UCONN HEALTH
UCONN JOHN DEMPSEY HOSPITAL

SECTION: PATIENT CARE NUMBER: 08-048

SUBJECT: UNIVERSAL PROTOCOL PAGE: 1 of 7

**PURPOSE**:
Universal Protocol is a National Patient Safety Goal of The Joint Commission intended to ensure safety of patients undergoing surgical and nonsurgical invasive procedures. Universal Protocol builds in high-reliability principles by establishing consistent, standardized guidelines to perform the correct procedure on the correct patient at the correct site.

**POLICY**:
1. Universal Protocol must be followed for all procedures that require informed consent and/or involve sedation (moderate or deep) or general anesthesia.
2. The attending physician must confirm correct patient, correct site, and correct procedure prior to patient transfer to the procedure location, except in extreme emergencies with risk of life or limb.
3. To the extent possible, the patient and, as needed, the family must be involved in the Universal Protocol process.
4. Site marking is required for procedures that involve laterality, multiple structures (fingers, toes), surfaces (dorsal, ventral), or spinal levels.
5. The attending physician must perform site marking and may not delegate it if they will be present for any portion of the procedure. When the procedure will be performed entirely by a practitioner (e.g., resident, fellow, PA or APRN) credentialed to do so without supervision by the attending physician, this confirmation may be delegated by the attending physician. For dermatologic lesions to be removed in an outpatient setting, the attending dermatologist must perform or supervise site marking if they will be present for any portion of the procedure. The attending dermatologist may delegate site marking to another practitioner (e.g., resident, fellow, PA or APRN) if the site marking is performed in the immediate presence, and under the supervision of, the attending physician.
6. If the attending physician performing the primary procedure is performing another procedure on another patient and has not marked the site on a patient who will receive regional nerve blockade anesthesia, the attending anesthesiologist may initiate blockade prior to site marking.
7. If the original informed consent includes any incorrect information related to Universal Protocol, a new consent must be completed. Revision of the incorrect consent is not allowed.
8. Hard Stop Time Out will involve at least the proceduralist and all other members of the team performing the procedure. If an RN is present on the unit, the nurse is responsible to initiate and document the event; if no RN is present on the unit, the Time Out will be initiated. The proceduralist may reserve the right to initiate Time Out under any circumstances.
9. When two or more procedures are being performed on the same patient and the person performing the procedures changes, a separate Time Out will be performed before each procedure is initiated.

**DEFINITIONS**:

**Pre-procedure verification:** the ongoing process of information gathering and confirmation prior to a patient being transferred into the location where an operative or invasive procedure takes place. The pre-procedure verification process may occur at more than one time and place before the procedure. This process begins with the determination to perform the procedure and continues through all settings and interventions up to and including the Hard Stop Time Out immediately prior to the procedure.

**Requirements for site marking:**

1. Laterality (left, right, bilateral)
2. Multiple structures (fingers, toes)
3. Multiple surfaces (dorsal, ventral)
4. Multiple spinal levels

**Exceptions to site marking:**

1. Emergency procedures, if delay or risk to life or limb
2. Endoscopic procedures without intended laterality
3. Midline, single organ procedures
4. Premature infants(< 37 weeks), for whom the mark may cause a permanent tattoo
5. Teeth, for which the operative tooth name(s) and number(s) are indicated on documentation or when the operative tooth(s) is marked on the dental radiograph or dental diagram
6. ECT procedures
7. Non-operative, non-sedation procedures in which the individual performing the procedure is in continuous attendance with the patient from the time of decision to perform the procedure until the conclusion of the procedure, or obvious sites such as lacerations and abscesses unless there is more than one site and not all are being treated.
8. All interventions where the operative site is not pre-determined, such as:
9. Cardiac catheterization
    a. Central line, midline, or PICC line placement
    b. Cardiac device insertion
    c. Epidural / spinal anesthesia
    d. Dialysis catheter placement

**Acceptable alternative to site marking:** placement of a wristband is the acceptable alternative process when it is technically impossible or impractical to mark the site for mucosal surfaces or perineum or when there is minimal access for procedures treating a lateralized internal organ, whether percutaneous or through a natural orifice.

**Unacceptable alternative to site marking:** adhesive markers that may loosen and detach.

**Hard Stop Time Out:** complete cessation of all activity immediately prior to the start of a procedure during which all persons present for a procedure focus on reviewing a standardized list to verify that all required items are available, and risks or concerns are addressed. It is conducted in the location w ere the procedure will be performed.

**Debriefing:** interactive, interdisciplinary communication that takes place at the end of the surgical procedure and prior to transfer of the patient to the PACU or other location.

1. It is intended to promote quality care and patient safety through the application of high reliability concepts of improved communication across disciplines.
2. It is also meant to provide assurance that equipment, personnel, and technology issues are being identified and addressed.

**Pre-procedural Verification Process**

*For electively scheduled surgical cases:*

1. The surgical scheduler (e.g., COA, MA, practitioner) will supply all necessary information for accurate and complete posting of the case request, including but not limited to:
    a. Correct patient identification
    b. Correct procedure(s)
    c. Correct site, as appropriate and that may include:
        i. Laterality (left, right, bilateral)
        ii. Structure (finger, toe)
        iii. Surface (dorsal, volar)
        iv. Spinal level
2. The OR Scheduler will:
    a. Review information supplied in the case entry and collaborate with the surgical scheduler or practitioner to assure completeness of the case request;
    b. Refer issues as needed to nursing or other leadership for intervention.
3. Support services such as Sterile Processing Dept. (SPD) and Procurement and Supply Chain Organization (PSCO) staff will review future schedules for necessary supplies, equipment, instrumentation and implants to assure smooth workflow on the day of the procedure.
4. The practitioner or their designee will notify support services, specialty vendors, or any outside entity / personnel needed for the procedure in conjunction with the booking request and surgical plan of care.

*For all other procedures:*

1. The practitioner(s) will:
    *a.* Obtain procedural consent and other consents as appropriate but not limited to: transfusion, anesthesia, investigational, and regulatory mandated consents
    *b.* Perform or update the history and physical, per policy (HAM 06-017).
    *c.* Communicate any required items for the procedure, such as instrumentation, implants, blood products, devices or special equipment.

   *d.* Assure any additional required documentation, including tests and images, are present and orders are complete.
   *e.* Performing site marking, per procedure.
2. Nursing will:
   *a.* Verify relevant documentation is consistent for the correct patient, correct procedure and correct site.
   *b.* Collaborate with practitioners and support services to assure availability of required items *(per 5c above).*
   *c.* Verify the procedural consent matches the scheduled procedure and, whenever possible, that the consent has been signed by the correct patient.
   *d.* Administer any ordered medications that must be completed prior to transferring the patient to the procedural location.
   *e.* Assist with site marking, per procedure.
   *f.* Complete any pending tests to be done on the day of the procedure.

*When transfer from the pre-procedure area occurs in an anesthetizing location, Nursing and Anesthesiology will collaborate when the patient reaches the procedural location to verify:*

- correct patient identity with 2 unique identifiers, with introduction of all staff members present;
- correct surgeon, consent and procedural site, with marking as appropriate;
- allergies;
- airway and aspiration risk;
- availability of implants, special equipment or supplies, and blood products, as needed; and anesthesia safety check

**Marking the Procedural / Operative Site**

The **attending practitioner** who is accountable for the procedure and who will be present when the procedure is performed will mark the site prior to the procedure as follows:

1. Obtain single-use skin marker.
2. Explain the site marking process to the awake and aware patient/family.
3. Mark initials at or near the intended site at a location that will be visible after completion of positioning, prepping, and draping.
4. For spinal procedures, in addition to the preoperative skin marking of the general spinal region, the proceduralist will use special intraoperative radiograph techniques to locate and mark the exact vertebral level(s).
5. If it is technically impossible or impractical to mark the site, the proceduralist will complete a wrist band that includes the entire procedure name and surgical site and apply it to the patient prior to transfer to the procedural location.
6. For a patient who refuses site marking, the proceduralist will discuss the safety implications / risks of refusing site marking and may elect not to perform the procedure. The proceduralist will document relevant information about the discussion and outcome.

*Per the Universal Protocol policy, if the proceduralist is not an attending practitioner, they will follow this procedure.*

The **nurse** will:

1. Provide a single-use sterile skin marker whenever site marking is indicated.
2. Provide a wrist band when site marking is technically impossible or impractical or the proceduralist elects to perform the procedure on a patient who refuses site marking.

**Hard Stop Time Out**

1. Initiate Time Out after the patient has been properly positioned, prepped and draped.
2. Suspend all activities and focus on verifying each element:
    a. Correct patient identity, using Safety Absolute with 2 unique identifiers
    b. Correct site
        i. if site marked, verify visibility after draping
        ii. if wrist band used, verify visibility of band
    c. Correct procedure, with accurate informed procedural consent
    d. Correct patient position, as appropriate
3. Include additional components, as appropriate:
    a. Prophylactic [parenteral antibiotics infused within appropriate time frame, when applicable;
    b. Relevant lab and imaging results properly labeled and appropriately displayed or available;
    c. Correct medications, implants, supplies, equipment, or other special equipment;
    d. Risk of and mitigating steps to prevent fire, VTE, and hypothermia;
    e. Anticipated critical events, including
        i. Proceduralist: critical steps, expected case duration, specimens, and blood loss; and for staggered cases only, the key portions of the procedure and availability of a second qualified surgeon
        ii. Anesthesia: patient-specific concerns
        iii. Nursing: patient- or procedure-specific concerns; labeled medication / irrigations available on sterile field

If any discrepancies are identified, suspend all activities until the entire team agrees on resolution; if resolution cannot be achieved, discontinue/ cancel the procedure.

**Post-procedural Debriefing** in the Operating Room:

Nursing will lead the post-procedure debriefing and all disciplines present will participate as follows:

1. Refrain from all non-essential activities to minimize distraction.
2. Confirm diagnosis and procedure(s) performed
3. Verify all final counts are correct or are not applicable
4. Assign accurate wound classification
5. Review all pathology specimens obtained and their proper disposition.
6. Identify any instrumentation or equipment problems to be addressed by support services, affixing repair tags as necessary.

7. Summarize any key concerns by all disciplines present for patient transfer to receiving location and post-procedure / post-anesthesia management, that may include but are not limited to:
    a. Pain management
    b. Medications or allergies
    c. Fluid balance and blood loss / replacement
    d. Glycemic control and thermoregulation
    e. Critical values and pending tests
    f. Significant concomitant disease
    *g.* Transitions in care, including disposition, admission orders *prn*
    h. Team performance
    i. Preference card modifications
8. Address any other care considerations relevant to the patient and/or procedure

**Incorporating High Reliability Principles into the use of Universal Protocol:** with the goal of **zero** wrong person, wrong procedure, wrong site surgeries, always, all disciplines must be vigilant every step of the way and consistently practice these principles:

1. *200% Accountability:* wrong site, wrong person, wrong procedure events are *Never Events* that continue to take place, so all disciplines need to critically think by looking out for one another to catch each other's mistakes and to build greater accountability for everyone's actions.
2. *Validate and Verify:* confirm consistency in all aspects of the plan of care, including but not limited to scheduled/ planned procedure(s), informed consent, and procedure preparation.
3. *Stop the Line:* all disciplines are empowered to *Stop the Line* and seek clarity whenever questions or concerns arise during the Universal Protocol process.
4. *Attention to Detail:* closely focusing attention on all aspects of Universal Protocol allows actions to be thoughtful and deliberate instead of rushed and hurried, which is when errors are more likely to occur.
5. *Speak Up for Safety (ARCC):* every employee is obligated to voice safety concerns. The ARCC technique is a way to express concern in a non-threatening way when sensing safety concerns, especially when *Power Distance* between disciplines may lead to resistance and result in errors.
6. *Practice and Accept a Questioning Attitude:* actively seek and process any additional information once the initial information looks correct.

**REFERENCES**:

1. National Patient Safety Goals 2019- UP 01.01.01, 02, 03 in The Joint Commission E-dition Hospital Accreditation Requirements, viewed on-line on 6/14/2019.
2. 5 Ways to Improve a Time Out Together - Association of periOperative Registered Nurses (AORN), viewed on-line on 6/14/2019 at https://www.aorn.org/about-aorn/aorn-newsroom/periop-today-newsletter/2019/2019-articles/improve-time-out
3. Speak Up for Safety, viewed on-line on 6/14/2019 at https:/www.jointcommission.org/assets/I/18/UP_Poster1.pdf

**LINK**:
Informed Consent, Clinical – Obtaining and Documenting (UConn Health Policy 2015-03).
https://health.uconn.edu/policies/wp-content/uplQad /sit s/28/2017/06/2015-03-Informed-Consent-Clinical-Obtaining-Documenting.pdf.

**APPROVAL**:

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Approval: OR Committee, Medical Board
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