UNIVERSITY of VIRGINIA HEALTH SYSTEM

Clinical Staff Executive Committee

MEDICAL CENTER POLICY NO. 0250

A. SUBJECT: Universal Protocol for Preoperative/Pre-Procedure Verification (formerly Site Verification for Surgical and Other Invasive Procedures)

B. EFFECTIVE DATE: November 1, 2011 (R)

C. POLICY:

The University of Virginia Medical Center utilizes a Universal Protocol for verification prior to surgical and invasive procedures, including procedures done in settings other than the operating room. Invasive procedures covered by this policy are those that expose patients to harm, including procedures involving puncture or incision of the skin (excluding venipuncture and peripheral IV placement), or insertion of an instrument or foreign material in the body (excluding indwelling urinary catheters and nasogastric tubes). The purpose of utilizing a Universal Protocol is to prevent wrong site/side, wrong procedure, and wrong person surgery and procedures.

There are three required components of the Universal Protocol:

1. Preoperative/Pre-procedure verification
2. Marking the procedural site
3. Final verification, "Time out"

D. PROCEDURE:

1. Preoperative/pre-procedure: Pre-procedure verification is an ongoing process of information gathering and verification, beginning with the decision to perform a procedure, and 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 pre-procedure verification is to ensure all of the relevant documents (including accurate and complete consent form), diagnostic results, blood products, equipment, and implants are available prior to the start of the operation/procedure. Immediately prior to moving the patient from the pre-procedure area to the procedure room, a checklist is used to (a) review all the information gathered during the pre-procedure verification; (b) verify the consistency of this information; (c) confirm that this information meets the patient's expectations; (d) verify that all information is consistent with the procedural team's understanding of the intended procedure and its site.
2. Marking the procedural site: Marking of the site is required for procedures involving right/left distinction, multiple structures (such as fingers and toes) or levels (as in spinal procedure), and the surface (flexor, extensor):

a. Site marking is done by a Licensed Independent Practitioner[1] (LIP) who is ultimately accountable for the procedure and will be present at the time the procedure is performed. In limited circumstances, a physician may delegate site marking to an individual who is permitted by the organization to participate in the procedure and has the following qualifications:

   i. A Graduate Medical Trainee who is being supervised by a physician performing the procedure; who is familiar with the patient; and who will be present when the procedure is performed.

   ii. A licensed individual who performs duties requiring a collaborative agreement or supervisory agreement with a physician performing the procedure (that is, an Advanced Practice Registered Nurse {A.P.R.N} or Physician Assistant {P.A.}); who is familiar with the patient; and who will be present when the procedure is performed.

b. The intended site is marked with the Licensed Independent Practitioner's initials using a permanent marker. The mark must be visible after the patient has been prepped and draped. Non-operative sites will be marked only if medically indicated. Adhesive markers shall be used only as an adjunct to the permanent marker.

c. Before the patient is moved to the location where the procedure will be performed, the site is marked and the marking verified by a member of the procedural team. Patients shall verify the marking to the extent of their capability, but shall not be required to perform the marking. If the patient is a minor or is unable to verify the site, the verification must be provided by an accompanying parent, guardian or the patient's authorized representative. If neither the patient nor his/her representative can assist in this process, a procedural team member not involved in making the initial site marking will independently verify the site.

d. Site marking may be omitted for cases in which the Licensed Independent Practitioner doing the procedure has been in continuous attendance with the patient from the time the decision is made to perform the procedure up until the time of the procedure itself. However, the requirement for time out verification still applies.

e. Marking for spinal procedures is a two stage process. The general spinal region is marked in the pre-procedure area. An intraoperative radiograph with immovable marker(s) shall be used to determine the exact location and level of surgery. The radiograph will be reviewed by the operating physician for confirmation followed by site marking with cautery, stitch, or bone bite before removing the radiographic marker.

f. If a cast or splint covers all of an extremity or digit, the site marking is placed on the cast or splint. The Licensed Independent Practitioner removing the cast or splint shall transfer the site mark to the skin before incision.

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[1] For the purposes of this policy, licensed independent practitioner includes physicians, physician assistants, and nurse practitioners.

g. If a patient refuses to have the site marked, or, in cases in which it is technically or anatomically impossible to mark the site (e.g., mucosal surfaces, premature infants for whom the mark may cause a permanent tattoo), the patient's physician will review with the patient (or where appropriate, the patient's authorized representative) the rationale for site marking. If the patient (or authorized representative) still refuses site marking, the procedural team shall utilize the process for alternate site marking and document in the area provided on the reverse of the Preoperative/Pre-Procedure Checklist.

h. Site marking of the catheter/instrument insertion site is not required for interventional procedure cases for which the catheter/instrument insertion site is not predetermined. However, laterality of the target site (right, left, or bilateral) is marked at the initial catheter/instrument insertion site. The mark must be visible after the patient is prepped and draped.

i. For minimal access procedures that intend to treat a lateralized internal organ, whether percutaneous or through a natural orifice, the intended side is marked with the Licensed Independent Practitioner's initials at or near the insertion site, and remains visible after the patient is prepped and draped.

j. For teeth, the operative tooth name(s) and number will be identified on the dental radiograph or dental diagram. The properly oriented radiograph or diagram will be available in the procedure room before the start of the procedure and will be used during time out to verify the correct teeth.

3. Final verification

a. "Time out" provides a final verification of the correct patient, procedure, site, positioning, test results, films, antibiotics or irrigation fluids, safety precautions based on patient history or medication use, and, as applicable, equipment and implants.

b. Time out is conducted by a designated member of the procedural team who shall actively engage the team in a process of review and questioning.

c. Immediately prior to incision, time out must be conducted in the location where the procedure will be performed. In the operating room, the surgeon, the anesthesia provider, circulating nurse and operating room technician must participate in the time out process. For procedures conducted in settings other than the operating room, time out must be conducted by the Licensed Independent Practitioner performing the procedure with the participation of other members of the procedural team who will be present for the procedure. In cases where only the Licensed Independent Practitioner performing the procedure is present during the procedure, that person shall briefly pause to confirm correct patient, procedure, and site.

d. During time out, other activities are suspended to the extent possible without compromising patient safety, and all members of the procedural team focus on the active verification of the correct patient, procedure, site, and other critical elements. The procedure shall not be started until all questions or concerns addressed in time out are resolved.

e. Whenever there is more than one procedure being performed by a single procedure

team, there must be time out performed before each incision or commencement that requires the patient to be re-prepped, re-draped or repositioned.

f. Whenever there is more than one procedure being performed by multiple procedure teams, there must be a time out prior to each team beginning its procedure. If there is more than one operative site that requires the patient to be re-prepped, re-draped or repositioned, then there shall also be additional time outs prior to the incision or commencement for each individual site.

This requirement does not apply in situations where separate procedure teams are performing multiple components during a single procedure – e.g. a mastectomy followed by reconstructive surgery- if members of both teams are there at the beginning of the first component. If the second team joins in later, there shall be an additional time out.

g. Whenever Medical Center Policy 0024, Informed Decision-making, requires more than one informed consent form for procedures to be performed on a patient, there shall be a time out prior to each procedure for which consent was obtained.

h. Certain procedures do not require a time out. These procedures are listed at: http://www.healthsystem.virginia.edu/pub/quality-and-performance-improvement/intranet/aboutus/hot-topic/timeoutexclist.pdf/at_download/file

4. The process set forth above in paragraphs D.1, 2 and 3 regarding pre-procedure verification, site marking, and time out, shall be documented using a pre-procedure checklist.

5. In circumstances where any member of the procedural team must hand off responsibility to a new or different member of the team, these team members shall verify the identity of the patient, the correct site, and the correct procedure before the hand off occurs.

SIGNATURE:

Robert S. Gibson, M.D. President, Clinical Staff

R. Edward Howell, CEO, UVA Medical Center

DATE: 10/20/11

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