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TITLE:
CLIN_163 UNIVERSAL PROTOCOL FOR PROCEDURE, SITE AND PATIENT VERIFICATION

APPLICABILITY
EDWARD HOSPITAL  (Edward)

POLICY STATEMENT(S)
All surgical and non-surgical invasive procedures that expose patients to more than a minimal risk, including procedures done in settings other than the operating room use the Universal Protocol for procedure, site, and patient verification.

DEFINITION(S)
Invasive Procedure: those procedures involving incision, percutaneous puncture or insertion of an instrument, or insertion of foreign material into the body for diagnostic or treatment-related purposes, and/or procedural sedation. Procedures specifically excluded from the Universal Protocol are electroconvulsive therapy (ECT), closed reduction, radiation therapy and venipuncture.
Minimal Risk Procedure: procedures that do not require a written signed informed consent. (See invasive procedure reference table link)

PROCEDURE
The components of the Universal Protocol include the pre-procedure verification, site marking and the time out. In addition, a sign-out is performed at the end of the procedure, prior to the physician and patient leaving the procedure area. The pre-procedure verification and the site marking precede the final verification of the time out. To the extent possible, the staff are to involve the patient, or family representative, in the ongoing process of information gathering and verification that begins with the decision to perform a procedure, and continues through all settings and interventions involved in the pre-procedure preparation of the patient, up to and including the time out.

1. **Pre-Procedure Verification:**
   Conduct a pre-procedure verification, with the patient involved, whenever possible. An anesthesia sign-in is also performed between the licensed health professional and anesthesia provider, prior to induction of anesthesia in appropriate areas.
   a. Verify the correct person, correct site, and correct procedure 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 in the facility for a procedure, whether elective or emergent
      • Before the patient leaves the pre-procedure area or enters the procedure room
      • With the anesthesia provider in appropriate areas. Anytime the responsibility of care for the patient is transferred to another member of the procedural care team (including anesthesia providers), at the time of, and during the procedure
      • In areas where there is no pre-operative holding area, the pre-verification checklist and the time out may be completed in the room in which the procedure takes place.
   b. Use a checklist to review and verify that the following items are available prior to the procedure:
• Relevant documentation (history and physical, or pre-procedural assessment, nursing assessment, anesthesia assessment) correctly identified, labeled and matched to the patient identifiers. See link: Invasive Procedure Reference Table
• Procedural consent form, accurately completed and signed is reviewed and is consistent with the patient’s expectations and the teams’ understanding of the intended patient, procedure and site.
• Labeled diagnostic (for example: pathology and biopsy reports) and radiology test results and/or images.
• Any required implants, devices and/or special equipment
• Any required blood products

c. Match the items that are to be available in the procedure area to the patient
d. Clarify and resolve any missing or conflicting information prior to the beginning of the procedure.

2. Site Marking:
Mark the procedure site before the procedure is performed
a. Non-Operative Settings:
• Site marking is not required when the individual doing the procedure is continuously in attendance with the patient from the time of the decision to perform the procedure, through to the performance of the procedure. However, the requirement for a final time out verification still applies.
• If the conditions noted in the bullet above are not met, then the site must be marked according to the operative setting site marking guidelines (section following), or if the procedure qualifies, through the alternative site marking process (section following).

b. Operative Settings:
• Site marking is not required in midline, single organ procedures, as well as endoscopies without intended laterality. Site marking is also not required before procedures in which there is no predetermined site of insertion, such as in cardiac catheterization and other interventional procedures.
• Site marking is required for all other procedures that involve incision or percutaneous puncture or insertion, including nerve blocks.
• The procedure site is marked by a licensed independent practitioner or other provider who is privileged or permitted by the hospital to perform the intended surgical or non-surgical invasive procedure. This same individual must be present when the procedure is performed and is ultimately accountable for the procedure. The licensed independent practitioner may delegate site marking to a qualified physician assistant (PA) who is permitted by the organization to participate in the procedure, is familiar with the patient, and who will be present when the procedure is performed.
• Whenever possible, the site marking occurs with the patient involved, awake and aware. If the patient is unable to effectively communicate with staff, and the family is not available, the physician and staff will use pertinent available medical information to determine the proper site.
• In non-emergent situations, if the patient is a minor, the legal guardian is required to be present for the site marking.
• The marking takes into consideration the laterality, the surface (flexor/extensor), the level (spine), or specific digit or lesion to be treated.
• For procedures that involve laterality of organs, but the incision(s) or approaches may be from the midline or from a natural orifice, the site is still marked and the laterality noted.
• Spinal procedures: site marking is a two-step procedure.
• Step 1: Pre operatively: the general spinal region must be marked (left or right side), (anterior posterior), and the general level (cervical, thoracic or lumbar).
• Step 2: Intra operatively: intra operative radiographic techniques must be used to mark the exact vertebral position.
• Teeth: the tooth number(s) must be indicated on documentation or, the operative tooth (teeth) and number(s) must be marked on the dental radiographs or dental diagrams.

c. Site Marking Characteristics:
• Use a surgical/permanent marker that is sufficiently permanent to remain visible after completion of the skin prep.
• Mark the site at or near the procedure site or the incision site using the initials of the practitioner.
• No non-operative/procedural site(s) are marked unless necessary for some aspect of care.
• Position the mark to be visible after the patient is prepped and draped.

d. Alternative Site Marking Process:
• Utilize the alternative process when there is a patient or practitioner concern for marking the site which arises because site marking is awkward or problematic to mark (for example: perineum, mucosal surfaces, or in premature infants).
• The alternative site marking process is as follows:
  • Place a temporary band on the patient
  • Write the intended site on the band
  • If laterality is involved, band the patient on the same side as the procedure.
  • The person performing the procedure will apply or initial the band prior to moving the patient into the room where the procedure will take place.
  • Remove the temporary band at completion of the procedure and before the patient leaves the operating/procedure room

e. Patient Refusal to Participate in Site Verification
If the patient refuses a site marking, information will be provided to the patient to understand why site marking is considered safe practice. If the patient refuses to cooperate in the site verification process as outlined, the following options may take place at the discretion of the surgeon:
  • The case may be canceled, or
  • A temporary band is placed on the patient’s wrist (which includes the intended site), in lieu of marking the site.
  • Document the patient’s refusal in the medical record.

3. Final Time Out:
Conduct a time out immediately before starting the invasive procedure or making the incision
a. The final time out is conducted in the location where the procedure will be done, immediately before starting the procedure. Suspend all other activities during the time out, 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 care elements.

b. The time out involves all members of the operative/procedural team and it is expected that any team member will openly and verbally express concerns, should they arise, during the procedural verification process. Each member of the team acknowledges their role with any relevant information to their responsibilities and agreement with a brief affirmative response. Any differences in responses that arise are reconciled prior to initiation of the invasive procedure and include a review of the pertinent documents in the patient medical record. If any member of the procedure team refuses to participate
in the time out procedure, the RN will notify the manager or director immediately and the procedure will not proceed.

c. When two or more procedures are being performed on the same patient, and the person performing the procedure changes, perform a time-out before each procedure is initiated.

d. Every time out must address, at a minimum, team agreement of the following:
   • Correct patient identity
   • Correct procedure
   • Correct procedure site

4. Sign –Out:
Conduct a sign-out post procedure prior to the patient leaving the procedure area, with the physician and anesthesia provider if applicable.
   • Confirm the procedure performed
   • Confirm and label any specimens obtained
   • Discuss equipment problems to be addressed
   • Address any issues for recovery of the patient

5. **Documentation of the completion of the time-out.**
The completed components of the Universal Protocol and time out process will be documented in one of two ways. It may be electronically captured in the procedural/operative record, or alternatively, the Universal Protocol checklist or Safe Surgery checklist paper form may be completed and placed on the patient chart. (See Exhibits).

**CROSS REFERENCE(S)**
*CLIN_198, Informed Consent*
*CLIN_137 History and Physical Examination (H&P)*