Quarterly Update on Preventing Wrong-Site Surgery

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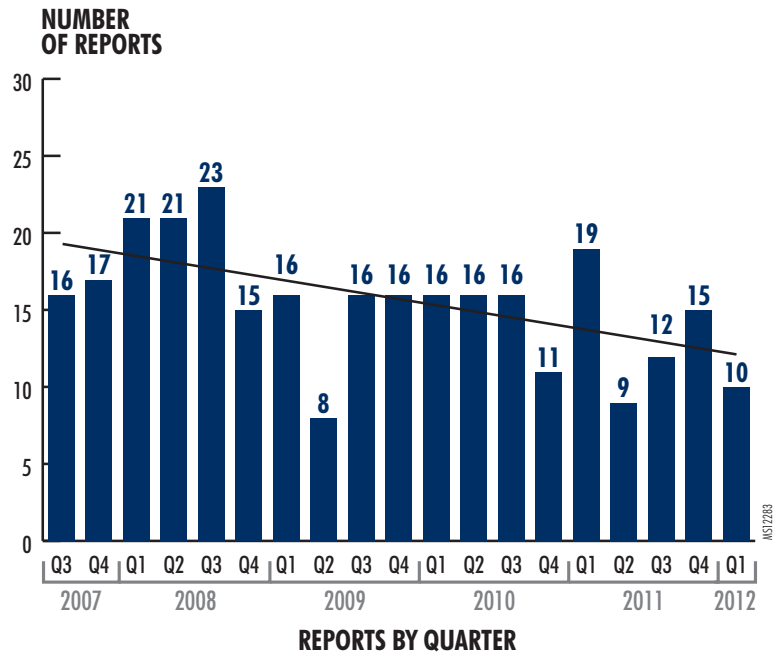
There were 10 reports of wrong-site surgeries this quarter (plus a belated report of an event in the third quarter of 2011), increasing the total to 480 since reporting began in July 2004. The program to prevent wrong-site surgery began at the end of June 2007.[1] The trend since then has been encouraging, albeit slower than desired, with a 37% decrease over 4¾ years from an average of 19 reports per quarter to an average of 12 per quarter.

As noted in the March 2012 issue of the *Pennsylvania Patient Safety Advisory*,[2] all of the improvements have occurred in those facilities that have made a serious commitment to implement wrong-site surgery prevention programs, including evidence-based best practices. This commitment to preventing wrong-site surgery continues with 26 facilities making the institutional commitment to join the upcoming collaborative learning initiative led by the Pennsylvania Patient Safety Authority as part of the Hospital and Healthsystem Association of Pennsylvania (HAP) Hospital Engagement Network funded by the Centers for Medicare and Medicaid Services.

Facilities that wish to join a collaborative learning project to prevent wrong-site surgery should contact the Authority or HAP. In particular, 13 facilities that have statistically significant higher rates than the state average of 2.1 per 100,000 procedures may wish to make the institutional commitment to join the upcoming collaboration.

To identify individual facilities that were outliers and could benefit from collaborative learning, the Authority obtained the number of procedures done in Pennsylvania hospitals and ambulatory surgical facilities from July 1, 2007, through June 30, 2011, from the Pennsylvania Health Care Cost Containment Council. The numbers of procedures were available for 275 licensed facilities. Less than 5,000 procedures were done in 79 facilities, less than 10,000 procedures were done in another 24 facilities, and the remaining 170 facilities did 10,000 or more procedures. Not all facilities had

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



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the number of procedures recorded. Not all facilities with data recorded had data from all quarters. When quarterly data was missing for a facility, any wrong-site surgeries from that facility during that quarter were removed.

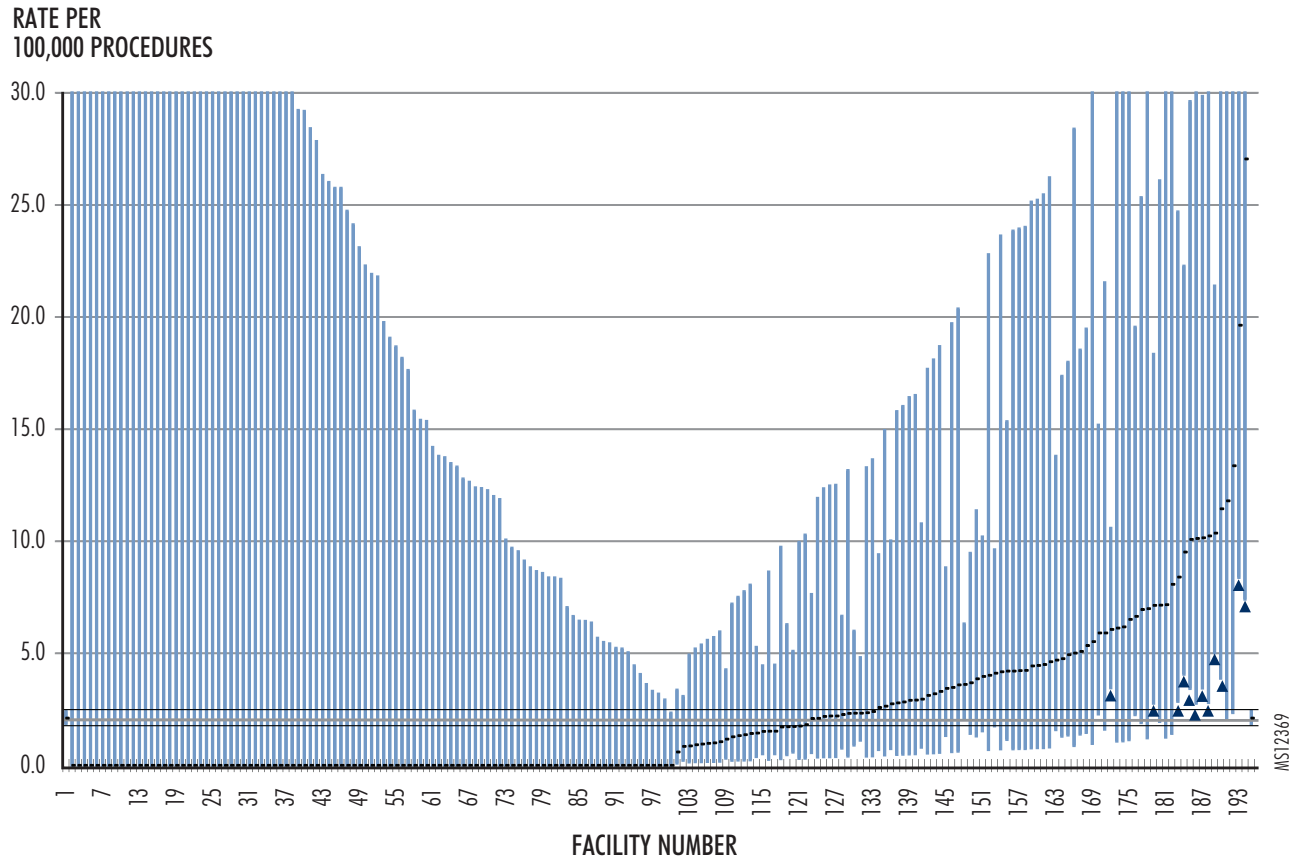
During the four-year time period, a total of 9,463,833 procedures were reported. During the same time period, a total of 200 wrong-site surgeries were reported during those quarters from these facilities. The rate of wrong-site surgery was 2.1 per 100,000 procedures (95% CI: 1.8 to 2.4); one wrong-site surgery occurred every 47,319 procedures (95% CI: 41,200 to 54,347 procedures). Wrong-site surgeries were reported by 95 facilities, while 180 facilities reported none during the quarters for which they reported procedure volumes for this four-year period. None of the facilities without wrong-site surgery had a sufficient volume of procedures to have a rate that was statistically significantly lower than the state average.

The improvement noted in Figure 1 was verified by a comparison of the first year of the program to prevent wrong-site surgery, July 2007 through June 2008, to the last year for which the number of procedures is known to PHC4, July 2010 through June 2011.

During the first year of the program (2007 to 2008), a total of 2,221,624 procedures were reported. During the same year, a total of 64 wrong-site surgeries were reported among these facilities. The rate of wrong-site surgery was 2.9 per 100,000 procedures (95% CI: 2.3 to 3.7); one wrong-site surgery occurred every 34,713 procedures (95% CI: 27,187 to 44,323 procedures).

During the last full year for which the number of procedures is known (2010 to 2011), a total of 2,544,122 procedures were reported, a 15% increase. During the same year, a total of 40 wrong-site surgeries were reported from these facilities, a 38% decrease. The rate of wrong-site surgery was 1.6 per 100,000 procedures (95% CI: 1.2 to 2.1); one wrong-site surgery occurred every 63,603 procedures (95% CI: 46,711 to 86,603 procedures). The rate of wrong-site surgery decreased 45%. This

Figure 2. Rates of Wrong-Site Surgery with 95% Confidence Intervals (truncated at 30.0 if beyond)



improvement was statistically significant by chi-square ($X2 = 9.3$, $p > 0.01$).

Thirteen facilities had wrong-site surgery rates that were statistically significantly higher than the state average, although only 12 facilities were outliers with more than one wrong-site surgery event. These facilities may wish to make the institutional commitment to join the next collaboration to prevent wrong-site surgery.

Figure 2 illustrates the rates of wrong-site surgery per 100,000 procedures for each of the 194 licensed Pennsylvania facilities that recorded more than 5,000 procedures, including the 12 outliers (indicated by caret on Figure 2) that had more than one wrong-site surgery.

CRITICAL NEAR-MISS REPORTS INVOLVING INCORRECT CONSENTS

In the December 2011 issue of the *Advisory*,[3] the Authority discussed three types of wrong-site near-miss events identified by the World Health Organization's High 5s project as critical near misses worthy of root-cause analyses, perhaps using the Authority's standard form. In the March 2012 *Advisory*,[2] the Authority suggested a fourth type.

Reports of critical wrong-site near misses:

1. Procedures that are done correctly on the correct patient despite incorrect information.
2. Errors caught by the last step of the Universal Protocol, the time-out.
3. Near-miss situations resulting in cancellation of the procedure.
4. Medically indicated procedures done, *with prior approval*, that differ from the originally scheduled procedure because of a near-miss event caught during the preparation of the patient for surgery.

This quarter saw four critical near-miss events in which a correct operation was done in the presence of an incorrect consent.

> *The patient's consent stated left vocal cord injection. Patient was marked on left neck, and left side was stated in the time-out procedure. Surgery was performed on the right vocal cord, which was the correct site; all other documentation and the surgeon's notes confirmed the right vocal cord as the correct site. The consent was incorrect.*

> *[The patient was] scheduled for a left leg procedure. Patient came into the operating room [OR] with the left leg marked by the doctor. The left leg was prepped and draped. The time-out was initiated. Both the surgeon and I stated the left leg was being operated on. Everyone in the room agreed. I did look at the consent during the time-out but overlooked what was actually written. [My relief nurse] noticed . . . the consent stated the right leg. The correct leg was the one that was operated on.*

> *A patient was consented for a cervical laminectomy with decompression at C4/5. At the operative time-out, the consent was read per policy. The surgeon stated he was doing a cervical laminectomy with decompression at C3/4 and C4/5. The surgeon was informed that the patient was not consented for the [C3/4] procedure. . . . The surgeon was aware of the incorrect surgical consent, which he had signed, and proceeded with the case anyway.*

> *A patient signed consent for right elbow medial epicondyle injection. The surgeon verified with the patient where the pain was. The patient indicated pain over the lateral epicondyle. The surgeon marked . . . the lateral elbow. OR nurse and pre-op nurse verified the consent and all other necessary documents were completed [and that the] patient was marked. During the time-out [in the OR], the OR nurse held up the consent for the surgeon to read. Then, the OR nurse read the consent to the room to verify the procedure. All staff members agreed to the time-out. Surgeon performed the procedure. Upon completion of the procedure, it was determined the surgeon did the procedure on the lateral aspect of the elbow. It was then determined that the surgeon had not changed the consent to reflect the patient's [identification] of pain on the lateral side.*

It is fortunate that these patients did not receive an operation at an incorrect site. However, the risk is high. Since this class of critical near-miss events has been monitored, there have also been two wrong-site surgeries involving an incorrect consent. Hence, one-third of the reports of operating with an incorrect consent involved doing a wrong-site procedure.

Furthermore, two of the facilities reporting these near-miss events involving an incorrect consent have had wrong-site surgeries involving an incorrect consent in the past. One of these two wrong-site events was a wrong-side vocal cord injection in the facility reporting the critical near miss during a vocal cord injection this quarter.

These failures of the Universal Protocol, to verify the correct surgical site against the consent, suggest real vulnerabilities for the occurrence of wrong-site procedures.

Related is another report received this quarter:

> *Consent for surgery states, "Posterior lumbosacral fusion at appropriate levels." . . . Surgeon was informed about missing information on consent and stated, "Consent is appropriate because it is written in general terms."*

The use of general terms decreases the chances that other members of the OR team can assist the surgeon by maintaining situational awareness. If the other members of the OR team do not know the information the surgeon knows, how are they going to help the surgeon stay on the correct path?

NOTES

1. Doing the "right" things to correct wrong-site surgery. PA PSRS Patient Saf Advis [online] 2007 Jun [cited 2012 May 8]. Available from Internet: http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2007/jun4(2)/Pages/29b.aspx.
2. Clarke JR. Quarterly update on preventing wrong-site surgery. Pa Patient Saf Advis [online] 2012 Mar [cited 2012 May 8]. Available from Internet: http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2012/mar;9(1)/Pages/28.aspx.
3. 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 May 8]. Available from Internet: http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2011/dec8(4)/Pages/144.aspx.

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