

## Quarterly Update on Wrong-Site Surgery: Trying to Hold the Gains

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Thirteen wrong-site procedures were reported to have occurred in Pennsylvania operating suites during the most recent reporting quarter (January through March), of which nine were reported to have occurred during March alone. Three of the procedures were hand operations at the wrong site. Three were lumbar spine operations done at the wrong level. Another two were wrong-site pain blocks; one illustrates the importance of using all relevant documents, as well as the patient, to verify the site marking:

*[After the] time-out was done, the nurse noticed that the surgeon injected local lidocaine into the patient's left mid-back and placed needles in the left mid-back in preparation of the transforaminal injection. The nurse questioned the surgeon regarding the proper side. The procedure was stopped. The surgeon verified that the correct side was the right; the needles were removed, and the procedure was then performed on the right T-12 area as scheduled. During the investigation of the event, the surgeon stated that during the marking process he asked the patient if the left side was the correct side. He stated that the patient did not dispute this, so he proceeded to mark the patient for a left thoracic procedure. As the nurse read the consent during time-out, the surgeon did not recognize that the marking was incorrect and proceeded with the procedure according to the marking.*

Two patients had multiple procedures that were more than they consented for. In both cases, the extra procedures were commonly paired with the consented procedures. Presumably, the surgeons were on autopilot and the operating room staffs were not maintaining situational awareness. One other patient had a graft harvest taken from the wrong site, illustrating the importance of having the harvest site specified in all the relevant documents. One procedure was done on the wrong patient due to a complication with the identification process.

The one wrong-site anesthesia block done this quarter was an intra-articular injection done by the operating surgeon, showing the importance of including any block in a time-out and referencing the mark during the time-out:

*In OR [operating room], circulating RN [registered nurse] prepped an unshaven, unmarked left leg. During the "time-out" the surgeon injected block medication into the left knee. The consent listed the right leg. The right knee had been shaved before the operation and marked by both patient and surgeon in pre-op. Once aware of the injection to the wrong site, the process stopped. Confirmation was made that the right leg was the accurate side. The patient was re-prepped and re-draped. Surgery on the accurate site was completed.*

Near-miss reports from this quarter also illustrate the importance of the principles associated with avoiding wrong-site surgery.<sup>1</sup>

The correct site of the operation should be specified when the procedure is scheduled:

*OR schedule listed incorrect site of surgery. Schedule stated ORIF [open reduction internal fixation] of left hip. The correct site was right [hip]. The OR consent was correct, x-rays were correct, and site identification was also correct.*

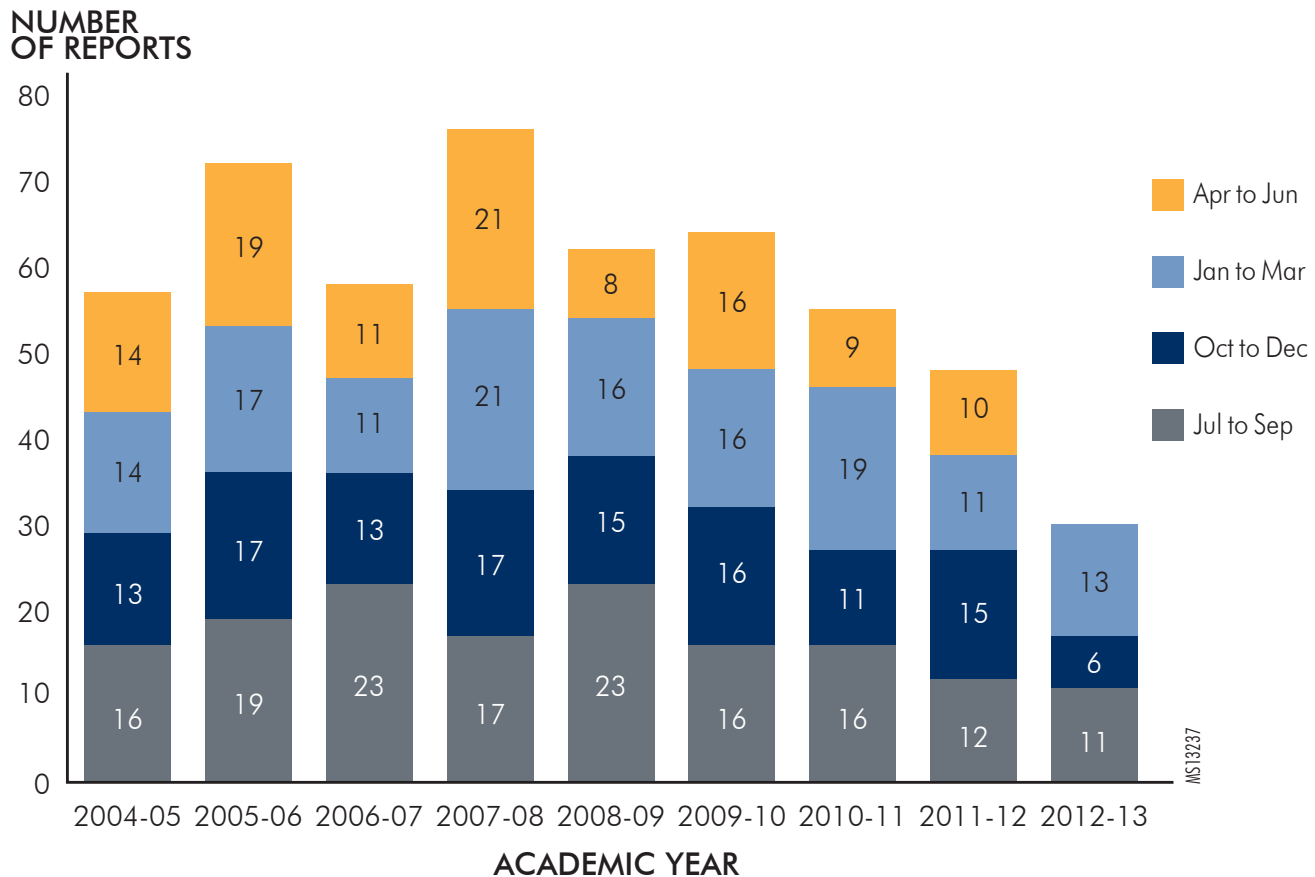
The correct operation and site should be specified on the informed consent:

*Patient presented to OR with both signed anesthesia consent and procedure consent. Upon reading consent, noticed that site (right vs. left) was not specified on consent. This was noticed before time-out. Informed physician, who confirmed that left side was the correct side by showing the MRI [magnetic resonance imaging] study on the computer as well as showing that he had marked the left side. Physician indicated he would correct the consent.*



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



When reading OR consent upon time-out, the RN noticed no right or left side noted in surgery consent. Time-out was stopped until clarified. Patient consented for open gastric bypass. Patient scheduled for laparoscopic possible open gastric bypass. Doctor's H&P [history and physical] states laparoscopic bypass. Patient stated laparoscopic gastric bypass when brought into the room. Open [gastric bypass] consent noted during time-out. Doctor [resolved] discrepancy.

Anyone reviewing the information should check for discrepancies and reconcile any noted with the surgeon:

Consent, OR schedule, and H&P state left foot. Patient informed nurse while doing phone assessment

it was right foot. OR schedule and documentation from doctor's office all state left foot. Doctor notified.

All information, including the patient's understanding, should be verified before the patient enters the operating room:

Patient admitted to pre-op for left foot surgery. Schedule, H&P, consent, and scheduling sheet all have wrong site listed. Patient is scheduled to have left foot surgery, and all documents state right. New documents created with correct site of surgery. OR, surgeon, and scheduler notified of change. Clinical manager contacted [regarding] errors in documentation and potential for wrongsite surgery.

During preparation for eye surgery upon admission, the patient stated she was having surgery on right eye.

ID [identification] band placed as such, and drops started. After dose of meds, it was discovered by comparison with her chart that she was to be having surgery on left eye. Patient still stated right eye. Confirmation with surgeon's [office] chart confirmed left eye was indeed to be operated on.

Patient identification should always be done with two unique patient identifiers:

Wrong patient was taken to OR room. Error realized, and patient returned to pre-op. Correct patient then taken for procedure.

All information, including the patient's understanding, should be verified by each provider caring for the patient. The site should be marked, with the accuracy

confirmed by both the relevant information and the patient:

*Patient scheduled for open reduction and internal fixation of left distal femur fracture. Verified with patient, consent, provider, and anesthesia that surgery was planned for the left leg. Anesthesia mark [a band around the ankle] was on the right leg. The operative site [had been] marked by the surgeon, and [the patient had] a traction pin. A regional block was administered to the left femoral area.*

*Surgical site was marked incorrectly. The incorrect side was on the request for services and the schedule. The consent and H&P were correct. The surgeon was called . . . and the correct site was marked.*

The site should be marked before any procedure:

*Patient for surgery on his right ankle. Physician did not go in to see patient and mark site [before] anesthesiologist . . . put in popliteal block.*

Information communicated during the time-out should be verified against the relevant documents:

*[The patient] presented for right knee arthroscopy. Consent states right, as well as H&P. Left knee was painted, cleansed, and draped. Incorrect side was realized during the time-out process, and correct knee operated on.*

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

*The patient was scheduled for right eye procedure. The right eye was marked by the surgeon as the correct site and confirmed by patient; the consent documented the right eye. [The patient] was taken into the OR; the right eye [was] prepped by circulator, and the left eye was draped by surgical tech. [It was] discovered by the OR team prior to initiating the time-out that wrong site was draped.*

*[This was a] near miss/good catch by the OR team. Patient re-prepped and re-draped to the correct site with the site marking visible within the sterile field.*

Other sources of misinformation:

*Patient consent was for left hip, but grease board stated right hip. [The information was] reviewed with the surgeon, and left hip is the correct operative site.*

*Tumor board registrar contacted pathology office to inform them that consent, anesthesia pre-op evaluation, and intra-op documentation all refer to left mastectomy; specimen ID in OR record indicates specimens are from the right breast. Surgeon called to confirm the left side should have been [labeled] on all specimens. Corrections to all path reports were made.*

And if you're not part of the solution, you're part of the problem:

*Operating surgeon spoke with assistant over the phone and instructed him to proceed with case by marking the patient and performing the time-out. Time-out completed. Recorded in chart that operating surgeon [was] not present for time-out. Upon arrival, operating surgeon asked if time-out was complete. OR staff replied yes; RN stated we should repeat it now that you are present. Operating surgeon refused, stated that the presence and participation of the assistant is sufficient. RN notified OR manager and charge nurse.*

## **A LOOK AT THE SUSTAINABILITY OF USING EVIDENCE-BASED BEST PRACTICES TO PREVENT WRONG-SITE SURGERY**

Thanks to the generous cooperation of participating facilities, the Pennsylvania Patient Safety Authority has been able to follow up from two past collaborations on the use of evidence-based practices to prevent wrong-site surgery.<sup>1</sup>

## **22-Month Follow-Up**

Sixteen facilities volunteered to resurvey their policies with evidence-based practices to prevent wrong-site surgery 22 months after participating in the Authority's second collaboration to prevent wrong-site surgery.<sup>2</sup> Twelve were hospitals and four were ambulatory surgical centers.

Of 97 potential elements in policies that would prevent wrong-site surgery by adhering to evidence-based practices, 9 were found in the same number of policies after 22 months, 57 were found in more policies, and 31 were found in fewer policies. However, the changes for the 16 facilities were statistically significant, by chi-square test, for only three policy elements; all three were improvements (see Table 1).

Five facilities had wrong-site surgery during the 22-month period, and 11 had no wrong-site surgery. One policy element was found significantly more commonly in the 11 facilities that did not experience wrong-site surgery during that period (8 of 11) than in the 5 that did (1 of 5), by chi-square test ( $p = 0.05$ ):

- Does the policy or procedure require that the surgeon obtain consent for surgery from the patient or legal representative prior to or at the time of scheduling the procedure?

Of the nine facilities with that policy element, five had added the element after the collaboration project ended; all five were facilities that experienced no wrong-site surgery in the interim.

Seventeen sites volunteered to resurvey their compliance with evidence-based practices to prevent wrong-site surgery 22 months after participating in the Authority's second collaboration to prevent wrong-site surgery.<sup>2</sup> Twelve were hospitals and five were ambulatory surgical centers; one of the five was part of one of the hospital systems, adhering to the same policies. Ten observations were used for each site, for a total of 170 observations.

Compliance with evidence-based practices to prevent wrong-site surgery showed a statistically significant decrease, by chi-square test, 22 months after participating in their collaboration to prevent wrong-site surgery for three best practices (see Table 2).

Compliance with evidence-based practices to prevent wrong-site surgery showed a statistically significant increase, by chi-square test, over the 22 months after finishing their collaboration to prevent wrong-site surgery for four best practices (see Table 3).

Five sites had wrong-site surgery during the 22-month period; 12 sites had no wrong-site procedures. Three evidence-based best practices were currently observed significantly more commonly at the 12 sites that did not experience wrong-site surgery than at the 5 that did, by chi-square test (see Table 4).

Compliance with two evidence-based best practices was associated with both a change over time and a difference between sites with and without wrong-site surgery during the 22-month interval:

1. At the end of the collaboration project to prevent wrong-site surgery, the site was marked, with the accuracy confirmed by images when relevant, at 100% of sites that had subsequent wrong-site surgery and 97% of sites that had no subsequent wrong-site surgery, for an overall compliance of 98%. Twenty-two months later, compliance had decreased to 71% among the sites that had wrong-site surgery during the interval and was 100% among the sites that had no wrong-site surgery during the interval, for an overall decrease in compliance to 82%.
2. At the end of the collaboration project to prevent wrong-site surgery, information communicated during the time-out was verified against the relevant documents (e.g., schedule, consent, H&P) at 90% of sites that

had subsequent wrong-site surgery and 81% of sites that had no subsequent wrong-site surgery, for an overall compliance of 83%. Twenty-two months later, compliance had decreased to 79% among the sites that had wrong-site surgery during the interval and increased to 98% among the sites that had no wrong-site surgery during the interval, for an overall increase in compliance to 93%.

### 48-Month Follow-Up

Four hospitals volunteered to resurvey their policies and compliance with evidence-based practices to prevent wrong-site surgery 48 months after participating

in the Authority's initial collaboration to prevent wrong-site surgery.<sup>3</sup>

Of 15 policies assessed by the four hospitals at both at baseline (the end of the collaboration project) and 48 months later, 7 remained universally consistent with evidence-based best practices. One became universally consistent: the requirement to include the exact description of the site when scheduling an operation. One became more consistent: the requirement to conduct separate time-outs for separate procedures. One became net more consistent: the requirement to remove patient information from the room with the patient. Two were less consistent with evidence-base best practices than reported at baseline: verification and reconciliation

Table 1. Policy Elements Found in Significantly More of 16 Facilities 22 Months after Finishing a Collaboration Project to Prevent Wrong-Site Surgery

POLICY ELEMENT	NO. OF FACILITIES, MAR 2011	NO. OF FACILITIES, JAN 2013	P =
Does the policy or procedure require that the surgeon state that other members of the operating team speak up if their understanding of the situation is different than the one stated in the time-out?	6	13	0.05
When an operation is done at the level of a particular vertebra or rib, does the policy or procedure require that the identity of the vertebra or rib be verified by fluoroscopy or radiograph (x-ray)?	3	12	0.001
When an operation is done to stent a ureter, does the policy or procedure require that the side of the ureter be verified by fluoroscopy, radiology (x-ray), or ultrasound?	2	10	0.01

Table 2. Decreased Compliance with Evidence-Based Best Practices at 17 Sites 22 Months after Finishing a Collaboration Project to Prevent Wrong-Site Surgery, Based on 170 Observations

PRACTICE	COMPLIANCE, MAR 2011	COMPLIANCE, JAN 2013	P =
The site should be marked by the provider's initials.	82%	50%	0.001
The site should be marked, with the accuracy confirmed by images when relevant.	98%	82%	0.01
The surgical field should be prepped and draped prior to the time-out	99%	92%	0.01

of all available relevant documents (1) at the time of scheduling and (2) prior to arriving in the preoperative holding area. Three had been reported as universally consistent at baseline but not at 48 months: (1) informing patients that all providers will be asking for identification, (2) marking the site after verification with all relevant documents, and (3) written verification of the correct spinal level by a radiologist as part of the intraoperative verification. Because of the small sample size, no changes were tested for statistical significance.

Three of the four hospitals observed compliance both at baseline and 48 months later. For each practice, they observed a cumulative average of 25 operations at baseline and 23 operations 48 months later. The compliance averaged 90% overall at baseline and 93% 48 months later. Only two practices showed statistically significant differences, by chi-square test, between the two observations:

1. Including the schedule in the preoperative verification improved from 45% (9 of 20) during the baseline at the end of the collaboration project to 92%

(23 of 25,  $p < 0.001$ ) 48 months later. The improved compliance was in concordance with the improvement to a universally consistent requirement to include the exact description of the site when scheduling an operation.

2. Radiographic verification of the spinal level intraoperatively improved from 55% (11 of 20) during the baseline at the end of the collaboration project to 100% (7 of 7,  $p < 0.05$ ) 48 months later. The difference in the percentage of opportunities (20 of 25 = 80% versus 7 of 23 = 30%) is significantly different ( $p < 0.001$  by chi-square test), suggesting that the samples for this subset may have been collected differently in the two time periods.

Table 3. Improved Compliance with Evidence-Based Best Practices at 17 Sites 22 Months after Finishing a Collaboration Project to Prevent Wrong-Site Surgery, Based on 170 Observations

PRACTICE	COMPLIANCE, MAR 2011	COMPLIANCE, JAN 2013	P =
The site should be marked, with the accuracy confirmed by all relevant documents.	96%	99%	0.05
Separate formal time-outs should be done for separate procedures, including anesthesia blocks.	85%	99%	0.01
Information communicated during the time-out should be verified against the relevant documents (e.g., schedule, consent, history and physical).	83%	93%	0.01
The surgeon actively participates in the time-out.	94%	99%	0.05

Table 4. Current Compliance with Evidence-Based Best Practices at 5 Sites with Wrong-Site Surgery versus 12 Sites without Wrong-Site Surgery during the 22 Months since Finishing a Collaboration Project to Prevent Wrong-Site Surgery, Based on 170 Observations

PRACTICE	COMPLIANCE, SITES WITH WRONG-SITE SURGERY	COMPLIANCE, SITES WITHOUT WRONG-SITE SURGERY	P =
The site should be marked, with the accuracy confirmed by images when relevant.	71%	100%	0.01
Information communicated during the time-out should be verified against the relevant documents (e.g., schedule, consent, history and physical).	80%	98%	0.001
Information communicated during the time-out should be verified against diagnostic test results, images, and/or pathology reports, if relevant.	79%	98%	0.001

### Interpretation of the Results of the Follow-Up Surveys

The results of follow-up surveys of policies and compliance with evidence-based practices to prevent wrong-site surgery in facilities that participated in collaborations to prevent wrong-site surgery showed interesting patterns, as described in this section.

The institution of policies and improved compliance continued in some facilities after completion of their participation in a collaboration to prevent wrong-site surgery. Three policy elements were found in significantly more facilities after 22 months (see Table 1). One policy element, requiring the surgeon to get the consent prior to or at the time of scheduling the procedure, was added only in facilities that had no wrong-site surgery during the 22-month period. Four evidence-based best practices were observed more frequently 22 months later (see Table 3). One of those practices, verifying information against relevant documents, improved only in facilities that had no wrong-site surgery during the 22-month period. At least one additional best practice was observed more frequently 48 months later.

Some policies and practices to prevent wrong-site surgery were no longer as prevalent at follow-up as they were at the end of the collaboration (see Table 2). Decreased compliance with one of these practices, confirming the accuracy of the site marking with images when relevant, was associated with wrong-site surgery during the 22 months before follow-up.

The policies to prevent wrong-site surgery that were significantly more prevalent after completion of the collaboration were as follows:

- The surgeon states that other members of the operating team should speak up if their understanding of the situation is different than the one stated in the time-out.
- When an operation is done at the level of a particular vertebra or rib, the identity of the vertebra or rib should be verified by fluoroscopy or radiograph (x-ray).
- When an operation is done to stent a ureter, the side of the ureter should be verified by fluoroscopy, radiology (x-ray), or ultrasound.
- The surgeon should obtain consent for surgery from the patient or legal representative prior to or at the time of scheduling the procedure.

These results suggest prolonged negotiations with surgeons on the medical staff to accept some policies affecting them.

Compliance with evidence-based practices to prevent wrong-site surgery increased over time after the collaboration for some practices and decreased for others. The best practices that were observed

significantly more frequently over time were as follows:

- The site should be marked, with the accuracy confirmed by all relevant documents.
- Separate formal time-outs should be done for separate procedures, including anesthesia blocks.
- Information communicated during the time-out should be verified against the relevant documents (e.g., schedule, consent, H&P).
- The surgeon actively participates in the time-out.

And, at 48-months, as follows:

- The schedule should be included in the preoperative verification.

The best practices that were observed significantly less frequently over time were as follows:

- The site should be marked by the provider's initials.
- The site should be marked, with the accuracy confirmed by images when relevant.
- The surgical field should be prepped and draped prior to the time-out.

All other best practices were maintained over 22 to 48 months—or at least compliance varied in ways that were not statistically significant.

Continued improvement in the presence of policies and compliance with evidence-based best practices to prevent wrong-site surgery was more common than decreased adherence to best-practice policies.

The underlying patterns for the observed changes over time can only be conjectured.

Presumably, the best practices that were maintained were supported by policies and by systems that facilitated compliance. They may have become good habits.

Presumably, continued improvements in compliance resulted from strengthening policies, reducing barriers to compliance, and/or providing effective incentives for compliance.

Presumably, decreased compliance over time resulted from persistence of behavior that did not match best practice. The failure to maintain compliance may be associated with resistance to the practice, continued barriers, ineffective incentives, lack of enforcement, and/or absence of monitoring and feedback.

The results of the follow-up surveys of facilities that had participated in collaborations to prevent wrong-site surgery demonstrate continued improvement in the presence of policies and compliance with evidence-based best practices. Most policies and best practices were maintained. Compliance with some best practices decreased, suggesting the need for periodic monitoring and feedback. Facilities committed to preventing wrong-site surgery should persist in efforts to adopt and comply with best practices.

The facilities that volunteered to participate in the repeat surveys are commended for their dedication to the project to prevent wrong-site surgery in Pennsylvania.

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## NOTES

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