

PENNSYLVANIA PATIENT SAFETY ADVISORY



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to the Pennsylvania
Patient Safety Authority

Vol. 9, Suppl. 1
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REVIEWS & ANALYSES

- 1 What Keeps Facilities from Implementing Best Practices to Prevent Wrong-Site Surgery? Barriers and Strategies for Overcoming Them**

The Authority surveyed Pennsylvania healthcare facilities to identify common barriers to and successful strategies for implementing the Authority's 21 potential recommendations to ensure correct-site surgery. Respondents most commonly cited physician behavior as a barrier and described a variety of strategies for meeting best-practice standards, including education, compliance audits, leadership, and empowerment of nurses.
- 16 Comments from Pennsylvania Medical Professional Societies on the Pennsylvania Patient Safety Authority's Potential Recommendations to Prevent Wrong-Site Surgery and the Authority's Responses**

The Authority responds to comments from Pennsylvania medical professional societies regarding the acceptability, feasibility, and cost of each of the Authority's 21 potential recommendations for preventing wrong-site surgery.

OBJECTIVE

The *Pennsylvania Patient Safety Advisory* provides timely original scientific evidence and reviews of scientific evidence that can be used by healthcare systems and providers to improve healthcare delivery systems and educate providers about safe healthcare practices. The emphasis is on problems reported to the Pennsylvania Patient Safety Authority, especially those associated with a high combination of frequency, severity, and possibility of solution; novel problems and solutions; and those in which urgent communication of information could have a significant impact on patient outcomes.

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What Keeps Facilities from Implementing Best Practices to Prevent Wrong-Site Surgery? Barriers and Strategies for Overcoming Them

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ABSTRACT

To identify the barriers to implementation and the strategies for successful implementation, the Pennsylvania Patient Safety Authority's 21 potential recommendations to prevent wrong-site surgery were sent to the 417 Pennsylvania facilities with operating rooms. The survey divided the 21 recommendations into five groups, with a total of six goals and eight potential measurement standards for the groups. For each of the six goals, 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 for successful implementation. And, they were asked to comment on the feasibility and potential cost impact of implementing the recommendations associated with the standard(s). Responses were received from 70 facilities, for a response rate of 17%. Two-thirds of the responses were from hospitals, and one-third were from ambulatory surgical facilities. 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. Strategies for successful implementation of the recommendations included education, audits, leadership, and empowerment of nurses to "stop the line." All of the recommendations were considered feasible. The recommendation that intraoperative imaging studies of the spine be verified by a second qualified physician was considered costly and was modified accordingly. (Pa Patient Saf Advis 2012 Nov 20;9 [Suppl 1]:1-15.)

INTRODUCTION

The Pennsylvania Patient Safety Authority wished to identify the barriers to implementation and the strategies used for successful implementation of the Authority's 21 potential recommendations for preventing wrong-site surgery (as represented in Tables 1 through 5).^{*} These recommendations were based on the Authority's 21 Principles for Reliable Performance of Correct-Site Surgery.¹

The evidence base for these recommendations has been presented in the past and is available from the Authority.² The potential impact of each recommendation on reducing wrong-site surgeries in Pennsylvania has also been presented.³

METHODS

Surveys about barriers to implementation and strategies for successful implementation of the Authority's 21 potential recommendations for best practices to prevent wrong-site surgery were sent to the 417 Pennsylvania facilities with operating rooms (ORs) (160 hospitals and 257 ambulatory surgical facilities). The Authority requested that the surveys be forwarded by the facilities' patient safety officers to the OR managers for completion.

The survey divided the 21 recommendations into five groups, with a total of six goals and eight potential measurement standards for the groups (see Tables 1 through 5). For each of the six goals and eight potential 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 or standards for the goal. They were asked to describe any strategies for successful implementation. They were also asked to comment on the feasibility and potential cost impact of implementing the recommendations associated with the standards.

RESULTS

Responses were received from 70 facilities, for a response rate of 17%. Two-thirds of the responses were from hospitals, and one-third were from ambulatory surgical facilities.

Summary of Barriers, Successful Strategies, and Comments on Feasibility and Costs

Overall, summarizing all the barriers to implementation for the six goals and eight measurement standards of the 21 recommendations, facilities cited physician behavior 50 times in 19 different categories, including surgeon intimidation, resistance, physician and surgeon noncompliance, lack of physician accountability, lack of physician acceptance, lack of commitment, lack of engagement, lack of cooperation from surgeons' offices, surgeons' perceived lack of value for processes, surgeons not being available, and surgeons' preferences overriding system protocols. Difficulty accessing accurate information prior to the patient's arrival in the preoperative holding area was cited 33 times in 13 different categories. Barriers to a second reading of the intraoperative verification of the spinal level were cited 13 times in four categories. The need to change

^{*} As of the date of publication, all recommendations in this supplement issue of the *Pennsylvania Patient Safety Advisory* are to be considered *potential* recommendations to prevent wrong-site surgery.

(continued on page 4)



Table 1. Potential Recommendations 1 through 4

WRONG-SITE SURGERY EVIDENCE-BASED RECOMMENDATIONS	GOAL(S) OF RECOMMENDATIONS (GOAL #1)	BARRIERS TO IMPLEMENTATION
<ol style="list-style-type: none"> 1. The correct site of the operation should be specified when the procedure is scheduled. 2. The correct operation and site should be noted on the record of the history and physical examination. 3. The correct operation and site should be specified on the informed consent. 	<p>The schedule, history and physical, and consent are complete and correct, and all such documents are consistent prior to the day of surgery or prior to the patient's arrival in the preoperative holding area if the procedure is not elective.</p>	<p>Difficulty getting accurate information prior to the patient's arrival in the preoperative holding area</p>
<ol style="list-style-type: none"> 4. 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. 	<p>MEASUREMENT STANDARD(S) (STANDARD #1)</p> <p>100% of documents are present, complete, correct, and in agreement on initial verification when the patient arrives in the preoperative holding area on the day of surgery.</p>	<p>STRATEGIES FOR SUCCESSFUL IMPLEMENTATION</p> <p>Verification and reconciliation during scheduling Verification and reconciliation by preadmission personnel Use of checklists Compliance auditing and monitoring</p>

Table 2. Potential Recommendations 5 through 11

WRONG-SITE SURGERY EVIDENCE-BASED RECOMMENDATIONS	GOAL(S) OF RECOMMENDATIONS (GOAL #2)	BARRIERS TO IMPLEMENTATION
<ol style="list-style-type: none"> 5. The surgeon should have supporting information uniquely found in the office records at the surgical facility on the day of surgery. 6. 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 [operating room]. 	<p>The physician doing the procedure properly verifies the information and properly marks the site prior to the patient entering the OR.</p>	<ol style="list-style-type: none"> A. Difficulty getting accurate information prior to the patient's arrival in the preoperative holding area B. Physician behavior The need to monitor compliance
<ol style="list-style-type: none"> 7. All verbal verification should be done using questions that require an active response of specific information rather than a passive agreement. 8. Patient identification should always require two unique patient identifiers. 9. Any discrepancies in the information should be resolved by the surgeon, based on primary sources of information, before the patient enters the OR. 10. The site should be marked by a health-care 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. 11. The site should be marked by the provider's initials. 	<p>MEASUREMENT STANDARD(S) (STANDARDS #2A AND #2B)</p> <ol style="list-style-type: none"> A. 100% compliance by the physician doing the procedure with verifying and reconciling the patient's understanding, the schedule, the history and physical, the consent, and any other relevant information B. 100% compliance by the physician doing the procedure with marking the site so that the initials can be seen in the prepped and draped field 	<p>STRATEGIES FOR SUCCESSFUL IMPLEMENTATION</p> <ol style="list-style-type: none"> A. Implementation of the recommendation for preoperative verification by the surgeon Analyses and improvement in processes to get information Documentation elements added to documents, including electronic health records Empowerment of nurses to "stop the line" for compliance Use of checklists Leadership B. Empowerment of nurses to "stop the line" for compliance Compliance auditing and monitoring Education of staff, including surgeons

Table 3. Potential Recommendations 12 through 17

WRONG-SITE SURGERY EVIDENCE-BASED RECOMMENDATIONS	GOAL(S) OF RECOMMENDATIONS (GOAL #3A AND #3B)	BARRIERS TO IMPLEMENTATION
<p>12. 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 [operating room].</p> <p>13. Separate formal time-outs should be done for separate procedures, including anesthetic blocks, with the person performing that procedure.</p> <p>14. All noncritical activities should stop during the time-out.</p> <p>15. The site mark should be visible and referenced in the prepped and draped field during the time-out.</p> <p>16. 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.</p> <p>17. All members of the operating team should verbally verify that their understanding matches the information in the relevant documents.</p>	<p>A. All members of the OR team give primary attention to the time-out and participate with active-voice responses.</p> <p>B. The physician doing the procedure points out the site mark in the prepped and draped field to the other members of the OR team during the time-out.</p>	<p>A. Physician and staff behavior and attitudes</p> <p>B. Physician behavior</p>
	MEASUREMENT STANDARD(S) (STANDARDS #3A AND #3B)	STRATEGIES FOR SUCCESSFUL IMPLEMENTATION
	<p>A. 100% compliance by the physician doing the procedure with verifying and reconciling the patient’s understanding, the schedule, the H&P, the consent, and any other relevant information</p> <p>B. 100% compliance by the physician doing the procedure with pointing out the site mark in the prepped and draped field</p>	<p>A. Compliance auditing and monitoring Feedback to noncompliant providers Education of staff Use of checklists</p> <p>B. Education of staff Compliance auditing and monitoring Leadership</p>

Table 4. Potential Recommendations 18 through 20

WRONG-SITE SURGERY EVIDENCE-BASED RECOMMENDATIONS	GOAL(S) OF RECOMMENDATIONS (GOAL #4)	BARRIERS TO IMPLEMENTATION
<p>18. The surgeon should specifically encourage operating team members to speak up if concerned during the time-out.</p> <p>19. Operating team members who have concerns should not agree to the information given in the time-out if their concerns have not been addressed.</p> <p>20. 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.</p>	<p>Members of the operating room team are told that they can speak up during the time-out if they have concerns and that those concerns will be addressed in the best interest of the patient.</p>	<p>A. Physician behavior The absence of the policy</p> <p>B. Physician behavior The need to educate personnel to complement the policy</p>
	MEASUREMENT STANDARD(S) (STANDARDS #4A AND #4B)	STRATEGIES FOR SUCCESSFUL IMPLEMENTATION
	<p>A. The facility has a policy that allows any member of the operating team to stop the procedure if he or she feels that his or her concerns have not been addressed.</p> <p>B. 100% compliance by the physician doing the procedure with actively empowering the other members of the operating team to speak up if concerned during the time-out.</p>	<p>A. Education of staff Leadership</p> <p>B. Change in policies Education of staff Leadership</p>



Table 5. Potential Recommendation 21

WRONG-SITE SURGERY EVIDENCE-BASED RECOMMENDATIONS	GOAL(S) OF RECOMMENDATIONS (GOAL #5)	BARRIERS TO IMPLEMENTATION
21. Verification of spinal level, rib resection level, or ureter stented should require radiological confirmation, using a stable marker and readings by both a radiologist and the surgeon.	When intraoperative verification by an imaging study is indicated, the properly executed intraoperative imaging study is read by the operating room surgeon and by a radiologist or other qualified physician to verify the correct anatomic location before doing the procedure.	Lack of availability of a radiologist or other qualified physician for a second reading of the intraoperative verification of the spinal level Perceived lack of value by the surgeons for a second reading Inability to transmit images to an off-site radiologist
	MEASUREMENT STANDARD(S) (STANDARD #5)	STRATEGIES FOR SUCCESSFUL IMPLEMENTATION
	100% of imaging studies have documentation that the anatomic site is correct by two physicians before the procedure is done <u>the operating surgeon before the procedure is done</u> and have documentation by a second qualified physician that the anatomic site is correct before the procedure is done, unless no other qualified physician can be made available and the imaging study cannot be transmitted to a second qualified physician within a reasonable time.	Picture archiving and communication system (PACS) System for real-time reading of films from fluoroscopy System for having radiologist in the operating room Change in policies, with compliance auditing and monitoring

Note: Recommendation 21 and its goal and measurement standard have been changed by deleting the struck-out text and adding the underlined text as a result of the survey responses identifying cost-prohibitive barriers.

(continued from page 1)

policies was cited 10 times in three categories. The need to monitor compliance was cited eight times in four categories. Time pressures were cited seven times in six categories. The need to educate personnel was cited six times in three categories. The perceived inability to see site markings in the field exposed by eye drapes was cited five times in three categories. General communication problems were cited four times in three categories. And the need to change the culture was cited three times in two categories.

Summaries of the strategies for successful implementation of the 21 recommendations to meet the eight measurement standards for the six goals are presented in Tables 6 and 7. Educational strategies included education of the physicians; topics included effective communication,

empowerment, and constructive feedback. Compliance auditing and monitoring was associated with investigation into the reasons for noncompliance and feedback to noncompliant physicians and other providers.

Leadership included surgical department buy-in and endorsement, physician compliance, respectful interactions with staff, and management support of staff. Empowerment enabled nurses to use “hard stops” to make sure processes were followed correctly.

Strategies for successful preadmission verification and reconciliation included preoperative phone calls and dedicated personnel responsible for getting—not just checking—required information. Some facilities did automated electronic reviews of scheduled procedures. Some facilities also added documentation elements to

their electronic health records (EHRs) to aid documentation. Systems for radiologists reading spine images included electronic access to the images rather than physical juxtaposition of the image and the radiologist.

Some facilities included staff and/or physicians in their system improvements and policy revisions. System improvements were frequently used to improve access to information.

Strategies to reinforce explicit expectations included written contracts. Alternatively, some facilities used encouragement and positive, respectful relationships to achieve their goals.

On average, 27 facilities commented about the feasibility and potential cost impact of implementing the recommendations associated with each of the

eight standards. An average of 20 had no concerns, indicating that the recommendations were in place or that they thought implementation was feasible at minimal cost. An average of seven expressed primarily cost concerns for each standard. There were only 11 concerns about feasibility expressed in the entire survey.

Concerns were expressed in 10% of the 70 surveys returned. The concerns represented 25% of all the explicit comments about feasibility and potential costs, for a ratio of three explicit statements of no concerns for each statement of concern. The standard that called for a second verification of intraoperative imaging studies, when done, was the only standard for which the ratio of no concerns to concerns was not at least two to one. For that standard, the number of facilities stating concerns outnumbered those stating no concerns by the reverse (nine to five).

Concerns about potential cost impact included the following: personnel time to verify and reconcile information, resources to monitor compliance, personnel time for redundant checking of information, resources needed to implement the evidence-based best practices, resources and time for education, resources to upgrade electronic and paper documents, possible increased staffing, OR delays and loss of business, and physician availability on-site or remotely for a second verification of intraoperative images. The Authority addresses those concerns in the discussion below.

GOAL #1 AND STANDARD #1 (FOR RECOMMENDATIONS 1 THROUGH 4)

Goal #1, covering recommendations 1 through 4 (see Table 1), is that the schedule, history and physical (H&P), and consent are complete, correct, and all in agreement prior to the day of surgery or prior to the patient's arrival in the preoperative holding area if the procedure is not elective.

The potential standard, standard #1, is that 100% of documents are present,

complete, correct, and in agreement on initial verification when the patient arrives in the preoperative holding area on the day of surgery.

Barriers to Meeting Standard #1 for Goal #1 (Recommendations 1 through 4)

Twenty-two facilities cited 32 barriers that prevented them from meeting the standard (#1) for those recommendations. The barriers fell into 12 categories.

Seven cited the failure of surgeons' offices to get the necessary documents to the facilities prior to the day of surgery:

Delays in paperwork from physicians' offices.

Getting all the components of the chart . . . is always an issue with the offices to have in hand prior to surgery. Many of these offices are noncompliant right up to the day of surgery. Having [the components] a day prior to surgery is always a goal but not consistently happening. This would be difficult in our environment.

Certain elements of the patient chart arrive in the pre-op area during the day of surgery.

We do not currently meet this standard, as there are a few physician offices that do not have their documents to the holding area prior to the patient's arrival.

Barriers: Implementation and adherence to policies in private surgical offices. Thoroughness and timeliness of pre-op documentation received.

Surgeon arrives with documentation on day of surgery.

This is difficult to coordinate, as the OR schedulers from the offices are not as committed and educated to the importance of correct-site [surgery], and often, cases are scheduled without a consent, which may not arrive for a couple days or sometimes on the day of surgery.

Four cited the problem that the required preoperative H&P examination was not done by the surgeon, so the correct site for the procedure was not noted or not considered reliable for verification.

Three cited last-minute scheduling, such as emergencies, add-ons, or scheduling changes.

Three cited the problem that the H&P was not done in advance of the day of surgery.

Three cited the problem that the consent was not present or done in advance of the day of surgery, and one indicated that surgeons don't indicate the site on the consent.

Three cited concerns about appropriate levels of enforcement to get compliance from surgeons and their offices while also being reasonable and fair to patients.

Two cited the need for education of office staff to get adequate compliance.

Two cited the need for reliable methods of communication with the surgeons and their offices and identification of those responsible for such communications.

Two cited the need for additional staff to follow-up on the discrepancies.

Other barriers identified were:

- Scheduling done outside the regular scheduling system
- Different scheduling requirements at different hospitals that the surgeons' offices scheduled with

Eleven facilities indicated that they had implemented the potential standard (#1) for recommendations 1 through 4, and another six facilities indicated they did not see any problems implementing the standard.

Strategies for Meeting Standard #1 for Goal #1 (Recommendations 1 through 4)

Forty-seven facilities described 80 strategies they used to successfully implement the potential standard (#1) for

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Table 6. Successful Strategies for Implementation of the 21 Potential Recommendations to Prevent Wrong-Site Surgery

TYPE OF STRATEGY	NO. OF CITATIONS	NO. OF CATEGORIES
Education	38	9
Development and use of checklists	36	10
Compliance auditing and monitoring	30	8
Leadership, including physician and management leadership	22	11
Empowerment of nurses to “stop the line”	22	9
Verification and reconciliation by preadmission personnel	18	3
Verification and reconciliation during scheduling	16	2
Documentation elements added to documents	11	6
Change in policies to recommended best practices	7	4
Feedback to noncompliant physicians and other providers	7	4
Mandated physician compliance with the recommendations	6	3
Team training	5	4
Inclusion of staff in process improvement	5	4
Development of systems for radiologist to read spine images for intraoperative site verification	4	4
Analysis and improvement of processes	3	3
Explicit expectations of responsible behavior	3	3
Positive reinforcement for desired behavior	3	2

Note: Based on responses from 70 Pennsylvania healthcare facilities with operating rooms.

Table 7. Successful Implementation of Specific Potential Recommendations to Prevent Wrong-Site Surgery

RECOMMENDATIONS IMPLEMENTED	NO. OF CITATIONS	NO. OF CATEGORIES
The surgeon marks the site preoperatively (recommendation 10)	8	2
Preoperative verification by the surgeon (recommendation 6)	7	2
Preoperative verification by multiple providers (recommendation 6)	7	2
Verification in the active voice during the time-out (recommendation 16)	4	3
No abbreviations for the side (recommendations 1 through 3)	1	1
Reconciliation throughout every step of the process (recommendation 4)	1	1
Preoperative verification by the anesthesia provider (recommendation 6)	1	1
A separate formal time-out for anesthesia blocks (recommendation 13)	1	1
Implementation of best-practice policies (nonspecific)	1	1
Total	31	14

Note: Based on responses from 70 Pennsylvania healthcare facilities with operating rooms.

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recommendations 1 through 4. The strategies fell into 20 categories.

The most commonly mentioned implementation strategies were preoperative verification and reconciliation of the information prior to the day of surgery by the OR schedulers (n = 12) and/or the preadmission nurses (n = 16), including embedding the verification into the electronic scheduling form (n = 4) and making phone calls to the patients the day before surgery (n = 4).

The use of checklists (n = 11) was also commonly mentioned, including comprehensive schedule-to-OR checklists (n = 5).

Other strategies mentioned by multiple facilities were:

- Audits of compliance (n = 5)
- Requiring multiple providers to do preoperative verification in the preoperative holding area (n = 5), typically the surgeon (n = 2) and/or the anesthesia provider (n = 1)
- Policies addressing resolution of discrepancies by the surgeon (n = 3)
- Use of the World Health Organization (WHO) Surgical Safety Checklist (n = 2)
- Involving staff in the development of improved policies and procedures (n = 2)
- Empowering nurses to “stop the line” (n = 2)

Other strategies mentioned were:

- Involving leadership in the implementation
- Requiring notation of the procedure, site, and side on all relevant documents
- Abolishing abbreviations for the side
- Implementing time-outs for localized anesthetic procedures
- Revising the time-out
- Educating the staff

Feasibility and Potential Costs of Meeting Standard #1 for Goal #1 (Recommendations 1 through 4)

Of the 47 facilities that commented about feasibility and/or costs, 34 had no concerns—21 indicated that the recommendations were in place, and 13 thought they were feasible at minimal cost. However, 12 facilities thought that personnel costs would be incurred for the time involved in verification and reconciliation before the day of surgery. One facility did not think that implementation was feasible without a culture change.

GOAL #2 AND STANDARDS #2A AND #2B (FOR RECOMMENDATIONS 5 THROUGH 11)

Goal #2, covering recommendations 5 through 11 (see Table 2), is that the physician doing the procedure should properly verify the information and properly mark the site prior to the patient entering the OR.

The potential standards are:

- Standard #2A: 100% compliance by the physician doing the procedure with verifying and reconciling the patient’s understanding, the schedule, the H&P, the consent, and any other relevant information
- Standard #2B: 100% compliance by the physician doing the procedure with marking the site so that the initials can be seen in the prepped and draped field

Barriers to Meeting Standard #2A for Goal #2 (Recommendations 5 through 11)

Twelve facilities cited 18 barriers that prevented them from meeting the first standard (#2A) for those recommendations. The barriers fell into nine categories.

Five cited the lack of a mechanism to obtain office records, if relevant, and two cited the lack of cooperation from

surgeons’ offices. Another facility cited the lack of a mechanism to obtain imaging studies.

Five cited resistance to using initials when marking the site. The respondent at one facility defended their current marking protocol by erroneously stating “using initials is not acceptable, as there have been reported issues in the literature in which the physician was actually carving initials into the patient’s skin.” The Authority was unable to find reports of such issues in a search of the literature and suspects the respondent was confusing site marking using initials with a well-publicized, but totally unrelated, news report of a surgeon/obstetrician carving his initials into the patient’s skin at the end of a caesarean section, which led to a conviction for assault and revocation of his medical license.⁴

Three cited difficulty in collecting the necessary documents from the surgeon or surgeon’s office before the day of surgery, including little time between scheduling and operating (n = 1) and H&Ps (n = 1) and consents (n = 1) not being available until the day of surgery.

Other barriers identified were:

- The lack of surgeon availability preoperatively
- General time pressures

Thirty-three facilities indicated that they had implemented the potential first standard (#2A) for recommendations 5 through 11, and another seven facilities indicated they did not see any problems implementing the standard.

Strategies for Meeting Standard #2A for Goal #2 (Recommendations 5 through 11)

The 33 facilities described 49 strategies they used to successfully implement the potential first standard (#2A) for recommendations 5 through 11. The strategies fell into 21 categories.



The most commonly mentioned implementation strategies were:

- Having the surgeon see the patient in the preoperative holding area (n = 5) and/or mark the surgical site before the patient enters the OR (n = 7).
- Developing systems to access critical office records (n = 5), with two specific mentions of eye surgery and imaging studies (n = 1) and H&Ps (n = 1).
- Integrating information needs with the EHR (n = 5).
- Developing a system to reconcile discrepancies (n = 1), instituting hard stops when discrepancies are identified (n = 4), and empowering nurses to make those stops (n = 1).
- Using checklists (n = 4).
- Involving leadership in the implementation (n = 3). One facility described how they used leadership particularly effectively:
We have implemented a perioperative process standardization team headed by a general surgeon to address the variations in practice that we have experienced in the past. The surgeon team leader addressed physician variability one-on-one and was successful in meeting all of our project objectives.
- Audits of compliance (n = 2).
- Verification and reconciliation throughout the process from schedule to OR (n = 1), prior to the day of operation (n = 1), and by multiple providers in the preoperative holding area (n = 2).

Other strategies mentioned were:

- Involving staff in the development of improved policies and procedures
- Aligning policies and procedures to be consistent with neighboring facilities

- Developing good working relationships with surgeons' offices
- Assigning a person to get, not just check for, missing documents
- Using alternative-site-designation wristband for sites that cannot be marked
- Educating the staff

Feasibility and Potential Costs of Meeting Standard #2A for Goal #2 (Recommendations 5 through 11)

Of the 34 facilities that commented about feasibility and/or costs, 26 had no concerns—7 indicated that the recommendations were in place, and 19 thought they were feasible at minimal cost. Comments included:

This takes 5 minutes of the surgeon's time before each surgery. Often done as the OR is being turned over. Therefore, no cost, except for less time for coffee.

Several years ago, the pre-op facilitator position was a full-time RN position added to allow all the pre-op patient needs to be addressed. The facilitator works closely with MDs to ensure that needed clearances and pre-op testing is done to reduce number of day-of-surgery cancellations. The facilitator is also instrumental in ensuring that H&Ps are available and current.

No appreciable cost increase when compared with cost of day-of-surgery cancellation.

Eight facilities cited five potential cost concerns: three cited resources to monitor compliance, and two cited time spent doing redundant checking. Other potential cost concerns cited were resources needed to implement the evidence-based best practices, the need to educate surgeons' office personnel, and any costs involved in the EHR.

However, two of the eight facilities thought that implementation might be compromised by the level of surgeons' compliance. One facility did not think that implementation was feasible without a culture change.

Barriers to Meeting Standard #2B for Goal #2 (Recommendations 5 through 11)

Thirteen facilities cited 13 barriers that prevented them from meeting the second standard (#2B) for those recommendations. The barriers fell into seven categories:

- Four cited problems monitoring compliance.
- Three cited the surgeons' resistance to using initials when marking the site.
- Two cited the ability of surgeons to override protocols with personal preferences.

Other barriers identified were:

- Difficulty communicating with the surgeon
- General time pressures
- The lack of surgeon availability to mark the site prior to anesthesia and, especially, eye drops
- Marking the site for eye surgery in a way that will be visible in the prepped and draped field

Eight facilities indicated that they had implemented the potential second standard (#2B) for recommendations 5 through 11, and another two facilities indicated they did not see any problems implementing the standard.

Strategies for Meeting Standard #2B for Goal #2 (Recommendations 5 through 11)

Eighteen facilities described 25 strategies they used to successfully implement the potential second standard (#2B) for

recommendations 5 through 11. The strategies fell into seven categories.

The most commonly mentioned strategies were enforcement strategies:

- Hard stops that required compliance before the patient entered the OR (n = 9)
- Audits of compliance (n = 5)
- Investigating instances of noncompliance (n = 2)
- Adding the requirement to the checklist (n = 1)

Other strategies mentioned by multiple facilities were:

- Education of staff (n = 4), including specific mention of education of surgeons (n = 2)
- Involving leadership in the implementation (n = 2)

Feasibility and Potential Costs of Meeting Standard #2B for Goal #2 (Recommendations 5 through 11)

Of the 28 facilities that commented about feasibility and/or costs, 20 had no concerns—6 indicated that the recommendations were in place, and 14 thought they were feasible at minimal cost. One facility thought the feasibility and potential costs were unknown. Six facilities expressed four potential cost concerns, including resources to change their systems (n = 2), increased staffing (n = 2), resources and time (n = 1), and resources to monitor compliance (n = 1). One facility did not think that implementation was feasible without the compliance of the surgeons.

One of the facilities desired help from other facilities: “[Would appreciate] information on how other hospitals mark and drape their patients for specific surgeries.”

GOALS #3A AND #3B AND STANDARDS #3A AND #3B (FOR RECOMMENDATIONS 12 THROUGH 17)

The two goals covering recommendations 12 through 17 (see Table 3) are:

- Goal #3A: All members of the OR team give primary attention to the time-out and participate with active-voice responses.
- Goal #3B: The physician doing the procedure points out the site mark in the prepped and draped field to the other members of the OR team during the time-out.

The potential standards are:

- Standard #3A: 100% compliance by the physician doing the procedure with verifying and reconciling the patient’s understanding, the schedule, the H&P, the consent, and any other relevant information
- Standard #3B: 100% compliance by the physician doing the procedure with marking the site so that the initials can be seen in the prepped and draped field

Barriers to Meeting Standard #3A for Goal #3A (Recommendations 12 through 17)

Twelve facilities cited 14 barriers that prevented them from meeting the first goal (#3A) and first standard (#3A) for those recommendations. The barriers fell into five categories.

Eleven of the 12 facilities citing barriers described attitudinal barriers, with 4 specifically mentioning physicians:

Some barriers are that not all activity is stopped during the time-out; some staff/surgeons take the suspension of activity more seriously than others.

Staff lack of engagement.

Complacent attitude.

Specific individuals do not “buy in” to the concept and are not giving it their full attention.

Time-outs are performed for each surgical procedure. Not all members pause or actively respond.

Active-voice response does not occur 100% of time. Currently, part of our performance improvement activities [is] to have active-voice responses, not just nodding.

The difficulty here is getting the surgeons to cooperate. Many times, they are not willing to take the time to verbally agree with the stated time-out.

Anesthesia and the surgeon just want to get started in most cases.

It is the nursing crew that halts the others to accomplish the time-out in the OR. There are a select few who initiate their time-out without prompting from nursing.

Some providers/services are very engaged and lead the dialogue, and some are passive to resistant.

Not all individuals think the time-out results in a reduction of errors.

Apparently, not all providers are aware of the evidence that active engagement of the entire OR staff in the time-out is associated with prevention of wrong-site surgery.²

Other barriers identified were:

- Need to observe compliance rather than rely on checkboxes.
- Anesthesia blocks done in a holding area before the operative site is marked.
- The openings in eye drapes are too small to allow the surgical mark to be seen.

This last potential barrier was also raised by a surveyed medical professional society.⁵ In response to the concern, an analyst from the Authority sampled the coverage of ophthalmic surgery drapes and observed



marking and time-out procedures during eye surgery. Ophthalmic drapes with midsize apertures allowed the surgical site marks, placed in the vicinity of the brows, to be visible through the apertures. It was the opinion of the analyst that surgical site marks placed near the bony prominences surrounding the orbit—in the vicinity of the brow, cheekbone, or lateral bridge of the nose—could be visible in a prepped and draped field.⁵

Seven facilities indicated that they had implemented recommendations 12 through 17 to address the first goal (#3A) and first standard (#3A) for those recommendations.

Strategies for Meeting Standard #3A for Goal #3A (Recommendations 12 through 17)

Twenty-six facilities described 39 strategies they used to successfully implement the potential first standard (#3A) for recommendations 12 through 17. The strategies fell into 17 categories.

The most commonly mentioned implementation strategies were:

- Audits of compliance (n = 8), including feedback to noncompliant providers (n = 3) and adding documentation areas to operating suite records (n = 1)
- Educating the staff (n = 8), including filming a proper time-out and having it available as a DVD (n = 1)

Other strategies mentioned by multiple facilities were:

- Using checklists (n = 4), including the WHO Surgical Safety Checklist (n = 1)
- Involving leadership in the implementation (n = 2)
- Integrating information needs with the EHR (n = 2)

- Mandating cessation of all activity (n = 2)

Other strategies mentioned were:

- Quality improvement analysis
- Training in crew resource management (CRM)
- Written commitments to follow policies
- Instituting hard stops
- Requiring active responses from all OR team members
- Posters with time-out scripts
- Changing policies

Feasibility and Potential Costs of Meeting Standard #3A for Goal #3A (Recommendations 12 through 17)

Of the 25 facilities that commented about feasibility and/or costs, 22 had no concerns—4 indicated that the recommendations were in place, and 18 thought they were feasible at minimal cost. One facility did not think that implementation was feasible without the compliance of the surgeons, and one without a culture change. One facility speculated:

Can be implemented by removing the noncompliant persons involved. Some financial impact with the loss of business.

Barriers to Meeting Standard #3B for Goal #3B (Recommendations 12 through 17)

Sixteen facilities cited 21 barriers that prevented them from meeting the second goal (#3B) and second standard (#3B) for recommendations 12 through 17. The barriers fell into nine categories.

Seven cited difficulty in changing physician behavior, either because of active resistance or because of difficulty in changing habits, including having the mark within the

surgical field (n = 3), having the surgeon reference the mark (n = 4), doing the time-out after prepping and draping (n = 2), and responding in the active voice (n = 1).

One respondent asked:

Why would the surgeon need to point out the site after [it is] prepped and draped? This is done during the time-out before incision. Area is identified by the site marking.

This comment implies that the site mark is used by the facility or surgeon to localize the area to be prepped and draped but is not used thereafter. There are numerous reports of the surgeon becoming confused about the correct site after the patient is prepped and draped. Examples from the Pennsylvania Patient Safety Reporting System database are provided below.

Multiple examples of operating on the wrong toe, such as:

Patient scheduled for [surgery on] toes 3, 4, 5. The physician inadvertently started to make an incision over toe 2 on the right. . . . Time-out procedure had been followed.

Multiple examples of operating on the wrong side of the elbow, such as:

Scheduled for lateral epicondyle release; had the incision made medially. . . .

Numerous examples of operating on the wrong part of the correct hand:

Surgeon performed procedure on left long finger after . . . verification of procedure was performed with all OR staff for procedure to be done on left ring finger. Surgeon turned from field to consult . . . records and turned back to field and picked up long finger and proceeded with surgery. He realized that the long finger was not the operative site after performing the procedure.

There are seven variations of the following example in the database:

. . . scheduled for left trigger thumb release; left arm site marked. . . . Left

hand positioned on OR table and draped; hand positioned by [assistant] for left carpal tunnel. Time-out called by circulating nurse, noting procedure: trigger thumb release on site left hand. Procedure started with 2 cm incision of skin for carpal tunnel; recognized; stopped; incision sutured and right trigger thumb was released.

Other barriers identified were:

- Inpatient physicians.
- Staffing.
- Communication.
- The openings in eye drapes are too small to allow the surgical mark to be seen (see discussion above).

Five facilities indicated that they had implemented recommendations 12 through 17 to address the second goal (#3B) and second standard (#3B) for those recommendations. One other facility indicated it did not see any problems implementing the standard.

Strategies for Meeting Standard #3B for Goal #3B (Recommendations 12 through 17)

Fifteen facilities described 28 strategies they used to successfully implement the potential second goal (#3B) and second standard (#3B) for recommendations 12 through 17. The strategies fell into 18 categories.

The most commonly mentioned implementation strategies were:

- Educating the staff (n = 6)
- Audits of compliance (n = 5), including feedback to noncompliant providers (n = 1) and accountability for noncompliance (n = 1)

Other strategies mentioned by multiple facilities were:

- Involving leadership in the implementation (n = 3)

- Using checklists (n = 2), including the WHO Surgical Safety Checklist (n = 1)

Other strategies mentioned were:

- Requiring the surgeon to mark the patient before entering the OR
- Integrating information needs with the EHR
- Training in CRM
- Changing policies
- Involving surgeons in the development of improved policies and procedures
- Instituting hard stops
- Requiring physician participation in the time-out
- Requiring active responses during the time-out
- Written commitments to follow policies

Feasibility and Potential Costs of Meeting Standard #3B for Goal #3B (Recommendations 12 through 17)

Of the 23 facilities that commented about feasibility and/or costs, 19 had no concerns—4 indicated that the recommendations were in place, and 15 thought they were feasible at minimal cost. Three facilities expressed potential cost concerns, including resources to monitor compliance, OR delays with noncompliance, and the cost of physician education. One facility did not think that implementation was feasible without a culture change.

GOAL #4 AND STANDARDS #4A AND #4B (FOR RECOMMENDATIONS 18 THROUGH 20)

Goal #4, covering recommendations 18 through 20 (see Table 4), is that members of the OR team are told that they can speak up during the time-out if they have concerns and that those concerns will

be addressed in the best interest of the patient. The potential standards are:

- Standard #4A: The facility has a policy that allows any member of the operating team to stop the procedure if he or she feels that his or her concerns have not been addressed.
- Standard #4B: 100% compliance by the physician doing the procedure with actively empowering the other members of the operating team to speak up if concerned during the time-out.

Barriers to Meeting Standard #4A for Goal #4 (Recommendations 18 through 20)

Nine facilities cited 10 barriers that prevented them from meeting the first standard (#4A) for those recommendations. The barriers fell into three categories.

Six cited surgeon intimidation and other behavioral and cultural factors:

OR staff are instructed to speak up, but some have a tendency to be intimidated by the surgeon and not speak up. It is difficult to change a person's personality.

Staff fear of surgeon.

Despite continued reminders to staff, still receive reports of staff feeling uncomfortable speaking up/out (not related to any one provider specifically).

Barriers are that some surgeons are not approachable [and] intimidate staff, so they [staff] may hesitate to ask questions.

The surgeons, for the most part, just want to push ahead.

Lack of respect for process in its purest sense . . .

Three cited just the lack of a policy.

The other barrier identified was the need for staff education to complement the policy.



Eight indicated that they had implemented the potential policy, satisfying the first standard (#4A) for recommendations 18 through 20, and another seven facilities indicated they did not see any problems implementing the policy to meet the standard.

Strategies for Meeting Standard #4A for Goal #4 (Recommendations 18 through 20)

Nineteen facilities described 26 strategies they used to successfully implement the potential policy, satisfying the first standard (#4A) for recommendations 18 through 20. The strategies fell into 11 categories.

By far, the most commonly mentioned implementation strategy was educating the staff (n = 11), including teamwork training (n = 2) using TeamSTEPPS and CRM, but especially about effective communication and empowerment:

Providers and staff are also being taught how to give and receive constructive feedback.

Other strategies mentioned by multiple facilities were:

- Staff support by management (n = 2), empowerment (n = 1), and physician leadership (n = 1)
- Audits of compliance (n = 2), including feedback to noncompliant providers (n = 1)
- Instituting hard stops (n = 2)
- Encouraging the staff to speak up (n = 2)

Other strategies mentioned were:

- Respect:
We work as a team, and the surgeons respect the OR staff and their judgment.
- The use of code words to signal concerns:
The surgeon at the end of the time-out reminds each staff member to

speak out if they have any “Red Flags.” The word “Omega” is used if there are any concerns for any of the surgical team.

Feasibility and Potential Costs of Meeting Standard #4A for Goal #4 (Recommendations 18 through 20)

Of the 24 facilities that commented about feasibility and/or costs, 20 had no concerns—10 indicated that the recommendations were in place, and 10 thought they were feasible at minimal cost. Two facilities expressed potential cost concerns, including time and costs to do team training and education about effective communication. One facility did not think that implementation was feasible without empowerment, and one without a culture change.

Barriers to Meeting Standard #4B for Goal #4 (Recommendations 18 through 20)

Ten facilities cited 13 barriers that prevented them from meeting the second standard (#4B) for those recommendations. The barriers fell into three categories.

Nine cited physician behavior:

Barriers are surgeons who are not amenable to having staff question; intimidate staff into remaining silent.

[Lack of] physician buy-in and failure to respect process.

. . . physician buy-in is necessary.

Surgeons who rush through the time-out.

Impatient surgeons.

Physician accountability.

Work in progress to change behavior.

. . . achieving that goal will require a change in practice by some surgeons/proceduralists.

This is individualized and dependent on the surgeon . . .

Three cited the need for staff education to complement the policy.

One cited the need for monitoring compliance.

Seven facilities indicated that they had implemented the potential second standard (#4B) for recommendations 18 through 20, and another facility indicated it did not see any problems implementing the standard.

Strategies for Meeting Standard #4B for Goal #4 (Recommendations 18 through 20)

Sixteen facilities described 23 strategies they used to successfully implement the potential second standard (#4B) for recommendations 18 through 20. The strategies fell into 11 categories.

The most commonly mentioned strategies were:

- Changing policies (n = 4), including involving staff in the development of improved policies and procedures (n = 1) and modifying the WHO checklist (n = 1)
- Education of staff (n = 4), including CRM team training (n = 1)
- Effective compliance by the surgeons (n = 4), including involving leadership and physician leadership in the implementation (n = 2) and getting endorsement and buy-in from the surgical department (n = 1):

Interdisciplinary team developed the standard. . . . Buy-in from department of surgery with endorsement of policy and procedures. [There is] strong physician team leadership.

Leadership support/physician leadership support. Teams know that at any time, they can call their frontline surgical supervisor to the OR to address any questions.

Other strategies mentioned by multiple facilities were:

- Monitoring compliance (n = 2)
- Using active-voice responses during time-outs (n = 2)

Other strategies mentioned were:

- Withholding the scalpel until a proper time-out has been done

Feasibility and Potential Costs of Meeting Standard #4B for Goal #4 (Recommendations 18 through 20)

Of the 21 facilities that commented about feasibility and/or costs, 16 had no concerns—8 indicated that the recommendations were in place, and 8 thought they were feasible at minimal cost. Three facilities expressed two potential cost concerns, including training costs (n = 2) and resources to monitor compliance (n = 1). Two facilities expressed concerns about the feasibility of expecting physician compliance with yet another physician requirement.

GOAL #5 AND STANDARD #5 (FOR RECOMMENDATION 21)

Goal #5, covering recommendation 21 (see Table 5), was that when intraoperative verification by an imaging study is indicated, the properly executed intraoperative imaging study is read by both the OR surgeon and a radiologist or other qualified physician to verify the correct anatomic location before doing the procedure.

The potential standard (#5) was that 100% of imaging studies have documentation that the anatomic site is correct by two physicians before the procedure is done.

Barriers to Meeting Standard #5 for Goal #5 (Recommendation 21)

Twelve facilities cited 18 barriers that prevented them from meeting the standard (#5)

for those recommendations. The barriers fell into seven categories.

Seven cited the lack of availability of a radiologist, and another two cited the lack of availability of a second physician. This seemed a particular problem in solo provider ambulatory surgical facilities and for procedures done on-call during nights and weekends (cited as barriers by two facilities).

Three cited a perceived lack of value by the surgeons for a second verification.

Two cited the inability to transmit fluoroscopy images to an off-site radiologist.

Other barriers identified were:

- The time delays in getting a second verification
- Lack of a mechanism for documenting verification

Four facilities indicated that they had implemented the potential standard (#5) for recommendation 21.

Strategies for Meeting Standard #5 for Goal #5 (Recommendation 21)

Those four facilities described their four strategies to successfully implement the potential standard (#5) for recommendation 21:

- Picture archiving and communication systems (PACS):

We have the PACS radiology software. The surgeon takes the intra-op picture. It immediately is downloaded onto the PACS system, and the radiologist reads the picture.

- Real-time reading of films from fluoroscopy:

Fluoroscopy real-time films are included so that, in addition to the surgeon, the radiologist also identifies the site.

- Radiologist in the OR:

Radiology is used in the OR to determine site if necessary.

- Policy with audits for compliance

One facility mentioned that the “surgeon and radiologist do document their readings but on different documents.” The Authority considers this acceptable documentation, provided the operating surgeon has received that second interpretation prior to doing the definitive procedure.

Feasibility and Potential Costs of Meeting Standard #5 for Goal #5 (Recommendation 21)

Of the 15 facilities that commented about feasibility and/or costs, five had no concerns—three indicated that the recommendations were in place, and two thought they were feasible at minimal cost. One was unsure about feasibility and costs.

However, nine facilities had 12 concerns in four areas:

- Six cited the costs of making a radiologist or other physician available for a second reading.
- Four cited concerns about workflow and delays in care.
- One cited resources needed to set up a confirmatory reading system.
- One cited resources for monitoring compliance.

GENERAL COMMENTS

Facilities could add general comments about the recommendations to prevent wrong-site surgery. Besides reiterating comments already made, eight facilities were supportive of the body of recommendations, as reflected by two of the comments:

I feel all these recommendations would be appropriate for a multispecialty center and could be implemented with minimal cost but would require the cooperation of all parties, especially the surgeons and facility owners.



I am very pleased to see the recommendations, and I hope the initiative is very successful. This issue requires constant vigilance, and any effort to find opportunities for improvement is always welcome.

Two facilities made pleas to avoid adding to the burden of regulation:

We in the [ambulatory surgery center] arena strive to balance patient safety, quality of care, and cost effectiveness on a daily basis. The burden of administrative regulatory requirements has become increasingly heavy over the past few years. While recommended practices are always appreciated, more regulation increases the burden. Please offer us help and direction without adding to the issues that we already deal with.

My opinion was voiced further back in the survey, and I do firmly believe that there is a general culture problem that needs changing and not more processes and time-out changes. I also believe that governing agencies are necessary, to a point, to ensure appropriate care and treatment of patients, but sometimes the requirements can backfire. In order to obtain reimbursement, facilities must meet so many standards, the focus moves from the patient to documentation, accolades, awards, etc. The patients end up being the losers instead of the winners. Facilities are short-staffed, [and] staff are fatigued and required to do work (documentation, statistics, data collection) that has really nothing to do with direct patient care. A majority of their time/efforts are non-patient-oriented. I think they may be guided inappropriately as to what is most important in their work. It's frustrating, and even the most conscientious of caregivers get burned out.

DISCUSSION OF THE RESULTS OF THE SURVEY OF BARRIERS TO IMPLEMENTATION AND STRATEGIES USED FOR SUCCESSFUL IMPLEMENTATION

The Authority did not make it clear to the respondents that the standard of 100% compliance does not mean 100% monitoring for compliance, but 100% compliance when monitored. The Authority recommends periodic monitoring and has a new observational monitoring tool with spaces to monitor 10 procedures.⁶

The Authority also did not make clear that 100% compliance with site marking does not mean that 100% of operative sites must be marked, but that 100% of the sites that should be marked are marked.

The intent of the Authority's 21 recommendations is to improve existing practices to match evidence-based best practices to prevent wrong-site surgery. Unfortunately, there are 21 ways to expose the patient to the risk of wrong-site surgery and 21—not 3—steps that need to be taken by members of the surgical team to prevent wrong-site surgery. There are more than 21 steps in most operations, and surgeons pride themselves in doing them all and to the best of their ability.

The intent is not to add to the complexity of surgical care. The intentions of the goals are to change current practices where practices are suboptimal, not to provide a layer of regulatory monitoring to practices. For instance, adding the side or site of the procedure to the scheduling form, with a hard stop if it is not filled in, provides an evidence-based protection from wrong-site surgery with minimal cost and time. Checklists are another low-cost aid to ensuring that all the necessary information for the patient's procedure is available and accurate.

When best practices are established, monitoring could be minimal: the measurement of up to eight actions on 10 patients⁶ monthly or quarterly. A new

observational monitoring tool for the wrong-site surgery prevention program is now available.⁶ This monitoring tool aligns observations with the goals and measurement standards associated with the 21 recommendations to prevent wrong-site surgery.

In keeping with its intent, the Authority concludes—from the responses describing perceived barriers to implementation of the 21 recommendations, strategies for successful implementation of the recommendations, and the perceived feasibility and costs of implementing the recommendations—that the potential standard for recommendation 21 should be modified. Based on the feedback from the facilities, the potential modification to the standard for recommendation 21 is:

- 100% of imaging studies have documentation that the anatomic site is correct by the operating surgeon before the procedure is done and have documentation by a second qualified physician that the anatomic site is correct before the procedure is done, unless no other qualified physician can be made available and the imaging study cannot be transmitted to a second qualified physician within a reasonable time

The complete modifications for recommendation 21 can be seen in Table 5.

The Authority has educational and monitoring resources readily available to minimize the burden on individual facilities to transition to evidence-based best practices to prevent wrong-site surgery. These resources are available on the Authority's Preventing Wrong-Site Surgery web page⁷ and through the Authority's patient safety liaison program.

Acknowledgments

Theresa V. Arnold, DPM, and Edward Finley, BS, of the Pennsylvania Patient Safety Authority, developed and disseminated the survey and collected the data.

NOTES

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Comments from Pennsylvania Medical Professional Societies on the Pennsylvania Patient Safety Authority's Potential Recommendations to Prevent Wrong-Site Surgery and the Authority's Responses

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Potential recommendations to prevent wrong-site surgery were sent to 27 medical professional societies in Pennsylvania for comment.* These recommendations were based on the Authority's 21 Principles for Reliable Performance of Correct-Site Surgery¹ (see "Principles for Reliable Performance of Correct-Site Surgery").

The evidence base for these recommendations has been presented in the past and is available from the Authority.² The potential impact of each recommendation on reducing wrong-site surgeries in Pennsylvania has also been presented.³

Medical professional societies in Pennsylvania were asked to comment on the acceptability, feasibility, and cost of each of the 21 recommendations. Twelve medical professional societies responded to the request for comments, including among them seven surgically-related specialty societies and two general medical provider societies.

No organization commented that any of seven recommendations were unacceptable, not feasible, or costly.

Those recommendations were recommendations 1, 2, 3, 7, 8, 17, and 20 (see "Principles for Reliable Performance of Correct-Site Surgery").

Six other recommendations also did not receive comments that they were unacceptable but did receive comments about feasibility or costs.

- One organization thought that reconciling discrepancies (recommendation 4) would not be feasible because of difficulties reaching the surgeons. One organization thought that additional manpower might be needed. *In response, the Authority notes that reconciliation must occur sometime preoperatively.*
- Three organizations thought that having information available that was unique to the office records (recommendation 5) was not feasible and was costly because of the lack of integration between the surgeons' records and the operating facilities' records. One organization thought that it could be easily achieved by faxing the supporting documents to the preoperative suite. *The Authority agrees with the proposed solution.*
- One organization thought that having both the nurse and the surgeon verify the patient's information preoperatively (recommendation 6) was not feasible. *In response, the Authority reiterates the strong evidence that the surgeon's preoperative verification is one of the most important actions for preventing wrong-site surgery.² Preoperative verification by the surgeon provides both a double check of the information used for the final time-out and a reminder for the surgeon of the correct information about that patient in preparation for his or her participation in the final time-out.*
- Two organizations thought that having the circulating nurse verify all information before taking the patient to the OR (recommendation 12) was costly because of the nursing time involved. *In response, the Authority reiterates the importance of making sure all patient information is correct before the patient enters the OR.²*
- One organization thought that separate time-outs for separate procedures (recommendation 13), including anesthetic blocks, was time consuming, although another organization commented that it required minimal additional time. *The*



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*As of the date of publication, all recommendations in this supplement issue of the *Pennsylvania Patient Safety Advisory* are to be considered *potential* recommendations to prevent wrong-site surgery.

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PRINCIPLES FOR RELIABLE PERFORMANCE OF CORRECT-SITE SURGERY

The following principles for reliable performance of correct-site surgery, identified by the Pennsylvania Patient Safety Authority during its Preventing Wrong-Site Surgery Project, should be consistently followed.

1. The correct site of the operation should be specified when the procedure is scheduled.
2. The correct operation and site should be noted on the record of the history and physical examination.
3. The correct operation and site should be specified on the informed consent.
4. 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.
5. The surgeon should have supporting information uniquely found in the office records at the surgical facility on the day of surgery.
6. 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, anesthesia provider, and surgeon before the patient enters the operating room (OR).
7. All verbal verification should be done using questions that require an active response of specific information rather than a passive agreement.
8. Patient identification should always require two unique patient identifiers.
9. Any discrepancies in the information should be resolved by the surgeon, based on primary sources of information, before the patient enters the OR.
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.
11. The site should be marked by the provider's initials.
12. 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.
13. Separate formal time-outs should be done for separate procedures, including anesthetic blocks, with the person performing that procedure.
14. All noncritical activities should stop during the time-out.
15. The site mark should be visible and referenced in the prepped and draped field during the time-out.
16. 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.
17. All members of the operating team should verbally verify that their understanding matches the information in the relevant documents.
18. The surgeon should specifically encourage operating team members to speak up if concerned during the time-out.
19. Operating team members who have concerns should not agree to the information given in the time-out if their concerns have not been addressed.
20. 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.
21. 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.

Source: Pennsylvania Patient Safety Authority. Principles for reliable performance of correct-site surgery [online]. 2010 Dec [cited 2012 Jun 25]. <http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Documents/principles.pdf>.



(continued from page 16)

Authority agrees with the comment that the time is minimal.

- One organization thought that the definition of “noncritical” activities that should be stopped during the time-out (recommendation 14) was not specific, making compliance difficult. *In response, the Authority agrees that the definition of “noncritical” activities is unstated. At this time, it recommends facilities include lists of exempt “critical” activities in their policies in lieu of a uniform definition for all facilities.*

Two recommendations received comments that they were unacceptable but did not receive specific comments about feasibility or costs.

- Two organizations did not agree that the site should be marked with the provider’s initials (recommendation 11), one arguing that the initials are sometimes illegible, and both proposing that other institutionally consistent methods should be acceptable. No organization commented that the recommendation was not feasible or was costly. *In response, the Authority notes that the evidence favoring the use of initials to mark the site is based on a single analysis² and is willing to consider an alternative to this evidence-based best practice recommendation if evidence is presented supporting the alternative.*
- One organization did not agree that the surgeon should specifically encourage operating team members to speak up if concerned during the time-out (recommendation 18) on the premise that such a statement “conveys the false impression that a) without it, teammates would not speak and b) other times are not safe to voice concern.” *In response, the Authority reiterates the very clear evidence that explicit empowerment is observed significantly more—almost twice as often—in analyses of near-miss events than wrong-site events.²*

Six recommendations received comments about acceptability and about feasibility or costs.

- One organization did not agree that surgeons should be responsible for resolving discrepancies in the patient’s information, using primary sources of information, before the patient enters the operating room (recommendation 9) and thought that having the surgeon do it was not feasible. However, the organization may have misunderstood what information needed to be resolved using primary sources, saying “license, passport” may not be available. The recommendation refers to the patient’s medical record.² Another organization thought this recommendation was not feasible, because surgeons may run multiple operating rooms. *In response, the Authority reiterates the strong evidence that the surgeon’s reconciliation of discrepancies is one of the most important actions for preventing wrong-site surgery.²*
- One organization did not agree that 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 (recommendation 10), offering a more stringent requirement that the marking be done by the attending surgeon or resident. One organization thought that the recommendation was not feasible under certain circumstances, such as for emergencies or court-appointed consents. *In response to the concerns about the feasibility of confirmation of the mark under certain circumstances, the Authority agrees that unusual circumstances may need to be covered by the facility’s marking policy, including the use of other healthcare providers as patient surrogates if necessary.*

- One organization had strong objections to the recommendation that the site mark be visible in the prepped and draped field during the time-out (recommendation 15), stating that, during eye surgery, only the eye itself is visible. The recommendations of the American Academy of Ophthalmology Wrong-Site Task Force⁴ include marking the site “if only one eye is to have surgery,” suggesting the mark be placed “around the eye” (meaning near, not surrounding). The recommendations further state that “if it is customary for the surgeon to put a towel over the patient’s forehead in the operating room prior to placing of the clear surgical drape, it may be beneficial for the identifying mark to be placed on the cheek rather than the forehead. In this way, the surgeon can visualize the identifying mark immediately before placing the surgical drape.”

In response to the concerns, an analyst from the Authority sampled the coverage of ophthalmic surgery drapes and observed marking and time-out procedures during three cataract procedures in an ambulatory surgical facility. 3M™ Steri-Drape™ ophthalmic drapes with apertures ranged in aperture size from 17.7 x 6.7 cm to 5.7 x 2.9 cm.⁵ The mid-size drapes used in the three procedures observed allowed the surgical site marks, placed in the vicinity of the brows, to be visible through the Steri-Drapes in the apertures. It was the opinion of the analyst that surgical site marks placed near the bony prominences surrounding the orbit—in the vicinity of the brow, cheekbone, or lateral bridge of the nose—could be visible in a prepped and draped field (see Figure). The Authority reviewed the 30 reports of wrong-side eye surgery; eight reports (27%) specifically mentioned that the correct eye had been marked prior to the wrong-side procedure.

Figure. Eye Drape Shows Space for Site Marking



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The Authority does not agree with the American Academy of Ophthalmology Wrong-Site Task Force that marking need only be done when one eye is involved. On logical grounds, one could not distinguish an unmarked eye during the start of a bilateral procedure from the wrong eye during a unilateral procedure. Confusion between unilateral and bilateral surgery may have contributed to wrong-site surgery, as described in this report.

OR nurse drew up proper drugs . . . for eye block. The doctor gave injection in . . . the right eye, then asked nurse for more block—which he then gave in the . . . left eye.

- One other organization thought that having the site mark visible in the prepped and draped field was not feasible, but this organization gave no reason. In response to general comments about having the site mark be visible in the prepped and draped field during the time-out, the Authority

reiterates the evidence that in a comparative analysis of wrong-site events and near-miss events, wrong-site events were significantly more likely to not have had the site mark visible in the prepped and draped field.²

- Two organizations did not agree that verification of information during the time-out should require an active communication, rather than a passive agreement, and be verified against the relevant documents (recommendation 16). One thought that passive agreement should be sufficient. One organization thought that the recommendation was not possible because “a gowned/gloved surgeon will not be able to reference relevant documents.” In response, the Authority notes that active responses are required of patients and should be required of providers for the same reasons. The latter organization may have misunderstood the recommendation. Verification of information by active

communication and verification against documents does not mean that a surgeon in sterile attire goes through the patient’s chart. It means that the surgeon responds to a question such as “Which side is the surgery on?” instead of “The surgery is on the left side. Do you agree?” The verification against the documents does not have to be done by each provider who is giving an active response but can be done by a single provider who is receiving the responses.

- One organization did not think that the recommendation that operating team members who have concerns should not agree to the information given in the time-out if their concerns have not been addressed (recommendation 19) should be included. However, the recommendation may have been misunderstood; the organization stated that it “would not include it in any form.” No reasons were given. In response, the Authority reiterates the very strong evidence that concerns are raised in near-miss events and not in wrong-site events.²
- One organization did not agree that verification of spinal level, rib resection level, or ureter to be stented should require radiological confirmation, including readings by both a radiologist and the surgeon (recommendation 21), although no reason was given. Three organizations raised concerns about the cost of radiological confirmation, especially by a radiologist. In response to the comments of organizations and the results of the survey of facilities,⁶ the Authority concludes that the potential standard for recommendation 21 should be modified. The potential modification to the measurement standard for recommendation 21 is as follows:
 - 100% of imaging studies have documentation that the



anatomic site is correct by the operating surgeon before the procedure is done and have documentation that the anatomic site is correct before the procedure is done by a second

physician, unless no second physician can be made available and the imaging study cannot be transmitted to a second physician within a reasonable time.⁶

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NOTES

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