Universal Protocol becomes less prescriptive in its 2010 version

The Joint Commission has modified the Universal Protocol for surgical site verification once again. Having tipped toward being more prescriptive in 2009, the protocol for 2010 is less prescriptive. The language is clearer and more direct. The revised protocol was issued in September 2009. Some revisions were effective immediately, with the rest effective January 1, 2010.

Key points were reviewed by John Rosing, MHA, FACHE, at the Managing Today’s OR Suite Conference October 7 to 9, 2009, in Las Vegas. His firm, Patton Healthcare Consulting, consults on accreditation. Revisions were also described in the October 2009 Joint Commission Perspectives, which can be downloaded for free (www.jointcommission.org). Also watch for clarification in frequently asked questions (FAQs) on the Joint Commission’s website.

Overview

Rosing highlighted these changes in the 2010 Universal Protocol:

• The time-out is simplified to refocus on 3 elements, compared with 8 in the 2009 protocol:
  —patient
  —site
  —procedure.
• The revised protocol applies to “all surgical and nonsurgical invasive procedures.” Less clear language referring to “other invasive procedures that expose patients to more than minimal risk” was deleted.
• Many details were moved to rationale statements for the Universal Protocol’s 3 standards; rationales offer guidance but are not scorable.

Confusion over WHO checklist

The World Health Organization (WHO) Surgical Safety Checklist, introduced in 2008 and boosted by a January 2009 report in the New England Journal of Medicine, has added to confusion about the Universal Protocol, Rosing says. The study showed use of the WHO checklist was linked to fewer patient deaths and complications. But the report was based on only 8 hospitals, 7 outside the US.

When the results were published, many hospitals rushed to adopt the WHO checklist because of the published evidence. The Institute for Healthcare Improvement (IHI) gave the WHO checklist an added push, promoting its adoption.

The confusion stems from the WHO’s original use of a “checklist” format, which implied each item had to be completed and a copy retained in the record. But the WHO checklist doesn’t match the 2009 Universal Protocol, which also called for a “checklist.”
“It would have been nice if they had all gotten together to develop something everyone could use,” Rosing says.

IHI has since clarified that the WHO checklist is meant to be modified by each organization, need not include checkboxes, and is not intended as a documentation tool but more as a memory aid or script.

Rosing says the aim of both WHO and the Joint Commission is to drive uniform practice and bring about a culture that encourages every team member to participate and speak up.

Each setting needs to develop a verification process that matches its setting and work flow.

(For an article on how ORs are reconciling the WHO checklist and Universal Protocol, see the September OR Manager.)

Rosing outlined the 2010 changes for the Universal Protocol’s 3 standards:

- preprocedure verification
- site marking
- time-out.

**Preprocedure verification**

The 2010 protocol is less prescriptive about where and when to do preprocedure verification. Among notable changes:

- The protocol no longer states where the verification must be done, for example, in the holding area or the OR.
  
  “Now that is up to you to decide. Write it in your policy and follow it,” Rosing advises.

- The protocol no longer requires a checklist for verification, referring instead to a “standardized list.” The Joint Commission says the expectation is that the standardized list “is available and used consistently,” but “it is not necessary to document that the standardized list was used for each patient.”

  Rosing warned against using a list with checkboxes, suggesting scripted bullet points instead. (See sidebar for an example.) “If you have check boxes, don’t leave any blank,” he warned. Otherwise, surveyors will note that you have failed to follow your form (or policy) as designed.

- Items to be available for a patient’s procedure are to be matched to the patient, but the protocol no longer says where the matching must be done.

**Site marking**

The 2010 protocol loosens up a bit on delegation of site marking. In 2009, the protocol said the site was to be marked by the physician (ie, licensed independent practitioner, or other privileged provider).

The 2010 protocol allows delegation in “limited circumstances” yet to be defined, probably in an FAQ. Rosing says there “still is a strong preference for the surgeon doing the marking.”

The delegation is limited to:

- a medical resident supervised by the licensed independent practitioner performing the procedure who is familiar with the patient and will be present when the procedure is performed
- a licensed individual (ie, an advanced practice RN or physician assistant) who has a collaborative or supervisory agreement with the independent practitioner performing the procedure, is familiar with the patient, and will be present when the procedure is performed.

The Joint Commission says it will continue to gather input and data on who should mark the site.
Rosing notes that having the surgeon mark the site is consistent with recommendations from the American College of Surgeons and the American Academy of Orthopaedic Surgeons, among others. The protocol no longer states the initial marking must be done before the patient is moved to the procedure area, saying only that the site must be marked before the procedure.

There is less detail about characteristics of site marking. The revised protocol states that the mark must be:

- unambiguous
- used consistently throughout the hospital
- made near the procedure site
- sufficiently permanent to be visible after skin preparation and draping. Adhesive markers are not to be the sole means of marking the site.

**Time-out**

In 2 key changes for the 2010 protocol:

- The time-out is shortened from 8 elements to 3 elements at a minimum:
  - correct patient identity
  - correct site
  - procedure to be done.
- Only the completion of the time-out has to be documented. Before, the Joint Commission implied all elements of the protocol and time-out had to be documented. (Be aware that all documentation must be timed.) An OR could, for example, have a poster in the rooms with the elements in the time-out. Then there would be a place in the record to indicate, for example, that “the correct patient, site, and procedure were confirmed per policy.”

Will the Joint Commission expect 2 time-outs, one before anesthesia and a second before the incision? The new element of performance (EP) simply says: “Conduct a time-out immediately before starting the invasive procedure or making the incision.”

Previously, there was also a statement saying that “ideally,” a time-out also is conducted prior to anesthesia. That statement has been removed, but a similar statement is now in the rationale stating; “A hospital may conduct the time-out before anesthesia or may add another time-out at that time.”

Rosing says it’s not clear whether surveyors will be looking for 2 time-outs. “If I were betting, I would say they want 2 time-outs, when the anesthesia is administered well in advance of the preincision time-out.”

Also gone from the EPs—a statement about using “interactive communication” during the time-out. But a new sentence appears in the rationale: “During the time-out, activities are suspended to the extent possible so that team members can focus on active confirmation of the patient, site, and procedure.”

**References**

American Academy of Orthopaedic Surgeons. Information statement:

Wrong-site surgery. www.aaos.org/about/papers/advisstmt/1015.asp


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**Sample of preprocedure verification list**

**Verification of patient, procedure, site at time of admission or entry.**

Relevant documents match to the correct patient, procedure, and site:

- History and physical (H&P) / progress note relevant to the intended procedure
- H&P updated if performed prior to day of procedure
- Nursing assessment
- Preanesthesia/sedation assessment performed
- Completed informed consent form signed by physician (licensed independent practitioner) and patient
- Correctly labeled diagnostic and radiology test results
- Required blood products, implants, devices, and/or special equipment
- Surgical Care Improvement Program (SCIP) measures: Antibiotic, venous thromboembolism (VTE) prophylaxis, beta blockers, etc.

An example of a "standardized list" that could be used under the 2010 Universal Protocol. This example combines elements of the Universal Protocol and WHO Surgical Safety Checklist.