Quarterly Update on Wrong-Site Surgery: Facilities with Barriers to Best Practices May Experience More Wrong-Site Surgeries

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There were 11 reports of wrong-site surgery submitted to the Pennsylvania Patient Safety Authority for the third quarter of 2012, plus one late report of wrong-site surgery for the first quarter of 2012, resulting in an unenviable total of 503 since reporting began June 28, 2004. Anesthesia blocks represented 4 of the 11 wrong-site procedures in the operating room (OR) this quarter.

However, the reports this quarter matched the fourth-lowest number of reports in a quarter since statewide reporting began (see Figure). During this quarter, Pennsylvania ORs went—for the fourth time—for more than a month without any reports of wrong-site surgery; the 39-day hiatus was the second-longest period since statewide reporting began. The period was bracketed by two wrong-site anesthesia blocks. Pennsylvania surgeons went 76 days without a wrong-site procedure. The rolling two-year average (49 per year) of wrong-site surgeries set a new low (see Figure).

The Authority knows the best practices to prevent wrong-site surgery.[1] When providers follow these best practices, they can eliminate wrong-site surgery.[2] And, as will be discussed below, providers who resist following best practices may experience more wrong-site surgeries than those who implement them.

The results of following—or not following—best practices are illustrated by reports from this quarter.

Two events involving anesthesia were reported during the quarter. One was a near miss that was caught during a time-out for the block. The other was an adverse event with no preoperative verification of the documents, no reference to the surgeon's mark, and no time-out.

> *A patient [was scheduled] for right ACL [anterior cruciate ligament] surgery. The anesthesiologist was preparing to perform nerve block on left leg. . . . The time-out was initiated and the block was performed on the correct side.*
>
> *The anesthesia provider identified the patient, introduced herself, did the H&P [history and physical], then went over the anesthetic plan with the patient: a block with IV [intravenous] sedation. The provider obtained the patient's consent and asked what side was to have surgery. The patient said–and pointed to–his right shoulder. The provider then prepared to place the IV. . . . The provider asked again what side was having surgery. The patient said right. The provider then [went somewhere] to gather the ultrasound and the items needed to place the block. When she returned, the patient's left shoulder was out of the gown and his right shoulder was in the gown. The provider proceeded to prep the left shoulder while discussing how the block worked with the patient's companion. At that point, the provider's supervisor arrived. The provider put her gloves on and proceeded to block the wrong shoulder.*

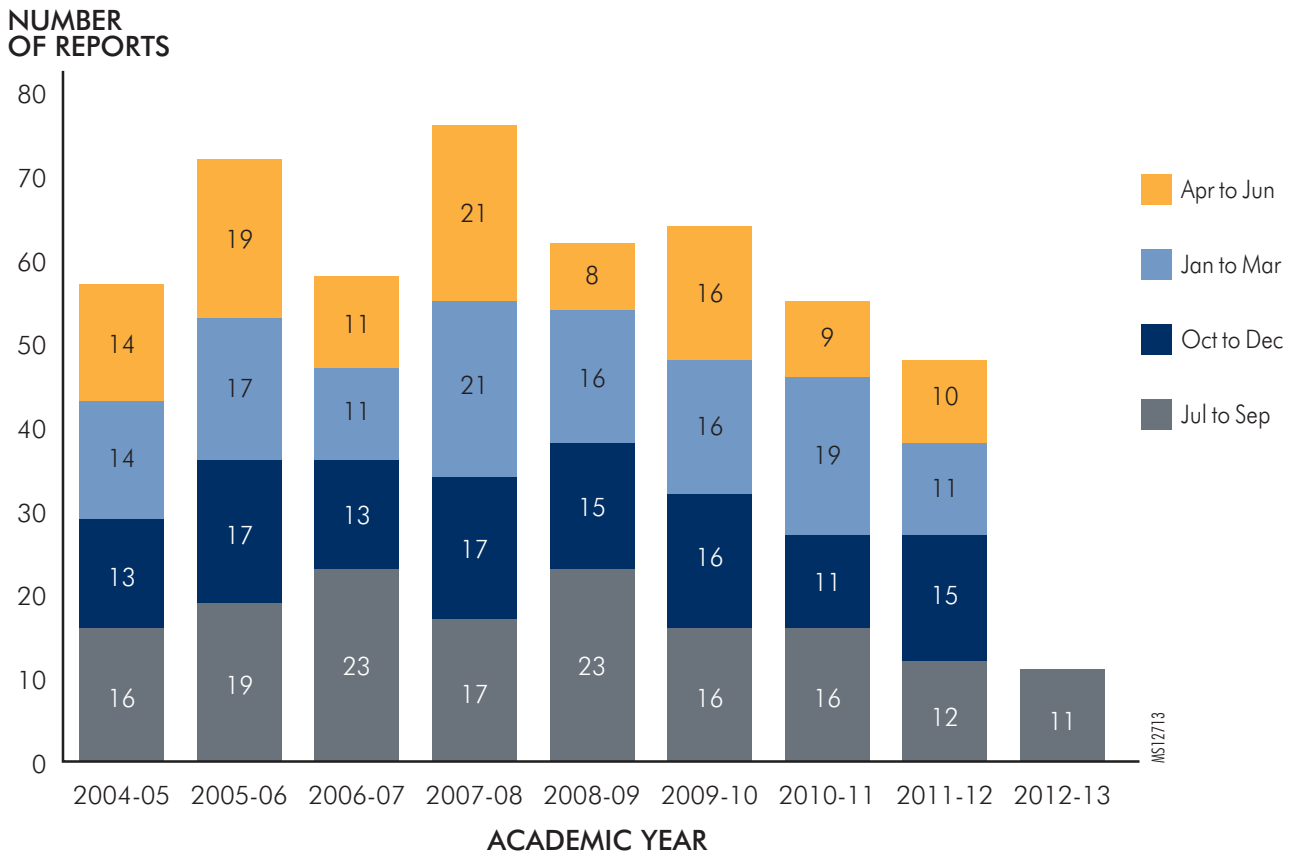
The following is another example of wrong-site surgeries this quarter that were associated with providers not following known best practices,[1] in this case, not referencing a visible site marking during the time-out.

> *Patient consented for repair of right inguinal hernia. The Universal Protocol was completed for the right side. The time-out was completed for the right. . . . The patient was marked preoperatively by the surgeon, but the marking was not visible after draping was completed. The surgery proceeded as usual until the surgeon asked for a left-side mesh. At that time, it was noted they were doing a left inguinal hernia.*

However, several near-miss reports this quarter illustrate that other providers are paying attention to best practices and catching potential problems.

Scan this code with your mobile device's QR reader to access the Authority's wrong-site surgery prevention toolkit.

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



The value of preoperative verification:

> *The preoperative screening department caught that the patient's surgical reservation, OR schedule, and consent stated "RIGHT" foot surgery. [But] when the patient was called for preoperative information, he stated "LEFT" and the H&P discussed "LEFT." The surgeon's office was called and verified the correct side was LEFT. A new reservation was obtained; the OR schedule was corrected according to the reservation, and a new consent was sent by the office.*

The value of verification during the time-out:

> *When consent was read out loud for OR time-out, the consent read for posterior cervical reduction and stabilization perched facet left C5/6. Surgeon agreed with level of fusion but stated, after reviewing the MRI [magnetic resonance image], the laterality would be the right side. Initial consent was established based on . . . reading of radiological studies, which read left-sided fracture. The surgeon reviewed the MRI . . . prior to procedure and determined the right facet was fractured, not the left. . . . The procedure was carried out according to MRI review, and right side confirmed the fracture intraoperatively. After procedure, the surgeon spoke with a radiologist, who also reviewed films and confirmed a fracture to the right facet.*

A recent article surveyed all payments for surgical malpractice reported to the National Practitioners Data Bank from its inception in 1990 to 2006.[3] Operating on the wrong body part was the source of 3.21% of surgically related malpractice payments in the United States during that time. Eliminating this preventable occurrence would, in theory, single-handedly reduce surgically related malpractice payments by 3%. Evidence accumulates that implementing best practices to prevent wrong-site surgery would achieve that objective.[2,4-7] Yet, implementation has not occurred in all Pennsylvania surgical facilities.

PROVIDERS WHO RESIST FOLLOWING BEST-PRACTICE STANDARDS MAY EXPERIENCE MORE WRONG-SITE SURGERY THAN THOSE WHO IMPLEMENT THEM

The Authority has previously published the results of a survey of facilities to identify the barriers to implementation and the strategies for successful implementation of the Authority's 21 potential recommendations to prevent wrong-site surgery.[8]

The survey divided the 21 potential recommendations into six major goals (1, 2, 3A, 3B, 4, and 5), with a total of eight proposed measurement standards (1, 2A, 2B, 3A, 3B, 4A, 4B, and 5). For each of the eight measurement standards, respondents for the facilities were asked to describe barriers to implementation of the recommendations that would prevent the facilities from meeting the standard(s) for the goal. They were asked to describe any strategies they had used for successful implementation. Seventy facilities responded. Physician behavior was cited most commonly as a barrier to implementation, followed by difficulty accessing accurate information prior to the patient's arrival in the preoperative holding area. Elements of successful strategies for implementation included leadership, empowerment, improved access to information, education, and monitoring of compliance.[8]

Since the survey, the Authority has identified 24 facilities (14 hospitals and 10 ambulatory surgical facilities [ASFs]) that described only processes for successful implementation of the standards and 8 facilities (4 hospitals and 4 ASFs) that described only barriers that prevented the facilities from meeting the standards. Excluded from the analysis were respondents from facilities that listed both, single respondents responsible for multiple facilities, anonymous respondents, and respondents from facilities that only did endoscopies or infertility treatments.

The 24 facilities describing successful implementation reported 1 wrong-site surgery among the 14 hospitals (7%) and none in the 10 ASFs in the previous academic year (July 2011 to June 2012). The 8 facilities describing barriers to implementation reported 1 wrong-site surgery among the 4 hospitals (25%), and none in the 4 ASFs. The difference was not statistically significant, given the small numbers.

The sample size was expanded to the last two years, consistent with the Authority's two-year empirical cycle and rolling average. The 24 facilities describing successful implementation reported 1 wrong-site surgery among the 14 hospitals (7%) and 1 in the 10 ASFs (10%) over the prior two-year cycle (July 2010 to June 2012). Of the 8 facilities describing barriers to implementation, 1 of the 4 hospitals (25%) reported 2 wrong-site surgeries (1 each year), and 2 wrong-site surgeries were reported among the 4 ASFs (50%). The difference was statistically significant by the chi-square test ($p < 0.05$) for the group as a whole, but not for either type of facility individually, perhaps again given the small numbers.

The Authority was reluctant to take the analysis back beyond the two-year cycle. It was confident that the barriers were still existent but suspicious that the successful strategies had not yet been implemented.

The Authority suspects that the high probability of wrong-site surgery among the facilities describing barriers (3 of 8) was likely due to reporting bias. Two of the facilities describing barriers and experiencing wrong-site surgery, including one with 2 events in 2 years, described barriers preventing them from meeting 5 of the 8 standards each, suggesting a high level of frustration.

The results suggest that persistent barriers to the implementation of evidence-based best-practice standards may be associated with more wrong-site surgeries.

READINESS FOR CHANGE

From prior analysis of facilities that self-corrected, experience with the collaborations to prevent wrong-site surgery,[2,5] and review of the descriptions of the barriers and successful strategies for implementation of best practices,[8] the Authority has identified four essential elements for successful implementation of standards to prevent wrong-site surgery:

1. Leadership. The chief executive officers are willing to empower the nurses to enforce the facility's best-practice policies and provide resources to improve systems and educate providers, including physicians.
2. Manpower. Identified champions, ideally a leading surgeon, anesthesiologist, and OR nurse, have the authority, time, and resources to work with providers to change systems so that they meet best-practice goals in a way that acknowledges realistic concerns of providers.
3. Information. Near-miss events are captured and analyzed for quality improvement, policy and system changes, and education.
4. Time. Improving systems to meet the goals of evidence-based best practice without significant compromise to workflow and educating providers about making the improvements takes time, typically about six months.

The Authority can help facilities by providing information about reported events, providing checklists and other tools for improvement, and providing educational resources. (See http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Pages/home.aspx for a complete listing.)

Facility leaders can make a commitment to implement evidence-based best practices and policies and procedures to prevent wrong-site surgery, use appropriate checklists to aid compliance, achieve

consistent compliance with those policies and procedures, and monitor for and review all wrong-site events, including, at least, critical near misses.[2,9]

COMPARISON OF THE AUTHORITY'S 21 EVIDENCE-BASED BEST PRACTICES TO PREVENT WRONG-SITE SURGERY AND THE JOINT COMMISSION'S 29 MAIN CAUSES AND SOLUTIONS FOR WRONG-SITE SURGERY

The Joint Commission Center for Transforming Healthcare Wrong-Site Surgery Project identified 29 main causes of wrong-site surgeries and their targeted solutions.[10] The Authority compared the solutions with its 21 evidence-based best practices to prevent wrong-site surgery.[1] There was overlap between the 29 main solutions identified by the Joint Commission and the 21 best practices identified by the Authority for most of the causes and best practices for prevention.

The Authority's 21 evidence-based best practices for the prevention of wrong-site surgery do not include the following specific points that were identified and tested by the Joint Commission's Robust Process Improvement methods:[10]

- Limit schedulers accepting verbal requests for surgical bookings instead of written documents by limiting "entry points for primary documentation . . . to a single fax number."
- "Confirm the presence and accuracy of primary documents critical to the verification process *prior to* the day of surgery." [italics added]

The Authority concurs with the general principle of written documentation collected and reconciled prior to the day of surgery and emphasizes that the site of the procedure is a critical piece of information that needs documentation.

The surgeon should mark the site, do it in the pre-op/holding area, and do it in an approved manner:[10]

- "Mark in the pre-op/holding area performed by the surgeon using a single-use surgical skin marker with a consistent mark type (e.g., surgeon's initials) placed as close as anatomically possible to the incision site."
- "Mark the site for every procedure; if not possible, document why a site-mark was not performed."
- "Do not move patient to the operating room before surgeon has marked the site."
- Document why site was marked in a nonapproved manner "even if a wrong site surgery event has not occurred."

The Authority has no specific evidence supporting the surgeon marking the site but agrees that the surgeon is the optimal provider for confirming that the site is marked accurately in a place that will be visible in the prepped and draped field. The Authority will further explore the sites at particular risk for wrong-site surgery.

The Authority realizes that its evidence-based best-practice principle #10 had an implicit assumption that the site would be marked before the patient enters the OR or procedure room. It has modified its principle to make that assumption explicit, as follows:

- 10. 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; the site should be marked before the patient enters the OR.

As an alternate to the site mark, when needed, the Joint Commission says that facilities should "confirm identification of patient by all team members using patient armband, patient speak back, or patient caregiver if patient has been sedated."

The Authority concurs that an alert patient or caregiver participating in the time-out is a logical substitute for a site mark—since the site mark is, itself, a surrogate for the verbal participation of an alert patient in the time-out—but that the patient's response should be confirmed by all the relevant information, as it would be if the site were being marked.

Another Joint Commission solution was to "perform a pre-operative briefing in the operating room with patient involvement, if possible, to verify patient identity, procedure site, and side, along with other critical elements that need to be verified and addressed but are not part of the Time Out process."

The Authority supports the use of a preoperative briefing, such as that in the WHO Surgical Safety Checklist,[11] when the patient enters the OR, prior to the final time-out. The elements in that briefing should be those that need time to address before the incision is made, such as the availability of blood. The elements in the time-out should be those that need confirmation just as the incision is being made, such as the location of the site mark in the prepped and draped field and the administration of prophylactic antibiotics. The Authority has a suggested merger of the Joint Commission's Universal Protocol and the WHO Surgical Safety Checklist.[12] The Association of periOperative Nurses has also merged the two into a Comprehensive Surgical Checklist.[13]

The Joint Commission's targeted solutions did not address the evidence-based value of four of the Authority's evidence-based best-practice principles: supporting information from the surgeon's office (#5), doing the preoperative verification before the patient enters the OR (#6), verification by the circulating nurse upon taking the patient to the OR (#12), and the need for intraoperative verification of spinal level, rib resection level, or ureter to be stented (#21).

NOTES

1. Pennsylvania Patient Safety Authority. Principles for reliable performance of correct-site surgery [online]. 2011 Dec [cited 2012 Oct 15]. http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Documents/principles.pdf.
2. Clarke JR. Quarterly update: what might be the impact of using evidence-based best practices for preventing wrong-site surgery? Results of objective assessments of facilities' error analyses. Pa Patient Saf Advis [online] 2011 Dec [cited 2012 Oct 15]. http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2011/dec8(4)/Pages/144.aspx.
3. Orosco RK, Talamini J, Chang DC, et al. Surgical malpractice in the United States, 1990-2006. *J Am Coll Surg* 2012 Oct;215(4):480-8.
4. Quarterly update on the Preventing Wrong-Site Surgery Project. Pa Patient Saf Advis [online] 2010 Jun [cited 2012 Oct 15]. http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2010/Jun7(2)/Pages/65.aspx.
5. Pelczarski KM, Braun PA, Young E. Hospitals collaborate to prevent wrong-site surgery. *Patient Saf Qual Healthc* 2010 Sep-Oct;7:20-6.
6. Quarterly update: the evidence base for best practices for preventing wrong-site surgery. Pa Patient Saf Advis [online] 2010 Dec [cited 2012 Oct 15]. http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2010/dec7(4)/Pages/151.aspx.
7. Clarke JR. Quarterly update: what might be the impact of using evidence-based best practices for preventing wrong-site surgery? Pa Patient Saf Advis [online] 2011 Sep [cited 2012 Jun 25]. http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2011/sep8(3)/Pages/109.aspx.
8. Clarke JR. What keeps facilities from implementing best practices to prevent wrong-site surgery? Barriers and strategies for overcoming them. Pa Patient Saf Advis [online] 2012 Nov 20 [cited 2012 Nov 20]. http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/Pages/Home.aspx.
9. Clarke JR. Quarterly update on preventing wrong-site surgery. Pa Patient Saf Advis [online] 2012 Mar [cited 2012 Oct 15]. http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2012/mar;9(1)/Pages/28.aspx.
10. Joint Commission Center for Transforming Healthcare. Reducing the risk of wrong site surgery [online]. 2012 Feb [cited 2012 Oct 15]. http://www.centerfortransforminghealthcare.org/assets/4/6/CTH_WSS_Storyboard_final_2011.pdf.
11. Clarke JR. Editorial: WHO Surgical Safety Checklist. Pa Patient Saf Advis [online] 2008 Sep [cited 2012 Oct 15]. http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2008/Sep5(3)/Pages/74.aspx.
12. Pennsylvania Patient Safety Authority. Possible integration of actions to satisfy Joint Commission Universal Protocol and WHO Surgical Safety Checklist [online]. 2011 [cited 2012 Oct 15]. http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Documents/crosswalk.pdf.
13. Association of periOperative Registered Nurses. Comprehensive surgical checklist [online]. 2010 Apr [cited 2012 Oct 15]. http://www.aorn.org/Clinical_Practice/ToolKits/Correct_Site_Surgery_Tool_Kit/Comprehensive_checklist.aspx.

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