September 30, 2014

Dear Practitioner:

Patient safety is foundational for the patients we are privileged to serve and we are committed to reaching and sustaining zero preventable harm. To achieve this goal, we need to create wide margins of safety. While education remains a cornerstone of enhanced patient safety, creating the highly reliable safe systems requires structured processes, simplified checklists, and supportive information technology.

During 2014 and beyond, we need to completely eliminate wrong site procedural and surgical events. To achieve this goal, we need your full support. Protection of our patients, our clinicians, and our facility is of the utmost importance. This commitment to the safety of our patients is part of our commitment to our institution and to the community we serve.

Every patient deserves the right procedure, at the right site every time. Before every surgical or invasive procedure, the patient’s identity, correct procedure, and correct site must be confirmed. This verification process must be completed in any area where invasive procedures are performed including:

- Operating Rooms
- Endoscopy Suites
- Interventional, Cath and EP Labs
- Emergency Departments
- Intensive Care Units
- Med/Surg/Peds Units
- Imaging and Therapeutic Areas

To support our safety goal, we have chosen to adopt and require compliance of the following:

- A single, organizational Procedural and Surgical Verification Policy
- A uniform procedural safety checklist by specialty area
- A pre-procedure verification that is completed prior to any sedation or anesthesia, and involves the patient or patient designee
- A pre-procedure verification that is completed prior to any bedside procedure when sedation or anesthesia is not necessary
- A Time Out that is fully supported by the physician, with active participation and agreement of all team members
- Having all necessary imaging studies in the procedure area and reviewed prior to initiation of time out
- A post-procedure debriefing
Beginning October 1, 2014 all members of the medical staff with a staff status of active, courtesy, provisional active or provisional courtesy will need to sign the attached attestation by December 31, 2014, indicating knowledge of how to properly perform the pre-procedure checklist, to be familiar with our policy on this matter, and to be aware of the education materials available to assist you with this critical patient safety initiative. All new practitioners will be required to complete and return the attestation statement during the initial appointment process. I ask for your help educating fellow clinicians, communicating the importance of this policy, and fostering an environment in which each member of the medical team feels comfortable voicing any concerns that may arise while caring for a patient.

In the coming weeks, we will provide additional information and educational resources to assist in implementing these measures as adopted and approved by your medical staff leadership. Access to the educational video on Safe Procedural and Surgical Verification can be obtained by contacting the Medical Staff /Credentialing Services Department at 405-271-5198.

We appreciate your assistance and cooperation.

Sincerely,

Charles L. Spicer, Jr., FACHE
President and Chief Executive Officer
OU Medical System

Enclosures/Attachments:
Safe Surgical and Procedural Verification Policy
Attestation Statement
Self-Addressed Stamped Return Envelope
OU Medical System
Safe Procedural and Surgical Verification

I hereby attest that I am aware of OUUMS Safe Procedural and Surgical Verification process.

I have received a copy of the OUUMS Policy on Safe Procedural and Surgical Verification.

I am aware of resources available regarding Safe Procedural and Surgical Verification.

____________________________________________________________________
SIGNATURE

____________________________________________________________________
PRINT

____________________________________________________________________
DATE

Please return to:
OU Medical System
Medical Staff Credentialing Services Department
1200 Everett Drive, #2315
Oklahoma City, OK 73104

Or fax
405-271-3602

Or E-mail
oumccredentialing@hcahealthcare.com

Please call 271-3741 for any questions
**SCOPE:**
This policy applies to all departments, areas, and sites where surgical or invasive procedures are performed.

**PURPOSE:**
This policy is intended to ensure the consistent use of a standardized approach to identify the correct patient, the correct procedure, and the correct side or site consistent with requirements of the Joint Commission (TJC), Centers for Medicare & Medicaid Services (CMS), and/or other regulatory agencies. This involves active communication among all members of the surgical/procedural team and the patient and/or patient’s representative. Implementation is most successful in facilities with a culture that promotes teamwork and where all individuals feel empowered to ensure patient safety.

**POLICY:**
HCA is dedicated to fostering a culture that supports patient safety. Consistent with the requirements of TJC, CMS, and/or other regulatory agencies, processes for reliable performance of safe surgical or invasive procedures will include pre-procedure verification, marking the operative or procedural site, and a Time-Out immediately prior to starting the procedure. These processes are to be consistent and standardized throughout the organization.

The verification process, which starts during the pre-operative phase, will be conducted throughout all phases of perioperative care, and will include the continuous sharing of pertinent information to include correct patient, procedure, and side/site.

The procedural or operative site is to be correctly identified and marked by the surgeon/proceduralist performing the procedure. The mark is to eliminate any ambiguity and ensure correct laterality and level, even after the patient is prepped and draped.

A Time-Out, which is initiated by the surgeon/proceduralist, will be performed immediately prior to starting the procedure by completing a final verification of correct patient, procedure, and side/site. Any member of the team may express questions or concerns, and all questions and concerns will be resolved prior to incision or start of the procedure.

**PROCEDURE:**

I. **Verification:** The verification process is to ensure that the correct patient, procedure, and side/site have been verified at every handoff of the patient from one person/location to another and that relevant documents have been assembled prior to the start of the procedure.

   A. Verification process must include identification of correct:

      1. Patient
      2. Procedure
      3. Side/site

   B. Verification is to occur at:

      1. Every transition of the patient from one person/location to another
      2. The time of surgery/procedure scheduling (including laterality, if applicable)
      3. The time of preadmission testing, if applicable
      4. The time of patient assessment
      5. The time the patient leaves the pre-operative/pre-procedure area or enters the procedure/surgical room
      6. The time prior to skin puncture or incision or start of procedure by physician
C. Patient involvement in verification must include:
   1. Requesting the patient or patient’s representative state:
      a. Patient name
      b. Patient birthdate
      c. Proposed procedure
      d. Procedure side/site
      e. Procedure laterality
   2. Matching the patient information to the patient’s armband and relevant documents
   3. Assuring armband is attached to patient at all times

D. Relevant documents (as applicable) to be reviewed include:
   1. H & P that meets the CMS conditions of participation
   2. Physician’s order for procedure
   3. Physician’s documentation of informed consent
   4. Patient’s signed informed consent
   5. Patient’s legal designation of representative
   6. Patient’s legally designated representative’s confirmation
   7. Registered Nurse pre-procedure assessment
   8. Appropriate relative studies or results with interpretation in the medical record, examples include EKG, imaging, catheterization laboratory, laboratory, pathology
   9. Anesthesiologist’s pre-procedure assessment

E. Surgeon/proceduralist and one other member of team (preferably the circulator) will verify:
   1. Patient identification
   2. Patient expectations
   3. Team’s understanding of the intended patient, procedure, and side/site
   4. Imaging studies and radiographs, which are correctly identified, labeled, and matched to patient identifiers and ready to display for the surgeon who will confirm their correct orientation
   5. Availability of sterile implants
   6. Pathology or biopsy reports, which are consistent with the laterality of the imaging studies displayed
   7. Availability of blood products, devices, and/or special equipment

II. Pre-Procedure Site Marking: Marking of the surgical site will be performed by the surgeon/proceduralist after verification and reconciliation of all available documents, prior to administration of regional or local anesthesia and/or sedation, and with participation of awake and aware patient and/or patient representative.

A. Purpose of marking is to unambiguously identify the intended site of incision or insertion.
   1. Marking will occur on the day of surgery or invasive procedure.
   2. Marking is to distinguish procedures involving right/left distinction, multiple structures (such as fingers and toes), or multiple spinal levels.
   3. The intended site is to be marked such that the marking will be visible after the patient has been prepped and draped.
4. Spinal procedures require a two-step process to assure accurate site marking:
   a. This includes marking the region of the spine (cervical, thoracic, lumbar) AND the side on which the patient is experiencing pain (right, left, or both).
   b. Spinal procedures will have mandatory intraoperative radiographic confirmation of the spinal level.

5. Site marking for the regional block will be performed by the anesthesiologist/proceduralist prior to the administration of the block.

B. Exemptions from marking (as applicable for setting):
   1. Interventionsal cases in which the catheter/instrument insertion site is not predetermined (e.g. cardiac catheterization, central line insertion, temporary pacemaker placement)
   2. Procedures on single organs
   3. Mid-line sternotomies for open heart surgery
   4. Infection at the proposed surgical site
   5. Cesarean sections
   6. Laparotomy and Laparoscopy
   7. Teeth
      a. Document the operative tooth name(s) and number(s) on a dental diagram or mark the operative tooth (teeth) and number(s) on the dental radiographs
   8. Premature infants, for whom the mark may cause a permanent tattoo
      a. Anatomical drawing may be used in this instance, with the surgeon and parent/guardian initialing the operative site on the drawing.

C. The mark should be made using a marker that is sufficiently permanent to remain visible after completion of the skin prep and drape.
   1. The mark will be at or near the incision site.
   2. The surgeon/proceduralist will mark “yes” at site.
   3. If a patient’s skin color prohibits adequate visualization of the site marking, an alternative method, such as a light-colored pen/marker, should be utilized.

D. If the patient will be moved to the procedural area, a final verification of the site marked will be conducted prior to transfer.

E. Member of the Surgical/Procedure Team will perform a reconfirmation of each of the following items:
   1. Medical Records (H & P, Progress notes, etc.)
   2. X-rays and other imaging studies
   3. Informed Consent
   4. Operating Room /Anesthesia Schedule, if applicable

F. Patient refusal of marking:
   1. The rationale for site marking should be reviewed with the patient by their physician. If the patient subsequently refuses site marking, the person responsible for marking the site will use a designated alternative method chosen by the facility. Acceptable methods include:
      a. A temporary, unique wrist band that contains the patient’s name and a
second identifier. This would be placed on the arm or leg on the proposed side of the procedure.

b. An anatomical drawing (see Appendix A) on which the surgeon and patient will collaboratively mark the operative site. The patient and surgeon will verify the identified site with the surgical consent and both parties will initial the drawing signifying verification of the operative site.

This page then becomes a permanent part of the chart.

2. There must be verbal confirmation with the patient indicating the side/site, witnessed by the surgeon/proceduralist performing the procedure AND the RN (circulator) responsible for patient’s welfare during the procedure.

III. Briefing, Time-Out, and Debriefing: Once the patient is in the operating room or procedure area, team members will stop activity and respond through active verbal acknowledgement and confirmation to each question of the Briefing, Time-Out, and Debriefing.

A. Briefing (immediately before administration of any type of anesthesia and/or sedation- will be done in holding in Operative Areas):

1. Identification of the patient using two identifiers (e.g., name and birthdate)
2. Verification of surgeon/proceduralist, proposed procedure, and site
3. Identification of allergies
4. Completion of safety check of anesthesia machine, if applicable
5. Delineation of any specific anesthesia risks, if applicable
6. Identification of any other procedures needed prior to scheduled procedure

B. Time-Out (immediately prior to incision and/or start of procedure):

1. Physician performing the procedure initiates Time-Out.
2. Team members introduce themselves by name and role or are designated on white board in room.
3. Correct patient is confirmed using two unique identifiers.
4. Correct procedure is confirmed and verified against signed consent.
5. Correct side, site, and position are confirmed by visualizing site marking within the sterile field.
6. Images are required for surgeries/procedures to support decisions on laterality. Such surgeries include, but are not limited to, the breasts, kidneys, brain, adrenal glands, lungs, hip, knee, and spine surgery. Images are confirmed for:
   a. The patient on whom the procedure is being performed.
   b. The most current image to the date and year.
   c. The correct display, by the physician performing procedure.
   d. The side and site on which the procedure is being performed.
7. Safety concerns are addressed in relation to scheduled procedure if not addressed during verification process. Safety concerns may include but are not limited to:
   a. Administration of antibiotics
   b. Risk of DVT
   c. Assurance of normothermia
   d. Anticipation of blood loss with availability of required blood products, if applicable
e. Patient history or medication – use precautions
f. Availability of correct implants and any special equipment or special requirements
g. Risk of fire associated with skin prep dry time (if alcohol-based)/above the waist procedures
h. Expected length of procedure

8. The procedure is not started until all questions or concerns are resolved.
   a. Any differences in team members’ response or understanding are immediately resolved.
   b. Surgeries requiring the presence and review of medical images will be postponed or canceled until the images are available.
   c. Department Manager/Director and/or Risk Manager/Director will be notified, if necessary, to facilitate reconciliation.

9. Time-Out completion and the time at which it was performed are documented in the medical record.

10. Time-Out process is performed before each procedure if two or more distinct procedures are being performed on the same patient in succession. If two procedures are being done concurrently, both Time-Outs can be conducted at the same time providing that both physicians are present during the Time-Out. If one of the physicians is not present, then a separate Time-Out will need to be completed prior to the next procedure.

C. Debriefing (Before physician and patient leave the procedure area):
   1. Items to be included in the Debriefing are dependent on procedure and may include, but are not limited to:
      a. Notification of the team regarding the results of the counts, including instruments, sponges, and needles
      b. Confirmation with physician of the actual procedure performed and diagnosis
      c. Confirmation that all specimens are accurately labeled
      d. Documentation of case delays
      e. Recording of necessary permanent changes to the preference card
      f. Equipment or instrument malfunctions or issues
      g. Key concerns for recovery and management of the patient.
      h. Securement of medications and proper disposal of pharmaceutical waste

DEFINITIONS:
The Surgical/Procedural Team is all members of the surgical/procedural team present at the beginning of the Time-Out, including the physician performing the procedure and the anesthesia personnel who will be participating in the procedure from the beginning. This includes all participants in the procedure.

Pre-procedure Verification is the process of reviewing all required data to verify the accuracy of the patient’s identity and the anticipated procedure. The purpose is to make sure that all relevant documents and related information or equipment are available before the start of the procedure. These items must be correctly identified, labeled, and matched to the patient’s identifiers. Any
documentation must have been reviewed and must be consistent with the patient’s expectations and with the team’s understanding of the intended patient, procedure, and side/site.

**Site Marking** is the initialing by the surgeon/proceduralist of the proposed site of an operative or other invasive procedure using a marking pen or other method of identification as outlined in this policy and procedure.

**Laterality** pertains to a side of the body. While laterality is the usual site designation, site designations are also necessary for multiple structures (such as fingers and toes), or levels (as in spinal procedures).

A **Briefing** is a period of time immediately before administration of any type of anesthesia and/or sedation in order to confirm the safety of proceeding.

A **Time-Out** is a period of time after induction and before puncture or incision during which all activity and conversation in the procedure area ceases. All members of the surgical/procedural team introduce themselves and participate in the positive verification of the patient, the intended procedure, and the visualization of the marked site of the procedure.

A **Debriefing** is a period of time during or immediately after wound closure, before removing the patient from operative or procedural room. The aim is to facilitate the transfer of important information to the care teams responsible for the care of the patient after surgery.

**ADOPTION:**
This Policy is being distributed to HCA Holdings, Inc. (“HCA”) affiliated licensed healthcare facilities through the Clinical Services Group (“CSG”) so that the facilities meet or exceed TJC, CMS and/or other regulatory requirements applicable to them. The facility, including its physician and employee staffed committees, medical staff, management, and board of trustees/governing board, has responsibility for the implementation and enforcement of, and monitoring compliance with, the Policy. This Policy does not supersede the paramount authority of a physician to control and direct individualized medical care to a patient.

**REFERENCES:**
Association of periOperative Registered Nurses. (2013) AORN Perioperative Standards and Recommended Practices
The Joint Commission on Accreditation of Healthcare Organizations
The Accreditation Association for Ambulatory Healthcare
World Health Organization
Centers for Medicare and Medicaid Services

**APPROVED BY:**
OUMS Policy and Procedure Committee: 9/29/2014
OUMS Medical Executive Committee: 5/13/2014
OUMS Board of Trustees: 5/19/2014
APPENDIX A

If used in the identification of an operative site as described in “Section 2.F.b” of this policy, the original document with both sets of initials will be retained as a permanent part of the patient’s chart.
Policy #: 04-03

Title: Safe Procedural and Surgical Verification

Surgery is scheduled

At time of scheduling, patient’s name, procedure, site, and laterality are repeated back to the office scheduler.

PAT phone call/visit

At time of PAT encounter, patient’s name, date of birth (DOB), procedure, site, and laterality are verified.

Morning of Procedure: Registration

In registration, patient’s name and DOB are verified with patient and the armband is checked for correct information.

Preoperative/Pre-procedural Area

When patient enters the care area, patient verification must be completed prior to care being rendered. The name and DOB should be verified on the patient’s armband.

Further verification of patient, procedure, site, and laterality should be conducted. Chart should be checked for completeness to include all required elements as defined by CMS.

Any regional blocks or other invasive procedure done to ready the patient should only be done after a correct Time-Out has been completed.

Each provider should conduct patient verification process at the initial contact.

Site should be labeled with performing physician’s initials.

Preanesthesia evaluation and consent completed.

Circulator reviews chart for completeness and verifies procedure scheduled correctly.

Pre-procedural Area/Holding Area

Patient is introduced to staff in room and “Briefing” is conducted.

Prior to incision the interactive time out is conducted.

Procedure WILL NOT start until all members of the team are in agreement and respond to all aspects of the time out.

Debriefing is conducted to ensure proper documentation of actual procedure, specimens collected, verified, and documented, status of count is relayed to the physician, and any concerns for post procedure care are identified.

Procedural/OR Suite

APPENDIX B