PPM
ANESTHESIA & the LAW
A RISK MANAGEMENT NEWSLETTER
PREFERRED PHYSICIANS MEDICAL RISK RETENTION GROUP, INC.

ISSUE 22

Wrong Site Surgery Update: 2009 Universal Protocol Moves in Right Direction

Background

In July 2008, an updated Universal Protocol was approved by the Joint Commission and **became effective January 1, 2009**. The revisions are based on feedback received at the Wrong Site Surgery Summit held in February 2007 to address concerns raised by a number of professional organizations, including Preferred Physicians Medical (PPM), regarding the continued increase in the occurrences of reported wrong site surgery cases. The revised Universal Protocol was released in June 2008. Feedback since this release provided information for clarifications, which are provided by the Joint Commission in the format of Frequently Asked Questions (FAQs).[1]

Changes to Universal Protocol

Surgical Site Marking

From PPM's perspective, the most significant improvement in the 2009 Universal Protocol is the change relating to the surgical site marking. The 2008 Universal Protocol surgical site marking standard indicated that the person performing the procedure "**should**" perform the site marking. In the past, all too often surgical site identification protocols allowed surgical site marking to be delegated to the nursing staff or other healthcare providers. These inferior surgical site identification protocols spread the responsibility among all providers, diluted individual responsibility and contributed to an increase in wrong site adverse outcomes.

The 2009 Universal Protocol surgical site marking standard ***requires*** the licensed independent practitioner or other provider privileged to perform the intended procedure to mark the site. PPM has long advocated focusing responsibility for marking the surgical site on the individual performing the procedure to reduce the number of wrong site adverse outcomes. PPM suggests that requiring the individual performing the procedure to mark the surgical site with the surgeon's or proceduralist's initials will reduce the number of wrong site adverse outcomes.

Pre-Procedure Verification Checklist

The use of a checklist during the pre-procedure verification process was optional under the 2008 Universal Protocol. The 2009 Universal Protocol ***requires*** the use of a checklist in the pre-procedure area and needs to be completed prior to moving the patient into the operating or procedure room. The checklist should include:

- Relevant documentation (e.g., history & physical, nursing assessment and pre-anesthesia assessment)
- Accurately completed and signed procedure consent form
- Correct diagnostic and radiology test results (e.g., radiology images and scans or pathology and biopsy reports)
- Any required blood products, implants, devices and/or special equipment for the procedure

Time-Outs

The 2009 Universal Protocol clarifies that the time-out should be conducted immediately prior to starting the procedure and "ideally, prior to the introduction of the anesthesia process (including general/regional anesthesia, local anesthesia, and spinal anesthesia), unless contraindicated." In discussing the time-out, the Joint Commission recognizes that wrong site anesthesia procedures do occur (e.g., wrong site regional anesthesia). However, an

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

"anesthesia time-out" separate and apart from the time-out for the procedure is still not required under the 2009 Universal Protocol.

The 2009 Universal Protocol FAQs relating to time-outs appear to contain some contradictions.

- On one hand, the FAQs require one and only one time-out for most procedures: either before anesthesia or after anesthesia and prior to incision. On the other hand, the FAQs seem to require two time-outs when a spinal or regional block is involved: prior to the block and again prior to incision.
- On one hand, the FAQs indicate that only one-time out is necessary when the same team will perform all portions of a multi-part procedure. On the other hand, it requires a separate time-out when the various parts of the procedure require separate consent forms.[2]

The FAQs also state that each organization must "define under which situations the time-out is required to be performed prior to anesthesia or when it is preferable to do so immediately prior to the procedure/incision." Because there are contradictions within the FAQs about time-outs, PPM strongly recommends advancing the time for the surgical marking and time-out in order to provide anesthesia providers site confirmation prior to placing any blocks or sedating the patient.

Procedures

The Universal Protocol applies to all operative and other invasive procedures that expose patients to more than minimal risk. The Joint Commission defines invasive procedures as those involving "the puncture or incision of the skin, insertion of an instrument, or insertion of foreign material into the body. Invasive procedures may be performed for diagnostic or treatment-related purposes."[3]

The Universal Protocol's expansion of procedures that are covered, notably all procedures involving percutaneous puncture, has created some confusion among healthcare providers. The Universal Protocol FAQs provide some clarification for what procedures are and are not to be included in the Universal Protocol. The FAQs state that "…certain routine 'minor' procedures" such as the following are **NOT** within the scope of the Universal Protocol:

- Venipuncture
- Peripheral intravenous line placement
- Nasogastric tube insertion
- Urinary catheter insertion
- Electroconvulsive therapy
- Closed reductions
- Radiation oncology
- Lithotripsy
- Dialysis
- Procedures that have a midline approach intended to treat a single, midline organ (for example, cesarean section or CABG)
- Endoscopies without intended laterality
- Obvious wound or lesion

Procedures that **ARE** within the scope of the Universal Protocol include:

- PICC line insertion
- Central line insertion
- Chest tube insertion and other similar types of procedures

The Universal Protocol FAQs state that "each organization is expected to clearly define those procedures that fall within the protocol."

Documentation

The completed components of the Universal Protocol and time-out are clearly documented in the patient's chart.

Overview of 2009 Universal Protocol

- Pre-procedure verification must be conducted*
- Procedure site is required to be marked by the practitioner or provider who is going to perform the procedure*
- Time-out is performed immediately prior to starting procedure verifying:
    1. Correct patient identity

[2] Id.
[3] Id.

2. Correct procedure consent form completed*
3. Agreement on procedure to be performed
4. Correct patient position
5. Relevant images and results are properly labeled and appropriately displayed
6. The need to administer antibiotics or fluids for irrigation purposes*
7. Safety precautions based on patient's history or medication use*

- Documentation of "time-out" required on patient chart*

(*New for 2009)

Problems with the 2009 Universal Protocol

While PPM strongly endorses the requirement that the licensed independent practitioner or other provider privileged to perform the intended procedure marks the surgical site, the implementation guidelines for the 2009 Universal Protocol still appear to be subject to interpretation on several important issues. The Universal Protocol still uses permissive rather than mandatory language with regard to two very important components.

First, the Universal Protocol indicates that the surgical marking includes, "**preferably**," the surgeon's or proceduralist's initials. PPM's considerable experience in investigating and defending wrong site adverse outcomes strongly suggests that significant differences in marking techniques ("X", "YES", "NO", dots, lines, etc.) continue to create uncertainty and lead to mistakes. From PPM's perspective, the 2009 Universal Protocol should **require** the surgeon's or proceduralist to mark the surgical site with his/her initials.

Second, by allowing health care facilities to determine when the time-out occurs creates further confusion and increases the likelihood of wrong site adverse outcomes. PPM strongly recommends requiring the surgical marking and time-out to occur **before** the introduction of the anesthesia process (including general/regional anesthesia, local anesthesia, and spinal anesthesia). Again, the Universal Protocol includes permissive language that "**ideally**" the surgical marking and time-out should be done prior to the introduction of the anesthesia process. From PPM's perspective, the better approach to reducing wrong site adverse outcomes would be to **require** the surgical marking and time-out to be completed **before** the introduction of the anesthesia process. It is important to note that after the implementation of the original Universal Protocol in 2004, the number or wrong site adverse outcomes, including wrong site blocks, actually increased.[4] PPM remains concerned that surgical site verification protocols that allow site marking to be conducted at less optimal times, including after a patient is sedated, will increase the likelihood of wrong site blocks. ❖

Risk Management Tips to Prevent Wrong Site Surgical Mistakes

From a risk management standpoint, PPM continues to strongly recommend the implementation of the "sign your site" protocol as endorsed by the American Academy of Orthopaedic Surgeons (AAOS)[5]. 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 or regional block.

With regard to the time-out, PPM policyholders should work with hospitals and health care facilities to develop and implement surgical site verification protocols that advance the time for surgical marking in order to provide anesthesia providers site confirmation prior to placing any blocks or sedating the patient. PPM also continues to strongly urge policyholders to actively participate in this very important safety step to prevent wrong site adverse outcomes. Often the surgical site time out is the anesthesiologist's only opportunity to verify the correct patient, procedure and surgical site. In several instances, PPM policyholders have reported that the members of the surgical team merely "went through the motions" without meaningful communication during the time-out verification process only to discover a wrong site surgical mistake after the procedure began. 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. ❖

[4] *See*, http://ppmrrg.com/, My PPMrrg, *Anesthesia & the Law* archives, Issue 18.
[5] *See*, "Sign Your Site" Protocol, American Academy of Orthopaedic Surgeons, http://www.aaos.org/.

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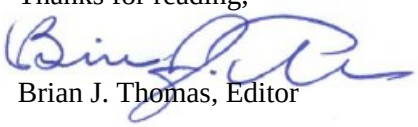
In This Issue

While the 2009 Universal Protocol for preventing wrong site, wrong procedure and wrong patient procedures includes significant improvements, the Universal Protocol continues to cause some confusion among healthcare providers. In this newsletter, we examine the 2009 Universal Protocol's changes - including the improvements and some apparent contradictions - and offer some clarification and recommendations for PPM policyholders. We also offer some risk management advice to prevent wrong site adverse outcomes.

Thanks for reading,



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