NOTICES

PATIENT SAFETY AUTHORITY

DEPARTMENT OF HEALTH

Final Recommendations to Ensure Correct Surgical Procedures and Correct Nerve Blocks

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This document outlines final recommendations to hospitals, ambulatory surgery facilities, birthing centers and abortion facilities in this Commonwealth to ensure the correct procedure is performed on the correct site, side and patient.

The Patient Safety Authority (Authority) is responsible for submitting recommendations to the Department of Health (Department) for changes in healthcare practices and procedures, which may be instituted for the purpose of reducing the number and severity of serious events and incidents. Once approved by the Department, the Authority is responsible for issuing recommendations to acute and ambulatory care facilities in this Commonwealth. These final recommendations were approved by the Authority's Board of Directors and the Acting Secretary of Health.

Background

Wrong-site surgery (WSS) is a patient safety event that should never occur.

The National Quality Forum (NQF) defines surgery as "an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or an instrument is introduced through a natural body orifice."[1] NQF states that surgery begins "regardless of setting, at the point of surgical incision, tissue puncture, or the insertion of an instrument into tissues, cavities, or organs," and ends "after counts have concluded, the surgical incision has been closed, and/or operative device(s) such as probes have been removed, regardless of setting."[1] These recommendations apply to all procedures requiring informed consent in this Commonwealth.

In support of the NQF definition of surgery, the Authority affirms that surgery is not limited to those procedures done in an operative room setting. Surgery includes procedures performed in other clinical departments of the healthcare facility, including those performed at the bedside.

The Authority has tracked WSS since July 2004. During that third quarter of 2004 (July—September) there was an average of 1.33 WSS events per week across this Commonwealth.[2] Fast-forward to the most recent study (2015—2019) and this Commonwealth is still experiencing 1.42 WSS events per week. These 368 events took place in 178 facilities in this Commonwealth.[3] As of December 2019, 380 licensed acute care facilities in this Commonwealth had not reported a WSS in the previous 5 years.

Prevention guidelines are well established. The Joint Commission first issued The Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ in 2003.[4] The

World Health Organization created the WHO Surgical Safety Checklist in association with the Harvard School of Public Health in 2008 to improve the safety of patients undergoing surgical procedures.[5] In September 2011, the Authority identified and published "Principles for Reliable Performance of Correct-Site Surgery" based on its findings during its Preventing Wrong-Site Surgery project.[6] The Authority published evidence to support each of the principles in the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ in 2011 and revised this document in 2017.[7] The Authority and the Pennsylvania Society of Anesthesiologists issued a consensus document "Principles for Reliable Performance of Correct-Site Nerve Blocks" in 2018.[8]

The Authority continues to support these prevention guidelines and believes WSS events continue to happen largely due to noncompliance with the established guidelines. The Authority conducted a survey of patient safety officers in this Commonwealth to identify barriers related to the implementation of prevention guidelines.

Barriers largely fell into two categories: noncompliance (including complacency, distractions and lack of buy-in) and time constraints.

The Authority is charged with issuing recommendations to medical facilities on a facility-specific or Statewide basis regarding changes, trends and improvements in healthcare practices and procedures, for the purpose of reducing the number and severity of serious events and incidents. Prior to issuing recommendations, consideration must be given to the expectation of improved quality care; implementation feasibility; other relevant implementation practices; and the cost impact to patients, payors and medical facilities.

The Authority submits that improved quality of care by following the principles it identifies for reliable performance of correct-site surgery is expected due to the supported evidence for each principle first published in 2011. The Authority submits that feasibility of implementation is no longer a consideration, as these practices are well established in the industry and have been implemented by most healthcare organizations across this Commonwealth, the United States and several parts of the world.

Medical facilities face nonpayment penalties for wrong-site surgeries, as well as the cost of litigation when these events occur. Negative cost implications for medical facilities may include the cost of training and the administrative cost related to quality assurance programs. The Authority does not believe that a cost will be incurred related to lost operating room time, as a time-out is already an accepted standard practice. The Authority is not recommending the length of the time out-be extended, but rather a concerted focus on the quality of the time spent during the time-out. There is no negative cost implication for patients or payors. While direct costs associated with WSSs are not reimbursed by most payors, there may be indirect long-term costs incurred with resulting health issues. Patients may experience out-of-pocket expenses for long-term effects of WSS and working individuals may experience a longer than expected absence from the workforce or be unable to return to the workforce at all.

Final recommendations to ensure correct surgical procedures and correct nerve blocks

The final recommendations to ensure the correct surgical procedures and correct nerve blocks appear as follows. Some of these recommendations have been revised in response to feedback the Authority and the Department received during the public comment period. Descriptions of all comments received and responses to those comments appear in the subsequent section.

Recommendations to ensure the correct surgical procedure is performed on the correct site, side and patient

Preoperative verification and reconciliation

1. The site and side of procedure should be specified when the procedure is scheduled.[9, 10]

2. The procedure, site and side should be noted in the medical record on the history and physical exam record[9, 10] or the procedure note.

3. The procedure, site and side should be discussed and documented on the informed consent form.[9, 10]

4. The individuals, including scheduling staff, registration clerks, ancillary staff, nursing staff, the operating provider and the patient, have an obligation to speak up if they note a discrepancy in any information on the schedule, consent, history and physical, and any office notes. Reconciliation of discrepancies is the responsibility of the operating provider prior to the procedure.

5. The information to verify the correct patient, procedure, side and site, including the patient's or family's verbal understanding, when possible, must be verified by the circulating nurse/designee, anesthesia provider and operating provider.[9, 10] This verification shall be documented in a manner determined by the healthcare facility.

6. Verbal verification with the patient or their representative should be conducted whenever possible. The verbal verification must be done using questions that require active response of specific information rather than passive agreement. Example: Can you tell me your full name? What is your date of birth? What procedure are you having performed today?[9, 10]

7. Patient identification must require at least two unique identifiers, for example, name and date of birth.[9, 10]

8. Discrepancies must be reconciled and documented by the operating provider prior to the procedure.[9—12, 14—16]

Site Marking—Site marking recommendations apply to all procedures where there is more than one possible location for the procedure.

9. The site must be marked by the provider responsible for the procedure, for example, surgeon, proceduralist or interventional radiologist, prior to the patient entering the procedure area. The mark must be confirmed by the attending nurse/designee. The mark must also be confirmed by an alert patient or patient representative when possible. The mark must coincide with the schedule, history and physical, and consent.[9—11, 14—18]

10. The site must be marked with the provider's initials with an indelible marker.[9—11, 14—21]

11. The mark must be made as close to the incision site as possible, so that it is visible in the prepped and draped field.[9—11, 15—18]

Time-out and intraoperative verification

12. Prior to the induction of anesthesia, the circulating nurse and the anesthesia provider, verify the patient's identity, procedure, site, side, consent and site marking. The patient is included in this verification whenever possible.[5]

13. The provider performing the procedure should announce the time-out. This occurs after the patient is prepped and draped, and immediately prior to skin incision/puncture.[9, 10, 17, 20, 21]

14. Separate formal time-outs must be done for separate procedures, including anesthetic blocks, by the person performing that procedure.[9—11, 17, 21]

15. The noncritical activities in the procedure area must stop during the time-out, including music and nonessential talking that could distract team members.[9—11, 14, 17]

16. The relevant patient documents should be available and actively confirmed during the time-out process.[9—11] Relevant documents include a history and physical, consent, operating room schedule and radiographic studies when applicable.

17. The site mark should be referenced in the prepped and draped field during the time-out.[9, 10, 21]

18. The members of the surgical team should actively and verbally verify agreement with the surgical site, side and relevant documents. Active participation should be used at all times. For example, "Which side is the surgery on?" instead of "The surgery is on the left side. Do you agree?"[9, 10, 14, 17, 19, 20—22]

19. Staff should be engaged in the process and the operating provider should specifically encourage team members to speak up with any concerns during the time-out. The operating provider is responsible for resolving any questions or concerns based on primary sources of information and to the satisfaction of all members of the team before proceeding.[9—11, 14, 19—22]

20. Utilize intraoperative imaging whenever possible for procedures where exact site is not easily determined through external visualization, for example, X-ray and fluoroscopy, to verify spinal level, rib section level or ureter to be stented.[9, 10, 14, 17, 23]

Accountability

21. Incorporate accountability for these recommendations into the facility's quality assurance and formal evaluation process. This includes both individual and team performance evaluations, ongoing professional practice evaluations and focused professional practice evaluations.

Recommendations to ensure nerve blocks are performed at the correct site and correct patient

Preoperative verification and reconciliation

1. Confirm patient identity using at least two forms of patient identification.[8]

2. Reconcile and verify the exact site and laterality of the surgical procedure and the perioperative nerve block site using all forms of available primary and confirmatory patient sources, including surgical consent, patient or representative, or both, operative provider's notes (if available), surgical schedule, and history and physical.[8]

3. If any sources differ, the process stops and a member from the anesthesia block team notifies the surgeon to resolve the conflicting information.[8]

Anesthesia site marking

4. After confirming the information in the preoperative verification, the responsible anesthesia provider will use a standardized, institutionally approved mark that is distinct from the one used for the surgical site to mark the perioperative nerve block site.[8]

5. Place the mark close to the injection site to ensure it is visible in the prepped and draped field.[8]

6. Repeat the marking process when there are multiple injection sites.[8]

Time out

7. Secure a block team consisting of at least two people with independent roles (for example, responsible anesthesia provider and preoperative or holding area nurse or circulating nurse).[8]

a. Engage the anesthesia provider to initiate the time-out.[8]

b. The anesthesia provider should be present during the time out and during the nerve block.[8]

8. Conduct a time-out before:

a. Sedating the patient, when possible.

b. Inserting the needle or as close to the procedure as possible.

c. Each nerve block.[8]

9. Minimize distractions and stop all unrelated activity before conducting the time-out.[8]

10. Both the anesthesia provider and block team member verify the procedure that is documented and on the surgical consent (and anesthesia consent if used).[8]

11. Locate and visibly confirm the anesthesia site mark during the time-out.[8]

12. Repeat the time-out process when there are changes to:

a. Block team.

b. Patient location within the perioperative area.

c. Patient positioning.

d. Planned nerve block site.[8]

Accountability

13. Incorporate accountability for these recommendations into the facility's quality assurance and formal evaluation process. This includes both individual and team performance evaluations, ongoing professional practice evaluations and focused professional practice evaluations.

Responses to comments on draft recommendations to ensure correct-site surgery

Two organizations and one individual submitted responses to the Authority in response to the Draft Recommendations to Ensure Correct-Site Surgery during the 30-day public comment period from October 23, 2021, through November 22, 2021. Of the 3 responses received, 12 comments or questions, or both, were identified. Responses to these comments or suggestions, or both, were prepared by the Authority and Department and follow. Note that the recommendations are intended to assist healthcare facilities in reducing harm to patients. They are not intended to guide clinical diagnosis or treatment options.

1. The Authority received one comment requesting clarification of the definition of "surgical procedures." The commenter states they interpret a surgical procedure as an invasive procedure that is prescheduled and takes place in an operating room or procedure room.

Response: The Authority supports the NQF definition of surgery as stated in the Background section of this document. As additionally stated in the Background section of this document, surgery is not limited to those procedures done in an operative room setting. Surgery is also not limited to prescheduled procedures. Surgery includes procedures performed in other clinical departments of the healthcare facility, including those performed at the bedside.

2. The Authority received one comment suggesting an expansion of the definition to include wrong technique or different provider, or both (as agreed upon).

Response: The Authority agrees that correct technique and correct provider are critically important—and may be considered for future recommendations.

3. The Authority received one comment related to the burden these recommendations will create for facilities and staff. They stated that The Joint Commission's Universal Protocol has been in place for many years and that the World Health Organization's Surgical Safety Checklist is widely used to prevent wrong-site surgeries. Additionally, they state the Joint Commission's Sentinel Event Policy and the MCARE law require reporting of wrong-site surgeries and that root cause analyses are performed. They state that by going a step further and making this a law is burdensome for facilities and the detailed requirements is distracting for the staff involved in the process. Adding additional laws, rules or regulations that mimic what is already in place does not seem useful in achieving the stated goal.

Response: These recommendations are not a law. While the Authority is aware that other organizations, such as The Joint Commission, have had measures in place for many years to prevent WSSs, the Authority does not believe those measures alone are adequate as evidenced by approximately 74 events occurring each year in the Commonwealth of Pennsylvania. These recommendations are intended to enhance existing guidelines. The Authority believes these recommendations, if followed, will reduce the number of WSSs and wrong-site nerve blocks in all Pennsylvania facilities.

4. The Authority received one comment related to recommendation 2 and the notation of procedure, site and side on the history and physical exam record. The commentator states that while this would be best practice there are situations that would preclude this information from being in the history and physical. The commentator states that current regulations/standards from the Department, the Centers for Medicare & Medicaid Services and The Joint Commission allow for a history and physical examination to be completed no more than 30 days prior to, or within 24 hours after, registration or inpatient admission but prior to surgery or a procedure requiring anesthesia services. They provide as an example that a patient may be admitted to the hospital and have a history and physical completed upon admission. The same patient may then have a surgery performed at a later date but within the same admission and within 30 days, that was not previously identified or expected at the time the original history and physical was completed. They ask what would the expectation be related to documentation of procedure, site and side, in a history or physical in these circumstances?

Response: The Authority agrees that noting the procedure, site, and side on the history and physical exam is best practice. The Authority is also aware that there are situations that fall out of the normal standards, but we believe that most patients should have the correct procedure, site, and side documented on this foundational source document or on the procedure note. Recommendation 2 is revised as follows:

The procedure, site, and side should be noted in the medical record on the history and physical exam record[9,10] or the procedure note.

5. The Authority received one comment regarding recommendation 4 and the responsibility for verification and reconciliation of all staff members, including ancillary staff, scheduling staff and registration clerks. The commentator states that ancillary staff is not defined; that this poses a HIPAA concern, as these staff members do not need to know this information to do their jobs; and that this responsibility is beyond the scope, education and training of these staff members.

Response: The Authority disagrees that this is beyond the responsibility of all staff members.

The staff members involved in a patient encounter in which the consent, history and physical, office notes, or schedule, or both, are used have an obligation to speak up if they note a discrepancy. This recommendation is not intended to imply that these staff members are obligated to review each of these documents and resolve the discrepancy themselves; however, if when registering a patient, the clerk notes that the patient is scheduled for right total knee replacement and during the registration process the patient states they are coming in for a shoulder replacement—that registration clerk has an obligation to make the discrepancy known.

Ancillary staff are any staff members, other than those specifically listed, that may encounter the patient and utilize patient verification data.

Recommendation 4 is revised as follows:

All individuals, including scheduling staff, registration clerks, ancillary staff, nursing staff, the operating provider, and the patient, have an obligation to speak up if they note a discrepancy in any information on the schedule, consent, history and physical, and any office notes. Reconciliation of discrepancies is the responsibility of the operating provider prior to the procedure.

6. The Authority received one comment related to recommendation 5 and the patient's or family's verbal understanding. The commentator states that the recommendation does not address when a patient may be unable to communicate understanding due to current medical or cognitive condition, nor does the recommendation address instances when a family member is not available. The commenter makes the suggestion to revise the language to include the phrase "when possible."

Response: The Authority agrees with the commenter. The recommendation is modified as follows:

All information to verify the correct patient, procedure, side, and site, including the patient's or family's verbal understanding, when possible, must be verified by the circulating nurse/designee, anesthesia provider, and operating provider.[9, 10] This verification shall be documented in a manner determined by the healthcare facility.

7. The Authority received three comments related to recommendation 9.

a. The patient or their representative, or both, confirming site marking: The commenter states that the recommendation does not address when a patient may be unable to confirm the marking due to a current medical or cognitive condition, nor does the recommendation address when a patient representative is not available. The commenter makes the suggestion to revise the language to include the phrase "when possible."

Response: The Authority agrees with the commenter. The recommendation is modified as follows:

The site must be marked by the provider responsible for the procedure, e.g., surgeon, proceduralist, or interventional radiologist, prior to the patient entering the procedure area. The mark must be confirmed by the attending nurse/designee. The mark must also be confirmed by an alert patient or patient representative when possible. The mark must coincide with the schedule, history and physical, and consent.[9—11, 14—18]

b. Other health professionals marking sites: The commenter states that while the Department of Health and the Centers for Medicare & Medicaid Services do not address other health professionals marking sites, The Joint Commission does in National Patient Safety Goal UP.01.02.02 EP3. The Joint Commission standard states, "In limited circumstances, the licensed independent practitioner may delegate the site marking to an individual who is permitted by the organization to participate in the procedure and has the following qualifications: An individual in a medical postgraduate education program who is being supervised by the licensed independent practitioner performing the procedure; who is familiar with the patient; and who will be present when the procedure is performed OR a licensed individual who performs duties requiring a collaborative agreement or supervisory agreement with the licensed independent practitioner performing the procedure (that is, an advanced practice registered nurse or physician assistant); who is familiar with the patient and who will be present when the procedure is performed." *Note*: The hospital's leaders define the limited circumstances (if any) in which site marking may be delegated to an individual meeting these qualifications.

Response: The Authority disagrees with the commenter and believes that site marking should not be delegated.

c. Site marking and certain procedures: The commenter stated that they rely on fluoroscopy for final site verification, due to the nature of the procedures and that marking the patient is not specific enough to prevent a wrong-site procedure.

Response: The Authority agrees that site marking alone is not sufficient for certain procedures. See recommendation 20. However, the use of intraoperative fluoroscopy does not negate the need to mark the site. A site mark should be made as close to the intended incision/puncture site as possible prior to the patient entering the operative/procedure room. This mark is intended to alert the team to the general site prior to initiating fluoroscopy to determine exact location.

8. The Authority received one comment related to recommendation 13 and the announcement of the time-out. The commenter stated the provider performing the procedure does not have visualization of the source of truth for the correct patient and procedure to be performed. They believe the circulating nurse, who is the staff member in the room and is able to visualize the consent, takes a more active role in the time-out.

Response: The recommendation is that the provider announces the time-out. The purpose of this recommendation is to shift responsibility for quality of the time-out process to the operating provider. The operating provider should ensure that the team stops all activity and is actively engaged before the time-out begins. The recommendation does not imply that the provider needs to ask the questions; this role may be designated to the most appropriate person on the team.

9. The Authority received one comment related to recommendation 14 and separate formal time-outs for separate procedures. The commenter states that they agree separate formal time-outs for separate procedures performed by different personnel are warranted. They also state that conducting separate formal time-outs for separate procedures performed by the same person is duplicative and suggest that a separate site and procedure verification process occur but not another formal time-out.

Response: The Authority believes that a separate formal time-out for separate procedures, even when the operating provider is the same, is important to ensure the correct procedures are

performed. This recommendation is supported by the American Academy of Orthopaedic Surgeons Information Statement 1043: Surgical Site and Procedure Confirmation (March 2015).

10. The Authority received one comment related to recommendation 16 and the use of office notes during the time-out. The commenter states they agree that relevant information such as history and physical, consent, and operating room schedule should be available, including the addition of nursing assessment and pre-anesthesia assessment; however, the use of office notes is unwarranted and duplicative in relation to the other documents already referenced. They also state that the term "office notes" is ambiguous and not well defined, as to the source of the notes or content.

Response: The Authority agrees with the commenter. Recommendation 16 will be revised as follows:

All relevant patient documents should be available and actively confirmed during the time-out process.[9—11] Relevant documents include a history and physical, consent, operating room schedule, and radiographic studies when applicable.

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