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PPM

Wrong-Site Nerve Blocks: Getting Them Right

Introduction

PPM insureds reported 33 wrong-site and wrong-side nerve blocks (WSNBs) in the past five years. Of those 33 adverse incidents, one resulted in a claim against the insured. However, even though most WSNBs do not result in claims or litigation, other significant negative consequences may occur. Patient anger and dissatisfaction arising from these preventable "never events"[1] may result in repercussions, including hospital administration, health department, and third-party payer investigations. Patients frequently demand writing off all or a portion of the anesthesia bill resulting in loss of revenue. PPM insureds have also reported clinician embarrassment and second-victim syndrome[2] following WSNB incidents. Additionally, as the following case study demonstrates, PPM has defended many insureds who became subject to state medical and nursing board complaints, investigations, and disciplinary actions that potentially jeopardize their professional licenses, reputations, and employment.

Case Study One

A 52-year-old male patient presented for knee arthroplasty. The anesthesiologist planned a general anesthetic with a preoperative femoral nerve block for postoperative pain control. The protocol at this facility required the surgeon to mark the surgical site before administering the block.

However, for this procedure, a new surgical technician was working at the facility. The anesthesiologist was showing the surgical technician how to set up the block table. After that, the anesthesiologist placed the block in the wrong leg before the surgeon marked the surgical site.

The surgeon and anesthesiologist decided to perform the surgery on the correct side without a block. The surgery was completed without incident. The patient was informed of the mistake when he was fully awake. The patient was not angry and did not pursue a claim or litigation.

However, the hospital reported this adverse event to the state medical licensing board (Board) as required by state law. The Board opened an investigation into this matter and notified the state department of health (Department).

The Department filed a formal administrative complaint against the anesthesiologist. Following its investigation, the Department proposed a settlement agreement that included a letter of concern from the Board, an administrative fine of $5,000, costs of approximately $2,000, continuing education, and 50 hours of community service. After a formal hearing that required the anesthesiologist and his counsel to appear in person, the Board approved the settlement.

Risk Management Analysis

This case study underscores three of the leading causes of WSNBs: distractions, surgical site not marked, and no time-out.[3] Several examples of reported distractions that contribute to WSNBs include an argument with the surgeon just before the block, time-out begun but interrupted and not completed, and attending anesthesiologists called out of the room.[4] Many states require reporting incidents involving WSNBs to medical licensing boards and health departments.[5] As highlighted in this case study, disciplinary actions may include significant fines and sanctions. Anesthesia professionals may also be required to report disciplinary investigations and actions on credentialing and privileging applications, recertifications, and renewals. Additionally, nearly all medical professional liability insurance companies require disclosing certain disciplinary investigations and actions on their application forms.

Case Study Two

A 91-year-old male patient presented to the hospital for pneumonia. He was diagnosed with aortic stenosis, and a stent was placed. During his hospitalization, he fell and

In This Issue

PPM insureds report wrong-site nerve blocks much more frequently than wrong-site surgeries. Wrong-site surgeries can cause catastrophic injuries to patients and often result in litigation against the entire OR team. Wrong-site nerve blocks typically do not result in permanent patient injuries and rarely develop into claims or litigation. However, several other adverse consequences may occur to anesthesia professionals who perform wrong-site nerve blocks. In this issue, we review three case studies involving wrong-site nerve blocks and the resulting repercussions that affected our insureds. We also offer risk management analysis and patient safety strategies to avoid these "never events."

Thanks for reading,

Brian J. Thomas, Editor

broke his hip. The patient was DNR, but his family wanted palliative care, so surgery was scheduled for his left hip.

The anesthesiologist was to provide a femoral block for postoperative pain. Before the surgery, the anesthesiologist met with the patient and his family and asked the patient on which hip he was having surgery. The patient said he did not know. The anesthesiologist asked him which hip hurt, and the patient stated his right hip was causing him pain. The anesthesiologist performed the femoral nerve block on the right side.

When the staff started prepping the left hip, the anesthesiologist questioned them and discovered the left hip was the operative site. The surgeon performed the procedure. While the patient was in recovery, the anesthesiologist performed a femoral block on the correct side. After being informed of this misadventure, neither the patient nor his family was upset.

However, the hospital's risk management and Quality Assurance (QA) departments investigated this adverse event. The hospital scheduled a Root Cause Analysis meeting and summoned the anesthesiologist to appear before the QA committee. The hospital also notified the state department of health (Department) about this WSNB.

PPM retained local defense counsel to prepare our insured for the Root Cause Analysis meeting and any potential investigation by the Department. After over a month of meetings and communications with defense counsel, the anesthesiologist appeared before the QA committee to explain how this WSNB occurred. Following the Root Cause Analysis and the QA committee meeting, the hospital took no action against the anesthesiologist's privileges.

Risk Management Analysis

Even though the anesthesiologist who performed a WSNB on this patient wasn't formally disciplined by the hospital, his personal and professional life was substantially disrupted by this adverse incident and subsequent investigation. Defense counsel noted the insured experienced significant stress and anxiety about protecting his hospital privileges and avoiding potential adverse effects on his employment with his practice group. He also lost income while taking time off to meet with defense counsel to prepare for and attend the QA committee meeting. Moreover, while nerve injury resulting from performing regional blocks is a known risk and complication that PPM successfully defends in most claims and lawsuits, nerve injury resulting from a WSNB would be much more challenging to defend.

Case Study Three

A 54-year-old female presented for shoulder surgery. The anesthesiologist was to provide an interscalene block for postoperative pain. After performing the time-out, the surgeon called him out of the room to discuss having a pre-med student observe the procedure. The anesthesiologist and the student went back into the room, and he introduced the student.

The anesthesiologist spoke with the patient about the block and administered some Versed. He then proceeded to the wrong side of the patient's neck, and the patient agreed that was the correct side. The patient's husband was also present in the room and did not speak up regarding the wrong side.

The patient experienced some paresthesia when the anesthesiologist inserted the needle. He moved the needle, looked down, and saw that the BP cuff was on the arm he was blocking. He asked the patient which shoulder she was having surgery on, and she stated the other side. He proceeded to place the block on the correct side.

Following the surgery performed under general anesthesia, the patient reported feeling the sensation of pins, needles, and tingling in the wrong arm. She was contacted that same evening and said she still had some symptoms.

The following day, the patient reported that all her symptoms had resolved. When the surgery center staff called the next day, she complained about her experience and stated that the surgery center should provide her with a discount because of what occurred. The anesthesiologist called the patient and explained that the mistake was not the surgery center's fault. He apologized and offered to waive her bill for the block and the general anesthetic, which the patient accepted.

Risk Management Analysis

After performing the time-out, the anesthesiologist was distracted by being called out of the room to meet the student. The anesthesiologist also relied on the patient and her husband to verify the correct side for the block. Engaging patients to participate in the site marking and time-out process, when possible, can be an additional step to safeguard against WSNBs.[6] However, PPM has investigated and defended numerous WSNBs in which the patient or a family member incorrectly identified the side or site for the block. This may because a patient has bilateral disease and procedures for both sides are planned at different times A patient may also have confusion, anxiety, or cognitive issues that may contribute to a WSNB.[7] This WSNB led to the patient making a complaint against the facility and a demand to discount her incurred charges for the procedure. The anesthesiologist appropriately contacted the patient to apologize and accept responsibility for the WSNB. He also agreed to waive the fees for the anesthesia services provided, resulting in a loss of revenue.

Other Factors That Contribute to WSNBs:[8]

- Time-out, Universal Protocol, or checklist are not done or utilized before performing the block
- Surgical site is not yet marked (surgeon unavailable)

- Failure to mark the block site
- Lack of standardized markings
- Mark erased or covered
- Other team members such as the surgeon, circulating nurse, or preop nurse are not present or available
- Block is performed by regional analgesia team not involved in anesthesia for the surgical procedure; location is in the preoperative area, not the OR
- Consent for the surgical procedure is not available at the time of the block
- Missing, incomplete, or inaccurate records
- Confusion regarding side when the patient is turned from supine to prone, especially for dual-site blocks (e.g., femoral and sciatic blocks for thigh surgery)
- Change in staff during the procedure
- Interruptions
- Poor communication among team members, patients, and family members
- Time pressure

Risk Management Considerations, Strategies, and Resources to Prevent WSNBs

Several anesthesia societies, including the American Society of Anesthesiologists, American Society of Regional Anesthesia and Pain Medicine, Society for Pediatric Anesthesia, and Pennsylvania Society of Anesthesiologists, have provided recommendations, protocols, and checklists for the prevention of WSNBs. Other patient safety and accrediting organizations such as the Anesthesia Patient Safety Foundation, Pennsylvania Patient Safety Authority, and the Joint Commission have supported and developed protocols to prevent WSNBs.

However, despite these patient safety initiatives and efforts, WSNBs continue to occur. The following is an overview of several of the most widely recognized and implemented WSNB prevention protocols, checklists, and recommendations:

The Joint Commission Universal Protocol: Following the American Academy of Orthopedic Surgeons introduction of the "Sign Your Site" safety program in 1998 to reduce wrong-site surgeries[9], the Joint Commission introduced the

Table 1 illustrates the Universal Protocol Revised for Regional Anesthesia or Pain Procedure.

TABLE

Universal Protocol Revised for Regional Anesthesia or Pain Procedure
Adapted from The Joint Commission Universal Protocol Poster available at
www.jointcommission.org/assets/1/18/UP_Poster1.PDF

Pre-procedure verification
• Verify correct procedure, for the correct patient, at the correct site; verify using at least two people, and verify using surgical consent, booking worksheet, chart, etc. • If possible, involve the patient in the process • Identify items critical to the procedure • Use a standardized list to ensure all elements are included
Check the procedure site mark (as performed by the surgeon)
• When possible, have surgeon mark the site prior to beginning the block procedure • Mark the site to be blocked if the surgeon's mark is not visible at the site. • If possible, involve patient in site marking • Use an unambiguous mark that is uniform throughout the institution • Use a mark that is at or near the block site • Mark should be permanent enough to be visible after skin preparation and draping
Perform a Time Out
• Conduct a Time Out immediately prior to starting. This should follow a standard script • Designated member of the team assigned to initiate the Time Out • Time Out should include at least one other member of the team • Time Out should verify the patient identity and the correct site • If multiple procedures or blocks are to be done, another Time Out should be performed prior to starting each subsequent procedure (i.e., after turning patient prone to perform sciatic block after performing supine femoral nerve block)

Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery (Universal Protocol) in 2004. However, despite implementing the Universal Protocol, PPM's loss data showed the number of wrong-site adverse events, including WSNBs, increased in the following three years.[10] One of the primary problems with the Universal Protocol was allowing surgical site marking to be delegated to the nursing staff or other health care providers. These inferior site identification protocols spread the responsibility among all providers, diluted individual responsibility, and increased wrong-site adverse incidents.

In 2008, the Joint Commission approved an updated Universal Protocol that became effective January 1, 2009. The revisions were based on feedback received at the Wrong Site Surgery Summit held in 2007 to address concerns raised by several professional organizations, including Preferred Physicians Medical (PPM), regarding the continued increase in reported wrong-site adverse incidents. The most significant improvements in the 2009 Universal Protocol were the requirement that the surgeon or proceduralist mark the site and the required use of a pre-procedure verification checklist.[11]

While PPM strongly endorsed the requirement that the surgeon or proceduralist mark the procedural site (with limited exceptions), the 2009 Universal Protocol implementation guidelines still appear to be subject to interpretation on several vital issues. For example, they do not require standardized marking (e.g., the surgeon's or proceduralist's initials) and allow health care facilities to determine when the time-out occurs (including after sedation or the introduction of general anesthesia).

The American Society of Regional Anesthesia and Pain Medicine published recommendations for a pre-block checklist specific to regional anesthesia that includes the following elements:[12]

1. Identification of patient using two criteria
2. Review allergies and anticoagulation status
3. Surgical procedure consent is confirmed
4. Block plan is verified, site is marked
5. Necessary equipment is present; drugs are prepared and labeled
6. Resuscitation equipment is immediately available
7. ASA-specified monitors are applied, I.V. access, sedation, and oxygen used as indicated
8. Aseptic technique is utilized (hand hygiene, mask, sterile gloves)
9. Time-Out is performed before needle insertion for each block site

In 2018, the Pennsylvania Society of Anesthesiologists partnered with the Pennsylvania Patient Safety Authority to develop a peer-driven, consensus-based, multi-disciplinary protocol for the Principles for Reliable Performance of Correct-Site Nerve Blocks. Anesthesiologists are encouraged to work with their organizations to establish the principles as standard surgical safety practices (see insert).[13]

Each of the referenced WSNB prevention protocols, checklists, principles, and recommendations provide a valuable framework, guidance, and processes to avoid these preventable "never events." However, the continued reports of WSNBs to PPM and in the medical literature illustrate that there is no one-size-fits-all, simple solution to this problem.

To prevent WSNBs, PPM recommends the following steps and processes:

1. Perform a separate time-out before each specific block or pain procedure
2. The time-out must include a team member other than the one performing the block and should verify the location of the surgery or block
3. The location of the surgery should be verified with the surgeon's mark and surgical consent
4. Ask patient open-ended questions to verify the surgical or block site, when possible
5. Formally document the time-out
6. Any inconsistency requires a halt until the discrepancy is resolved
7. If the block is performed by a team other than the OR team, formal communication must occur between the teams before and after the block, including the site and type of block to be performed, single-shot versus catheter, test dose, and volume and type of anesthetic injected
8. Avoid performing blocks while the patient is sedated or anesthetized unless medically indicated; if medically indicated, discuss and document potential increased risk of nerve injury
9. Every facility must require that the pre-block protocol and time-out be performed correctly for every block every time

PPM's in-house attorneys and claims staff are prepared to assist PPM policyholders in working with hospitals and facilities to implement improved surgical and regional block site verification protocols.

Underwriter's Spotlight

Changing Places, Practices, Names, Email Addresses, etc.? Let Us Know

At PPM, we understand that our policyholders' and insureds' personal and professional situations and needs change throughout their lives and careers.

For PPM to continue to provide the best customer service and benefits to our policyholders and insureds, we ask that you notify us of any of the following changes:

- Name, address (personal residence and practice), phone number, email address
- Addition or removal of practice locations; relocation to another state
- Change in or additional practice model (e.g., office-based, mobile, pain, locum tenens, etc.)
- Leave of absence due to health related issues, missionary or volunteer medical services, sabbaticals
- New hires and employee departures from anesthesia practice groups

PPM's entire team, including our policyholder service representatives, underwriters, in-house claims attorneys and staff, and business development representatives, is available to assist you with any changes that affect your anesthesia practice. "We offer an array of benefits and special services, such as providing information regarding specific states or jurisdictions for our policyholders who are interested in relocating. Additionally, PPM's in-house attorneys and claims staff are available to review anesthesia services agreements, other contracts, informed consent documents, and practice policies and protocols to ensure our policyholders' liability exposures are properly protected," according to Gena Knust, Senior Underwriter.

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PREFERRED PHYSICIANS MEDICAL RISK RETENTION GROUP
11880 College Boulevard, Suite 300
Overland Park, KS 66210-2141

T 913.262.2585 • 800.562.5589
F 913.262.3633

NEWSLETTER EDITOR
Brian J. Thomas, JD
Vice President-Risk Management

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Principles for Reliable Performance of Correct-Site Nerve Blocks

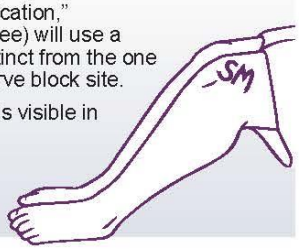
I. Process of Care

Preoperative Verification

1. Confirm patient identity using at least two forms of patient identification.
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:
    a. Primary: Surgical consent
    b. Primary: Patient and/or representative
    c. Primary: Surgeon's notes (if available)
    d. Confirmatory: Operating room schedule
    e. Confirmatory: History & physical
3. If any of these sources differ, the process stops and a member of the anesthesia block team alerts the surgeon to resolve the disagreement.

Anesthesia Site Marking

1. After confirming the information in "Preoperative Verification," the responsible attending anesthesiologist (not a trainee) 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.
2. Place the mark close to the injection site to ensure it is visible in the prepped and draped field.
3. Repeat the marking process when there are multiple injection sites.

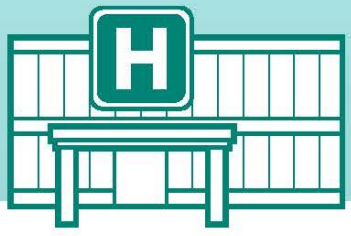


Time-out

1. Secure a block team consisting of at least two people with independent roles (e.g., responsible attending anesthesiologist and pre-operative or holding area nurse or circulating nurse):
    a. Engage the responsible attending anesthesiologist to INITIATE or ask for the time-out.
    b. Require that the responsible attending anesthesiologist be present during the time-out and nerve block
2. 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
3. Minimize distractions and stop all unrelated activity before conducting the time-out.
4. Both the responsible attending anesthesiologist and block team member verify the procedure that is documented on the surgical consent (and anesthesia consent, if used).
5. Locate and verbally confirm the visible anesthesia site mark during the time-out.
6. 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

II. Healthcare Facility Structure and Culture of Safety

- Develop and maintain a single, consistent systemwide perioperative nerve block process similar to that implemented by other services to prevent wrong-site procedures (e.g., surgery, radiology).
- Engage a multidisciplinary stakeholder team to develop the nerve block process.
- Educate and train anesthesia, pain service teams, and preoperative nursing staff about the perioperative nerve block process (e.g., simulation).
- Use checklists, posters, stickers or other cognitive aids in the block area to encourage sustainability of the nerve block process for clinicians and patients.
- Designate a department leader or administrator (e.g., a liaison to administration and physicians) to support block team staff and to address non-compliance for the nerve block process.
- Empower all members of the block team to speak up if there is a safety concern.
- Engage patients and their representatives as active participants in the pre-nerve block process.
- Audit nerve block processes at regular intervals (e.g., monthly, quarterly).
- Obtain ongoing evaluation and feedback from anesthesia, pain services, and perioperative nursing staff to ensure process is consistent and maintains provider engagement.



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Patient Safety Authority

PENNSYLVANIA society of ANESTHESIOLOGISTS