cause of WSS. Characteristics of site verification protocols (Level 2)	Malpractice liability insurer data from 20-year period from one-third of Massachusetts physicians and approximately 30 hospitals. Site verification protocols in 2004 from 28 hospitals covered by 4 malpractice insurers in New England and Texas. Retrospective medical records reviewed on 13 of 24 identified cases of WSS.		Wrong-site surgery is rare as is major injury from WSS. Current protocols for site verification could have prevented only 2/3 of examined cases.
Makary 2007[36]	Communication	Pretest and post-test study	Survey	306 operating room (OR) staff (e.g., surgeons, nurses, and anesthesiologists) at one academic medical center (85% response rate)	Administered a version of the Safety Attitudes Questionnaire before and after initiation of an OR briefing program.	OR briefings reduced perceived risk for WSS, improved perceived collaboration/teamwork among OR staff, and promoted using team discussions.
Mawji 2002[29]	Surgical site identification protocol	Quality improvement project	Root-cause analysis of near misses, for project implementation using the Plan-Do-Study-Act method.	800-bed, 3-site academic hospital and network	Implementation of surgical site policy, marking “yes” on the surgical site and “no” on the other side.	Surgical site marking policy was not being followed. • Handoffs were missing critical information. • Nature of marking was problematic. • Laterality of markings not included in policy.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Meinberg 2003[7]	Incidence of wrong-site surgery in hand surgeons	Noncomparative study	Survey	1,560 active members of the American Society for Surgery of the Hand (ASSH) were polled by mail. Return rate of 67%.	29-question survey to determine incidence of WSS	Estimated number of WSS was 1 in 27,686 hand procedures. 21% hand surgeons reported performing wrong-site surgery at least once during their career; wrong finger occurred 63% of the 242 reported events.
Rogers 2004[31]	Barriers to implementing Wrong Site Surgery Guidelines	Changing practice projects/ research	Observational study of surgical cases at 4 facilities: 2 outpatient surgical units 1 large metropolitan teaching university 1moderate-size Federal facility	October 2001 to February 2002 Field observation and semi-structured interview questions. Total of 40 observational hours.		Surgical process is tightly coupled, complex system that includes multiple layers of interaction. Unlikely to error proof completely the process in such a dynamic environment, but measures can enhance the resiliency, such as having data available to all practitioners that is updated for everyone to see to prevent overreliance on memory. Avoid hidden assumptions, for example, that encourage patients to be involved in site-marking process as it assumes the patient is physically, cognitively, and emotionally able to correct any errors.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Sexton 2006[30]	Teamwork climate in OR – preverification process	Noncomparative study	Safety Attitudes Questionnaire Survey	2,135 OR caregivers in a 60-hospital health system, including surgeons, surgical technicians, anesthesiologists, CRNAs, and OR nurses.		A high level of teamwork was perceived by the attending surgeons (64%) and residents (74%), which was markedly different from the attending anesthesiologists (39%), surgical nurses (28%), anesthesia nurses (25%), and anesthesia residents (10%). When attending surgeons were asked about a fellow, resident, or medical student questioning their decision, 45% of attending surgeons indicated that hierarchical systems should be in place, compared to 94% of airline crew members who preferred no hierarchies (Sexton et al., 2000). When asked the question, "Even when fatigued, I perform effectively during critical times," the surgical team response ranged from 47% to 70% in agreement, compared with 26% of pilots who agreed with this statement (Sexton et al., 2000).