

The Evidence Base for the Principles for Reliable Performance of the Universal Protocol

Facilities may wish to use this information to inform surgeons and anesthesiologists of the rationale behind implementing best practices¹ for following The Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery.[™]

Principle. *The correct site of the operation should be specified when the procedure is scheduled.*

Evidence. An analysis of data in the retrospective review² of 161 serious reportable events of wrong-site surgery showed that 7 (4%) were associated with misinformation on the operating room (OR) schedule. A later regression of the number of wrong-site scheduling errors and wrong-site surgeries per facility showed that wrong-site scheduling errors accounted for 5% of wrong-site surgery errors ($R^2=0.05$) and there was an increase of 1 wrong-site surgery for every 10 wrong-site scheduling errors. The statewide comparison of policies and procedures in 37 facilities that had wrong-site surgery and 96 facilities that had none³ showed that preadmission verification included verification of the schedule in 63% of the facilities that had wrong-site surgery and 83% of the facilities that had none, a statistically significant difference ($p<0.05$).

Principle. *The correct operation and site should be noted on the record of the history and physical examination.*

Evidence. In the retrospective comparison of 253 near-miss reports,² in which the potential error was caught before patient contact, and 174 events in which the patient contact occurred at the wrong site, the information from the history and physical examination was 1.9 times more likely to be a source for correction ($n=$) than a source for error ($n=25$). An analysis of data in the retrospective review² of 161 serious reportable events of wrong-site surgery showed that 11 (7%) were associated with misinformation on the history and physical examination.

Principle. *The correct operation and site should be specified on the informed consent.*

Evidence. In the retrospective comparison of 253 near-miss reports,² in which the potential error was caught before patient contact, and 174 events in which the patient contact occurred at the wrong site, the information on the informed consent was 2.1 times more likely to be a source for correction ($n=48$) than a source for error ($n=23$). An analysis of data in the retrospective review² of 161 serious reportable events of wrong-site surgery showed that 12 (7%) were associated with misinformation on the informed consent. The statewide comparison of policies and procedures in 37 facilities that had wrong-site surgery and 96 facilities that had none³ showed that the side of the procedure, when applicable, was required to be included in the consent in 89% of the facilities that had wrong-site surgery and 99% of the facilities that had none, a statistically significant difference ($p<0.01$).

Principle. *Anyone reviewing the schedule, consent, history and physical examination, or reports documenting the diagnosis, should check for discrepancies among all those parts of the patient's record and reconcile any discrepancies with the surgeon when noted.*

Evidence (in addition to the above information about the value of appropriate information on the schedule, the record of the history and physical examination, and the informed consent). In the retrospective comparison of 253 near-miss reports,² in which the potential error was caught before patient contact, and 174 events in which the patient contact occurred at the wrong site, the preoperative verification of the patient's record by the preoperative nurse was 2.3 times more likely to be a source for correction ($n=30$) than a source for error ($n=13$).

Principle. *The surgeon should have supporting information uniquely found in the office records at the surgical facility on the day of surgery.*

Evidence. In the retrospective comparison of 253 near-miss reports,² in which the potential error was caught before patient contact, and 174 events in which the patient contact occurred at the wrong site, the information from the office records were 5.8 times more likely to be a source for correction ($n=35$) than a source for error ($n=6$).

Principle. *All information that should be used to support the correct patient, operation, and site, including the patient's or family's verbal understanding, should be verified by the nurse and surgeon before the patient enters the OR.*

Evidence. In the retrospective comparison of 253 near-miss reports,² in which the potential error was caught before patient contact, and 174 events in which the patient contact occurred at the wrong site, the patient's or family's verbal understanding was 2.6 times more likely to be a source for correction ($n=62$) than a source for error ($n=24$). In addition to the above information about the value of the preoperative verification of the patient's record by the preoperative nurse, the preoperative verification of the patient's record by the surgeon was 5.7 times more likely to be a source for correction ($n=51$) than a source for error ($n=9$) in the same study.² The regional comparison of 245 observations of compliance with the Universal Protocol in 11 facilities that had wrong-site surgery and 16 facilities that had none⁴ showed that preoperative verification was done by two or more providers in 90% of the cases in facilities that had wrong-site surgery and 98% of the cases in facilities that had none, 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, all documents were verified during the time-out in 92% of the cases in facilities that had wrong-site surgery and 100% of the cases in facilities that had none, a statistically significant difference ($p<0.05$).

Principle. All verbal verification should be done using questions that require an active response of specific information, rather than a passive agreement.

Evidence. 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,⁵ patients stated their dates of birth as part of the preoperative identification in 100% of the near-miss events and in 95% of the wrong-site surgery events, a statistically significant difference ($p<0.05$).

Principle. Patient identification should always require two unique patient identifiers.

Evidence. 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,⁵ patients were identified by both information from their charts and their wristbands in 99% of the near-miss events and in 85% of the wrong-site surgery events, a statistically significant difference ($p<0.01$).

Principle. Any discrepancies in the information should be resolved by the surgeon, based on primary sources of information, before the patient enters the OR.

Evidence. As noted above, in the retrospective comparison of 253 near-miss reports,² in which the potential error was caught before patient contact, and 174 events in which the patient contact occurred at the wrong site, the preoperative verification of the patient's record by the surgeon was 5.7 times more likely to be a source for correction ($n=51$) than a source for error ($n=9$). 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,⁵ the surgeon did a preoperative verification in 91% of the near-miss events and in 74% of the wrong-site surgery events, a statistically significant difference ($p<0.05$).

Principle. The site should be marked by a healthcare professional familiar with the facility's marking policy, with the accuracy confirmed both by all the relevant information and by an alert patient or patient surrogate if the patient is a minor or mentally incapacitated.

Evidence. An analysis of data in the retrospective review² of 161 serious reportable events of wrong-site surgery showed that 6 (4%) were associated with misinformation based on the site marking. The statewide comparison of policies and procedures in 37 facilities that had wrong-site surgery and 96 facilities that had none³ showed that the site markings were required to be verified against all documents in 62% of the facilities that had wrong-site surgery and 89% of the facilities that had none, a statistically significant difference ($p<0.01$).

Principle. The site should be marked by the provider's initials.

Evidence. 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 site was marked by the provider's initials in 65% of the cases in facilities that had wrong-site surgery and 95% of the cases in facilities that had none, a statistically significant difference ($p<0.001$).

Principle. All information that should be used to support the correct patient, operation, and site, including the patient's or family's verbal understanding, should be verified by the circulating nurse upon taking the patient to the OR.

Evidence. In the retrospective comparison of 253 near-miss reports,² in which the potential error was caught before patient contact, and 174 events in which the patient contact occurred at the wrong site, the circulating nurse was 5.3 times more likely to be a source for correction ($n=21$) than a source for error ($n=4$). An analysis of data in the retrospective review² of 161 serious reportable events of wrong-site surgery showed that 12 (7%) occurred with misinformation on the consent, 11 (7%) occurred with misinformation on the history and physical examination, and 7 (4%) occurred with misinformation on the OR schedule.

Principle. Separate formal time-outs should be done for separate procedures, including anesthetic blocks, with the person performing that procedure.

Evidence. As reported in an Advisory update,⁶ wrong-site anesthetic blocks represent 29% of all reports of wrong-site procedures in the surgical suite as of December 2009.

Principle. All noncritical activities should stop during the time-out.

Evidence. In recent, unpublished comparisons—in a second region of Pennsylvania—of 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 ($p<0.001$).

Principle. The site mark should be visible and referenced in the prepped and draped field during the time-out.

Evidence. 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,⁵ 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 100% of the cases in facilities that had none, a statistically significant difference ($p<0.01$).

Principle. 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.

Evidence. 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, 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 and/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 ($p<0.01$).

Principle. All members of the operating team should verbally verify that their understanding matches the information in the relevant documents.

Evidence. 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,⁵ 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 ($p < 0.05$).

Principle. The surgeon should specifically encourage operating team members to speak up if concerned during the time-out.

Evidence. The statewide comparison of policies and procedures in 37 facilities that had wrong-site surgery and 96 facilities that had none³ 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 ($p < 0.05$).

Principle. Operating team members who have concerns should not agree to the information given in the time-out if their concerns have not been addressed.

Evidence. 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,⁵ 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 ($p < 0.001$).

Principle. 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.

Evidence. 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,⁵ 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 ($p < 0.001$).

Principle. Verification of spinal level, rib resection level, or ureter to be stented should require radiological confirmation, using a stable marker and readings, by both a radiologist and the surgeon.

Evidence. The North American Spine Society Clinical Care Checklist for Safety to Prevent Wrong-Site Surgery includes consideration of an intraoperative radiograph during surgery, after surgical exposure of the operative site, using markers that do not move, to confirm the vertebral level to be operated on. It also includes consideration of radiologist's reading, in addition to the surgeon's reading.⁷

An analysis of wrong-side ureteral stents revealed 20 reports, accounting for 6% of all 357 wrong-site surgery reports submitted to the Pennsylvania Patient Safety Authority as of the end of 2009.⁶ Six stents were placed on the wrong side despite specific reference to doing a time-out. The reports suggested that wrong-side ureteral stenting might have occurred because the intervention on the wrong side occurred after the operation had begun, rather than initially, and that the side of the instrumented ureter may have been known only to the surgeon visualizing the landmarks, not to the other members of the OR team, who had limited views of the procedure, if any. A review of the reports showed that the failure to do intraoperative imaging was cited as a contributing factor in one report. Patients were returned to the OR to correct errors documented by intraoperative radiographs on two occasions and, most certainly, by a postoperative computed tomography scan on a third occasion. An error identified by fluoroscopy was corrected midprocedure. The remaining error was detected by the radiologic technologist. The analysis suggested that urologists should follow the same principles as vertebral surgeons by obtaining an intraoperative imaging study to confirm proper stent placement, with the interpretation documented at the time. Pregnant patients could have ultrasound imaging.⁶

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Notes

1. Pennsylvania Patient Safety Authority. Principles for reliable performance of correct-site surgery [online]. 2011 Dec [cited 2011 Dec 1]. Available from Internet: <http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Pages/principles.aspx>.
2. Clarke JR, Johnston J, Finley ED. Getting surgery right. *Ann Surg* 2007 Sep;246(3):395-405.
3. Quarterly update on the preventing wrong-site surgery project. Pa Patient Saf Advis [online] 2008 Jun [cited 2010 Nov 1]. Available from Internet: [http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2008/Jun5\(2\)/Pages/69.aspx](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2008/Jun5(2)/Pages/69.aspx).
4. Pelczarski KM, Braun PA, Young E. Hospitals Collaborate to Prevent Wrong-Site Surgery. *Patient Saf Qual Health* 2010 Sep-Oct:20-6.
5. Blanco M, Clarke JR, Martindell DP. Wrong site surgery near misses and actual occurrences. *AORN J* 2009 Aug; 90(2):215-8, 221-2.
6. Quarterly update on the preventing wrong-site surgery project: digging deeper. Pa Patient Saf Advis [online] 2010 Mar [cited 2010 Nov 1]. Available from Internet: [http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2010/Mar7\(1\)/Pages/26.aspx](http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2010/Mar7(1)/Pages/26.aspx).
7. North American Spine Society. Sign, mark & x-ray (SMaX): prevent wrong-site surgery [online]. [cited 2011 Jul 17]. Available from Internet: <http://www.spine.org/Pages/PracticePolicy/ClinicalCare/SMAX/Default.aspx>.