

SUBJECT: VERIFICATION OF CORRECT PATIENT, INVASIVE PROCEDURE

POLICY NO. 380

AND SURGICAL SITE (UNIVERSAL PROTOCOL)

CATEGORY: Provision of Care	EFFECTIVE DATE: 3/02
POLICY CONTACT: Brant Putnam, MD	UPDATE/REVISION DATE: 4/23
REVIEWED BY COMMITTEE(S): Operating Room, Medical Executive	

#### **PURPOSE:**

To provide a safe and effective methodology to ensure that invasive procedures are performed on the correct patient and appropriate surgical site.

#### **POLICY:**

The verification process to confirm and document the correct patient, invasive procedure and operative site shall occur prior to the start of any surgery or invasive procedure with inherent medical risk requiring informed consent. The use of the Universal Protocol is required in all settings where invasive procedures that require informed consent are performed, and is not limited to operating rooms. No invasive procedure may be performed without prior immediate access to and review of the appropriate written or electronic medical information justifying the indication for the procedure.

#### PROCESS OVERVIEW:

The correctness of the patient, invasive procedure and operative site must be verified through a defined series of pre-procedure verbal, electronic and/or written checks beginning at the time the surgery/procedure is scheduled, and again, at the time of admission or entry into the facility, and anytime the responsibility for care of the patient is transferred to another caregiver. This pre-procedure verification is conducted by staff in cooperation with the patient or his/her legal representative or next-of-kin, whenever reasonably possible and appropriate. This verification process applies to procedures performed in the operating room (OR) as well as those performed in non-OR settings (e.g., endoscopy suite, interventional radiology, cardiac catheterization, bedside, and clinic). While it is the physician's responsibility to diagnose the patient's need for the invasive procedure/surgery and to determine and mark the surgical site, verification of the correct patient, procedure, and surgical site, immediately prior to and at the time of procedure/surgery, is a responsibility of the operative/procedural team, and is shared by involved physician, nursing, technician, and anesthesia providers as well. This verification process can be expected to maximize patient safety and well-being.

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#### PROCEDURE:

### I. VERIFICATION PROCESS

- The responsible Resident or Attending Physician will obtain a written informed consent for all
  anticipated procedures. This will be documented by completion of the appropriate consent form
  and an informed consent note in the medical record. Whenever appropriate, these documents
  should specify the anatomic site and side (right, left, or midline), level if a spinal procedure is
  planned, and use of any implantable devices.
- If the planned procedure includes a preoperative anesthesia interview and evaluation, the
  Anesthesia provider will confirm the accuracy of the site specification of the planned procedure as
  documented in the medical record by direct inquiry to the patient or their representative. Notation of
  this activity will be made in the medical record. If any discrepancy is discovered, the procedure will
  be postponed until it is clarified and corrected and appropriate notation is made in the medical
  record.
- At the time of the inpatient or outpatient pre-procedure/operative nursing interview and evaluation,
  the Emergency Department (ED), Urgent Care, ward, or ICU nurse will confirm the accuracy of the
  planned procedure and site specification as documented in the medical record by direct inquiry of
  the patient or his/her representative. Documentation of this activity will be completed in IView
  utilizing the PreOp Checklist. If any discrepancy is discovered, the procedure will be postponed
  until it is clarified and corrected, and appropriate notation is made in the medical record.
- The nurse receiving the patient in L&D, PreOp, PACU, Operating Room Suite or Procedure Room will verify and document consistency of the planned procedure and operative site, including side and spinal level where appropriate. Examples of information sources that may be used to verify the planned operative site include, but are not limited to the following:
  - Patient
  - Consent Form
  - Patient medical records
  - ORCHID Tracking Board/Procedure Room schedule
  - Resident or Attending Physician

Documentation of this activity will be completed utilizing the PreOp Checklist. If any discrepancy is discovered, the procedure will be postponed until it is clarified and corrected and the appropriate entry is made in the medical record.

- The anesthesia provider will query the patient, confirm the operative procedure and site, and record this activity in the Anesthesia Record.
- Operating physicians are responsible to ensure that relevant images are available and able to be displayed prior to the planned surgery/procedure.

### II. MARKING THE OPERATIVE SITE

Site marking is required for all surgical sites/invasive procedures where there is more than one possible location for the procedure, and when performing the procedure in a different location would negatively affect quality or safety. This includes procedures involving right/left distinction, including those with midline approach (e.g., ureteroscopic procedures, endoscopic sinus procedures, laparoscopic procedures involving lateralized structures, thoracoscopic procedures confined to one hemithorax), multiple structures (e.g., fingers, toes), or levels (e.g., spinal procedures).

• The Operating Resident or Attending Physician will write the word "YES" on the patient's skin at or near the planned operative site using a clear and indelible method. The person marking the site must be familiar with the patient and a participant in the actual procedure. The operating physician



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should utilize whatever information is available in order to be confident that the correct site, side, and appropriate level (where applicable) will be marked. Whenever possible and before sedation or the induction of anesthesia, the patient will be involved in the marking process\*. Examples of information sources that may be used to identify the planned operative site include, but are not limited to the following:

- Patient or parent, if applicable
- Surgical Consent Form
- Informed Consent Note
- Imaging studies and reports
- Patient medical records
- Operating Room schedule
- \* If a patient refuses site marking for any reason, the physician must document said refusal in the progress/procedure note and communicate the patient's refusal to other members of the team prior to the surgery/procedure. Refer to Section IV: EXCEPTIONS TO SURGICAL SITE VERIFICATION PROCEDURES, b., Alternative Approaches for Site Marking
- Whenever possible, the surgical site marking procedure should be accomplished prior to the patient's arrival to the Preoperative Area, Operating Room Suite or Procedure Room. This should be routine for pediatric patients in circumstances where the parent/guardian would have the opportunity to confirm the correct placement of the operating physician's "YES" prior to delivery of the patient to the Preoperative Area, Operating Room Suite or Procedure Room.
- Whenever reasonable and appropriate, the preparation and draping of the surgical site, and any
  changes in patient position should allow for viewing of the previously placed operating physician's
  "YES". If multiple invasive procedures are performed, each site should be separately marked and
  visible, especially if a change in the patient's position is involved between procedures.
- In addition to preoperative skin marking for procedures involving spinal levels, intraoperative radiographic techniques will be used to mark the exact vertebral level.

### III. PROVISION OF NEURAXIAL, EPIDURAL, AND REGIONAL BLOCK ANESTHESIA

When the provision of Neuraxial, Epidural, and Regional Block Anesthesia, occurs preoperatively (prior to patient transport into the procedure or operating room) the RN and Anesthesia Provider will utilize the PreOp Checklist "Universal Protocol Time Out" and actively verify each component with the Attending Surgeon or his/her designee (either in person or via phone).

If any disagreement or reasonable doubt occurs regarding the correctness of the components of the Time Out, the procedure should not be started until this is addressed and corrected to the satisfaction of all parties involved (Patient, Anesthesia Provider, and Nurse).

#### IV. "PRE-OPERATIVE BRIEF"

Prior to patient transport into the operating room, members of the surgical team will verify and discuss the following (utilizing ORCHID, the paper chart, and the surgical plan):

- Patient's Name, DOB, MRUN #
- Planned procedure: Pre-op note matches consent; All services are present; Positioning
- Does patient have: Allergies; Special medications (Aspirin, Plavix, Beta Blocker, Statin, Antithrombolitic)



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- Anesthesia: Type/risk for difficult airway; Invasive monitoring needed (A-line, Central Line); Preoperative antibiotic
- Availability: Special equipment (Implants, Grafts, Cell Saver, etc.); Attending supervision status;
   Images displayed; Post-operative disposition (Ward, ICU, or PACU); Blood, T & S, or T & C

#### V. VERIFICATION OF PATIENT IDENTITY

All patients are properly identified prior to transporting patient into procedural or operating room area, provision of care, treatment, or service. (Harbor-UCLA Policy # 452 Patient Identification).

At least two patient identifiers are used to verify the patient's identity, except in the case of a life-threatening emergency.

### VI. "TIME OUT"

A "DHS Standardized Surgical Final Time Out" will be performed:

- Immediately prior to skin incision, surgical start, or invasive procedure after the patient is prepped and draped. (DHS Policy #321.005 DHS Standardized Surgical Final Time Out).
- When two or more procedures are performed on the same patient and the physician(s) performing the procedure change, Time Out will be completed before each procedure is initiated.

A "DHS Standardized Non-OR Procedural Time Out" will be performed when procedures requiring written informed consent are performed outside of an OR/surgical area. (DHS Policy # 321.006 DHS Standardized Non-OR Procedural Time out Policy).

During either "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 (as indicated on the applicable consent), site, and other critical elements.

The team must utilize the DHS Standardized Time Out Checklist and must actively verify each Time Out component is completed.

The attestation on the use of the DHS Standardized Time Out Checklist, final confirmation of correct patient's identity, correct site, correct procedure(s), consents, list of team members participating in the activity, and the date and time when the Time Out is conducted are all documented in the patient's medical record.

If additional staff participate later in the procedure, communication will take place between the appropriate individuals which will include the patient's identity, surgical site, side, level and other critical elements.

If any disagreement or reasonable doubt occurs regarding the correctness of the components of the Time Out, the procedure should not be started until this is addressed and corrected to the satisfaction of all parties involved (Patient, Physician, Anesthesia Provider, and Nurse). Appropriate documentation should be made in the medical record.



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### VII. EXCEPTIONS TO SURGICAL SITE VERIFICATION PROCEDURES

- If an acute life-threatening, limb-threatening, or organ-threatening illness or injury requires an emergency procedure/operation, the application of some or all of the procedures defined herein may be suspended at the discretion of the Attending or Resident Physician.
- Site marking:

Is not required in:

- Single organ cases (e.g., Cesarean section, cardiac surgery).
- Cases in which both-sided organs are evaluated (e.g., diagnostic laparoscopy to evaluate both ovaries)
- Interventional cases for which the catheter/instrument insertion site is not predetermined (e.g., cardiac catheterization).
- Non-OR Procedures (including bedside) for cases in which the individual doing the
  procedure is in continuous attendance with the patient from the time of decision to
  performing the procedure, consent from the patient, through to the conducting of the
  procedure.

Exceptions to site marking are not exceptions to the entire Universal Protocol. In such site marking exemptions, the operating physician and other operating/procedure personnel must still have oral agreement as to the correct site, side and level of the planned operation/procedure through the usual time-out process described above.

- Alternative approaches for site marking:
  - Teeth: The operative tooth should be clearly marked on the dental X-ray or diagram).
  - Premature infants, for whom the mark may cause a permanent tattoo.
     For an infant who is less than 40 weeks corrected age, and is at risk for a permanent tattoo from a marker, a temporary unique wrist band is to be placed on the side of the procedure site and contain the patient's name, MRUN, intended procedure and site. During the procedure "Time Out" the site marking is identified and confirmed to be correct for the procedure and patient.
  - Patients who refuse site marking or who are unable to be marked, as it is technically or
    anatomically impossible or impractical to mark the site (i.e., mucosal surfaces, perineum,
    lack of cutaneous integrity or other anatomic conditions), an alternative method for visually
    identifying the correct side is used: a temporary wrist band which contains the patient's
    name, DOB, the intended procedure and site, which is applied by the surgeon or
    proceduralist.

## VIII. SHOULD WRONG PROCEDURE/SITE SURGERY OCCUR

- If the error is discovered intraoperatively while the patient is under general anesthesia, it may be appropriate for the operating physician to proceed to the correct site and complete the intended surgery unless medically contraindicated.
- If the error is discovered and the patient is under local or regional anesthesia, it may be appropriate for the physician to proceed and complete the intended procedure/surgery unless medically contraindicated or the patient instructs the physician to terminate the procedure/operation.
- The physician should discuss openly and frankly with the patient and their family the circumstances surrounding the wrong procedure/site surgery, the likely medical consequences of the error, and the plans to restore the patient as quickly as possible to their pre-procedure/operative condition or best



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possible state of health and well-being. It is strongly recommended that the physician have a witness present during such discussions with the patient and family. A detailed note documenting the discussion(s) in the medical record is mandatory.

- The following parties should immediately be notified of any wrong invasive procedure/site surgery utilizing the Medical and Nursing chain of command:
  - Attending Physician
  - Division Chief
  - Department Chair
  - Chief Medical Officer
  - Risk Manager
  - Patient and their family, significant other, or legal guardian
  - Operating Room Nurse Manager
  - **Nursing House Supervisor**
- A root cause analysis will be promptly conducted.

Reviewed and approved by:

Medical Executive Committee 4/2023

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