Quarterly Update on the Preventing Wrong-Site Surgery Project: Digging Deeper

Don't you love it when you find a cache of old things in your drawers . . . and it is overdue bills! Pennsylvania Patient Safety Authority analysts noted a wrong-site surgery report that was not captured by the reporting system identification algorithm and followed the thread to discover four missed reports going back to the second quarter of 2008. This article includes these past reports. On the other hand, five tube thoracostomies, previously in the database, were identified as having not been done in the operating room (OR) or ambulatory surgical venues. Although wrong-site events in other parts of the healthcare system are a problem in their own right, the focus—and metrics—of this project has been on events in OR and surgical procedure room venues; therefore, those reports have been deleted from this operating team project. The latest figures incorporate these adjustments, among other updates and corrections (see Figure 1). The good results in the second quarter of 2009 now stand uniquely luring to the potential for improvement.

Is Pennsylvania making progress? Possibly, although not as fast as theoretically possible. Perhaps, comparing the downward trend in Pennsylvania to other publicly available trends for wrong-site surgery (see Figure 2). Although the downward trend in Pennsylvania is not statistically significant, it is at least in the right direction. Although the trends may be informative, the numbers of events reported from each source should not be compared, because the populations which they cover, the exact time periods for each year, and the exact criteria for reporting are not the same among the entities (see the caption for Figure 2 for qualifications about each source). The downward trend in Pennsylvania is notably volatile, suggesting inconsistent compliance with known best practices or wide variation in compliance with known best practices among facilities.

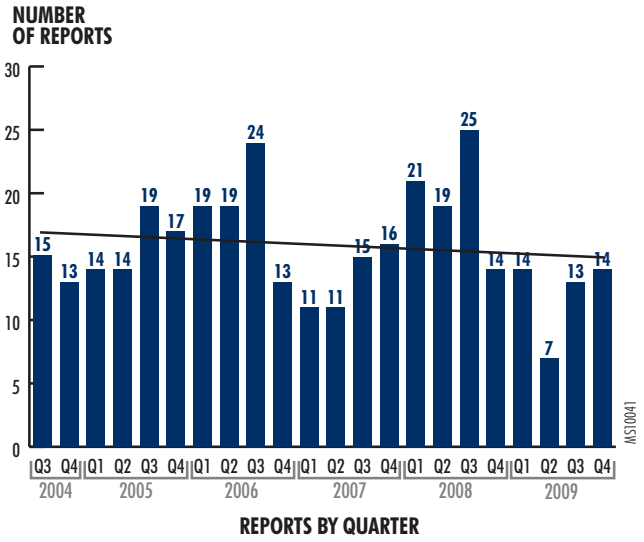
Unfortunately, the successive shutouts of wrong-site surgery by the Health Care Improvement Foundation's regional collaborative to prevent wrong-site surgery have come to an end with wrong-site blocks.

Local and Regional Anesthesia Blocks

Wrong-site local and regional anesthesia blocks represent a major portion of wrong-site OR procedures in the recent past. This quarter, 7 of the 14 reports (50%) were wrong-site local or regional anesthetic blocks, as follows:*

> *I asked the patient which side the procedure was on; the left leg was raised. A left femoral nerve block was performed with the patient awake. Upon turning prone for the popliteal block, I discovered the wrong-side error.*

Figure 1. Pennsylvania Patient Safety Authority Wrong-Site Surgery Reports by Quarter

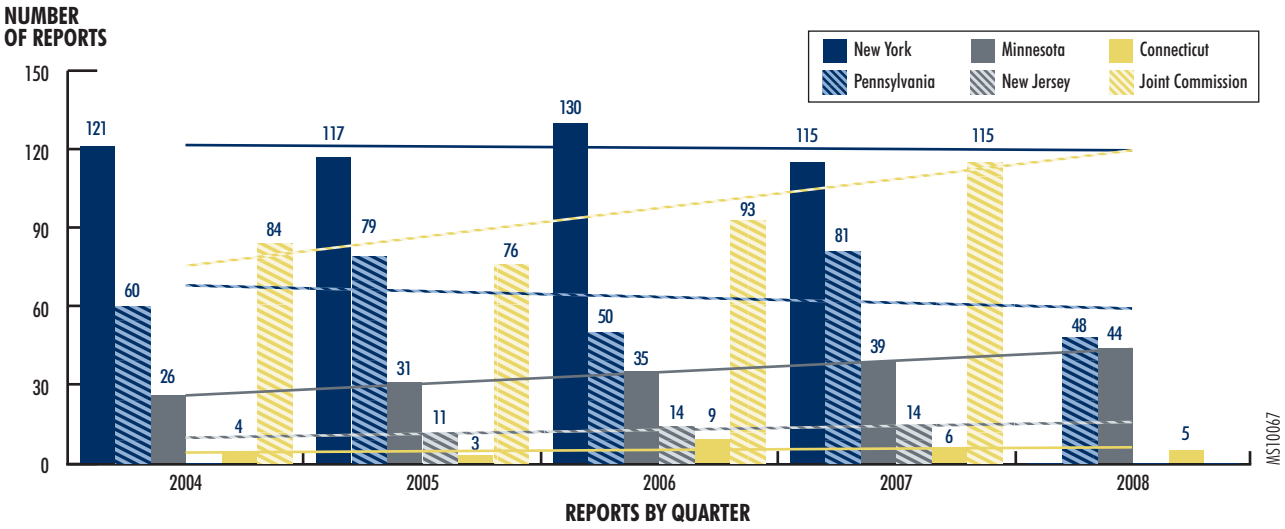


> *I asked the patient again which side we were doing, and the patient pointed to the right. The patient then underwent a right popliteal block.*
>
> *The patient, prior to left knee surgery, was given a right sciatic nerve block by the anesthesiologist. During the block time-out, the patient told the anesthesiologist that the operative side was the right side. A right-sided sciatic block was performed. The anesthesiologist then performed a left sciatic block.*
>
> *A femoral nerve block was performed on the wrong leg prior to surgery. An alternative method of pain management was implemented postoperatively.*
>
> *At the time of time-out, the staff discovered the surgeon had begun to inject local anesthesia around the right ear. The surgery was consented and scheduled for the left ear.*
>
> *The patient was prepped, and a femoral nerve catheter was inserted on the wrong side; the right side procedure was then completed without complication.*
>
> *The left knee site was marked for arthroscopy according to the surgical consent and patient's verbal response. In the OR, the doctor injected the right knee with 15 ml of lidocaine. The site discrepancy was discovered by staff. The procedure on the left knee was confirmed by time-out, and the left knee arthroscopy was performed.*
>
> *A femoral block [was performed] on the left leg in error. The time-out was completed with the correct leg identified. [It was an] anesthesiologist error.*

Notable in all seven reports is the limited use of information to confirm the side. The Authority has shown that it is necessary to validate the side against

* All reports have been edited to remove identifying information or have not been reported if that could not be done.

Figure 2. Comparison of Pennsylvania Trend and Publicly Available Trends for Wrong-Site Surgery



New York data are NYPORTS codes 911: Wrong Patient, Wrong Site – Surgical Procedure and 912: Incorrect Procedure or Treatment – Invasive. New York data includes procedures performed in settings other than the operating room (OR). Data are for calendar years 2005 to 2008; data for calendar year 2009 (79 reports) is currently incomplete because of reporting delays. Data courtesy of NYPORTS (personal communication with John N. Morley, MD, and Ruth W. Leslie).

Pennsylvania data are for wrong-site, wrong-procedure, and wrong-patient reports, restricted to OR and ambulatory surgical facility procedures. Data are reported for years running from October to September to match Minnesota data. Pennsylvania's downward slope is not statistically significant.

Minnesota data are for wrong-site, wrong-procedure, and wrong-patient reports for years running from October to September Minnesota data include reports from outside of the OR. The data are from the Minnesota Department of Health's Adverse Health Events in Minnesota Reports from 2005 through 2010. See: http://www.health.state.mn.us/patientsafety/publications/index.html.

New Jersey data are for wrong-body-part, wrong-patient, and wrong-procedure reports. Data are for calendar years 2005 to 2007 only. The data are from the New Jersey Department of Health and Senior Services' Patient Safety Initiative 2007 Summary Report. See: http://www.state.nj.us/health/ps/documents/ps_initiative_report07.pdf.

Connecticut data are for surgery performed on the wrong body part, surgery performed on the wrong patient, and wrong surgical procedure performed on a patient. Data are from July to June. Data are from Connecticut Department of Health's Legislative Report to the General Assembly on Adverse Event Reporting, October 2009. See: http://www.ct.gov/dph/lib/dph/hisr/hcqsar/healthcare/pdf/adverseeventreportoct2009.pdf.

Joint Commission data are for reviewable sentinel events involving surgery on the wrong patient or wrong body part. Data are for calendar years 2005 to 2008. The data can be seen graphically on the Joint Commission sentinel event trends reported by year—updated through 2008. See: http://www.jointcommission.org/NR/rdonlyres/67297896-4E16-4BB7-BF0F-5DA4A87B02F2/0/se_stats_trends_year.pdf.

the patient's understanding and all documents (the consent, the history and physical examination, and the schedule at a minimum) to minimize the risk for error.

Wrong-site blocks represent 29% of all reports of wrong-site procedures in the surgical suites, the largest cohort of wrong-site procedures within a single specialty in the suites. Over time, wrong-site blocks have increased significantly from less than 20% of all reports to more than 40% of all reports (see Figure 3, $p < 0.05$ by Pearson's Correlation Coefficient), suggesting that the implementation of best-practices to prevent wrong-site blocks lags behind other efforts to prevent wrong-site surgery. The proportion of wrong-site anesthesia blocks is more notable given that only a fraction of patients who are vulnerable to wrong-site surgery receive anesthesia in the form of blocks.

The 2010 revision of the Joint Commission's Universal Protocol will, in the analysts' opinion, aggravate this concerning trend. The 2009 version of the Universal Protocol stated that the time-out should be done before the start of anesthesia; the 2010 version reverts to stating that the time-out should be done prior to the incision.[1] Based on multiple studies from its Preventing Wrong-Site Surgery Project,* *the Authority strongly advises that a formal time-out be done with the anesthesia provider just before any anesthetic block and that another time-out be done with the surgeon just before the incision*, unless the surgeon performs the anesthetic block and incision in continuity after the surgical field has been prepped and draped.

Pain Management Procedures

Pain management is not immune from wrong-site problems, even though the patients are awake, as

* The Pennsylvania Patient Safety Authority has a Web page devoted to educational tools for preventing wrong-site surgery (available at http://www.patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Pages/home.aspx). Its resources include all of the Authority's publications on the subject, including self-assessment tools, sample forms and checklists, educational posters and videos, illustrative figures and tables, and patient education brochures, as well as links to information from other Web sites.

The Authority strongly advises that a formal time-out be done with the anesthesia provider just before any anesthetic block and that another time-out be done with the surgeon just before the incision.

noted in another of the most recent 14 reports, as follows:

> *The patient was admitted to the procedure room. The physician reviewed the medical record; then, the physician and nurse performed the time-out procedure. The physician performed the preprocedural skin prep, then inserted the spinal needle into the left side of the patient's sacral (SI) epidural space rather than the right side. We did not learn of the error until the spouse questioned [bandages] on the left side of the spine rather than the right.*

The 30 wrong-site procedures for pain management represent another 8% of the wrong-site procedures done in surgical suites. An earlier 2009 report illustrates another need to follow the Universal Protocol for pain management procedures, as follows:

> *The patient was scheduled for left cervical injection. The time-out was done prior to procedure, and all parties, including the patient, verified the procedure was to be done on the left side. The doctor injected the right side. He did not mark the site since he was in constant attendance with the patient. The patient asked after the procedure why the right was injected rather than the left. The doctor was notified, and the correct side was then done. No adverse outcomes were noted from the injections.*

A site marking, visible in the prepped and draped field, is essential to avoid problems arising from disorientation, right-left confusion, and confirmation bias.

Ureteral Stenting

Two of the reports this quarter involved stenting the wrong ureter:

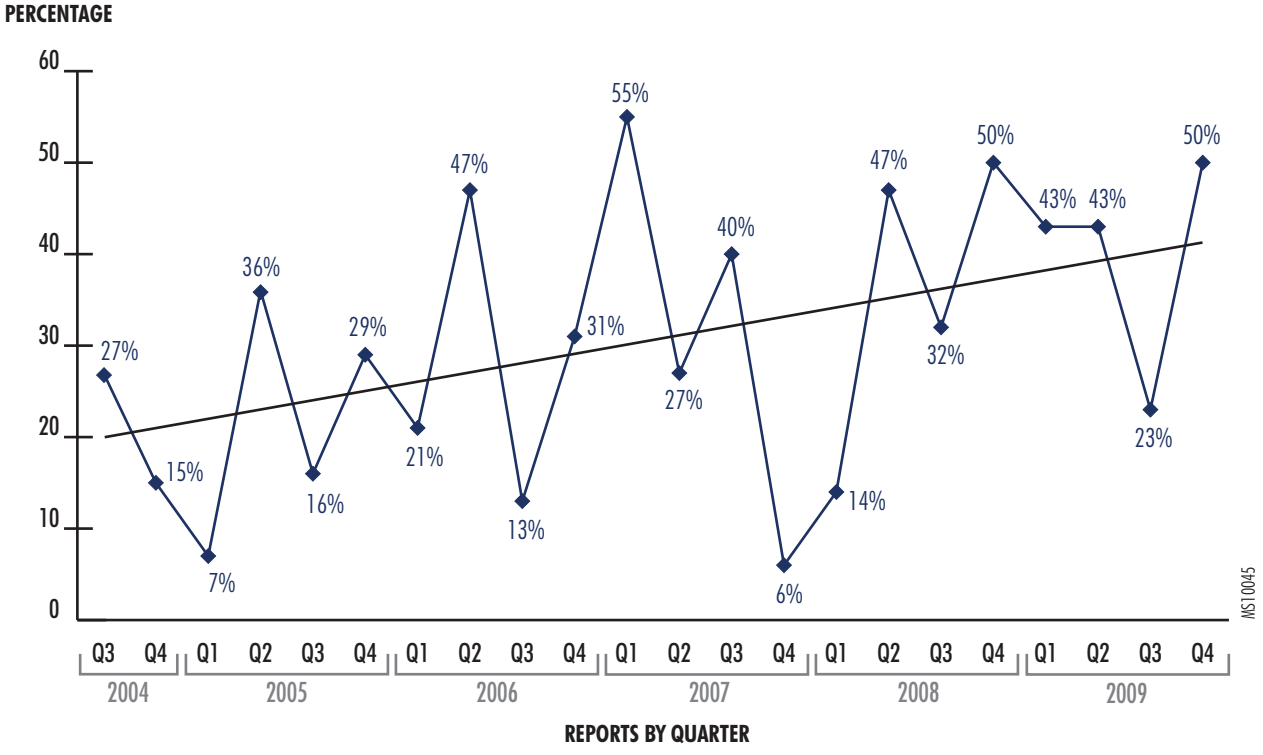
> *A stent was placed in the left ureter instead of the right.*

> *Following scheduled cystoscopy, with right retrograde, and placement of right ureteral stent, the x-ray tech stated "stent in left ureter, not right." Physician was informed. Procedure was repeated with removal of left ureteral stent, . . . and the right ureteral stent was placed in patient without any complications or problems.*

Overall, ureteral procedures account for 21 (6%) of all wrong-site surgery reports and 81% of wrong-site urological procedures. All but one were wrong-side procedures, and all but one occurred in hospital ORs. Some of the other examples of stenting the wrong ureter in the Authority reporting system database include the following:

> *Patient with signed consent for cystoscopy and right stent replacement. The final time-out was completed. During the cystoscopy, the surgeon stated the anatomy*

Figure 3. Percentage of Wrong-Site Surgery Reports that Describe Wrong-Site Anesthesia Blocks



caused him to insert stent in the left side. The procedure was not done under x-ray visualization. The surgeon assumed the consent was in error. After patient was in PACU [postanesthesia care unit], the surgeon confirmed with his office that the right side was the correct side. [Staff] took the patient back to the OR; the surgeon removed the left-sided stent and placed the right stent.

Medical evaluation of a [patient] revealed obstructing calculus within the range of the left ureteropelvic junction, producing hydronephosis. The patient was taken to the OR . . . for stenting of the left ureter. The time-out verifying right patient, right procedure, right side was performed. Upon arrival in the PACU, the physician reviewed x-ray films completed during the procedure and confirmed misplacement of the stent in the right ureter instead of the intended left ureter. The . . . patient was returned to the OR for removal of the right urethral stent and placement of a left urethral stent. The procedure occurred without further complication. Complete disclosure was [done].

[A patient was] admitted for insertion of a ureteral stent. [The patient] had stones bilaterally. One side was worse than the other. Per radiology interpretation, insertion of stent was planned and completed for the left side. [Staff] determined following procedure [that] the stones in the right side were actually more problematic. The patient returned to the OR. Left-side stent was removed; right-side stent was inserted.

Office incorrectly scheduled case. Schedule read ureteroscopy with possible insertion of stent. Consent read right ureteroscopy with possible insertion of stent. The OR nurse confirmed with patient, at the time of preoperative checklist completion, and the patient confirmed above. A time-out was completed in the room, and staff confirmed with consent and surgeon the right ureteroscopy and stent. After completing the procedure, the surgeon reviewed his office record and noted that the procedure should have been completed on the left side.

Patient underwent left ureter stent placement [instead of] right. Consent, preoperative interview, and holding area confirmed with patient for right cystoscopy with stone retrieval from right ureter. A time-out was completed prior to procedure. The surgeon completed procedure. The patient was taken to PACU. The surgeon was documenting and noted that the stent was placed in the wrong side. The patient was returned to surgery for right side ureter stone retrieval.

The physician inserted the stent into the wrong ureter even after discussion with staff and the time-out process. The patient was taken from the recovery room back into the OR where the stent was removed and placed in the right kidney.

A physician reported to the patient safety officer that he had placed a right ureteral stent in a patient when he should have placed the stent on the left. The physician was clear that the hospital OR staff had correctly followed the Universal Protocol on time-out prior to surgery, had hung the correct CT [computed tomography] films, etc. He removed the incorrect stent in his office the day following the original procedure, and the patient came back to the hospital two days later to have the correct stent placed.

The patient, with a history of bilateral kidney stones, was scheduled to have a left kidney stone removed due to left-sided pain. Preoperatively, the surgeon spoke with the patient and verbally identified with the patient that surgery was to be performed on the right side; the surgeon marked the right side. In the OR, the surgeon identified the patient and the fact that he was doing a right -sided ureteroscopy, which he performed, inserting a stent in the right ureter. The surgeon then realized the surgery was to be on the left side, and he proceeded to do a ureteroscopy with removal of the stone on the left side. The patient did well postoperatively and was discharged home.

The patient was scheduled for a left ureteroscopy and left retrograde with removal of stone. The patient went back to the OR and underwent a right ureteroscopy. The procedure was completed; no stone was found. In the PACU, the surgeon said he was to do the left, and he did the right. The patient was taken back to the OR to undergo the left ureteroscopy and removal of stone.

Procedure was consented for right ureteroscopy. No stone [was] seen in right ureter. A stone was seen in the left ureter. A left ureterosopy was performed. The surgeon called the office to review [imaging] results, which reported a large stone in the patient's left ureter.

Patient had a cystoscopy and right retrograde for ureteral calculus. When the radiologist was reviewing intraoperative films the next day, she recognized discrepancy between the preoperative CT [film] and the intraoperative films. The preoperative CT [film] indicated left ureteral calculus. A cystoscopy and left retrograde were performed the next day.

The physician originally told office staff to schedule patient for a left ureteroscopic stone removal. After review of a subsequent CT scan, the patient was consented for a right ureteroscopic stone extraction. In the OR, the patient confirmed left side, and the left side was done. When no stone was found, the right side was then done.

Preoperatively, patient, surgeon, and nurse identified right side for procedure, and the right side was marked. In room before procedure began, a time-out was performed stating the right side was the correct site. Near the end of the case, the anesthesia provider asked the surgeon to state the procedure. The surgeon stated that he had done a left retrograde and stent insertion. The nurse then stated that the permit, history and physical, and markings all stated right. Surgeon then removed the left stent and did a right retrograde and stent insertion.

A patient was scheduled and consented for a right ureteroscopy and placement of a right ureteral stent. During procedure, a renal stone was identified to be on left side by the doctor and verified by in-room fluoroscopy. [Staff] scheduled a procedure to be performed on left side.

The provider inserted a stent into left ureter and then discovered after viewing CT and images that he placed the stent in the wrong side.

The patient consented to cystoscopy with left ureteral stent insertion. The RN [registered nurse] confirmed operative consent verbally with patient, and a bracelet was applied confirming left side. Intraoperatively, it was discovered that it should have been right ureter. The procedure was stopped, and physician spoke [with the] patient and family and then did the right side.

The patient was diagnosed with bilateral renal stones with left urethral obstruction. The patient inadvertently consented to have urethral stent placed on the right side instead of the left side that was obstructed. The patient underwent the right-side stent placement. It was discovered, while the patient was in the PACU, that the incorrect side was stented. Consent was obtained for the patient to return to the OR to have the left-side stent placed. The patient and family were informed of the error.

Contributing factors that were reported multiple times included bilateral pathology (four times), patient indicated the incorrect side (four times), schedule was incorrect (three times), consent was incorrect (three times), preoperative image was not referenced (three times), and office notes were not referenced (three times). Overall, 10 (50%) of the reports specifically mentioned some form of misinformation, correctable prior to entering the OR, as a contributing factor.

Six stents were placed on the wrong side despite specific reference to doing a time-out. This suggests that perhaps the side is not referenced during the time-out. The reports also suggest that wrong-side ureteral stenting can still occur because the intervention on the wrong side occurs *after* the operation has begun, rather than initially, and that the side of the instrumented ureter may only be known to the surgeon visualizing the landmarks, not to the other members of the OR team, who have more limited views of the procedure, if any. These reports suggest that stenting of the ureters has similarities with localization of the vertebral levels. The surgeon may be victim to right-left confusion or the fact that the two ureteral orifices are only about 4 cm apart, but are usually not in the same field of vision.

A review of the reports shows that the failure to do intraoperative imaging was cited as a contributing factor in one case and that patients were returned to the OR to correct errors documented by intraoperative radiographs on two occasions and, most certainly, by a postoperative CT scan on a third occasion. The error identified by fluoroscopy was corrected in mid-procedure, and one of the recent confusions was detected by the radiography technician. These experiences suggest that the 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.

The review of wrong-side stents suggests that they could be prevented by mentioning the correct side when scheduling; verifying and reconciling the side on the schedule, the consent, the history and physical examination and/or the office notes, and the preoperative imaging studies, rather than relying on memory; and properly marking the side before entering the OR. During the time-out, the surgeon should be engaged, the side should be mentioned, and, as with all time-outs, the OR staff should be explicitly empowered by the surgeon to speak up if concerned.

It may be helpful to "call out" the placement of the stent, including the side, when it is placed intraoperatively and have the circulating nurse verify this information mid-operation against the documents.

Finally, it may be useful to follow an intraoperative verification protocol, similar to that for spinal surgery, using an intraoperative imaging study to confirm proper stent placement, with the interpretation documented at the time.

Hand Surgery

One report this quarter involved hand surgery, as follows:

The patient was scheduled for left trigger thumb release. The surgeon made the incision for carpal tunnel release. The surgical technician questioned the procedure. The correct procedure was then done.

Overall, hand surgery accounts for 21 (6%) of all the wrong-site surgery reports. All of the wrong sites were on the correct hand, but in the wrong part of the hand; 11 were the wrong procedure altogether, and the other 10 were the correct procedure but on the wrong digit. Remarkably, 7 of the 11 incorrect procedures were carpal tunnel releases when the patients were scheduled for release of "trigger fingers" (or "trigger thumbs"). Of the other 10, 7 mentioned both the correct and incorrect locations and, in all cases, involved adjacent digits, albeit not in any pattern.

Misinformation in the schedule and consent was only mentioned in one report, whereas misorientation was a factor in six: a loss of orientation in one, the absence of a proper mark in two, and starting before or without a time-out in the other three. The absence of a proper mark and the loss of orientation resulted in reports of mental lapses, as indicated by the following reports in the series:

Scheduled, consented, and marked for release of trigger; area prepped [with] alcohol; during prep site, mark washed off [with] alcohol; time-out done;

surgeon proceeded to do carpal tunnel . . . surgeon told staff he was thinking about a patient he had done the previous day.

Verification of procedure was performed with all OR staff for the procedure to be done on the left ring finger. The surgeon turned from field to consult records, turned back to field, picked up long finger, and proceeded with surgery.

The errors were reported to have been detected and corrected during 17 of the procedures. Seven were realized by the surgeon, four were brought to the attention of the surgeon by members of the OR staff (as in the example above), and three by the patients; the remaining three did not mention how the error was detected.

It appears that wrong-site hand surgery is almost always the wrong procedure or in the wrong location of the correct hand documentation. Five reports mentioned that an appropriate time-out was done. As illustrated in the examples, the reports suggest that the errors resulting in wrong-site hand surgery frequently begin with confusion in the mind of the surgeon between the pause for a time-out and the incision. This confusion at the start of the operation is in contrast to heart surgeons and upper abdominal surgeons. No reports have been submitted to the Authority of a surgeon intending to do a coronary artery bypass and doing a valve replacement instead (or vice versa) or of a surgeon intending to remove one upper abdominal organ and removing another instead. And, hand surgeons even have the advantage of being able to mark different, specific incision locations unique to the correct procedures.

Errors were brought to the surgeons' attention by others as often as self-correction occurred. The majority of this help came from members of the staff, reinforcing the importance of specifically empowering the OR staff to speak up if concerned during the time-out.

The review of hand surgery reports suggests that errors would best be prevented if the surgeon made the mark as close as possible to mimicking the incision and by doing the time-out as close as possible to actually making the incision. The surgeon should be engaged in the time-out by actively stating the procedure to be done and by pointing to the marks in the areas of the planned incisions. The surgeon should explicitly empower the OR staff to speak up if concerned.

The Wrong-Site Surgery Consultation Program

The Authority has begun an on-site consultation program for Pennsylvania facilities that wish to analyze their vulnerability for wrong-site surgery, particularly following a wrong-site event (or a close call) in a surgical suite. Requests can be made through the Authority office or the regional Patient Safety Liaison. The Authority clinical specialists will assist facilities in assessing policies and procedures, measuring staff compliance, and doing a thorough analysis of any events, using resources developed by the Authority (see footnote on page 27).

The Pennsylvania Patient Safety Authority is committed to having no patient experience wrong-site surgery. Are you?

Note

1. Joint Commission. Revised Universal Protocol; some changes are effective immediately. Joint Commission Online 2009 Sep 9 [cited 2010 Jan 25]. Available from Internet: http://www.jointcommission.org/NR/rdonlyres/25D5EC4D-F17C-4DCB-B0D2-8967EE48D5F1/0/jconlineSept909.pdf.

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THE PENNSYLVANIA PATIENT SAFETY AUTHORITY AND ITS CONTRACTORS

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An Independent Agency of the Commonwealth of Pennsylvania

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

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