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Memo

TO: Hospital Quality Committee

FROM: Catherine Carson, V.P. Quality and Performance Improvement

Date: October 22, 2008

SUBJECT: Universal Protocol Policy Template 2009

At the Committee's request, I have researched to proposed requirements for the National Patient Safety Goal on Universal Protocol and have developed the template following that can be used in revision of or development of a new policy. Please be aware that the Joint Commission has not yet published FAQ's on the new requirements.

Universal Protocol Policy Template

I. Conduct a preoperative / pre-invasive procedure verification process in all settings.

1. Verification of the correct person (using the two identifiers as selected by the organization), procedure, and site occurs:
    a. At the time the surgery/procedure is scheduled.
    b. At the time of preadmission testing and assessment.
    c. At the time of admission or entry into the facility for a procedure – elective or emergent.
    d. Before the patient leaves the pre-operative area or enters the procedure/surgical room.
    e. Anytime the responsibility for care of the patient is transferred to another caregiver, including the anesthesia providers at the time of, and during, the procedure.
    f. With the patient involved, awake and aware, if possible.
    g. Whenever the patient is repositioned, specifically for a block, or an additional invasive site marking performed by another or the same practitioner.

2. A preoperative verification checklist (hard copy or electronic) is used to review and ensure availability of the following items prior to the start of the procedure: (Checklist is one approach to validate/document that a preoperative verification process has been carried out)
    a. Relevant documentation (e.g., H&P, consent, nursing, and pre-anesthesia assessments).

b. Relevant and appropriate diagnostic and radiology test results (e.g. radiology images and scans or pathology and biopsy reports).
c. Relevant images and results are properly labeled and able to be appropriately displayed.
d. Confirming the on-site availability of any required implants, devices, and/or special equipment for the procedure.

II. Marking the operative or procedural site.

1. Mark the site of all cases involving incision, percutaneous instrumentation, or placement of instruments through a natural orifice with specific attention to laterality, surface (flexor, extensor), level (spine), or specific digit or lesion to be treated.

2. The site is initially marked before the patient is moved to the location where the procedure will be performed.

3. Marking takes place with the patient involved, awake, and aware, if possible.

4. A licensed independent practitioner, who will be involved directly with, and present at the time of performing the procedure, marks the procedure site.

5. The mark is made at or near the intended incision site. Do not mark any nonoperative site(s) unless necessary for some other aspect of care.

6. The method of marking the site and the type of mark is unambiguous and is used consistently throughout the organization. The mark is the surgeon's or proceduralist's initials, representing the proposed incision.

7. The mark is made using a marker that is sufficiently permanent to remain visible after completion of the skin prep and sterile draping (Note: adhesive site markers are not to be used as the sole means of marking the site).

8. The mark is positioned to be visible after the patient's skin is prepped, the patient is positioned, and sterile draping completed.

9. For spinal procedures, in addition to pre-operative skin marking (the surgeon's or proceduralist's initials, with or without a line representing the proposed incision), of the general spinal region (identifying the side and level, i.e. Left, L5_S1), special intraoperative radiographic techniques are used for marking the exact vertebral level.

10. For cranial procedures, the surgeon marks the preauricular (in front of the ear) area of the face, on the side that the procedure will be performed, and/or identifies the procedure utilizing a hospital-determined colored wristband, placed on the same side of the body as the procedure.

11. Multiple sites must be marked. Exception to marking is the single cavity or organ procedure with no identified laterality.

12. Eye procedures are marked above the operative eye by the surgeon's or proceduralist's initials, with or without a line representing the proposed incision. The colored arm band may be used when performing eye procedures on children.

13. Site marking is not required during emergency or immediate intervention or if delay may risk life or limb or when the surgeon or proceduralist is not leaving the bedside after diagnosis, and is immediately doing the procedure.

14. Obvious sites such as lacerations and abscesses do not need to be marked unless there is more than one site and not all are being treated.

15. For diagnostic radiological procedures in which the site/level/laterality is determined at the time of the procedure, site marking is not required. If, however, the site/level/laterally is pre-determined by the ordering physician, site marking is required by the radiologist before beginning the procedure.

16. For minimal access procedures that intend to treat a lateralized internal organ, whether percutaneous or through a natural orifice, the intended side must be indicated by a mark at or near the insertion site, and remains visible after completion of the skin prep and sterile draping.
17. Final confirmation and verification of the site mark takes place during the "timeout."

** Exceptions to site marking are "minor" procedures such as venipuncture, peripheral IV line placement, insertion of NG tube, or Foley catheter insertion. Site marking is not required for other procedures that may include midline sternotomy, Cesarean section, laparotomy and laparoscopy, cardiac catheterization and other interventional procedures <u>for which the site of the insertion is not predetermined</u>. (Source: TJC Universal Protocol FAQs.)

III. A defined procedure is in place for patients who refuse site marking or who are unable to be marked.

1. Alternative approaches for site marking may be used for the following:
    a. Premature infants, for whom the mark may cause a permanent tattoo.
    b. Interventional cases for which the catheter/instrument insertion site is not predetermined (e.g., cardiac catheterization, pacemaker insertion, and dialysis catheters.)
    c. Teeth—*but* the operative tooth name(s) and number are indicated on documentation *or* the operative tooth (teeth) is marked on the dental radiographs or dental diagram. The documentation, images, and/or diagrams are available in the procedure room before the start of the procedure.
    d. For cases in which it is technically or anatomically impossible or impractical to mark the site (mucosal surfaces, perineum, premature infants).
    e. An alternative method for visually identifying the correct side is used: a temporary unique (colored) wrist band on the side of the procedure,

which contains the patient's name, DOB, the intended procedure, and site, which is applied by the surgeon or proceduralist. The arm band is removed prior to prepping and draping, verified to the consent, and utilized during the final verification "time out".

IV. Conduct final "Time out" verification immediately before starting the procedure.

1. This final procedure verification step is conducted prior to starting the actual procedure, in the location where the procedure will be performed, and with the patient properly positioned for the procedure Note: this includes at a minimum; a review of the signed informed consent, verifying the correct procedure(s), laterality, and site(s).

2. The "time out" must be initiated in a standardized fashion, as defined by the organization, and involves all the individuals of the entire procedure team who will be participating with the procedure at its inception.

3. Interactive verbal communication between all team members and the ability for any team member to express concerns about the procedure verification is promoted.

4. During the "time out," other activities are suspended—to the extent possible without compromising the safety of the patient—so that all members of the team are focused on the active verification of the correct patient, procedure, site, and other critical elements.

5. There is a defined process for reconciling differences in responses during the "time out."

6. When two or more procedures are being performed on the same patient, a "timeout" is performed to verify each subsequent procedure before they are initiated.

7. The "time out" must, at the least, include:
    a. Correct patient identity (using hospital selected two identifiers)
    b. Correct side and site
    c. Agreement on the procedure to be done
    d. Correct patient position
    e. Availability of appropriate diagnostic and radiology test results (e.g. radiology images and scans or pathology and biopsy reports).
    f. Relevant images and results are properly labeled and appropriately displayed.
    g. Availability of correct implants, devices and any special equipment or special requirements
    h. Need for special medications or fluids for irrigation purposes.
    i. Safety precautions based on patient history or medication use.

V. The completed components of the Universal Protocol and "time-out" are clearly documented on the pre-procedure checklist.