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## Universal Protocol

The organization meets the expectations of the Universal Protocol.

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### UP.01.01.01

Conduct a pre-procedure verification process.

#### Rationale for UP.01.01.01

The pre-procedure verification is an ongoing process of information gathering and verification, beginning with the decision to perform a procedure, continuing through all settings and interventions involved in the pre-procedure preparation of the [patient], up to and including the time-out just before the start of the procedure.

The purpose of the pre-procedure verification process is to make sure that all relevant documents and related information or equipment are:

- Available prior to the start of the procedure.
- Correctly identified, labeled, and matched to the [patient]'s identifiers.
- Reviewed and are consistent with the [patient]'s expectations and with the team's understanding of the intended [patient], procedure, and site.

Missing information or discrepancies are addressed before starting the procedure.

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#### Elements of Performance for UP.01.01.01

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- 1 Verification of the correct person, correct site, and correct procedure occurs at the following times:
  - At the time the procedure is scheduled.
  - At the time of preadmission testing and assessment.
  - At the time of admission or entry into the facility for a procedure, whether elective or emergent.
  - Before the patient leaves the pre-procedure area or enters the procedure room.
  - Anytime the responsibility for care of the patient is transferred to another member of the procedural care team, (including the anesthesia providers) at the time of, and during, the procedure.
  - With the patient involved, awake and aware, if possible.
  
- 2 When the patient is in the pre-procedure area, immediately prior to moving the patient to the procedure room, a checklist (for example, paper, electronic, or other medium such as a wall-mounted white-board) is used to review and verify that the following items are available and accurately matched to the patient:
  - Relevant documentation (for example, history and physical, nursing assessment, and pre-anesthesia assessment).
  - Accurately completed, and signed, procedure consent form.
  - Correct diagnostic and radiology test results (for example, radiology images and scans, or pathology and biopsy reports) that are properly labeled.
  - Any required blood products, implants, devices and/or special equipment for the procedure.

**UP.01.02.01**

Mark the procedure site.

**Rationale for UP.01.02.01**

Marking the procedure site allows staff to identify without ambiguity the intended site for the procedure.

**Elements of Performance for UP.01.02.01**

- 1 For all procedures involving incision or percutaneous puncture or insertion, the intended procedure site is marked. The marking takes into consideration laterality, the surface (flexor, extensor), the level (spine), or specific digit or lesion to be treated.  
Note: For procedures that involve laterality of organs but the incision(s) or approaches may be from the mid-line or from a natural orifice, the site is still marked and the laterality noted.
- 2 The procedure site is initially marked before the patient is moved to the location where the procedure will be performed and takes place with the patient involved, awake and aware, if possible.
- 3 The procedure site is marked by a licensed independent practitioner or other provider who is privileged or permitted by the critical access hospital to perform the intended surgical or non-surgical invasive procedure. This individual will be involved directly in the procedure and will be present at the time the procedure is performed.  
Note: Final confirmation and verification of the site mark takes place during the time-out.
- 4 The method of marking the site and the type of mark is unambiguous and is used consistently throughout the critical access hospital.
- 5 The mark addresses the following:
  - Is made at or near the procedure site or the incision site. Other non-procedure site(s) are not marked unless necessary for some other aspect of care.
  - Includes, preferably, the surgeon's or proceduralist's initials, with or without a line representing the proposed incision.
  - Is made using a marker that is sufficiently permanent to remain visible after completion of the skin prep and sterile draping. Adhesive site markers are not to be used as the sole means of marking the site.
  - Is positioned to be visible after the patient has his or her skin prepped, is in his or her final position, and sterile draping is completed.
- 6 For spinal procedures, in addition to pre-operative skin marking of the general spinal region, special intraoperative radiographic techniques are used for marking the exact vertebral level.

- 7 A defined, alternative process is in place for patients who refuse site marking or who cannot easily be marked under the following conditions:
- For cases in which it is technically or anatomically impossible or impractical to mark the site (mucosal surfaces, perineum, premature infants), an alternative method for visually identifying the correct side and site is used. For example, the critical access hospital may place a temporary, unique wrist band on the side of the procedure containing the patient's name, and use a second identifier for the intended procedure and site.
  - For minimal access procedures that intend to treat a lateralized internal organ, whether percutaneous or through a natural orifice, the intended side is indicated by a mark at or near the insertion site, and remains visible after completion of the skin prep and sterile draping.
  - For interventional procedure cases for which the catheter/instrument insertion site is not predetermined (for example, cardiac catheterization, pacemaker insertion).
  - For teeth, 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.
  - For premature infants, for whom the mark may cause a permanent tattoo.

**UP.01.03.01**

A time-out is performed immediately prior to starting procedures.

**Rationale for UP.01.03.01**

The purpose of the time-out immediately before starting the procedure is to conduct a final assessment that the correct [patient], site, positioning, and procedure are identified and that, as applicable, all relevant documents, related information, and necessary equipment are available.

The time-out is consistently initiated by a designated member of the team and includes active communication among all relevant members of the procedure team. It is conducted in a standardized fail-safe mode (that is, the procedure is not started until all questions or concerns are resolved).

**Elements of Performance for UP.01.03.01**

- 1 The time-out is conducted 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.
- 2 The time-out has the following characteristics:
  - It is standardized (as defined by the critical access hospital).
  - It is initiated by a designated member of the team.
  - It involves the immediate members of the procedure team including the proceduralist(s), the anesthesia providers, the circulating nurse, the operating room technician, and other active participants as appropriate for the procedure, who will be participating in the procedure at its inception.
  - It involves interactive verbal communication between all team members, and any team member is able to express concerns about the procedure verification.
  - It includes a defined process for reconciling differences in responses.
- 3 During the time-out, other activities are suspended, to the extent possible without compromising patient safety, so that all relevant members of the team are focused on the active confirmation of the correct patient, procedure, site, and other critical elements.
- 4 When two or more procedures are being performed on the same patient, a time-out is performed to confirm each subsequent procedure before it is initiated.
- 5 The time-out addresses the following:
  - Correct patient identity.
  - Confirmation that the correct side and site are marked.
  - An accurate procedure consent form.
  - Agreement on the procedure to be done.
  - Correct patient position.
  - Relevant images and results are properly labeled and appropriately displayed.
  - The need to administer antibiotics or fluids for irrigation purposes. (See also NPSG.07.05.01, EP 7)
  - Safety precautions based on patient history or medication use.

6 The completed components of the Universal Protocol and time-out are clearly documented.