This Issue: Wrong Site Surgery

Executive Summary

• Nationally, wrong site surgeries continue in spite of the Joint Commission’s mandate to use the Universal Protocol.
• Within DoD, Wrong Site Surgery (WSS) has been the leading event type during the time that the Patient Safety Center (PSC) has collected and analyzed RCAs (1999 – present).
• The leading specialties reporting the most WSS events are in descending order: chairside dentistry, anesthesia, general surgery, and ophthalmology surgery; with wrong side and wrong site procedures as the leading subcategory events.
• During the last two years WSS events have decreased in frequency in the main OR and are now increasingly occurring in the ambulatory and patient care units (ward, ICU).
• There was a favorable trend for most of the events occurring post anesthesia and prior to procedure, with an opportunity for rescue and the correct procedure subsequently being performed. Although the anesthetic was administered incorrectly, the subsequent “time out” for the non-anesthetic procedure enabled the team to identify the error and perform the correct procedure. The matter was mitigated because of the Universal Protocol.
• Another favorable trend was the decrease since 2006 in the frequency of WSS events involving ophthalmology.
• All of the military treatment facilities that submitted RCAs reported that they had implemented some process to prevent WSS events several years before the Universal Protocol had been mandated, demonstrating their commitment to providing safe healthcare to patients.

DoD Case Summary

Patient underwent surgery for a ruptured left ring finger. The dorsal side of the left wrist was marked with an “x” and a line extending to the left ring finger via an arrow. The arrow was inadvertently removed during the scrub and surgery was performed on the middle left finger, dorsal side.

This case illustrates the perils of wrong site surgery and the need for accurate and indelible surgical markings.

Wrong site surgery events can result in catastrophic outcomes for the patient and have an adverse impact on healthcare professionals and institutions. This Focused Review analyzes DoD wrong site surgery RCAs and suggests risk reduction strategies.

National Incidence

The frequency of wrong site surgery (this term includes wrong side/side/patient/level/implant) continues to increase in spite of the Joint Commission’s May 2004 Universal Protocol. Wrong site surgery is the third most common type of Sentinel Event reported to the Joint Commission. In Pennsylvania, for example, 400 wrong site reports have been submitted to the Pennsylvania Safety Reporting System since its inception in 2004.

Incidence Within DoD

In contrast to its third place national incidence, wrong site surgery is the leading type of event within DoD. The actual incidence of wrong site surgery is very low, as illustrated by the actual numbers for dental procedures, which lead in this category. In FY 2007, the dental service performed some 1,450,000 procedures.

![Fig. 1](image)
that could have led to a wrong site surgery outcome, but the actual number of events reported was 6, a rate of only 0.0004%. Nonetheless, wrong site surgery persistently ranks as a leading event type within DoD. Figure 1 shows the number (based on calendar years) of wrong site surgery RCAs submitted since the inception of the DoD Patient Safety Program. The total for 2007 is as of January 30, 2008, and the data can change due to a 90 day reporting lag.

While the Universal Protocol did not come into effect until May of 2004, many DoD military treatment facilities had already implemented wrong site surgery preventative protocols. Figure 2 shows the breakdown by Service of military treatment facilities reporting wrong site surgery events. Figure 3 illustrates trended event types per Service. The various subcategories within wrong site surgery are shown by Service in Figure 4.

**Occurrence Rates**

The DoD Root Cause Analysis Short Form includes a section that asks “Has this type of event or near miss occurred before?” First time occurrences were 75% of the total responses, and the remaining 25% were re-occurrences. A follow-up question asked “If yes, were corrective actions to the previous event developed and implemented?” Ninety-six percent responded that they had developed and implemented corrective actions. Those military treatment facilities that had not implemented corrective actions indicated that proposed policies were awaiting approval. During this waiting period, a similar event re-occurred within all of these facilities. In contrast, of the 96% of facilities that had implemented corrective actions, those that reported a re-occurrence noted that the subsequent event had no relation to the previous event. The leading causal factor identified for a wrong site surgery re-occurrence was that the previous corrective action did not cover the circumstances of the subsequent event (e.g., local anesthetics involving laterality).

**Event Discovery**

The Universal Protocol provides a systematic process for correctly identifying the patient, procedure, and site. The requisite “time-out” enables the team to collectively engage and confirm that the intended procedure, patient, and site are correct. If a wrong site surgery event occurred, when was it identified and was the adverse outcome mitigated? Figure 5 summarizes when the facility discovered the wrong site surgery event. Fifty-eight percent of these events were discovered post operatively—immediately post procedure (while the patient was in the
procedure room), in the recovery room, and during the postoperative visit. The longest time frame for discovery was three months. Approximately 20% of the discoveries were noted by the patient.

For most of the events that occurred post anesthesia and prior to procedure, there was an opportunity for rescue, with the correct procedure subsequently being performed. Although the anesthetic was administered incorrectly, the subsequent “time out” for the non-anesthetic procedure enabled the team to identify the error and perform the correct procedure. The matter was mitigated because of the Universal Protocol, and the patient subsequently had the correct procedure.

**Demographic Findings**

**Duty Status and Age**

*Figure 6* summarizes the duty status of the patients involved in wrong site events. The age spectrum was between two and 82 years.

**Patient Status**

At the time of the event, 95% of the patients were ambulatory and the remaining 5% were inpatients. While a significant number of procedures were performed in the main OR, most patients were admitted as same day procedure and were discharged to home within 24 hours. Those individuals who were inpatient were either on the ward or in the ICU.

**Anatomical Location**

Wrong site surgery events involved various parts of the anatomy. The leading areas (those with at least 3 events) are represented in *Figure 7*. While each event may result in some level of patient trauma (psychological/physical), those events having significant morbidity included a mastectomy (no cancer found) and three events that rendered the patient sterile (tubal ligation, total abdominal hysterectomy, and a vasectomy).

**Types of Reported Errors**

Throughout the decade of WSS reporting, there has been a sustained increase in the reporting of events involving teeth (wrong site) since 2005, followed by an increase in anesthetic events (wrong side) since 2005. In contrast, the frequency of events involving ophthalmology has decreased since 2006.

*Figure 8* summarizes the types of DoD wrong site RCAs according to type. Wrong side events were the leading event type with 38 events (35.8%). Other event types were: wrong site with 33 events (31.1%), wrong patient with 15 events (14.1%), wrong procedure with 14 events (13.2%), wrong implant with 4 events (3.7%), and wrong level with 4 events (3.7%).
The leading wrong side events involved anatomical laterality—eye, vertebrae, abdominal structures, and extremities. Wrong site events most commonly involved the teeth. Wrong implant events most commonly involved the eyes, and wrong level events most commonly involved the vertebrae.

**Involved Clinical Specialties**

While the entire procedure team is involved in all of these events, *Figure 9* summarizes the clinical specialties directly involved with this event type. The dental specialties, with 42 events (35.8%), were most often involved. The 42 events were divided between 20 wrong site procedures involving tooth extractions (48%) and 22 wrong site procedures events involving restorations (52%). Anesthesiology had 13 events (12.3%) involving anesthetic blocks to the wrong side. General surgery had 12 events (11.3%), and ophthalmology had 11 events (9.4%). *Figure 10* shows wrong site surgery by service.

The top five specialties from *Figure 9* are listed in the following material, along with the most common clinical situations that contributed to their wrong site events.

**Dental**
The majority of events occurred in chair-side dentistry.
- Incorrect tooth marking on chart/radiograph
- Incorrect radiograph mounting
- Incorrect patient identification

**Anesthesiology**
- No policy for local anesthetic administration
- Patient rotation/repositioning
- Scheduling (provider hand-offs)

**Orthopedics**
- Inadequate site marking on digits/extremities
- Wrong side local anesthetic administration

**General Surgery**
- Incomplete/unavailable documentation
- Consults

**Ophthalmology**
- Human Factors relative to use of equipment
- Ensuring availability of correct lens implants

*The 42 dental events could not be broken down by specialty, in contrast to the 69 medical/surgical events.*

*Fig. 9*
System Breakdowns

Some examples of Universal Protocol breakdowns within DoD are listed below.

Patient Identification

- Patient B presented to the ER with lower right flank pain. The ER physician ordered IVP (intravenous pyelography) for Patient B. Patient A presented to ER with intractable nausea and vomiting. The ER nurse erroneously transported Patient A to radiology for IVP. Verbal verification of the patient’s name was performed by radiology tech and ER nurse. IVP was incorrectly performed on Patient A.

- Two patients were scheduled for the same type of eye surgery. The charts were switched, and one patient received the other patient's treatment.

Wrong Information/Incomplete Information

- Patient complained of left flank pain radiating to left groin and was subsequently scheduled for a left orchietomy. The surgeon was under the impression that the patient had another testicle. Volume 1 of the patient's medical history was not located and surgery was performed without additional information. Patient’s only remaining testicle was removed.

- The consent form noted “excision of bone tumor, left zygoma.” H and P noted an abnormal lesion in the right side maxilla. Images were not viewed prior to surgery and surgery was performed on the wrong side—left instead of right.

- Patient admitted for excision of a ganglion cyst on the volar side of the left wrist. RN #1 noted site discrepancies between the history and the physical, and on the consent form. RN #1 communicated this information to RN #2 during the handoff. Patient was prepped and an incision made on the dorsal side of wrist. RN #2 assumed RN #1 had resolved the discrepancies.

Wrong Site

- A patient was admitted to have a biopsy of a right cervical node. The consent noted the correct laterality but not the actual site. During the third time out the site was marked, however, during the surgical prep the marking came off. When the patient recovered in the post anesthesia unit she informed the staff that the biopsy was taken from the wrong side.

- A patient was scheduled to have four wisdom teeth extracted (#1, #16, #17, and #32). Correct site verification and time-out were performed prior to the procedure. The dentist mistakenly extracted tooth #31.

Wrong Side

- Patient presented to the ambulatory procedure unit for arthroscopic surgery to the right knee. The orthopedic surgeon injected the left knee with a local anesthetic without confirming the site/marking the site, reviewing the consent, or communicating with the staff.
Wrong Procedure

- Patient was admitted to the CCU with an acute MI. He was diagnosed with severe mitral valve regurgitation and taken to the OR for a mitral valve replacement. During the procedure the mechanical valve was placed in the tricuspid position instead of the mitral position.

- Patient A was scheduled for shoulder arthroscopy. Patients B and C were scheduled for shoulder arthroscopy and clavicle resection. The same surgeon was scheduled to perform successive procedures on all three patients. Patient A received an unconsented clavicle resection.

- Female patient with a history of uterine fibroids, ovarian cyst, and recent miscarriage consented to a diagnostic laparoscopy under general anesthesia. The surgeon documented that visualization was impeded by pathology to the involved organs. The procedure was converted to a laparotomy, enabling the surgeon to visualize the organs. The surgeon performed a total abdominal hysterectomy with bilateral salpingo-oopherectomy, leaving the patient sterile and hormonally dependent.

Risk Factors

Facility leadership plays a significant role in both the implementation of, and adherence to, the Universal Protocol. At the Joint Commission Wrong Site Surgery Summit convened in February 2007, attendee consensus was that “effective organization management of this issue requires local ownership of changes in relevant policies and procedures and active engagement by the CEO and the Board [Executive Leadership].”

During the analysis of DoD WSS events there were situations that had an impact on staff compliance with the Universal Protocol. The following cases illustrate these challenges. Facilities are encouraged to consider how these unique situations may affect staff and revise procedures/training accordingly.

Dual Site Procedures Markings

- Patient was scheduled to have surgery on his right leg, as well as a post-op pain control block. The anesthesiologist administered sedation to the anxious patient and prepared the set-up for administration of a regional peripheral nerve block. Following protocol, the surgeon marked the site on the left leg. The Anesthesiologist also used the surgeon’s marking, however, he was subsequently called away and was relieved by a CRNA who confirmed the name of the patient, type and side of the surgery. The CRNA verbally reconfirmed the procedure site and touched the patient’s right leg, to which the patient said “yes”, that the right leg was the correct side. (The surgeon’s marking was no longer visible). The CRNA proceeded to administer a block to the incorrect leg with the assistance of the returning anesthesiologist.

Lessons Learned: Site marking will have greater impact when the institution agrees on one method. Markings should be applied when the patient is awake, before entering the OR, and the marking should remain visible after the surgical site is prepared. Site marking should be applied by the person doing the procedure. Facilities should include a section on how to manage a patient who refuses to have the site physically marked.

Scheduling

- A patient had the wrong tooth extracted. The resident attributed this to the need to stay on schedule and to a lack of optimum visibility (trainee dental tech had difficulty in using the equipment).

Lessons Learned: Scheduling has an impact on patient flow and affects the skill competency of individuals being trained. Consider using flexible schedules when trainees are precepting onto the treatment team.
Equipment

- Patient had an intra-ocular scan. Calibration was performed, but the equipment was not corrected by the technician prior to performing subsequent tests. There was no indicator on the screen or on the printout that scan mode was active. Physicians had been taught to interpret scans, but were unfamiliar with the placement of calipers on the scan printout and how to distinguish between contact mode and immersion mode. This resulted in the patient having a wrong intraocular lens implanted after a cataract was removed.

**Lessons Learned:** We know from the events reported to the Patient Safety Center that different technologies and A-Scan methods are being used across the military health system. As providers and staff make permanent changes of station from one military treatment facility to another, we need to prepare them for these differences, whether they are “major” differences (e.g., different manufacturers’ equipment) or “minor” differences (e.g., an older/newer model being used). Both differences have the potential to alter the measurements if the same formula is applied. With the differences in our military treatment facility locations, populations, and breadth of available staff and services, we would expect the military health system to also have variances. This makes the handoff between staff members even more crucial. Often there is little or no overlap between old/new staff members, so there must be clear documentation and unambiguous guidance from existing staff members, if available. This will ensure that the new staff members get the crucial information they need, whether it is in relation to the constants, or the setup and use of the equipment.

Patient/family involvement

- ED patient “A” was scheduled for IVP; ED patient “B” was incorrectly taken to radiology for the procedure and answered affirmatively to the wrong name. An IVP performed on the wrong patient.
- Patient “A” was scheduled for a Photo-Refractive Keratectomy. The patient reported for surgery and pre-op verification was completed. As an identifier, the patient’s name was placed on the operative cap. The chart was placed outside the procedure room. There was a change of technicians with a briefing given by the primary technician. Charts for patient “A” and a patient “B” were brought into the operative suite. Multiple charts were open in the operative suite. The provider discussed the patient “B” chart information and the laser technician displayed the information for patient “B” on the computer screen. Patient “A” was brought into the operative suite and not verbally introduced. The laser operator verified the name, social security number, and date of birth with patient “A”, but not against any documents. A final time-out was not performed and the surgeon did not check the name on the operative cap. The surgeon verbally addressed patient “A” as patient “B” and the patient did not respond. The procedure was performed and incorrect treatment was given.

**Lessons Learned:** Patients/family members are an integral part of an accurate patient identification/Universal Protocol process. These summaries illustrate that alert patients may answer incorrectly when identified. Facilities are encouraged to ask patients to state (not confirm): 1) their full name, 2) full SSN or date of birth, and 3) the procedure to be performed and the site of the procedure; or follow applicable command policy.

Training

- Patient consented for right-side lumbar surgical procedure. The neurosurgeon (newly assigned and temporary) performed surgery on the wrong side and level. The RCAT (Root Cause Analysis Team) determined that the surgeon was unfamiliar with the facility and with the Universal Protocol.

**Lessons Learned:** The military treatment facility had a policy that mandated anesthesia to use a “Time-Out” stamp for all invasive procedures involving anesthesia (blocks, epidurals). The required practice was not always uniformly applied and verified. Facilities are encouraged to ensure that all staff receive the appropriate training (general and unit specific) prior to providing patient care; additionally, this training must be verified and documented accordingly. Moreover, management must ensure that once staff is trained that they are constantly adhering to all portions of the Universal Protocol.

Taxonomy

- Patient was consented to have an osteotomy of the fifth metatarsal prominence. The surgical schedule listed surgery for a distal head osteotomy on the right foot. Patient was marked for operative “side” (right foot) and not “site”. Without interviewing the patient or reviewing the history/physical, the surgeon looked at the top of the consent form and performed surgery on the first rather than the fifth metatarsal.

**Lessons Learned:** The RCAT identified that all hospital staff appeared to interpret laterality (“side”) as also meaning operative “site”. Certain anatomical structures require description for both the site and the side. Affected anatomical structures include digits and extremities (ventral/dorsal). Facilities are encouraged to use taxonomy that promotes clear and precise understanding for the staff and patient. Additionally, consider training the staff/patient to document both the “site” and the “side” for this special anatomical class. Illustrations may prove to be a useful vehicle for promoting a clear and consistent understanding for staff and patient/family member. Also consider making the distinction between “site” and “side” in your training and policy/procedure.
Procedures/Protocols

- Patient delivered a baby by C-section. An unconscouted tubal ligation was performed immediately following the C-section. Resident assumed that the attending had obtained the consent herself and did not speak up when the attending said “moving on to the tubal.”

- Patient consented for a right cervical lymph node biopsy, procedure performed on the left side. Staff did not challenge the provider.

- Wrong tooth extracted. Although the resident had identified the teeth to be extracted on the radiograph, he did not use a standardized count down process. A similar event had occurred at the facility less than 30 days prior. The action plan resulting from the first event included a standardized verbal count down process for the teeth; however, the policy was not implemented pending a Board of Directors briefing.

Lessons Learned: There are numerous reasons why individuals (staff and patients) do not speak up during wrong site events. In addition to team building initiatives, provide staff with a policy that directs them to challenge regardless of personality or rank.

The last case summary illustrates the need for timely implementation of policy changes. The facility delayed implementing the policy until it had been presented to a higher management level. The RCAT learned that the policy could have been implemented prior to the Board of Directors briefing. Facilities are encouraged to enact patient safety initiatives in a timely fashion. Considerations relative to implementation may necessitate special call meetings for stakeholder input/buy-in/endorsement. Keeping the policy and procedures simple and efficient will promote greater compliance and timely adoption.

Consults

- Patient had a core needle biopsy read initially as Ductal Carcinoma in situ by the pathology department. Pathology sought second opinion/consultation at AFIP. AFIP review of pathology concluded no cancer. Patient was scheduled for a mastectomy with auxiliary dissection. The consult report was missed or overlooked by the attending surgeon. Operative pathology finding of breast tissue showed no carcinoma.

Lessons Learned: This case illustrates the criticality of having a definitive treatment plan supported by diagnostic reports, completed consults, and collaborative team discussion before beginning definitive treatment. This facility’s corrective action plan included re-establishing the Tumor Registry for cancer patients.

Patient position change

- Patient consented for localized left breast biopsy. Patient moved to block area for a paravertebral block procedure. Final time-out performed with marking. Patient positioned, rotated and right paravertebral block given.

- Patient’s right ear was prepped for surgery; surgery was performed on the right ear instead of the left. Three final site verifications were performed before re-positioning the patient. The surgeon rotated the patient 180° for better accessibility.

- Patient underwent surgery for thoracoscopic repair of a hernia of the diaphragm. The patient was placed in a prone position with the site marking not visible. The surgeon started the surgery on the wrong side of the diaphragm.

Lessons Learned: These examples illustrate the perils of patient rotation during procedures. Wrong site could be reduced by conducting a final time-out when the patient is placed in the position just before the procedure begins. During this final time-out it is imperative that there is visualization and verification of the site-marking before the procedure instrument is placed in the provider’s hand.

Successive Procedures

While the Patient Safety Center has not received RCAs relative to the issue of successive procedures, facilities are encouraged to include guidance to staff on how to manage patients who have the risk factor of successive procedures. Dr. Peter Angood of The Joint Commission recommends the following: “multiple sites, multiple lesions, multiple types of procedures do create some problems, and with the Universal Protocol we have to be very clear in the pre-op verification process that everyone understands what those procedures are. There needs to be a unique type of verification for each of those areas. If there are different surgeons or different teams, there needs to be individual types of markings so that they are distinct. Ideally, a surgeon could initial that site in a fashion that’s distinct for that individual, and then during the time-out process there’s the opportunity to re-verify, recheck the site, and reaffirm for the team that this is what is going on for the patient.” (Joint Commission Telephone Conference Call)
Causal Factors

Table 1 shows the leading causal factors in wrong site events. The leading corrective actions taken by the facilities are summarized in Table 2. Training involved all disciplines (provider/nursing/techs/support staff) and involved reinforcing the protocol and or educating the staff on a new/revised policy. The most common training vehicle included in-service, briefings and stand-downs. The use of SBAR was cited as the method for conducting hand-offs. Checklists were a common tool that RCATs developed with varying styles (e.g., standard checks only/signatures of principal staff members).

Communication Focus

The leading causal factor for wrong site involved some aspect of inadequate communication (Table 1). These events occur because of a process failure. Table 3 reflects the conduct that contributed to the wrong site. This information is provided not to assign blame, but to better analyze related issues involving this event category. The following provides context and measures to promote effective communication.

The Team

The “time out” requirement is a communication tool that provides a final safety check between the surgical, nursing, and anesthesia care teams. A number of RCAs noted that the team inadequately complied with the Universal Protocol. Additionally, even when a “time-out” was performed, a wrong procedure resulted. The leading finding involved a fragmented “time-out” process. The team typically completed the “time-out” independent of the collective pause. The letter of the “time-out” was achieved; however, the spirit of this process was not achieved. Additionally, the team was noted to be complacent with adhering to the Universal Protocol. Another finding noted that management was less vigorous in enforcing team compliance with the Universal Protocol. Finally, RCATs identified past work relationships as influencing perceptions of staff members’ accuracy.

Table 1

<table>
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<tr>
<th>Reported Causal Factor</th>
<th>Number</th>
<th>Percent</th>
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<tbody>
<tr>
<td>Communication NI</td>
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<td>88%</td>
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<td>Incomplete Policy/Procedure</td>
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<td>Incomplete Documentation Review/Reconciliation</td>
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<td>Fragmented “Time Out”</td>
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Table 2

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<tr>
<td>Revise Policy/Procedure</td>
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<tr>
<td>Create Policy/Procedure</td>
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<td>64%</td>
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<tr>
<td>Develop/Revise Checklist</td>
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<td>Audit Documentation</td>
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Table 3

<table>
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<td>Provider</td>
<td>55</td>
<td>50%</td>
<td>Failure to follow policy; failure to review/reconcile documentation.</td>
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<td>Provider Trainee</td>
<td>18</td>
<td>17%</td>
<td>Miscalculation of anatomical structure (failure to communicate plan of care); not speaking up.</td>
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<tr>
<td>Tech</td>
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<td>16%</td>
<td>User error (equipment—ophthalmology, radiology); incorrect patient verification; inadequate process verification.</td>
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<td>Team</td>
<td>7</td>
<td>7%</td>
<td>Failure to follow policy (fragmented process verifications /time outs); patient verification.</td>
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<td>Staff</td>
<td>5</td>
<td>5%</td>
<td>Failure to follow policy; not speaking up.</td>
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<td>RN</td>
<td>4</td>
<td>4%</td>
<td>Failure to communicate findings and actions taken relative to incorrect or inconsistent documentation.</td>
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<tr>
<td>Front Desk</td>
<td>3</td>
<td>2%</td>
<td>Failure to communicate findings (documentation inconsistency); not following the policy (patient verification).</td>
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</table>

Recommendations

− Enforce compliance with the Universal Protocol.
− Perform periodic observations to assess communication dynamics.
− Ensure that all team members are actively engaged in the “time-out.”

Staff

Staff can be encouraged to speak up with suggestions for process variations if there is a prescriptive policy that explains the process for addressing staff insecurity. Team-STEPPS provides a range of tools for expressing concern,
e.g., CUS (Concerned Uncomfortable Safety issue), SBAR, IPASSTHEBATON. Consider conducting drills using these tools to assess and coach members who are less apt to speak up. A simple mock drill may include having a surgeon planted to purposely violate the Universal Protocol and observe the staff’s response.

Providers

Providers significantly contribute to the occurrence of wrong site events. RCATs noted that providers were either unfamiliar with the Universal Protocol requirements, marked the wrong site, ineffectively communicated a clear plan of care, and failed to reconcile inconsistencies in diagnostics/documentation.

Recommendations

- Standardize the Universal Protocol facility-wide and include the provider in multidisciplinary training whenever possible.
- Include Universal Protocol requirements as part of the provider’s annual competency assessment/credentialing.
- Enroll providers and trainees in QI activities (e.g., observations, peer review, documentation).
- Include discussion of “near-miss” wrong procedure/surgery events during grand rounds.
- Provide periodic Universal Protocol training throughout the year.

Patients

The majority of the RCAs recognized that the patient needed to be more actively involved in the pre-op process for correctly identifying the procedure site; however, the actions did not consistently demonstrate how this would be achieved. Involve the patient as soon as possible. Active questions engage the patient more cognitively, e.g., “Mr. Jones why are you here today? What procedure are you having and point to the site.” Explain to the patient that several team members will be asking the same questions and assure the patient that this process is a safety check of which they are an integral part.

While not reflected in Table 3, a number of RCAs involved patients not speaking up. Patients are a part of the team and can be the final safeguard for preventing a wrong site event.

Recommendations

- Involve the patients throughout the pre-operative/procedure process.
- Use open ended questions during a series of encounters before the procedure begins.
- Include anatomical illustrations when possible and have the patient mark or describe what procedure is to be done.

Emerging Issues

Internal Organs Involving Laterality

- Patient diagnosed with right ureteral stone; consented for cystoscopy and placement of a stent in the right ureter. The procedures were performed in the urology clinic. Using visual and fluoroscopic guidance, a stent was placed in the left ureter.

Surgical procedures involving anatomical structures with laterality and hemispheric considerations require vigilance to ensure correct and safe site identification.

Recommendations

- Review Universal Protocol to assess whether the issue of internal organ laterality is addressed.
- Consider adding an additional time-out once the incision has been made and the cavity has been entered.
- Encourage the provider to verbally verify where the procedure is to be performed.
- Note that the verified structure has been extracted.
- Obtain surgical team consensus as to site during the final “time-out” before proceeding.

Consecutive or Multiple Procedures

While DoD has not reported any wrong site cases involving consecutive or multiple procedures, facilities are encouraged to address this issue in their operative policies. Redo every step of the Universal Protocol as if the patient were entering the operative suite for the first time.

Continuous Quality Improvement

Document and analyze near miss wrong site catches. Hospital personnel may incorrectly identify a patient before surgery. If the error is caught this constitutes a “near miss,” and presents a valuable opportunity for the facility to examine the process. With wrong site, near misses may include prepping the wrong site, setting up for the wrong procedure, or identifying an incorrect procedural consent. Facilities are encouraged to investigate process deviations if the “near miss” allows the facility to come close to performing surgery, or if there is a breach in a defense/safeguard.
Joint Commission WP/S Highlights*

Site Survey – Site surveyors will evaluate the consistency with which the preop verification process is performed, without mandating the use of a checklist if the organization has decided to use a different approach. JC requires documentation of the “time-out”.

Procedures not Involving Laterality/Hemisphere – For those procedures in which site markings are not required, the other requirements for preventing wrong site, wrong procedure, wrong person surgery still apply.

Patient Refusal – Develop a section of your policy that addresses patients who refuse to be marked as part of the site verification process.

Dental Procedures – These procedures are considered exempt from the site marking requirement. In lieu of directly-marking the teeth, The Joint Commission concurs with the following recommendations of the American Dental Association:

- Develop an educational program (case-based materials, information feedback, and clinical guidelines) for The entire staff on preventing wrong-site tooth extractions.
- Design a more informative referral slip without ambiguities; contact referring dentist for any questions or confusion.
- The ADA recognizes two different numbering systems, implement the system best suited for your patients and organization.
- Inform the patient/parent/guardian, and with a handheld patient mirror, which tooth/teeth are to extracted at the initial consultation appointment.
- Confirm that the patient, chart, and x-ray are correct (ensure that radiographs are correctly oriented) and confirm which tooth is to be extracted at the surgical appointment.
- Consider marking the radiograph or dental diagram.
- Follow the Universal Protocol—perform and document the “time-out”.
- Check the tooth position before and after application of the forceps.

* The JC is currently developing revisions for release in 2008 that will be applicable in 2009. These additions to the UP will help to further clarify its requirements.

Additional Risk Reduction Strategies

Figure 11 is an example of how the Veterans Health Administration ensures correct surgery in its facilities. In addition, please see the note in Figure 11 with the Patient Safety Center recommendation to add “visualize the operative marking/site” to Step 4, and to add to Step 5 “and correct orientation of the radiograph must be jointly determined by the two OR team members.” The Patient Safety Center recommends the following additional strategies for risk reduction:

- Develop and implement checklists. Checklists reduce reliance on memory and vigilance.
- Standardize policies and procedures throughout the facility.
- Whenever possible have the same personnel move/transfer the patient, thus minimizing the need for additional handoffs.
- After the final time-out is satisfactorily completed, the scrub nurse places the blade in the scalpel handle.
- For sites that can not be marked (urology, pediatric cases), colored wristbands can be used on the operative site/side with the following information: surgical site, person placing the wristband, initials, date, and time.
- Ocular Implants: Use a verification process for each patient that includes the A-Scan sheet to identify the intraocular lens power, lens type, and procedure prescribed from the ophthalmology surgery schedule. This should be done with the MD and OR nurse before the patient is prepped and draped for surgery. Include a second “time-out” process just prior to implant placement. This will include the physician, lens tech, and nurse to again verify the lens power prior to placement. Develop an OR list of scheduled procedures specific to the ophthalmology operating room each morning prior to beginning of procedures. The list should include: patient name, lens type, and lens power (in large print).

Conclusion

Wrong site continues to be a perennial problem within DoD and the civilian community. Over time, these events have spread from the main OR to virtually every area where patient procedures are performed. Facilities are encouraged to capture and analyze near miss wrong site occurrences. Use this data to, when appropriate, refine your processes, and continually support your staff by providing them with information. Recognize and celebrate with your staff when the Universal Protocol is
performed appropriately, and challenge those divisions to improve compliance. This publication provides you with the tools to help guide your facility in making wrong site a “never event.”

References


Step 1: Consent Form

The consent form must include:
♦ patient’s full name
♦ procedure site and side
♦ name of procedure
♦ reason for procedure

Step 2: Patient Identification

OR staff shall ask the patient to state (NOT confirm):
♦ their full name
♦ full SSN or date of birth
♦ site for procedure

Check responses against marked site, ID band, consent form and other documents

Step 3: Mark Site

The operative site must be marked by a physician or other privileged provider who is a member of the operating team.

Do NOT mark non-operative sites

Step 4: “Time Out”

Within the OR when the patient is present and prior to beginning the procedure, OR staff must verbally/visually confirm through a “time out”:
♦ presence of the correct patient
♦ patient properly positioned
♦ marking of the correct site and side
♦ procedure to be performed
♦ availability of the correct implant

Step 5: Imaging Data

If imaging data is used to confirm the surgical site, two members of the OR team must confirm the images are correct and properly labeled

* The Patient Safety Center recommends adding “visualize the operative marking/site” to Step 4, and adding to Step 5 “and correct orientation of the radiograph must be jointly determined by the two OR team members.”


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**About the DoD Patient Safety Center**

The DoD Patient Safety Center is dedicated to improving patient safety in all military healthcare settings through the study of adverse patient care events in military treatment facilities.

Established by the 2001 National Defense Authorization Act, under the Armed Forces Institute of Pathology, the Patient safety Center was directed to “implement a centralized process for reporting, compilation, and analysis of errors in the provision of health care under the defense health program that endanger patients beyond the normal risks associated with the care and treatment of such patients.”

The Patient Safety Focused Review is published by the Department of Defense Patient Safety Center, located at the Armed Forces Institute of Pathology (AFIP). This bulletin provides advisory information in the field of patient safety.

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