POLICY: UNIVERSAL PROTOCOL AND SAFE SURGERY CHECKLIST

PURPOSE:
- To confirm identification of patient and surgical site.
- 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.
- To identify all critical elements regarding patient safety.

SUPPORTING DATA:
Wrong site surgery and other preventable errors still occur too frequently in Operating Rooms around the world. In July 2003, the Joint Commission Board approved the Universal Protocol for Preventing Wrong Site/Wrong Procedure/Wrong Person Surgery and this became mandatory in July 2004. In addition, the WHO Safe Surgery Saves Lives Checklist was created with the goal of improving the safety of patients undergoing surgical procedures. This Universal Protocol/Safe Surgery Checklist includes:
   a. implementing a preoperative verification process of all relevant documents and studies before the start of the procedure.
   b. marking the surgical site.
   c. conducting a “Check In” immediately following the patient’s arrival to the procedural area, performing a “Time-Out” immediately prior to incision, and conducting a “Check Out” upon initiation of wound closure.

CONTENT:
There are five safety components required for surgical procedures:
1. Preoperative/Pre-procedure Verification.
2. Marking the procedural site
3. Check In
4. Final Verification- Time Out
5. Check Out

1. Preoperative/Pre-procedure:
   a. Pre-procedure verification is an ongoing process of information gathering and verification (Medical Center Policy 0250 “Universal Protocol for Preoperative/Pre-procedure Verification”).
   b. Epic Pre-Procedural Safety Checks:
      • review all the information gathered during the pre-procedure verification
      • verify the consistency of this information
      • confirm that this information meets the patient’s expectations
      • verify that all information is consistent with the procedural team’s understanding of the intended procedure and its site.
      • The five (5) Epic Pre-Procedural Safety Checks will be completed for all surgical procedures. Those Pre-Procedural Safety Checks include:
         o H&P complete
• Anesthesia ready
• Pre-op complete (as applicable for SAS admission)
• OR ready
• Surgeon ready

- Any Epic Pre-Procedure Safety Check that is not complete/green as appropriate will be a Hard Stop. The patient shall not be transported to procedure area except in cases involving life threatening emergency (impending respiratory/circulatory collapse or other IMMEDIATE threat to patient survival).

2. Marking the Procedural site:

   a. Marking of the site is required for procedures involving right/left distinction, multiple structures (fingers and toes) or levels (as in spinal procedure), and the surface (flexor, extensor) (MC Policy 0250).

   b. Site marking is performed by A Licensed Independent Practitioner (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. (MC Policy 0250)

   c. 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. Adhesive markers shall be used only as an adjunct to the permanent marker. (MC Policy 0250)

   d. The site shall be marked before the patient is moved to the location where the procedure will be performed. Patients shall verify the marking to the extent of their capability, but shall not be required to perform the marking. (MC Policy 0250)

   e. Site marking may occur on the day of procedure/surgery or prior as long as the mark is visible at the time of procedure/surgery.

   f. Prior to marking the site (s), the LIP performing the site marking verifies the patient’s identity using 2 patient identifiers and consent(s) to confirm accuracy.

   g. The health care professional asks the patient (or family/legal guardian) to state the procedure(s) and site(s)/side(s) of surgery (have patient provide visual clues, if appropriate, such as pointing).

   h. Actions taken and resolution of any discrepancy is to be documented by the operating physician and/or RN.

   i. A team member needing to perform treatment (e.g., anesthesia block) will mark site after the patient verification process, which includes: confirmation of the patient identification, verifying the patient’s verbal responses with the ID band, medical record, and informed consent(s) prior to the administration of anesthetic block or administration of medication(s).

   j. If a patient refuses to have the site marked, or, in cases in which it is impossible to mark the site (e.g., mucosal surfaces, premature infants for whom the mark may cause a permanent tattoo), the patient’s physician/LIP will review with the patient (or 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 the site on the Alternate Site Marking Form. Patient refusal and the alternative method of site marking is documented.

k. **Exemptions to site marking:**
   - **Procedures exempt from site marking include:** single organ cases, gastroenterology endoscopic cases, tonsillectomy, hemorrhoidectomy, open wound sites, or teeth

l. **Site markings are specific per surgical site and per surgical specialties:**
   - **Multiple sides or site:**
     If the procedure involves multiple sides/sites during the same operation, each side and site must be marked, i.e. bilateral organs must both be marked.
   - **Spine surgery is a two stage marking process.**
     **Stage I - Preoperatively:**
     1. The skin incision site is to be marked at the level of the procedure (e.g., cervical, thoracic, or lumbar) by the surgeon.
     2. The skin marked will, of course, indicate anterior vs. posterior.
     **Stage II - Intraoperatively:**
     3. Intraoperative x-rays with immovable marker(s) will be used to determine exact location and level of surgery.
     4. X-ray(s) will be reviewed by (operating physician) for confirmation. The circulating RN will document who read the intraoperative film on the Time-out screen in Epic. **Note:** once confirmed, the surgeon should mark the site with cautery, stitch, or bone bite before removing the x-ray marker).
   - **Laparoscopic surgery:**
     - The surgical site will be marked for laparoscopic cases that involve operating on organs that have laterality. The marking must be done near the proposed site or near the proposed incision/insertion site and will indicate the correct side. The mark must be visible after draping.
     - If it is technically impossible to be visible, an alternative method should be used.
   - **Ophthalmology surgery:** Marking will be above the operative eye.
   - **Dental surgery (Per MC Policy 0250):**
     - Teeth do not need to be marked.
     - The tooth number(s) or tooth/surgical site will be identified on the diagram or radiograph to be included as part of the medical record and site confirmation.
     - Radiographs will be checked for proper orientation and visually confirm correct teeth or tissue charted.
   - **Skin that is not intact:**
     - The skin mark will not be placed on an open wound or lesion. In this case, the Alternative Site Marking form will be completed by marking the provided diagram in lieu of marking the patient.
In the case of multiple lesions and when only some lesions are to be treated, the sites should be identified prior to the procedure itself.

- **Emergency procedure:**
  - Site marking may be waived in critical emergencies at the discretion of the operating physician, but a “time out” or pause should be conducted unless there is more risk than benefit to the patient.

- **GYN/GU procedures:**
  - Site marking will occur on lateral sites (e.g., testicular/ovarian procedure/surgery). Bilateral sites must be marked.
  - When operating through a natural orifice, for example during cystoureteroscopy procedure involving a single ureter which is impossible to mark and the mark would not be visible after draping; an alternative method may be used.

- **Sentinel node biopsy procedures per ENT:**
  - Site marking will NOT interfere with Radiologist’s marking of sentinel nodes marking.
  - Site marking will occur on the earlobe of the affected side using the site marker’s initials.

- **Finger surgery:**
  - Fingers should be marked by placing the site marker’s initials on the pulp of each finger involved in the surgery.

- **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 (LIP) removing the cast or splint shall transfer the site mark to the skin before incision or use the alternative site marking procedure.

**NOTE:** In the case of SITE MARK EXEMPTIONS: cited above, e.g. emergent, open wound, etc.) as long as the person performing the procedure identifies the patient and confirms all data, including consent, history and physical, and radiographs; and is in continuous attendance, he/she may perform the procedure without marking the site. A “time out” still must occur prior to the start of the procedure.

**Note:** At completion of the case, attempt should be made to remove the site mark in the event that the patient will be having subsequent surgical procedures (e.g., trauma).

3. **Check In:**
   a. Check-In is conducted by the Circulating nurse with the Anesthesia care provider who shall actively engage in a process of review and questioning. For content of Check in, see Appendix #1.
   b. Check In will be performed immediately upon arrival to the procedure area and prior to anesthesia induction or nerve block except in cases involving
impending respiratory/circulatory collapse or other IMMEDIATE threat to patient survival.

Note: Pre-Procedure Injection Verification must be completed for injections that occur before the time out is completed (prepping and draping).

- “Pre-Procedure Injection Verification”, will minimally include the physician performing the pre-procedure injection and the circulator.
- It will include verification of pt., procedure, site, laterality and consent.
- The “Pre-Procedure Injection Verification” will be documented in the medical record.

4. Time Out:

a. **Time Out is led by either the Surgeon or Circulator** and will take place in the location where the procedure will be performed.

b. **Surgical/Procedural Attending shall be present for Time Out and should define the critical steps of the procedure.**

c. **Time out will be conducted immediately prior to incision/start of surgical procedure.** Exception: cases of impending respiratory/circulatory collapse or other IMMEDIATE threat to patient survival.

d. **For content of “Time Out”, see Appendix #1.**

e. **All members of the patient care team who are present shall participate in the time out.** This group includes but is not limited to: Anesthesia attending, Anesthesia provider, Surgical Residents, RNs, Surgical Technologists, ancillary staff and students. All team members must introduce themselves by name and role. Names and roles shall be recorded by the circulator on a “whiteboard” and shall be readable from any location in the room.

f. **During the time out, activities are suspended** to the extent possible without compromising patient safety. All members of the patient care team shall focus on active verification of the critical elements.

g. **The procedure shall not be started** (instruments shall not be passed) until all questions or concerns addressed in time out are resolved by all members of patient care team.

h. During the Time Out for procedures involving incisions above the xiphoid or any part of the airway and/or pulmonary system, the Oxygen concentration will be verified with Anesthesia during the Fire Risk Assessment.

i. Whenever there is more than one procedure being performed by separate procedure teams at separate operative sites, there shall be a Time Out prior to each team commencing its procedure. 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.(MC Policy 2050),

j. Whenever there is more than one procedure being performed by a single procedural team at more than one distinct operative site there shall be a separate, unique, and individual Time Out prior to each procedure,
especially when such procedures occur in fields that are individually or sequentially prepped and draped, or when the patient must be repositioned to be re-prepped and re-draped – e.g. a Bronchoscopy, Mediastinoscopy and Thoracotomy procedure will require First time out for Bronch and Mediastinoscopy and second time out for Thoracotomy. A Lap Nissen procedure will require only one Time Out. A Belsey procedure will require two Time Outs due to positioning change. An Ivor-Lewis will require two Time outs due to positioning change. Anterior posterior spine fusion will require two Time Outs.

k. Whenever non-invasive procedures (usually done in ER or Clinic) are performed by different surgical service in conjunction with primary surgical procedure, the Time Out may be done by the Primary Surgical /Procedural Attending if agreeable to all parties i.e Attending of the Primary surgical procedure and Attending of surgical sub-specialty service- e.g, Repair of Facial Laceration by Plastic Surgery during ORIF procedure by Orthopedic Surgery, The Orthopedic Attending may perform the Time Out for Facial laceration by Plastic Surgery Resident if agreeable to both Attending surgeons.

l. For situations where multiple procedures involving multiple surgical (interventional) services are to be performed when a patient is taken to the operating room, ALL procedures ideally would be discussed by the Attending surgeon/physician for the primary procedure during the ‘Time Out’. The covering attending for the primary case will in effect be the attending of record for the add on cases. Examples of such cases include suturing simple lacerations, insertion of traction pins, splinting extremities, extracting teeth, getting images, putting in lines etc… Typically these add on cases would be done in the ED setting or without an anesthetic. Before the patient goes to the OR, the surgeon/resident who is to perform the add on procedure should inform the patient/family (if possible) and inform the primary team of their intent to do this procedure. The surgeon/resident should document in the EMR that the procedure is to be performed and indicate the covering attending agreement with the plan.

m. EUA Procedures: If an EUA is performed as a part of a normal preparation for a procedure, no time out is needed prior to this EUA. If the EUA will be used to determine approach of any additional procedures or may possibly be the only procedure performed, a time out should occur prior to it.

5. Check Out:

a. Check Out is conducted by the circulating nurse with a member of the procedural team and anesthesia care provider. All will actively engage in a process of review and questioning. The RN will document the check out in their Epic documentation.

b. Check out will be performed during or immediately after wound closure but before removing the patient from the Operating room.

c. Whenever there is more than one procedure being performed by separate procedure teams at separate operative sites, there shall be a Check-Out prior to each team completing its procedure.

d. For content of Check-Out see Appendix #1 “Safe Surgery Checklist”.

SECTION
B
e. In circumstances where a member of the procedural team must hand off responsibility to a 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.

DOCUMENTATION:

• Documentation of Check In, Time Out and Check Out in Epic Optime record.
• Completion of the Alternative Site Marking form as appropriate.

EFFECTIVE DATE: August 30, 2010

REFERENCES:

• Medical Center policy 0250 “Universal protocol for preoperative/pre-procedure verification”
• WORLD HEALTH ORGANIZATION Safe Surgery Guidelines

DATE OF APPROVAL: 7/19/2010 – OR Committee Meeting
REVIEW: 02/12; 01/15; 12/17
REVISION: 02/12; 01/15; 12/17

This Policy/Procedure is posted in both the OR Policy Manual and the OR Procedure Manual

THIS DOCUMENT IS A SHARED DOCUMENT BETWEEN MOR AND OPSC
Appendix #1: Safe Surgery Checklist

Safe Surgery Checklist

<table>
<thead>
<tr>
<th>Check In (Upon arrival to Procedure area / prior to induction)</th>
<th>Time Out (Immediately Prior to Incision)</th>
<th>Check Out (Initiation of Closure)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Circulator leads</strong></td>
<td><strong>Surgeon / Circulator leads</strong></td>
<td><strong>Circulator leads</strong></td>
</tr>
<tr>
<td>• Patient Confirmation</td>
<td>• Activity stopped / room quiet?</td>
<td>• ID Band on patient?</td>
</tr>
<tr>
<td>Name and MRN</td>
<td>• Introductions</td>
<td>• Procedure(s) performed?</td>
</tr>
<tr>
<td>ID Band verified with consent?</td>
<td>• OR Team Verbally Confirms</td>
<td>• Specimen verification</td>
</tr>
<tr>
<td>• Patient known allergy?</td>
<td>1. Patient name</td>
<td>1. Read aloud patient name.</td>
</tr>
<tr>
<td>• VTE prophylaxis Plan?</td>
<td>2. Procedure(s)</td>
<td>2. Specimen name?</td>
</tr>
<tr>
<td>• Antibiotic prophylaxis given /</td>
<td>3. Site / side verification</td>
<td>3. Destination?</td>
</tr>
<tr>
<td>documented within 60 minutes of incision?</td>
<td>4. Fire risk assessment</td>
<td>4. Transport Mode?</td>
</tr>
<tr>
<td>• Anticipated EBL / Blood Plan?</td>
<td>5. Implants (✓ Exp. Date) / equipment</td>
<td>• Specific concerns for recovery</td>
</tr>
<tr>
<td>• 2 IVs / Central Line for Peds EBL &gt; 7m4kg</td>
<td>6. Essential Imaging displayed?</td>
<td>management of this patient?</td>
</tr>
<tr>
<td>• Anticipated implants / equipment available?</td>
<td>7. Sharps safety risk assessment</td>
<td>• Inform surgeon of status of</td>
</tr>
<tr>
<td>• Anesthesia machine and medicine check complete?</td>
<td></td>
<td>closing count.</td>
</tr>
<tr>
<td>• Functioning Pulse oximeter?</td>
<td></td>
<td>• Instrument, supply, or implant</td>
</tr>
<tr>
<td>• Difficult airway / aspiration risk?</td>
<td></td>
<td>issues for DPC?</td>
</tr>
<tr>
<td>• Temperature management plan for normothermia?</td>
<td></td>
<td>• Brief Op Note prior to transfer?</td>
</tr>
<tr>
<td>• Cleanliness of environment?</td>
<td></td>
<td>• Remove Foley Catheter?</td>
</tr>
<tr>
<td>Hand Hygiene followed?</td>
<td></td>
<td>If not, place maintenance orders</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Opportunities for improvement = BSE</td>
</tr>
</tbody>
</table>

World Health Organization  
University of Virginia Health System