PPM ANESTHESIA MALPRACTICE INSURANCE

ANESTHESIA & the LAW

A RISK MANAGEMENT NEWSLETTER

PREFERRED PHYSICIANS MEDICAL RISK RETENTION GROUP, INC.

ISSUE 18

Wrong Site Surgery: Universal Protocol Misses the Mark

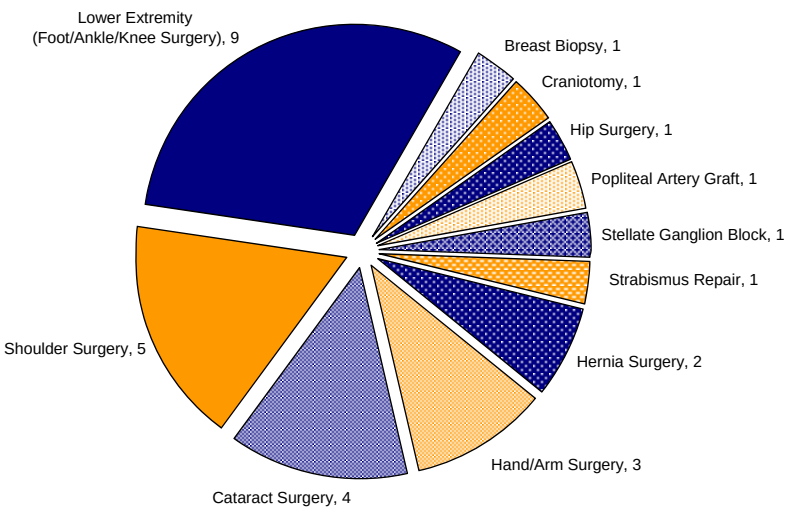
Despite the implementation of the Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery[1] (Universal Protocol) in July 2004, wrong site adverse outcomes continue to be reported to Preferred Physicians Medical (PPM). Disturbingly, the number of wrong site adverse outcomes reported to PPM has actually increased in the three years since the implementation of the Universal Protocol.

In the three years immediately prior to the implementation of the Universal Protocol, twenty-three (23) wrong site adverse outcomes were reported to PPM by its policyholders. In the three years immediately following the implementation of the Universal Protocol, PPM policyholders reported twenty-nine (29) wrong site adverse outcomes.

Even more concerning for PPM's policyholders is that sixteen (16) of the twenty-nine (29) wrong site adverse outcomes reported to PPM following the implementation of the Universal Protocol involved wrong site nerve blocks. In the three years prior to the implementation of the Universal Protocol, only eight (8) of twenty-three (23) wrong site adverse outcomes involved wrong site nerve blocks.

The chart below illustrates the types of surgeries in which wrong site adverse outcomes have been reported since July 1, 2004:

Wrong Site Adverse Outcomes Reported to PPM by Policyholders After Implementation of Universal Protocol
Listed by Surgery Type: 7/1/2004 to 6/30/2007



In this Issue

Wrong site surgical mistakes continue to jeopardize patient safety, increase insurance costs and subject health care providers to significant disciplinary actions. From a risk management standpoint, PPM has identified wrong site surgeries as a preventable malpractice claim and we have devoted significant efforts alerting PPM's policyholders about the important safety steps that all facilities should take to prevent wrong site surgeries. Unfortunately, an ongoing failure by hospitals and other health care facilities to implement "gold standard" sign your site protocols has resulted in continued reports of wrong site surgeries and patient mix-ups. In this newsletter, we examine the problems with the Universal Protocol and why we believe it has failed to reduce the number of wrong site surgical mistakes. We also offer some risk management advice to prevent wrong site adverse outcomes.

Thanks for reading,

Brian J. Thomas, Editor

[1] *See*, www.jointcommission.org/PatientSafety/UniversalProtocol.

Problems with the Universal Protocol

The Joint Commission and the American Society of Anesthesiologists (ASA) have also recognized the Universal Protocol has not proven to be an effective methodology for preventing wrong site adverse outcomes. Recently, the Joint Commission, ASA and several other organizations convened a summit to solicit suggestions on how to improve the Universal Protocol. Much of the debate and the proposals that followed continue to focus on the surgical time-out procedures and when the time out should occur.[2] From PPM's perspective, focusing more attention on time out procedures continues to miss the mark in terms of identifying the flaws associated with the Universal Protocol.

Based on our investigation of numerous wrong site adverse outcomes, PPM continues to suggest that a more effective approach to preventing wrong site procedures is to focus responsibility on the individual performing the procedure – the surgeon. PPM's investigation of wrong site adverse outcomes indicates that spreading responsibility among all providers is a significant weakness in the Universal Protocol. "Shared responsibility only dilutes individual responsibility. Too often health care providers assume someone else has verified the proper site. Mandatory time outs become pro forma and mistakes continue," notes Steve Sanford, PPM Executive Vice President and Chief Operating Officer. Shared responsibility protocols also open the door to significant finger-pointing between health care providers. Such finger-pointing dramatically increases the likelihood of litigation and the costs of defense for all involved. It also delays early resolution and drives up the cost of wrong site settlements.

In addition, PPM remains concerned that most surgical site identification protocols are implemented to accommodate surgeons by allowing site marking to be delegated to the nursing staff or permitting the site identification to be conducted at less optimal times, including after a patient is sedated. Unfortunately, many such accommodations appear to increase the likelihood of a wrong site nerve block. PPM recommends advancing the time for surgical marking in order to provide anesthesia providers site confirmation prior to placing any blocks.

Common Mistakes

The implementation guidelines for the Universal Protocol also appear too generic and subject to interpretation to effectively prevent wrong site adverse outcomes. Widely varied site identification protocols create confusion. Significant differences in marking techniques ("X", "YES", "NO", dots, lines, etc.), timing of the mark and involvement of various health care providers create additional uncertainty. Time out protocols that allow the time out to occur prior to the arrival of all members of the operative team contribute to further confusion and mistakes. The following wrong site adverse outcomes reported to PPM underscore the need for greater uniformity in the Universal Protocol guidelines:

- An 86 year-old male presented via the ER with a subdural hematoma. The neurosurgeon transferred the patient directly to the OR for a craniotomy. The surgeon examined the chart and marked "right" on the consent and History & Physical; however, the surgeon did not mark the surgical site. The surgical team participated in a time out and confirmed a right sided surgery. No hematoma was found on the right side. The surgeon checked the CT scans and noted the hematoma was on the left side.
- A 68 year-old female was scheduled for cataract surgery on her left eye with the anesthesiologist administering a retrobulbar block. The left eye was marked with a red dot. However, the patient's surgical cap slid down covering the surgical marking. The anesthesiologist blocked the right (incorrect) eye. The case was cancelled after the mistake was discovered.
- A 40 year-old female presented for right shoulder arthroscopy. The anesthesiologist placed a block in the left shoulder. The anesthesiologist realized he was blocking the wrong side and stopped after administering 6 cc of medication. The facility had a "sign your site" protocol in place; however, the anesthesiologist reported there were no marks when he placed the block. Post-operatively the patient complained of numbness and weakness in her left arm.

[2] ASA Newsletter, *Preventing Wrong Site Surgery*, August 2008, Vol. 71, No. 8, pp. 21-23.

- A 70 year-old female was scheduled for cataract surgery on her left eye. The surgeon planned to administer a local anesthetic with the anesthesiologist providing sedation. The patient's left eye was prepped for the anesthetic injection; however, the procedure was interrupted. Thereafter, the surgeon injected the anesthetic into the patient's right (incorrect) eye. The patient filed litigation against all physicians involved claiming she suffered from pain and double vision due to the block in the incorrect eye.

- A 40 year-old male was scheduled for a left elbow arthroscopy with an interscalene block. Prior to the procedure the patient's left elbow was marked. There was a power outage and cases were backed up and rooms were being flipped. The nursing staff took the patient to the operating room and draped the patient. The patient's right arm was exposed and the anesthesiologist assumed this was the correct arm. The anesthesiologist administered the interscalene block on the right (incorrect) side. A time out was performed before the surgery started and it was noted at that time that the wrong side had been blocked.

Risk Management Tips to Prevent Wrong Site Surgical Mistakes

From a risk management standpoint, PPM continues to strongly recommend the adoption of the "sign your site" protocol as endorsed by the American Academy of Orthopaedic Surgeons (AAOS).[3] The key feature of this protocol is that it requires the surgeon, in consultation with the patient, to mark the surgeon's initials on the operative site in advance of the surgical procedure and prior to sedation. This requirement recognizes that the best way to prevent wrong site surgical mistakes is to place the primary responsibility for site identification on the surgeon. While accommodating revenue producers may be a fact of life in many hospitals and surgery centers, PPM endorses the more rigorous AAOS approach and encourages its policyholders to advocate this approach.

Additional protocol requirements such as independent verification by both the nursing staff and anesthesia providers and a surgical time out can also provide redundancies that help to ensure patient safety. Unfortunately, these procedures by themselves have proven to be wholly inadequate when implemented without the surgeon being required to sign the surgical site.

With regard to the surgical time out, PPM strongly urges policyholders to actively participate in this very important safety step to prevent wrong site surgeries. Often the surgical time out is the anesthesiologist's only opportunity to verify the correct patient, procedure and surgical site. In several instances, policyholders have reported that the members of the surgical team merely provided lip service to the time out verification process only to discover a wrong site surgical mistake after the procedure began. The time out should involve the entire surgical team, use active communication, be briefly documented and should include: correct patient identity, correct side and site, agreement on the procedure to be performed and correct patient position. The hospital or health care facility should also have processes and systems in place for reconciling differences or disagreements among the surgical team members, i.e. the procedure is not started until any questions or concerns are resolved.

Finally, PPM's in-house attorneys are prepared to assist PPM policyholders in working with hospitals and health care facilities to implement improved surgical site verification safety protocols. ❖

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[3] *See*, "Sign Your Site" Protocol, American Academy of Orthopaedic Surgeons, www.aaos.org.

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- Problems with the Universal Protocol
- Common Mistakes
- Risk Management Tips to Prevent Wrong Site Surgical Mistakes