PA PSRS Pennsylvania Patient Safety Reporting System

Patient Safety Advisory

Produced by ECRI Institute & ISMP under contract to the Patient Safety Authority

Doing the "Right" Things to Correct Wrong-Site Surgery

A patient was summoned from the waiting room by name for an epidural injection. The nurse escorted the patient to an examination room and verified allergies consistent with the patient's history and physical. The physician entered and identified the patient by her first and last name. The patient responded affirmatively. The physician reviewed the procedure and obtained the patient's informed consent for injection, with a registered nurse as witness. The operating room [OR] nurse entered and identified the patient by name, and the patient again responded affirmatively. The patient gave the nurse a telephone number of her ride home, and the nurse spelled the patient's last name, and the patient responded affirmatively. The patient was taken to the pain procedure room, and the consenting physician performed an epidural steroid injection procedure. The patient was taken to recovery for discharge instructions, at which point she stated, "All this to have a tooth out." At that point, the patient's true identity was determined, and she was discharged from the ambulatory surgical facility and taken to the adjacent oral surgery practice for the intended treatment.

Wrong-site surgery has been considered an exceedingly rare adverse event that may have devastating consequences to both the patient and the healthcare team when it does occur.[1] Kwaan et al.[2] estimated it occurs in 1 of 112,994 operations, based on reports to a medical malpractice insurer. However, PA-PSRS data indicates that wrong-site serious events and near misses occur more frequently. Since the inception of PA-PSRS, more than 400 wrong-site reports have been submitted, or an average of 1 wrong-site surgery report each year in a 300-bed hospital.

A review of the Physician Insurers Association of America's closed claims files between 1985 and 1997 revealed that the average indemnity payment for wrong-site surgery was $54,790.[3] Recent anecdotal evidence of the financial penalty of wrong-site surgery is more significant. For example, we located the following two incidents from 2005 using an Internet search engine. One involved wrong-side arthroscopy for which a choreographer in New York was awarded $450,000.[4] The other involved removal of the wrong cervical disc for which a man in Wyoming was awarded $1,175,000.[5]

Because wrong-site surgery is also preventable, the National Quality Forum (NQF) has listed it as one of its serious reportable events (colloquially called "never events"),[6] and the Joint Commission requires the reporting of wrong-site surgery as a sentinel event.[7] Only Pennsylvania requires reporting of near-miss events that do not harm the patient, and these provide insight into the causes and potential recovery mechanisms for this chronic problem.

This article compares experiences reported to PA-PSRS, such as the one above, with information based on the experience of others. A more detailed scientific analysis of the PA-PSRS experience will be published in the *Annals of Surgery* this fall; until then, the article will be available to subscribers at http://www.annalsofsurgery.com under "Ahead of Print."

Definition

Wrong-site surgery involves all surgical procedures performed on the wrong patient, wrong body part, wrong side of the body, or wrong level of a correctly identified anatomic site.[2,3] Wrong-patient surgery may include patients who were never scheduled for a procedure, procedures performed that were not scheduled, and procedures scheduled correctly in which a different one was performed.[3]

Incidence

Since its inception in June 2004 through December 2006, 427 reports were submitted to PA-PSRS that reflected some aspect of wrong-site surgery (i.e., about one report every two days). More than 40% of

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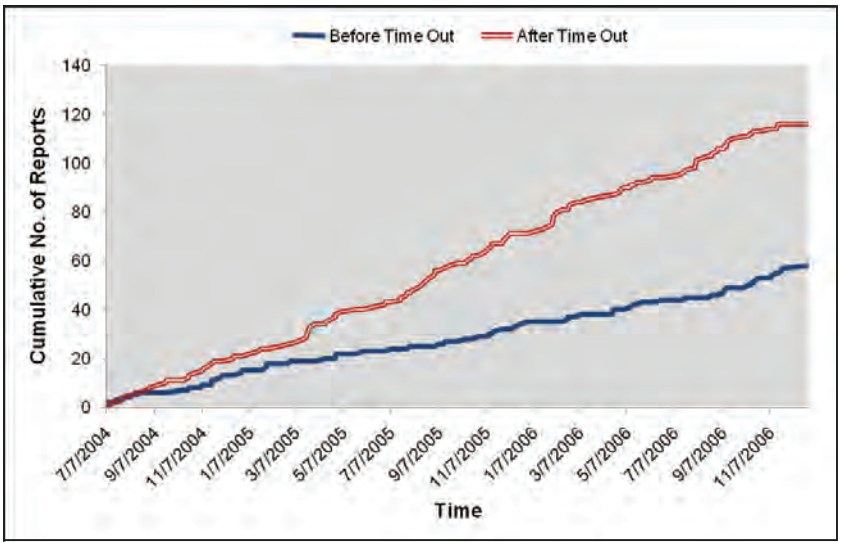

Figure. Cumulative Frequency of Events.
There has been no reduction in the frequency of wrong-site surgery reports submitted to PA-PSRS since 2004. Of the wrong-site surgery reports submitted to PA-PSRS, 174 reached the patient. 2004 was the implementation year for both PA-PSRS and the Joint Commission universal protocol.

"Before time out" means the event occurred before the team performed the time out, prior to incision (e.g., the anesthesia block).

"After time out" means the event occurred after the team performed the time out, prior to incision.

these errors actually reached the patient, and nearly 20% actually involved completion of a wrong-site procedure. Reports were submitted from about one of every three acute care hospitals.

The Joint Commission implemented the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ in 2004.[8] PA-PSRS was also implemented in 2004. Since that time, however, there has been no reduction in the frequency of wrong-site surgery reports submitted to PA-PSRS (see Figure).

The actual incidence of wrong-site surgery is unknown.[9,10] Several studies, however, provide some insight as to the scope of the problem (See Table 1).

Types of Errors Reported

More than two-thirds of the wrong-site reports submitted to PA-PSRS involved actual or potential wrong-side errors. The most common sites involved in wrong-site surgery were procedures related to lower extremities.

From 1995 through 2003, wrong-site surgery sentinel event reports submitted to the Joint Commission included the following types of errors: wrong site (76%), wrong person (13%), and wrong procedure (11%).[11]

Specialty

Joint Commission's evaluations of 126 root cause analyses (RCAs) revealed the following specialties were most commonly involved in reported wrong-site surgeries:[11]

- Orthopedic/podiatric (41%)
- General surgery (20%)
- Neurosurgery (14%)
- Urology (11%)
- Maxillofacial, cardiovascular, otolaryngology, and ophthalmology (14%)

PA-PSRS reports do not identify providers, but few anatomic structures were spared the potential for wrong-site surgery, and no surgical specialty was immune from error. Most wrong-side surgeries involved symmetrical anatomic structures: lower extremities (30%), head/neck (24%), and genital/urinary/pelvis/groin (21%).

Setting

Joint Commission data[11] indicates that the settings in which sentinel event wrong-site surgery occurs are ambulatory surgery (58%), inpatient ORs (29%), and other inpatient sites such as emergency departments and intensive care units (13%).

PA-PSRS reports of both serious events and near misses reveal that 85% of the reports were submitted by hospitals and only 15% were reported by ambulatory surgical facilities.

Incidence

Reported rates may not provide a true reflection of the incidence of wrong-site surgery. Incidence rates based on insurance claims and reports of malpractice carriers underestimate the true rate because not all wrong-site surgery cases are reported to insurance companies.[12]

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Source	Time Frame	No. of Wrong-Site Surgery Cases	No. of Closed Claims	Rate	Comments
Survey of Hand Surgeons[1]	—	—	—	—	21% reported having at least 1 wrong-site surgery during career
Physician's Insurance Association of America[2]	10 years (1985 to 1995)	331	1,000	—	—
State Volunteer Mutual Insurance Company of Tennessee[2]	20 years (1977 to 1997)	37	—	—	—
Hand procedures[3]	—	—	—	1:27,686	—
Survey of Orthopedic Surgeons[4]	—	—	—	—	1 of 4 surgeons practicing for 35 years reported having at least 1 wrong-site surgery
National Patient Safety Agency—National Reporting and Learning System[5]	14 months	7	—	—	5 were prevented before surgery
Washington University School of Medicine, St. Louis, Missouri[6]	—	—	—	1:17,000	4,000 wrong site surgeries in United States each year; third most frequent life-threatening medical error
Kwaan et al — review of large malpractice insurer wrong-site surgery nonspine surgery cases[7]	19 years (1985 to 2004)	—	—	1:112,994	1 wrong-site surgery claim or lawsuit filed once every 5 to 10 years at a single hospital
National Practitioner Data Bank[8]	13 years (1990 to 2003)	5,940: 2,217 wrong side, 3,723 wrong treatment/procedure	—	—	Approximately 400 cases per year
Florida Code 15 Occurrences[8]	12 years (1991 to 2003)	494	—	—	Average 75 per year since 2000; 1 per 51,540 cases in Florida; estimate 1 per 1,466 cases in United States per year
ASA Closed Claims Project[8]	—	—	54	—	—
New York Patient Occurrence and Tracking System[9]	2001	—	—	1:15,500	—
Virginia[9]	—	—	—	1:30,000	—
Minnesota Department of Health Wrong-Site Surgery Adverse Health Events					
• Second Annual Public Report[10]	1 year (10/7/2004 to 10/6/2005)	26	—	—	—
• Third Annual Public Report[11]	1 year (10/7/2005 to 10/6/2006)	31	—	—	—
PA-PSRS	2.5 years (6/7/2004 to 12/31/2006)	427	—	—	Near misses and adverse events: estimate 1 each year in a 300-bed hospital

Table 1. Wrong-Site Surgery Incidence. (Citations appear on page 15.)

The same is true for estimates based on incident reports.[13] For example, during a six-year period, the Joint Commission received 114 wrong-site surgery sentinel events that were self reported from patient complaints, the press, and other sources.[13] During a two-year period, however, the New York State Department of Health received 46 wrong-site surgery reports through its mandatory reporting

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system.[13] This suggests that voluntary incident reporting may underestimate the true incidence of this error by a factor of at least 20.[13]

Moreover, the Joint Commission has received an increase in wrong-site surgery sentinel events over the years. This may reflect a greater awareness of the problem, more openness in reporting such events, and/or better reporting systems rather than an increase in actual occurrences.[8,13]

System Breakdowns

Contributing factors involved in wrong-site surgery reported to PA-PSRS were the following:

- The actions of the surgeon in the OR (e.g., specifying the wrong site)
- Not completing a proper time out
- Anesthesia interventions prior to a time out
- Not verifying consents or site markings
- Inaccurate consents/diagnostic reports/ images
- Patient positioning (either concealing the surgical mark or promoting site confusion)

In reports to PA-PSRS, wrong-site surgeries frequently occurred despite site verifications with the patient, marking the site, and apparently proper time outs.

Recovery

Near-miss reports indicated the following factors that prevented wrong-site surgery from occurring:

- The surgeons and nurses verifying consent/ medical record
- The surgeons and nurses conducting verification procedures in the preoperative holding area
- The patients providing correct information
- The circulating nurses providing correct information

Ensuring the correct surgical site involves a series of processes involving many healthcare personnel in multiple locations. Such complexity makes operative site verification prone to error.[14]

PA-PSRS Examples

Here are some examples from PA-PSRS reports that illustrate just a few system breakdowns relating to surgical site verification, grouped by how the error was initiated.

Receiving incorrect information from a source outside the OR:

> *During time out, during prep, and in holding, all paperwork and patient/family, and consent identified surgery was to take place on right foot. In the OR, films from outside hospital identified foot as left. C-arm was brought in and right ankle was confirmed. Films from outside hospital had lead markers reversed, so that the right ankle film was marked as left. No harm to patient.*

> *A patient underwent a thyroidectomy based on pathology results of a needle-guided biopsy of the thyroid that indicated malignancy. Pathology examination of the thyroid, however, indicated no cancer. Investigation suggested that tissue pathology results for two patients were switched at dictation.*

Wrong information communicated in the operative suite:

> *A patient stated she was having YAG laser surgery on her left eye. Drops were instilled to dilate the eye preoperatively. Upon further conversation with the patient and the patient's attendant, it was stated that the procedure was to be performed on the right eye. Upon review of the patient's chart, it was noted that the right eye was the operative eye. Eye drops were then instilled in the right eye.*

> *The physician told the nurse, "We're doing the right side." The consent was completed accordingly. Time out was completed. After injection, the physician realized the patient was having more pain on the left side, which is what the physician originally wanted to do.*

Wrong position, prepping, draping:

> *A patient was taken urgently to the OR for burr hole evacuation of a left-sided subdural hematoma. Despite completing the time out procedure prior to the prep, the patient's head was positioned with the right side up instead of the left. The right side of the head*

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was prepped, and the initial skin incision was made when it was determined that the surgical site was incorrect. The incision was sutured. The patient was then correctly positioned for left-sided burr holes, and the procedure was completed without further incident.

Patient consented to removal of rheumatoid nodules of posterior aspect of left heel. Left foot was marked for surgery. The patient was taken to the OR and placed in prone position. The podiatric resident applied a tourniquet to the right foot, and surgery was completed on the right heel.

Site marking failures:

During the preoperative interview, the patient and family member pointed out the operative site for wide excision of melanoma to the nurse. The patient was to have injection of the lesion preoperatively with radioactive contrast to tract lymphatic drainage, then go to the OR for wide surgical excision of the lesion and lymph nodes. The nurse marked a spot remote from the lesion with an "L" to signify the left side of the patient as the operative side. The radiologist injected the patient at the site of the "L" rather than the site of the lesion. Therefore the lymphatic drainage related to the lesion was not traced.

The patient identified the eye to be operated on in pre-op as the right eye. The pre-op nurse noted that the right eye was identified on the consent form, and he documented the site with an "X" above the right eye with a surgical marker and on the preoperative assessment form. The patient went to the OR. A time out was performed by the circulating nurse verifying patient identification, allergy, procedure type, and location. The surgeon verified patient identification. No scrub nurse was present as the physician fellow completed the scrub and drape. Anesthesia flowsheet and post-op note indicated surgical site as right eye. When patient was in PACU, nurse identified surgical site as left eye.

The patient was placed on OR table. Time out occurred immediately prior to the procedure, but the patient was not marked. Physician inserted a K-wire into the third metacarpal. After the patient was x-rayed, it was discovered that the K-wire was inserted in the wrong finger. The K-wire was removed and inserted into the correct finger.

Patient consented to right Achilles repair and left metacarpophalangeal joint (MPJ) procedure. Patient was identified, time out done, and surgical sites were marked appropriately with patient lying on back. Patient was turned to lie on stomach, removing site markings from visual field, and the procedures were performed in reverse.

Time out failures:

During exploration, a right healthy kidney was identified. Surgeon then requested MRI findings to be read. MRI indicated possible carcinoma left kidney. The patient was repositioned, reprepped, and appropriate surgery was performed on the left kidney.

A patient was scheduled for a right-knee arthroscopy. A time out procedure was done prior to the patient's limb being placed in the limb holder. After the time out was done, the surgeon placed the left leg in the limb holder. The needle was inserted into the left knee. Then the surgeon noted the procedure was to be on the right knee, and the needle was withdrawn.

The patient was to have a left wrist ganglion excised. Prior to doing a time out, the surgeon picked up the scalpel and started to make an incision into the left palm for a carpal tunnel procedure. The OR team stopped the surgeon. An 8 mm incision had been made and was sutured by the surgeon. The OR team then conducted a time out, and the left wrist ganglion was excised.

The patient was to have a cyst removed on the tip of the right fifth finger. No surgical site verification occurred prior to the procedure. During surgery, the unsedated patient questioned a pressure sensation in the palm of the hand and stated that the site of the cyst was on the tip of the fifth finger. The surgeon sutured the incorrect incision and proceeded to complete the cyst excision.

PA-PSRS reports also indicate successful wrong-site recoveries that prevented patient harm:

When the patient arrived in the holding area, the surgeon marked the patient's left side. A

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review of the consent, OR schedule, and discussion with patient's decision makers determined this site to be incorrect. The surgeon came back to the holding area and marked the correct side, and the incorrect mark was removed. After matching the schedule, consent, side re-marking and re-discussion with patient's decision maker, the patient was taken to the OR.

The pre-op nurse was reviewing the chart of a patient scheduled for surgery the next day. The nurse noted that the consent and OR schedule did not match. Investigation showed that the information was from two different patients, and the wrong procedure had been scheduled by the office. The OR schedule was corrected prior to the final print out for the next day.

The physician's office scheduled a patient via reservation form for a manipulation under anesthesia of the right knee. During the preoperative admission process, it was noted that the patient was to have a manipulation of the right shoulder. The surgical electronic documentation system had already prepopulated the procedure field as manipulation of right knee. The pre-op nurse notified the OR and anesthesia to inform them of the error, and the correct procedure was done on the patient. The electronic record later had an addendum added to indicate the correct procedure.

Risk Factors

The Joint Commission[3] and Rogers et al.[15] have described why certain causes of errors create barriers to compliance with a site verification protocol, based on RCAs and direct observation, respectively. Many of these causes are reasons for other errors as well.

Emergency Cases

When actions are implemented urgently, usual procedures are less likely to be completed. Because of the patient's medical condition, there may not be time to adequately identify or prepare the patient, or to complete the site verification process.[3]

Unusual Physical Characteristics/Equipment Set Up

Morbidly obese patients or those with physical deformities may require additional staff, special equipment, changes in patient positioning, or other accommodations that are not routinely used. This variation from the routine may increase the risk of surgical site error.[3]

While the surgical team may be familiar with equipment to be used, unique patient physical characteristics may require the set up of equipment in unusual, non-standard fashion, which may also increase the risk of error.[3]

Multiple Procedures and/or Multiple Surgeons

The risk of wrong-site surgery increases

- if more than one primary surgeon is in the OR;
- if care is transferred from one surgeon to another; or
- if multiple procedures are performed during one surgical encounter, especially when these procedures are scheduled/performed on different sides/areas of the body.[3]

Surgeon Characteristics

It has been suggested that because most people are right-handed and equipment set-ups are usually set up for right-handed personnel, reversal of set-ups for left-handed surgeons may contribute to wrong-site surgery.[3]

Time Pressures

Perioperative time pressures are created by the facility, the surgeon, and other members of the healthcare team. Site verification protocols have their greatest impact on preoperative procedures and, therefore, time pressures are likely to negatively affect the full implementation of such protocols.[3,16] Such pressures occur in the following scenarios:

- Fast-moving environment (e.g., the need to complete procedures more quickly, quick turnover times)[10,17]
- Delayed start time to initiate the surgical procedure (e.g., a previous procedure takes longer than expected)[10,18]

Communication Breakdowns

The root cause in more than 70% of the wrong-site surgery sentinel events reported to Joint Commission involved communication breakdowns.[3,19] Breakdowns may include failure to

- involve the patient and/or family member/significant other in identifying the correct operative site;[3]

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- communicate between surgical team members, such as when team members fill unfamiliar roles;[3]
- communicate or share correct information;[10]
- understand correct information[9,10] (e.g., "right" interpreted as laterality/side or "correct," language/accents prevent understanding); and
- communicate changes in information/correction of errors to the whole healthcare team.[9]

Incomplete Preoperative Assessment

Assessment may not include a review of the medical record or imaging studies immediately preceding the operative procedure because the documents are unavailable or documents are present in the OR but not reviewed.[3]

Inadequate Procedures to Verify Correct Surgical Site

Correct-site surgery cannot be promoted if facility policies and procedures:

- Lack a formal site verification procedure[3]
- Lack a standard oral communication process to verify the correct site[3]
- Lack a formal check in the OR immediately before starting the procedure[3]
- Do not require the presence and review of relevant information sources in the OR[3]
- Lack a standard checklist to ensure that all appropriate information is present and reviewed in the OR[3]
- Exclude some or specifically do not include all members of the surgical team in the site verification process[3]
- Place complete reliance on the surgeon to verify the surgical site[3]
- Lack cross checking to confirm consistency of the surgical site by comparing the consent, schedule, medical record notes, and imaging reports[15]
- For ambulatory surgery, not using the outpatient/community healthcare setting as a primary source for site verification (This is where the patient is awake and alert, and diagnostic reports are available. In this setting, surgery is scheduled, surgical consent is signed, and there is an opportunity to collect and review multiple documents that each list the surgical site and procedure.)[15]

Organizational Culture[3]

If the informal cultural norms include the following, wrong-site surgery may not be prevented:

- Attitude that a surgeon's decision should never be questioned
- Lack of teamwork
- Opinion that certain surgical team members or the patient are not important to the surgical site verification process

Care Processes

In a study involving more than 40 hours of direct observation of the entire care process conducted in two hospitals, Rogers et al.[15] identified the following factors that may contribute to wrong-site surgery.

Site marking.[15] Permanency of marking may be problematic. If marking occurs too far in advance of a procedure, normal activities of daily living may remove the mark. The mark may also be removed during the surgical prep immediately prior to the operative procedure. If the mark is too permanent, this may be unacceptable to the patient. Moreover, an incorrect marking made in permanent ink may be difficult to remove. Finally, if a patient touches a marked extremity to another part of the body, an additional mark can be inadvertently transferred to the incorrect body site/part.

When multiple surgeons or multiple procedures are planned, the complexity of site marking increases, and errors can occur if standard marking procedures are not followed. The risk of incorrect marking also increases when there is no visible sign of disease or when both sides seem to be equally involved.

Patient/family involvement.[15] Several factors may prevent successful collaboration with the patient/family in the site verification process. For example, if the site verification/marking occurs only in the OR, the sedated patient may not have the capacity to contribute accurately to the site verification process.

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Patient/family participation in site verification may be impaired by the following:

- Cognitive problems (e.g., anxiety, confusion, dementia)
- Medications/sedation
- Time pressures (e.g., sense that staff is harried)
- Generational/cultural issues (e.g., passive recipient of care, belief that healthcare team must be correct)
- Level of understanding (e.g., medical vocabulary, literacy level)
- Physical limitations (e.g., ability to hear in a noisy environment without hearing aids or to see without eyeglasses)
- Physical condition of the patient that may impair the patient's ability to discuss/identify correct surgical site (e.g., severe pain; stroke; severe liver, respiratory, or renal disease)

Change management. Rogers et al.[15] also identified the concept of change management as a potential problem when observing site verification processes. When a mistake is made in the documents that initiate the surgical process (history and physical, handwritten or dictated notes, OR schedule, consent), there is no consistent process to track or to change all the documents involved in the site verification process.

This issue was also highlighted by another study conducted at an ophthalmic hospital in the United Kingdom[20] involving the review of the clinical notes of 100 randomly selected patients. The notes were analyzed to determine the number of left/right transpositions that occurred, in which part of the notes, and whether these errors were corrected. Forty-four transpositions were found in 32 sets of notes, but only 19 of these errors were corrected. While no wrong-site surgery actually occurred in this study, such transpositions could increase the likelihood of wrong-site surgery if other preventive mechanisms fail.[20]

Protocols

Joint Commission

In May 2003, the Joint Commission hosted a Wrong Site Surgery Summit in an effort to reach consensus on adopting a universal protocol for preventing wrong site, wrong procedure, and wrong person surgery. The protocol was approved by the Joint Commission Board of Commissioners in July 2003. More than 50 professional associations and organizations,[21] including the American Academy of Orthopaedic Surgeons (AAOS),[22] North American Spine Society (NASS),[23] and NQF,[24] have endorsed it. Moreover, the universal protocol has become part of the Joint Commission's National Patient Safety Goals.[25]

Elements of the protocol include a standardized approach for the following:[8,11,23,25]

- Verifying the patient's identity
- Marking the surgical site and requiring patients or a legally designated representative to be involved in the marking procedure
- Using a preoperative site verification process such as a checklist
- Confirming the availability of appropriate documents and studies before the start of the procedure
- Taking a brief time out immediately before skin incision, in which all members of the surgical team actively communicate and provide oral verification of
  - patient's identity;
  - surgical site;
  - surgical procedure;
  - administration of preoperative medications; and
  - presence of appropriate medical records, imaging studies, and equipment
- Monitoring compliance with protocol recommendations

The protocol is designed to be flexible so it can be adapted to meet specific patient needs, operations and other invasive procedures, including those performed in settings other than the OR.

The universal protocol is organized into three phases:[8,10,25]

1. Preoperative verification process.
   In this phase, all relevant documents/studies are available for review for consistency with each other, the patient's expectations, and the surgical team's understanding of the

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patient, procedure, site, and implants. Missing information/discrepancies are addressed. Ongoing information gathering and verification occurs from determination to do the procedure through the time out.

2. Marking the operative site.
   For left/right distinction, multiple structures, and multiple levels, the intended site is marked so that the mark is visible after the patient is prepped and draped. The site is marked unambiguously. Site marking must be[26]
   - — marked by a physician with his/her initials or "yes," never with an "X";
   - — never marked on the nonoperative site;
   - — marked and numbered for multiple wounds/lesions; and
   - — visible after the patient is prepped and draped.

Adhesive site markers may be used as an adjunct, but cannot replace direct marking of the skin.[26]

3. Time out — immediately before starting the procedure.
   This phase includes final verification of the correct patient, procedure, and site. The phase is initiated by a designated team member. Active communication occurs among all surgical/procedure team members. Finally, the phase is conducted in a "fail-safe" mode — the procedure is not started until questions/concerns are resolved. The time out includes a check for the presence of implants, special equipment, and instruments.

The following procedures are exempt from the preoperative marking process, but must still have a time out:[26]

- Single organ cases
- Interventional procedures with sites/ insertions that are not predetermined and can be either left or right
- Premature infants

Procedures done at the bedside require marking and a time out.[26]

Other Protocols

A vast array of site verification interventions exist throughout the world. Table 2 presents the elements of a variety of these protocols. Common strategies evident in most of these protocols include[15] marking the surgical site and using a standard checklist to capture information related to the site verification process. Another common element involves using active, in addition to passive, communication: by the patient/family/significant other/designated responsible person in marking and/or verification of the surgical site; by each member of the surgical team in the OR for verification; and through a time out to confirm the correct patient, procedure, and surgical site. Monitoring compliance with site verification procedures is another common element.

Resources

The Association of periOperative Registered Nurses[16] has developed several resources to help facilities implement a correct surgical site protocol consistent with the Joint Commission. These include an educational program, a reference card, a checklist, FAQs, form letters, and other items. Information about these resources is available at http://www.aorn.org/PracticeResources/ToolKits/.

Reported Risk Reduction Strategies

Several healthcare organizations have developed strategies that support or supplement the interventions specified in the universal protocol.

A few examples include the following:

Institute for Healthcare Improvement (IHI)

Through many collaboratives, IHI has developed several measures to reduce the risk of wrong-site surgery, based on general error reduction strategies.[10,27] A checklist can be used to reduce reliance on memory and vigilance. Policies, procedures, and competencies promote standardization. For online records, required fields provide forcing functions to ensure that proper identification and verification are documented. Having the same personnel move/transfer patients reduces handoffs. Establishing a review mechanism for identifying system errors to reduce errors, rather than focusing on individual blame, drives out fear and encourages error reporting.

Partnership for Health and Accountability — Georgia

The "Operative/Invasive Procedure Verification Checklist"[28] has been creatively organized to capture laterality of site verification information. Left-side procedure verification is documented on the left column of the checklist, while right-side information is documented on the right column. Site verifications that do not involve laterality are documented in the center column of the form.

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Major Elements	Organization								
	Canadian Orthopaedic Association[1]	Joint Commission[2-5]	National Patient Safety Agency (UK)[6-7]	Veterans Administration, Department of Veterans Affairs[8-9]	Tennessee Improving Patient Safety[10]	Institute for Clinical Systems Improvement[11]	New York State Department of Health[12]	VHA, Inc.[13]	Partnership for Health and Accountability—Georgia[14]
Scheduling				✓		✓	✓	✓	
Preoperative verification	✓	✓	✓	✓	✓	✓	✓	✓	✓
Consent	✓	✓	✓	✓		✓	✓		✓
Site marking	✓	✓	✓	✓	✓	✓	✓	✓	✓
Time out/pause		✓	✓	✓	✓	✓	✓	✓	✓
Verification checklist		✓	✓	✓	✓	✓	✓		✓
Policies/procedures		✓		✓		✓	✓	✓	✓
Monitoring		✓			✓	✓	✓	✓	✓

Table 2. Elements Included in Selected Correct Surgery Protocols. (Citations appear on page 15.)

VHA, Inc.

VHA, Inc. has developed the "Seven Absolutes to Avoid Surgical Site Errors" to standardize and simplify the site verification process.[29] The following concepts are included.

Preoperatively:

1. The surgeon's office schedules each procedure involving laterality with a right or left designation.

2. The registered nurse (RN) verifies each correct surgery site with the OR schedule and the patient's current medical record.

3. The patient, designee, or hospital care provider verifies each surgical site in the presence of an RN and when applicable will mark each side (right or left).

4. The circulating RN and anesthesia provider interview the patient and review the patient's current medical record to verify each surgical site and procedure.

Intraoperatively:

5. The circulating RN, anesthesia provider, and surgeon review the patient's medical record and the results of the diagnostic tests and verbally confirm each site.

6. After the patient is draped, the surgical team pauses and verbally confirms each site prior to incision.

7. The circulating RN documents the verification process in the patient's medical record.

When performing multiple procedures, repeat the fifth through seventh steps for each additional procedure.

For unmarkable sites (e.g., urology; ear, nose, and throat pediatric cases), colored wristbands can be

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used on the operative side/site with the following information on them: surgical site, person placing the wristband, initials, date, and time.

Preoperative Briefing: PREPARETOR
John M. Purvis, MD, developed the following PREPARETOR site verification protocol, which was a winning submission in the 2004 AAOS Patient Safety Tip Contest.[23] The use of an mnemonic reduces reliance on memory.

During preoperative holding:

*P*rocedure/*P*lan	Discuss everything with the OR team
*R*adiology	Images in the room, equipment requested
*E*quipment	Implants and supplies available and in working order
*P*atient	Correct patient: check ID bracelet, surgical site mark
*A*nesthesia	Be aware of surgical plan, positioning, special needs (e.g., hypotension)
*R*x given	Prophylactic antibiotics, patient-specific needs
*E*xceptions	Any special considerations

During surgery/in OR:

*T*ime *O*ut	Check patient identity, records, imaging, surgical procedure, site marking
*R*adiograph	Confirm level with intraoperative radiograph

Time Out Script
Glenbrook Hospital in Illinois developed a script to reduce communication inconsistency during the time out process prior to the start of each invasive procedure.[30] This standard phrasing is used for every time out by every circulating RN in the system. The script includes six necessary elements of the time out, and it also ensures that all members of the surgical team actively participate.

Newcastle General Hospital, United Kingdom
This hospital universally applies a method called "knife check" as part of its site verification process.[31] The scrub nurse does not hand the surgeon the scalpel for incision until after final site verification is completed.

PA-PSRS
One wrong-site surgery report submitted to PA-PSRS resulted in a subsequent procedure change. Now, the scrub person does not place a blade onto the scalpel handle until a time out is satisfactorily completed.

NASS
NASS was one of the first professional organizations in the United States to develop a protocol to prevent wrong-site surgery, known as the SMaX Campaign (Sign, Mark, and X-ray).[23] One tool of this campaign is a "Patient Diagnosis Diagram" that is given to the patient by the surgeon during the preoperative discussion.[32] The surgeon indicates the pathology on the spinal diagrams and documents the plan for the proposed surgery. The patient can share this document with other healthcare providers, such as physical therapy. The patient can also bring this form to surgery, and it provides an additional check of the side and level of the anticipated surgical procedure. NASS now endorses the Joint Commission universal protocol, as well.

Technology
Certain technologies have been developed that may have a positive impact upon ensuring correct-site surgery.[33,34] However, further study is needed to determine their appropriateness and efficacy in the surgical services environment.[15]

Additional Site Verification Considerations
Even though the Joint Commission universal protocol has wide acceptance, there is great variability in the ways facilities interpret the protocol.[12] For example, Kwaan et al.[2] reviewed 16 site verification protocols covering 28 hospitals. One area of inconsistency in these protocols related to site marking; specifically, which cases require it, who is responsible, and how is it performed.

The following concepts may contribute to system reliability, resulting in fewer site verification errors and adverse events.

Simplicity
Many protocols require significant staff time and several, redundant checks (up to 20 checks per patient).[2] A simple site verification protocol is more likely to promote compliance, efficiency, and system reliability than a complex protocol involving multiple redundant checks.[2,35]

Doing the "Right" Things to Correct Wrong-Site Surgery (Continued)

Preoperative Verification Process

Greater accuracy results when verification involves two patient identifiers, as well as the procedure and the site/side or vertebral level.[2,35] Room number is not a patient identifier.[35] The verification process involves at least two healthcare staff (one of whom is the surgeon) and the patient.[2,31,35] Staff members can compare the OR schedule, the informed consent, and all available imaging studies to determine whether inconsistencies exist.[2,35] A time out that includes all surgical team members before the incision provides final verbal verification and direct observation of the correct site.[2,35]

Site Marking

The surgeon or designee marks only the correct site with initials or "yes."[2,35] The site is specified in a clear, unambiguous, indelible, and hypoallergenic method.[35] Written policies and procedures need to clearly indicate when, how, and by whom the site is marked.[2]

Patient Involvement

Involve the patient during site marking, verification, and consenting.[12] Performing a mini-mental status examination will identify patients who need family members or designated representatives to act as a surrogate in the verification process.[15]

Patient involvement can be enhanced by preoperative education. Explaining to patients what is done and listening to their questions/concerns is an important intervention to reduce site verification errors.[20] Patients can be informed that they will be asked to identify the surgical site several times before surgery.[36] A patient brochure describing what is correct-site surgery protocol can be provided, such as the one developed by the American College of Surgeons.[37]

Distractions

Because of the critical nature of surgical/invasive procedures, all surgical team members should be focused on the work at hand and distractions minimized.[31]

Checklists

Checklists promote standardization and reduce reliance on memory. They ensure that all information and site verifications are completed before incision — during the preoperative period until just before the time of the incision.[3,35] Simple, flexible checklists may be more likely to be completed.[31]

Verification Discrepancies

A site verification protocol specifies how inconsistencies are resolved before the procedure is begun.[2,35] Inconsistencies are resolved by the surgeon with agreement of the patient/decision maker and another member of the healthcare team.

Documentation

Many initial site errors begin with documentation in the outpatient/office/clinic notes prior to surgery and are carried through in incorrect OR scheduling or radiology reports.[12] Steps to ensure site verification in these settings will ensure correct-site surgery. One method is to note the correct site whenever documentation entries are made.[3] The informed consent should be specific concerning laterality, vertebral level, or which multiple structure (finger, toe, tooth).[2,35] The procedure listed on the OR schedule also must contain comparable detail.[2]

Critical Patient Information, Updates, and Changes

Such information needs to be visible for the entire surgical team to see to facilitate a reduction of reliance on memory, team coordination and communication, change management, and cross-checking.[15] A standard method of managing changes to this data will ensure that it will not be overlooked.[15]

Teamwork

Each member of the team should be permitted to question the decision of any other team member concerning such issues as patient identity, procedure, site, and equipment/implant availability.[3] An anesthesia care provider should be involved in determining the correct surgical site. This healthcare team member may be the only person in the OR whose view of the patient is the same as his/her physical orientation.[3]

Briefings and debriefings were shown to improve the culture of teamwork, thus enhancing communication and collaboration in patient safety.[38]

Double Checks

Double checks reduce reliance on the memory of surgeons.[15] Such checks involve the patient to verify the site and procedure before the surgical procedure and before anesthesia/sedation.[3] Conferring with staff about the proper site, room set up, and equipment/implant ensures the team is properly prepared for the procedure.[3] Reviewing documents and imaging and conferring with radiologists, if needed, to reread previous imaging studies or to interpret intraoperative studies further ensures that the procedure is conducted at the correct site.[3]

Monitoring

Monitoring the compliance with the site verification protocol will identify opportunities for system

Doing the "Right" Things to Correct Wrong-Site Surgery (Continued)

improvement, which can improve the effectiveness of the protocol and, with this, patient safety.

The following are examples of measures of performance concerning wrong-site surgery:[28,39]

- Outcome measures: The rates/numbers of reports related to surgeries performed on the wrong body part, wrong patient, and wrong procedure per month; the rates/numbers of near misses reported per month.

- Process measures: The percentage of
  - patients with documentation of verification of correct patient, correct site/side/level and correct procedure;
  - patients whose site was marked by surgeons preoperatively;
  - cases in which active verbal time out was conducted by all members of the surgical team prior to incision;
  - patients who had all required components of the site verification protocol met; and
  - surveys of surgical team evaluations of teamwork/collaboration, patients' involvement in surgical site verification process, and communication with the surgical team.

Feedback can be provided to all personnel involved in surgical/invasive procedures and integrated into the leadership dashboard, including the following:

- Compliance with site verification protocols

- Evidence of education/training/competencies of caregivers, including medical staff who participate in operative and invasive procedures

- Percent of individuals completing initial and refresher education/competency sessions concerning site verification processes

Limitations of Site Verification Protocols

Considering the number of wrong-site surgery protocols published in the literature, little scientific evidence exists concerning the effectiveness of surgical site verification interventions analyzed in a controlled observational design or a clinical trial.[2,13] The most widely published outcome measures are the number of insurance claims/litigation cases of wrong-site surgery, retrospective reviews of medical record information, and surveys. Because it is not known to what extent reports and malpractice claims/litigation reflect the actual incidence of wrong-site surgery, it is not possible to accurately measure what effect site verification protocols have on improving patient safety.[10]

Wrong-site surgery has been addressed locally in many areas of the country. Moreover, no evidence supports a specific approach to surgical site verification. The existence of different protocols may itself contribute to increased confusion and the likelihood of error.[13] The Joint Commission universal protocol is endorsed widely and is the closest to a national standard to eliminate wrong-site surgery at this time.[40]

Written checklists are also prone to errors, such as skipping steps because of interruptions, distractions, and time pressures, as well as checking an item when it was not, in fact, completed.[2] Redundant checks can decrease errors only if each is independently performed. Multiple checks, however, may not be completed if they are perceived as ineffectual "busy work."[41] The fast pace of patient flow may promote the view that violating the protocol to save time is acceptable or necessary.[2]

Focusing on a single process component, such as surgical site marking or the time out, rather than considering wrong-site surgery prevention processes as a whole, cannot prevent wrong-site surgery.[13,23,26] Multifaceted protocols — combining standard site marking methods with collaborative processes for verification by all members of the surgical team — should be implemented within the context of planned observational studies.[13]

Conclusion

Wrong-site surgery errors must be viewed in the context of human limitations, not as failings of individuals. Incidence of errors is a sign of breakdown in the system and teamwork. Disciplinary action will not prevent these system errors. Changing the culture from culpability to one founded upon human factors engineering,[42] group dynamics,[41] and the psychology of errors[31] will separate the mistake from the blame. Studying the psychology behind the errors will more effectively identify factors that can optimize work systems, reduce stress, improve performance, prevent or detect system breakdowns before they occur, and thereby improve patient safety.

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Doing the "Right" Things to Correct Wrong-Site Surgery (Continued)

Visit the Patient Safety Authority Web site (http://www.psa.state.pa.us) to view or download "Doing the 'Right' Things to Correct Wrong-Site Surgery," a brief informational video based on this article. Click on "Advisories and Related Resources" in the left-hand column of the Authority's home page. Then, click on "Resources Associated with Patient Safety Articles."

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Self-Assessment Questions

The following questions about this article may be useful for internal education and assessment. You may use the following examples or come up with your own.

1. The Joint Commission universal protocol has solved the problem of wrong-site surgery when used.
   A. True
   B. False

2. Most wrong-site surgery is wrong-side surgery.
   A. True
   B. False

3. The Joint Commission universal protocol is a hospital policy and compliance is the responsibility of the operating room nurses, not the medical staff.
   A. True
   B. False

4. The Joint Commission universal protocol includes all EXCEPT which one of the following?
   A. Verification of the patient's identity
   B. Reconciliation of the schedule, consent, history and physical exam documents, and patient's expectations
   C. Marking the surgical site
   D. Having the surgeon position the patient
   E. Having all members of the operating team participate in a time out immediately before the skin incision

5. The operative site should be marked by
   A. the patient prior to coming to the operating room.
   B. the nurse preoperatively with the collaboration of the patient.
   C. the surgeon or designated member of the operating team preoperatively with the collaboration of the patient.
   D. the anesthesia provider.
   E. the surgeon or designated member of the operating team in the operating room as part of the time out.

6. The protocol for operative site markings includes which one of the following?
   A. It should be based on the schedule, consent, examination, and the patient's input.
   B. It should be done with an "X" over the operative site.
   C. A "NO" should be marked on the incorrect side to prevent wrong-side confusions.
   D. It should be done in a way that will be visible when the patient is brought into the room.
   E. It should be done in a way that can be removed or covered when preparing and draping the site.

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The *PA-PSRS Patient Safety Advisory* is issued quarterly, with periodic supplements. Previous issues are available on the Patient Safety Authority Web site at http://www.psa.state.pa.us. Click on "Advisories and Related Resources" in the left-hand menu bar.

Selected articles in previous issues include:

- "Airway Fires during Surgery" (March 2007)
- "Bone Cement Implantation Syndrome" (December 2006)
- "Delays in the OR: Stress between 'Running Two Rooms' and 'Time Outs'" (September 2006)
- "Forgotten But Not Gone: Tourniquets Left on Patients" (June 2005)
- "I'm Stuck and I Can't Get Out! Hospital Bed Entrapment" (December 2006)
- "Improving Safety of Telephone or Verbal Orders" (June 2006)
- "Risk of Fire from Alcohol-Based Solutions" (June 2005)
- "Safety in Using Promethazine (Phenergan)" (March 2007)
- "Skin Tears: The Clinical Challenge" (September 2006)
- "Who Administers Propofol in Your Organization?" (March 2006)

An Independent Agency of the Commonwealth of Pennsylvania

The Patient Safety Authority is an independent state agency created by Act 13 of 2002, the Medical Care Availability and Reduction of Error ("Mcare") Act. Consistent with Act 13, ECRI Institute, as contractor for the PA-PSRS program, is issuing this publication to advise medical facilities of immediate changes that can be instituted to reduce Serious Events and Incidents. For more information about the PA-PSRS program or the Patient Safety Authority, see the Authority's Web site at www.psa.state.pa.us.

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ECRI Institute, a non-profit organization, dedicates itself to bringing the discipline of applied scientific research in healthcare to uncover the best approaches to improving patient care. As pioneers in this science for nearly 40 years, ECRI Institute marries experience and independence with the objectivity of evidence-based research. More than 5,000 healthcare organizations worldwide rely on ECRI Institute's expertise in patient safety improvement, risk and quality management, and healthcare processes, devices, procedures and drug technology.

The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit organization dedicated solely to medication error prevention and safe medication use. ISMP provides recommendations for the safe use of medications to the healthcare community including healthcare professionals, government agencies, accrediting organizations, and consumers. ISMP's efforts are built on a non-punitive approach and systems-based solutions.