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 Surgery[1] (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.

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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 analysis[2] 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 Force[4] 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 boney 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]

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

1. Pennsylvania Patient Safety Authority. Principles for reliable performance of correct-site surgery [online]. 2011 Dec [cited 2012 Jun 25]. http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Documents/principles.pdf.
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