Ohio Surgical/Procedural Verification Protocol

Wrong site, wrong procedure, and wrong person surgery/procedure can be prevented. This statewide protocol is intended to achieve that goal. All Ohio facilities and professionals involved with surgery or procedures in all settings are asked to incorporate the following protocol to facilitate continuity and reduce variance across settings, thereby reducing or eliminating the possibilities for error. This protocol uses the JCAHO Universal Protocol as the foundation, with reference to recommendations by professional organizations. It is based on consensus from relevant clinical specialties and professional disciplines throughout Ohio.

This protocol focuses on traditional surgical settings, and provides a template for areas where invasive procedures are performed in non-surgical settings, such as the bedside. It is recognized that the process may need to be modified in some settings; however, minimal deviation from the protocol is encouraged.

The Ohio protocol is divided into three primary processes: Pre-operative verification, marking the operative site, and “time-out” immediately prior to starting the procedure.

Pre-operative Verification:
Purpose: To ensure the effective and safe transition of the operative patient through the pre-operative phase, beginning with the physician’s office and concluding upon the patient’s arrival to the operating room suite.
Process: The continuous sharing of pertinent information to ensure appropriate verification of correct patient, correct procedure and correct site.

Marking the Operative Site:
Purpose: To identify the correct operative/procedure site.
Process: Clearly marking the surgical site to eliminate any ambiguity and ensure correct bilaterality/level, even once the patient is prepped and draped.

“Time-out” Immediately Prior to Starting the Procedure
Purpose: To prevent medical error by conducting a final verification of correct patient, procedure, and site.
Process: Active (two-way) communication among all surgical/procedural team members that is consistently preformed prior to all procedures.

Application in Non-OR setting
- Verification, site marking, and time-out procedures should be consistent as possible throughout the organization, including OR as well as non-OR locations where invasive procedures are done.
- Site marking should be done for any procedure that involves laterality, multiple structures or levels (even if procedure takes place outside of an OR)
  - Exception: Cases in which the individual doing the procedure is in continuous attendance with the patient from the time of decision through the conduct of the procedure may be exempted from marking the site. However, the requirement for final time-out verification applies.

Endorsements:
The following organizations have endorsed this protocol:
Ohio Patient Safety Institute
Ohio Hospital Association
Ohio State Medical Association
Ohio State Medical Board
Ohio Patient Safety Discussion Forum
Ohio Department of Health
Ohio KePRO
Ohio Osteopathic Association
Ohio Chapter American College of Surgeons
Ohio Association of Ambulatory Surgery Centers
Ohio Organization of Nurse Executives
Ohio Society of Anesthesiologists

OPSI, OHA, PSDF© March 2004
Implementing the Ohio Surgical/Procedural Verification Protocol

Pre-Op Verification
Pre-op verification occurs at every transition of the patient from one setting/personnel to another. Organizations need to review the number of “hand-offs” in their process and determine what level of verification is needed at each transition. The following identifies the level of verification at several of the key transitions. The initial verification begins in the surgeon’s office. Each written document in this verification process should be legible and NOT contain unacceptable abbreviations.

- Pre-Op Verification at/from the Physician Office should include the patient’s name, with at least two identifiers such as date of birth, pre-op diagnosis, procedure specific to site (special positioning if applicable), surgeons involved, special equipment/supplies/implants or radiographic images to be available, and any key medical information.
  - Recommend a two-way communication process between the surgeon’s office and surgical center/hospital after scheduling for verification (such as “read-back,” or confirmation phone call/email/fax).
  - In the event of a discrepancy, a verbal/written re-verification process needs to occur.
- Locations such as Pre-Admission processes, On-site Verification, and initial check-in entails the patient’s name, including two identifiers and having the patient/caretaker state the procedure to be done in their words.
- Pre-op Verification Before OR includes the patient’s name with at least two identifiers, verification of consent ensuring each surgeon/procedure is identified, H&P, patient/caretaker verbalizes procedure, and site marked when applicable.
  - If there is a discrepancy in any part, a method of confirming and communicating this change should be in place and the procedure should be STOPPED until validated. One person at each transitional step is responsible for overseeing the entire transition and verifying each step is completed (that individual has the authority to stop process until completed). Patient cannot go to surgery until accurate verification is completed.
  - When Patient is Taken to OR, verify the patient’s name with at least two identifiers, H&P, consent ensuring each surgeon/procedure is identified, availability of requested images, patient/caretaker verbalizes procedure, and site marked when applicable.
  - The individual responsible for this transition correlates the site marking, consent, printed OR schedule, H & P, and patient name – if any part is not matching, the process is STOPPED until validated. If a discrepancy occurs, the next step is to call the surgeon to provide adequate documentation to resolve discrepancy. The surgeon must document in the medical record the appropriate procedure before the procedure takes place. This CANNOT be a verbal validation. If there are multiple physicians, each physician is responsible for their own site documentation.

Marking the Site
This step should be completed as early as feasible in the process, with the patient being an active participant. The patient can still participate even if pre-sedation has been administered, but should ideally occur before regional anesthesia.

- The site is marked as early as possible but PRIOR to entering the operating room.
- The surgeon or designee is responsible for the marking the site.
- Surgeon/designee actively engages the patient in the marking of the site.
- Mark the site at or near incision. “Near” means visible once patient is prepped and draped.
- The site is to be marked with the marker’s initials using persistent marker that remains visible once patient is prepped and draped.
- Each operative/procedural sites involving laterality, multiple structures or levels should be marked.

Exceptions:
- Single organ cases such as cesarean section, midline sternotomy, laparotomy, laparoscopy
- Cardiac catheterization and other interventional procedures which the site of incision is not pre-determined
- For teeth, the operative tooth name(s) must be indicated on medical record OR marked on the dental radiographs or dental diagram
- If site is a traumatic site (obvious surgical site), it does not have to be marked.
- Premature infants less than 2.5 pounds
- If patient refuses marking, document!
- Mark a visually sensitive site (e.g. face) with a dot or small visible mark with persistent marking.
  - Do NOT mark non-operative site.
  - DO NOT use X’s or stickers.
- There are no known infection control issues related to marking but use this time to perform an inspection of the skin to identify opportunities for infection (skin breaks/tears, etc).

Time-out
The time-out is to be performed immediately before the procedure. That is, “prior to the incision” or if no incision is required, then prior to the initiation of the procedure. For multiple procedures/surgeries, conduct a brief time-out prior to the start of each procedure or change of surgeons.

- Suggested Procedure: Utilize a visual checklist posted in the OR suite.
- Briefly document in the medical record that the time-out was completed.
- Organization must define who is responsible to initiate the time-out, but all those present are accountable for the time-out.
  - The surgeon, anesthesia provider, circulating nurse and surgical technician MUST participate in the time-out.
  - During a time-out, the following elements are to be verified, as appropriate: patient’s name using two identifiers, site (including marking), procedure, correct position, equipment/implants present, and imaging data.
  - Any differences/discrepancies must be reconciled immediately (procedure can NOT start until discrepancies are corrected). Report all discrepancies (even those corrected) through the organization’s predetermined process.
  - If a surgical procedure begins without a time-out, it must be reported for peer review or Quality Improvement processes.
Pre-Op Verification: Prior to Surgery

**Step 1: Patient Verification**
At a minimum Patient Verification (Pre-admission processes, Initial check-in, anytime the patient is transferred to another caregiver) includes:
- Two patient identifiers
- Procedure to be performed

At a minimum Patient Verification (When surgery/procedure scheduled, Pre-op before OR, patient taken to OR) includes:
- Two patient identifiers
- Procedure to be performed
- Site of procedure confirmed
- Surgeon(s) involved

In the event of a discrepancy, at any transition, re-verification is required

Marking the Site: Before Entering OR

**Step 2: Marking the Site**
Marking the Site includes:
- Surgeon/designee mark the site
- Patient actively engaged in process
- Physically marking the site includes:
  - Mark on or near incision site
  - Mark with marker’s initials using a persistent marker
  - Mark visible once patient draped/prepped
  - Mark ALL sites involving right/left distinction, multiple structures, or multiple levels
- **EXCEPTIONS**
  - Single organ cases
  - Interventional procedures where incision site is not pre-determined
  - Teeth

Marking occurs:
- As early as feasible
- Prior to entering the OR room

Do NOT mark non-operative sites.

Time-Out Prior to Incision

**Step 3: Time Out**
Time Out includes:
- Surgeon, anesthesia provider, circulating nurse and surgical technician
- Verification includes:
  - Two patient identifiers
  - Site, including marking
  - Procedure
  - Patient position, if appropriate
  - Equipment/implants present, if appropriate
  - Imaging data, if appropriate

Time Out occurs:
- Prior to initiation of surgery
- Prior to the start of each procedure (if multiple incisions)

Time Out must be documented.

Use of a visual Checklist for Time Out is recommended.

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