Time-Out! Wrong-Site Surgery Update

EVENT EXAMPLES

Edited versions of two recent reports show the importance of a properly conducted time-out:

A patient was an add-on to the OR schedule for a RIGHT side procedure. The patient was brought to the OR; sign-in procedure was followed; time-out was started and the surgeon left the room. Staff completed the time-out without him, but when he returned to the room, they did a complete time-out all over again. Everyone agreed on the RIGHT side. The patient was not positioned in any manner that emphasized the laterality. The tech and the surgeon were talking but the circulator did not hear the conversation. The surgeon was viewing real-time images with the tech. The procedure was completed without event. The circulating nurse and CRNA [certified registered nurse anesthetist] took the patient to the recovery room. The surgeon was in the recovery room talking to the recovery room nurse about the case. The circulator overheard him say we did the LEFT side. She said you mean RIGHT side and he said no, LEFT. The nurse reminded him that he had signed off on RIGHT. The patient was rolled, confirming LEFT side was done. The nurse said she could not hear the discussion between the surgeon and tech. The tech did admit he knew that RIGHT was agreed upon but he did not alert anyone. … It appears initially that only the tech knew that the doctor was doing the LEFT side instead of the RIGHT. The tech did not make anyone else on the OR team aware of this but clearly documented LEFT side on the documentation form postprocedure.

The patient's incorrect leg was prepped and draped for surgery. The error was noticed during time-out, and no incision was made. The patient's leg was not marked in pre-op. The nurse did not check to ensure the leg was marked prior to taking to OR. During time-out, it was noted that incorrect leg was prepped and draped. The drapes were taken down. The patient's correct leg was prepped and draped. A new time-out was completed and all documents were rechecked.

Wrong-site surgery continues to occur in Pennsylvania (see "Event Examples"). This update focuses on knowledge about doing a time-out effectively. It also addresses a query about the value of reviewing imaging studies in the operating room (OR).

Updated wrong-site surgery reports are shown in the Figure. In the most recent quarter, six (32%) were wrong-site anesthetic blocks. Wrong-site surgery events seem to follow a puzzling multiyear cycle. A yearly cycle could be explained by the seasonal variation in operating volumes or by the learning curve in academic medical centers. For a multiyear cycle, one can only speculate that events increase attention and lack of events diminishes attention—and that the memory of events and the attention to preventing another event lasts at least a year. If a multiyear cycle is real and the speculation proves valid, the implication is that prevention of wrong-site surgery requires continued attention to detail, not just system improvements, and that one must see continuous improvement for a minimum of two years to be sure the improvement is real.

TIME-OUT

Evidence-Based Best Practices

The Pennsylvania Patient Safety Authority has established, from prior studies, principles that should be followed during a time-out:[1]

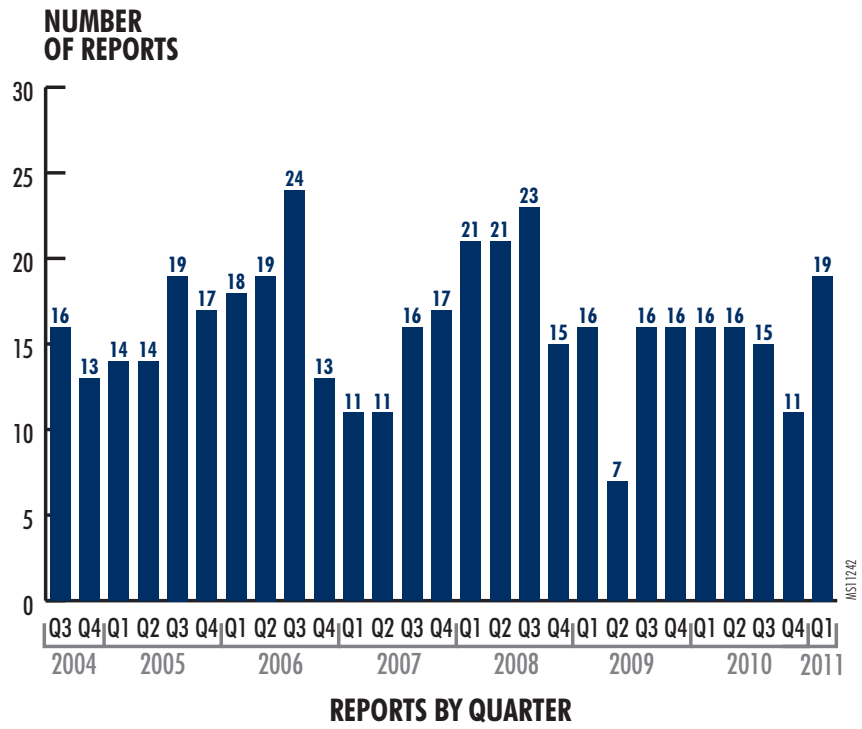
All noncritical activities should stop during the time-out. In 31 observations of the time-out processes in 10 facilities that had wrong-site surgery and 4 facilities that had none, noncritical activities stopped in 9% of the cases in facilities that had wrong-site surgery and 75% of the cases in facilities that had none, a statistically significant difference ($p < 0.001$).

The site mark should be visible and referenced in the prepped and draped field during the time-out. In a year-long, prospective comparison of 97 near-miss reports, in which the potential error was caught before the skin was punctured, and 44 wrong-site surgeries, using a common event analysis form,[2] the time-out was done after the patient was prepped and draped in 88% of the near-miss events and in 64% of the wrong-site surgery events, a statistically significant difference ($p < 0.01$); the mark was visible in 87% of the near-miss events and in 69% of the wrong-site surgery events, a statistically significant difference ($p < 0.05$). In recent, unpublished comparisons—in a second region of Pennsylvania—of 169 observations of compliance with the Universal Protocol in 12 facilities that had wrong-site surgery and 6 facilities that had none, the time-out was done after the patient was prepped and draped in 85% of the cases in facilities that had wrong-site surgery and in 100% of the cases in facilities that had none, a statistically significant difference ($p < 0.01$).

Verification of information during the time-out should require an active communication of specific information, rather than a passive agreement, and be verified against the relevant documents. In 169 observations of compliance with the Universal Protocol in 12 facilities that had wrong-site surgery and 6 facilities that had none, all documents were verified during the time-out in 66% of the cases in facilities that had wrong-site surgery and 86% of the cases in facilities that had none, a statistically significant difference ($p < 0.05$); critical diagnostic test results or imaging studies were verified during the time-out in 73% of the applicable cases in facilities that had wrong-site surgery and 100% of the applicable cases in facilities that had none, a statistically significant difference ($p < 0.01$).

All members of the operating team should verbally verify that their understanding matches the information in the relevant documents. In the year-long, prospective comparison of 97 near-miss reports, in which the potential error was caught before the skin

Figure. Pennsylvania Patient Safety Authority Wrong-Site Surgery Reports by Quarter



was punctured, and 44 wrong-site surgeries, using a common event analysis form,[2] the nurse, the surgeon, and the anesthesia provider were all involved in 98% of the near-miss events and in 88% of the wrong-site surgery events, a statistically significant difference ($p < 0.05$).

The surgeon should specifically encourage operating team members to speak up if concerned during the time-out. The statewide comparison of policies and procedures in 37 facilities that had wrong-site surgery and 96 facilities that had none[3] showed that including an explicit request by the surgeon for operating team members to speak up if concerned during the time-out was cited in 40% of the facilities that had wrong-site surgery and 76% of the facilities that had none, a statistically significant difference ($p < 0.05$).

Operating team members who have concerns should not agree to the information given in the time-out if their concerns have not been addressed. In the year-long, prospective comparison of 97 near-miss reports, where the potential error was caught before the skin was punctured, and 44 wrong-site surgeries, using a common event analysis form,[2] operating team members raised concerns in 79% of the near-miss events and in 22% of the wrong-site surgery events, a statistically significant difference ($p < 0.001$).

Any concerns should be resolved by the surgeon, based on primary sources of information, to the satisfaction of all members of the operating team before proceeding. In the year-long, prospective comparison of 97 near-miss reports, in which the potential error was caught before the skin was punctured, and 44 wrong-site surgeries, using a common event analysis form,[2] the surgeon addressed concerns that were raised in 82% of the near-miss events and in 40% of the wrong-site surgery events, a statistically significant difference ($p < 0.001$).

Time-Out Survey Results

Hospitals that do surgery and ambulatory surgical facilities (ASFs) in Pennsylvania recently cooperated with the Authority to complete a new survey on the conduct of time-outs. Surveys were forwarded to the OR managers of the 151 acute care, community, and children's hospitals and the 247 ASFs in the commonwealth.

Responses were received from 58 hospitals (38%) and 94 ASFs (also 38%), for a total of 152 responses. Among the hospitals responding, 32 (55%) had reported a wrong-site surgery event. Among the ASFs, 23 (24%) had reported a wrong-site surgery event. The difference between the experience with wrong-site surgery between the responding hospitals and ASFs was significant by Chi-square test ($p = 0.001$). The difference is consistent with the fact that 110 hospitals had reported wrong-site surgery events before the time of the survey (73% of all hospitals doing surgery), whereas only 63 ASFs had reported wrong-site surgery (26% of all ASFs). Responses were received from 32 hospitals that had reported wrong-site surgery (29%) and 23 ASFs that had reported wrong-site surgery (37%). This difference in survey response rates was not statistically significant. Nevertheless, the survey results were analyzed separately for hospitals and ASFs, rather than combined, because of the differences between the two types of facilities.

Because some ASFs specialize in procedures that may be less likely to result in wrong-site surgery (e.g., endoscopies), secondary analyses were done to look for differences between hospitals and ASFs that had reported wrong-site procedures and, therefore, did procedures that were at risk for wrong-site errors.

Most time-outs were led by the circulating nurses. The circulation nurses led the time-outs in 86% of the responding hospitals and 73% of the responding ASFs. Surgeons led the time-outs in 9% of the responding hospitals and 10% of the responding ASFs; anesthesia providers, in

3% and 6%, respectively; and scrub technicians, in 2% and 11%, respectively. The differences between hospitals and ASFs were not statistically significant. These findings were also valid for the subsets that had reported wrong-site procedures.

The site markings were referenced during the time-out in 82% of the responding hospitals and 73% of the responding ASFs; the difference was not statistically significant.

All facilities, without exception, verified the patient's identity during the time-out. Almost all verified the procedure (100% of hospitals and 99% of ASFs). The side or specific location was verified by all hospitals, but only by 84% of ASFs, a statistically significant difference ($p = 0.05$ by Chi-square). However, this difference disappeared for facilities that had reported wrong-site procedures (100% of hospitals and 96% of ASFs), suggesting the difference may be due to the types of procedures done (e.g., endoscopies). Only 55% of hospitals and 20% of ASFs included the patient's position under the drapes (e.g., supine, prone) in the time-out. This difference between hospitals and ASFs was statistically significant ($p = 0.001$) and persisted in the subset of facilities reporting wrong-site procedures.

Information about the patient, procedure, and site was verified a single item at a time according to 22% of hospitals and an almost identical 26% of ASFs, whereas the majority of facilities accepted a single response to verify all the information presented.

Not all facilities required all OR team members to respond. These exemptions were more common in ASFs (see Table 1). The differences persisted for anesthesia providers and scrub technicians in the subset of facilities reporting wrong-site procedures.

Active communication of information, rather than passive agreement, was expected for verification responses by a minority of facilities responding: 43% of the hospitals and 35% of the ASFs. The difference was not statistically significant, although it was significantly lower for the subset of ASFs that had wrong-site surgery than for hospitals that had wrong-site surgery (53% of hospitals, 26% of ASFs, $p = 0.05$).

The documents used for verifying the responses during the time-outs varied (see Table 2). In particular, pathology reports were not likely to be checked in any facilities. Imaging and pathology reports were significantly less likely to be checked during the time-out in ASFs than in hospitals, although the differences held up only for imaging reports in facilities that had reported wrong-site procedures.

There were no consistent significant differences in how time-outs were conducted among hospitals and among ASFs that had and had not reported wrong-site surgery. Therefore, comparisons can be made only against the previously established evidence-based best practices.

A comparison of the results of this survey of current time-out practices with previously established evidence-based best practices shows that improvements in time-out protocols can be made in the following:

- Specifically referencing the site marking during the time-out
- Including the specific location of the procedure and, possibly, the position of the patient under the drapes during the time-out
- Considering active responses to single elements needing verification during the time-out
- Having all members of the OR team engage in responding during the time-out

Diane Rydrych, of the Minnesota Department of Health, and Kathleen Harder, PhD, of the University of Minnesota, have observed time-outs in facilities across Minnesota and made a number of recommendations for Minnesota facilities,[4] including the following:

1. The operating team uses a "time-out towel" or other visual aid to cover the Mayo stand before the procedure.

Table 1. Results of Survey of Time-Out Protocols

WHO RESPONDS DURING YOUR TIME-OUTS?	HOSPITAL	AMBULATORY SURGICAL FACILITY	P*
Surgeon	98%	98%	—
Circulating nurse	93	77	0.01
Anesthesia provider	100	82	0.001
Scrub technician	90	73	0.05

* Chi-square test

Table 2. Results of Survey of Time-Out Protocols

WHAT SOURCES ARE USED TO VERIFY VERBAL RESPONSES?	HOSPITAL	AMBULATORY SURGICAL FACILITY	P*
Consent	100%	99%	—
History and physical	70	63	—
Operating room schedule	72	69	—
Imaging studies	75	24	0.001
Pathology report	24	11	0.05†

* Chi-square test

† See text for qualification

2. The surgeon initiates the time-out immediately before the incision.
3. All team members cease activity except to ventilate the patient.
4. The circulating nurse reads the pertinent information out loud to the team, using source documents.
5. Each member of the team independently provides the pertinent information out loud from the information he or she knows. The anesthesia professional reads the patient's name, medical record number, and procedure from the anesthesia record. The scrub tech states the procedure he or she is set up for, visualizes the site mark, and states where it is located. The surgeon states the patient's name, complete procedure, and site from memory. The surgeon goes last to minimize the confirmation bias that sometimes happens when team members defer to the surgeon and are reluctant to correct misinformation.
6. For multiple procedures, a time-out is done before each procedure.
7. Other information addressed during the time-out is minimal and, if possible, is addressed earlier, during a preoperative briefing.

A structured analysis of interviews of surgeons, OR nurse managers, and OR nurses in a hospital in Australia[5] identified multiple reasons for "ambivalent compliance" with time-outs. Among the important findings are that (1) the surgeons are included in the development of time-out protocols to achieve surgeon ownership and to avoid exclusively nurse-driven protocols, and (2) the surgeons are educated about time-outs.

The UPMC Health System in Pittsburgh recently had surgeons, anesthesiologists, and OR staff develop a uniform time-out for the system that would be consistent with both the Joint Commission's Universal Protocol[6] and with the World Health Organization's Safe Surgery Checklist,[7] which the system wished to introduce into the ORs. One item the providers added to the time-out script was a mention of the patient's position (personal communication). This addition addresses one of the two main causes of wrong-site surgery: disorientation in the operating room when a patient is not in the conventional supine position. (The other main cause is misinformation.)[8]

The Reading Hospital SurgiCenter at Spring Ridge, in Wyomissing, Pennsylvania, produced a video, in response to a near-miss event, that shows how to apply the components of the Universal Protocol, including the time-out. The facility uses the video for staff education and is monitoring compliance with the Universal Protocol monthly. The video is described and available online through the website of *Outpatient Surgery Magazine*[9] and, for

EVALUATING TIME-OUT PROTOCOLS OR SCRIPTS

The following rubric can be used to evaluate examples available from the Pennsylvania Patient Safety Authority, as well as facility-specific time-out protocols or scripts:

- ☐ The time-out protocol was developed with input from and approval of providers representing all roles in the time-out.
- ☐ A program is available for educating all providers involved in time-outs,
- ☐ The time-out protocol expects that the time-out will be done after the patient is prepped and draped and just before the procedure is begun.
- ☐ The time-out protocol expects all providers to stop noncritical activities to participate in the time-out.
- ☐ The time-out protocol allows for flexibility in posing and responding to the information requested in the time-out protocol, so that the emphasis is on engaging the participants, not on rote memorization.
- ☐ The time-out protocol expects that the information verified will include the patient's identity, the procedure, the site identified by the site marking, and the site identified by any imaging or pathology studies. The protocol may include verification of the patient's position under the drapes.
- ☐ The time-out protocol expects individual responses to individual questions by the leading provider for each role in the operating room (OR) team.
- ☐ The time-out protocol requires that all responses to questions be in the active voice, that is, that they transmit information, not just agreement with information.
- ☐ The time-out protocol requires that any site marking be specifically pointed out by the surgeon during the time-out.
- ☐ The time-out protocol expects that the information communicated in all responses be checked against all documents that could be used to verify that information.
- ☐ The time-out protocol should stipulate that the operating surgeons should explicitly empower other OR team members to speak up if concerned.
- ☐ The time-out protocol permits any OR team member to put a hold on noncritical activities until any concerns have been reconciled.

Pennsylvania facilities, is available through the Authority's PassKey website.

Other time-out scripts were published in a previous *Pennsylvania Patient Safety Advisory* article.[10] (See "Evaluating Time-Out Protocols or Scripts.")

The Authority would like to receive time-out protocols meeting these qualifications to post on the Authority's Preventing Wrong-Site Surgery web page.

THE ROLE OF IMAGING STUDIES IN WRONG-SITE SURGERY

A query about the importance of reviewing imaging studies in the OR as a step in preventing wrong-site surgery prompted analysis of the 415 wrong-site surgery reports in the Authority's wrong-site surgery database through 2010.

The analysis did not assume that imaging studies would have been reviewed by anesthesiologists to prevent wrong-site blocks. Unless otherwise stated, colon lesions were assumed to have been localized by colonoscopy. Wrong-site procedures addressing lung lesions and fractures were assumed to have benefited from review of images unless the description of the event indicated otherwise. Wrong-site arthroscopies, ureteroscopies, and spinal procedures were not automatically included. The report had to specifically suggest that a preoperative review of the imaging study might have corrected an information error. Wrong-site emergencies were not included. Reviewing imaging studies might have been helpful in preventing information errors in other reports; some descriptions were too sparse to make any inference.

Reviewing images in the OR might have corrected information errors leading to 42 wrong-site procedures, as follows:

- 14 instances of stenting of the wrong ureter
- 7 wrong-site orthopedic procedures, including one hip replacement, one hip fracture, one sacral fixation, and four fixations of finger injuries
- 6 operations at the wrong spinal site, four at the wrong level, and two on the wrong side
- 5 operations on the wrong lung for localized pathology
- 3 wrong-site breast procedures, including two on the wrong side and one at the wrong site on the correct side
- 2 craniotomies on the wrong side
- 2 wrong-side intraabdominal procedures that might have benefited from localization of the lesions on imaging studies, one involving a computed tomography (CT) scan showing ovarian pathology and one involving an magnetic resonance imaging scan showing renal pathology
- 1 vascular procedure on the wrong leg
- 1 dental surgical procedure
- 1 incorrect localization of a foreign body

Nine reports indicated that erroneous information in available imaging studies led to wrong-site surgery. Four involved incorrect interpretations before spinal surgery. Two involved incorrect interpretations of sinus lesions on CT scans. One was misleading ultrasound documentation of a breast lesion. One was a misleading radiographic interpretation of kidney stones. One resulted from interpreting the wrong patient's films in the OR.

The analysts concluded that there is a net benefit to reviewing imaging studies in the OR before surgery.

NOTES

1. Quarterly update: The evidence base for best practices for preventing wrong-site surgery. Pa Patient Saf Advis [online] 2010 Dec [cited 2011 May 5]. Available from Internet: http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2010/Dec7(4)/Pages/151.aspx.
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3. Quarterly update on the preventing wrong-site surgery project. Pa Patient Saf Advis [online] 2008 Jun [cited 2011 May 5]. Available from Internet: http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2008/Jun5(2)/Pages/69.aspx.
4. Minnesota Department of Health. Time-out process in Minnesota [online]. 2008 Sep [cited 2011 May 5]. Available from Internet: http://www.health.state.mn.us/patientsafety/ae/wsssummaryfs.pdf.
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6. Joint Commission. The universal protocol for preventing wrong-site, wrong-procedure, and wrong-person surgery [poster online]. [cited 2011 May 5]. Available from Internet: http://www.jointcommission.org/assets/1/18/UP_Poster.pdf.
7. World Health Organization. Safe surgery saves lives. [cited 2011 May 5]. Available from Internet: http://www.who.int/patientsafety/safesurgery/en.
8. Insight into preventing wrong-site surgery. Pa Patient Saf Advis [online]. 2007 Dec [cited 2011 May 5]. Available from Internet: http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2007/dec4(4)/Pages/109b.aspx.
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