

DEPARTMENT OF THE ARMY
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MEDCOM Regulation
No. 40-54

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Medical Services
UNIVERSAL PROTOCOL: PROCEDURE VERIFICATION POLICY

Supplementation of this regulation and establishment of forms other than MEDCOM forms are prohibited without prior approval from HQ MEDCOM, ATTN: MCHO-CP-A.

1. History. This issue publishes a revision of this regulation.

2. Purpose

a. Function. This regulation provides a standard process and procedure for surgical and procedural site verification of patients undergoing operative or other invasive procedures.

b. Scope. This regulation addresses all operative and other invasive procedures that expose patients to more than minimal risk of harm inclusive of settings beyond the operating room in medical and dental treatment facilities.

(1) This policy addresses all operative procedures and other invasive procedures involving incisions or percutaneous puncture or insertion. These procedures include biopsies, cardiac and vascular catheterizations, and endoscopies.

(2) Routine minor procedures such as venipuncture, peripheral IV line placement, insertion of nasogastric tube, or Foley catheter insertion are not within the scope of the policy.

c. Objective. The intent of this regulation is to provide healthcare team members a standardized approach for preventing harm to patients undergoing operative or other invasive procedures through effective communication and handoff of information. *The Joint Commission (TJC) Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery* has been incorporated into this regulation.

*This regulation supersedes MEDCOM Regulation 40-54, 23 Feb 2009.

3. Applicability. This policy applies to all U.S. Army Medical Command (MEDCOM) and Dental Command (DENCOT) healthcare professionals and paraprofessionals involved in operative and invasive procedures. This policy applies in both inpatient and outpatient settings.

4. References. References are listed in appendix A.

5. Explanation of abbreviations and terms. Abbreviations and terms used in this publication are explained in the glossary.

6. Policy

a. Three components are universally addressed by professional organizations and TJC to ensure the patient's safety and to prevent the occurrence of wrong person, wrong site, wrong procedure/surgery. They include—

(1) Pre-operative/pre-procedural verification to prevent errors and promote safe patient care.

(2) Marking of the operative/procedural site.

(3) Time-Out for all surgeries or procedures to ensure that the correct patient, site, and procedure are consistent with the plan of care. The Time-Out is required for all surgeries or procedures.

b. All required elements of documentation for operating room procedures are listed in the MEDCOM Form 741 (Medical Record-Universal Protocol: Procedure Verification Checklist). All required elements of documentation for procedures conducted outside the operating room are included in the MEDCOM Form 741-1 (Universal Protocol: Non-OR Procedure Verification Checklist).

(1) Documentation of the surgical/procedural verification process performed in the operating room may be documented MEDCOM Form 741. If an alternate documentation is used (for example, on an electronic form), then all documentation elements in the 741 must be included in the alternate documentation.

(2) Documentation of procedure verification process done outside of the operating room (for example, in a clinic) may be documented on MEDCOM Form 741 or MEDCOM Form 741-1. If alternate documentation is used (for example, on an electronic form), then all documentation elements in the 741-1 must be included in the alternate documentation.

7. Overview

a. The verification process is designed with redundancy as a safety mechanism to ensure multiple checks. Every member of the healthcare team has the responsibility to actively engage in the process consistent with his/her position on the team.

b. Verification of the correct person, correct site, and correct procedure occurs at the following times:

(1) At the time the procedure is scheduled,

(2) At the time of pre-admission testing and assessment,

(3) Upon admission or entry into the facility,

(4) Any time a caregiver transfers responsibility of the patient to another clinical staff member (handoff),

(5) Before the patient leaves the preoperative area or enters the operating/procedural room, and

(6) Immediately before the provider begins the procedure, as part of the Time-Out.

8. Procedures

a. Pre-operative/pre-procedural verification.

(1) The elements of the pre-operative/pre-procedural verification should be completed by a licensed staff member. The verification may be completed by a clinical non-licensed staff member only if normal and customary practice involves a non-licensed assistant.

(2) The process confirms the patient's identification using the patient's full name and date of birth and confirms that the patient's identification is consistent with signed consent(s) (for example, OF 522 (Medical Record-Request for Administration of Anesthesia and Performance of Operations and Other Procedures)) and other relevant documents.

(3) When the patient is in the pre-procedure area and immediately prior to moving the patient to the operating room or procedure room, verify that the following items are available and accurately matched to the patient:

(a) Relevant documentation (history and physical/progress note, pre-anesthesia assessment).

(b) Accurate, complete, and signed consent form.

(c) Correct and properly labeled diagnostic and radiology test results (for example, radiology images and scans or pathology and biopsy reports).

(d) Any required blood products, implants, devices, and/or special equipment for the procedure.

(e) The patient will not be transferred to the procedure area until the privileged provider marks the site or an alternative marking method (procedure identification band) is in place.

(4) When there is no pre-procedural area, the operating provider will ensure that procedures conducted outside the operating room have the verifications described above.

b. Marking the operative/procedural site.

(1) All staff members are responsible for educating the patient as to the purpose and importance of the site marking.

(2) Site marking or the alternative marking method (see para (6), below) is required for all operative procedures and invasive procedures unless noted as exceptions (listed in para (5)(k), below).

(3) The operating provider who is privileged to perform the procedure will mark the site, using his/her initials. This individual must be directly involved in the procedure and must be present at the time the procedure is performed. Residents in graduate medical education (GME) programs, an advanced practice registered nurse (APRN), or physician assistant (PA) who is familiar with the patient and who will be present when the procedure is performed may mark the site.

(4) If it is not possible for the operating provider to mark the site using his/her initials, an alternate marking method will be used as described in paragraph (6), below.

(5) Marking specifics.

(a) When possible, the patient/guardian should participate in marking the site by verifying the procedure and site to be marked.

(b) The site will be marked prior to moving the patient to the procedural area. If the procedure is performed in an area other than an operative suite, such as a clinic office, the site will be marked prior to the Time-Out.

(c) The mark will be made at or near the procedure site and take into consideration laterality, the surface (flexor, extensor), the level (spine), or specific digit or lesion to be treated. Non procedural sites will not be marked unless medically indicated (for example, pedal pulse mark or “no B/P” mark).

(d) The mark must be made with an indelible marker that remains visible after site prepping and draping is completed.

(e) For procedures that involve laterality of organs with incision(s) or approaches from the midline or from a natural orifice, the entry/incision site will be marked and laterality of the organ indicated.

(f) For spinal procedures, in addition to skin marking of the general spinal region, special intra-operative radiographic techniques must be used to mark the exact vertebral level.

(g) For procedures involving the eye, the skin next to the appropriate eye will be marked.

(h) For dental procedures, marking will be on the radiograph or dental diagram.

(i) For skin biopsies, when site marking with initials could lead to potential specimen mishandling, alternate skin marking such as circling the lesion is acceptable.

(j) For burn operating room—

- Sites will be marked according to the TJC Universal Protocol unless contraindicated.
- If skin marking is contraindicated due to the skin integrity, or due to the possibility of causing a permanent mark on fragile skin, or on skin that will be used for grafting, the provider will pause and point to the incision site while the circulating nurse is reading the consent during the Time-Out.

(k) Exceptions to marking. Site marking is not required for procedures conducted outside the operating room where patients are generally fully conscious and in which—

- Interventional procedures for which the insertion site is not predetermined, such as cardiac catheterization or central line placement; or,
- The procedure will be performed on a midline structure or single organ; or,
- The procedure is without intended laterality such as endoscopy, cystoscopy, colposcopy, or trans-nasal esophagoscopy; or

- The wound or lesion is obvious. (*Note:* If there are multiple wounds or lesions and only some of them are to be treated, and the decision and direction for which ones are to be treated is determined prior to the procedure, then the sites to be treated must be marked.)
- When the individual doing the procedure is continuously with the patient from the time of consent, or decision to do the procedure, through to the performance of the procedure.

(6) Alternate marking method.

(a) The primary alternate marking method is to mark a procedure identification band instead of marking the patient.

(b) The alternate marking method will be used for the following situations:

- When it is technically or anatomically impossible or impractical to mark the site (that is, mucosal surfaces and perineum).
- With premature infants.
- When the patient refuses the marking.

(c) The operating provider will write the location (side/level/site) of the procedure incision/entry site on the procedure identification band (as opposed to marking it on the patient's skin). In this case, the operating provider must be privileged to perform the procedure and he/she must be directly involved and/or present during the procedure. Residents in GME programs, an APRN, or PA who is familiar with the patient and who will be present when the procedure is performed may mark the site.

(d) The operating provider will place the procedure identification band on the patient (typically on the patient's wrist).

(e) For patients who are not candidates for the procedure identification band placement on their body (for example, neonates), the band will be co-located with the patient during the pre-procedure verification and the Time-Out.

(f) The procedure identification band will be removed and disposed of by the post-anesthesia care unit (PACU) staff or upon completion of the procedure if the patient is not admitted to the PACU.

c. Time-Out.

(1) A Time-Out is required for all invasive procedures.

(2) The Time-Out is the final check and ideally conducted prior to anesthesia induction unless contraindicated. The Time-Out must be completed by the operating or procedural team immediately prior to the incision, insertion, or start of the procedure. Time-Outs are required for all procedures, and in some instances, multiple Time-Outs are required. For example, surgical procedures done under spinal anesthesia will require two Time-Outs; one for the anesthesia and the second for the actual surgical procedure.

(3) The Time-Out is lead by the operating provider and involves the entire team. It is done using interactive verbal communication. It involves the immediate members of the procedure team, including the individual performing the procedure, the anesthesia providers, the circulating nurse, the operating room technician, and other active participants who will be participating in the procedure from the beginning. All team members must be actively engaged in the Time-Out. The operating provider must remain in the procedure room between the Time-Out and the start of the procedure. For procedures outside of the operating room, the team members will include at minimum the operating provider and one other clinical staff member (nurse, technician, or provider). The exception is when the procedure is performed by a sole provider, and the provider does not leave the procedural area after marking the site (for example, skin biopsies). All team members must be actively engaged in the Time-Out. The operating provider must remain in the procedure room between the Time-Out and the start of the procedure.

(4) During a Time-Out, activities are suspended to the extent possible so that team members can focus on active confirmation of the patient, site, and procedure.

(5) When two or more procedures are being performed on the same patient, and the person performing the procedure changes, perform a Time-Out before initiation of each procedure.

(6) All members of the healthcare team have the responsibility to stop the procedure and request clarification if there is any question, difference, or discrepancy. The procedure is not started until all questions or concerns of the team are resolved.

(7) The Time-Out confirms that—

(a) The correct patient is in place by comparing the procedure identification band (if applicable) against the consent.

(b) The correct consent is present, and team members agree on the planned procedure.

(c) The correct side/site is identified and marked.

9. Special verifications

a. Regional anesthesia procedures verification processes. Regional anesthesia procedures performed in conjunction with other procedures are subject to the following:

(1) Regional anesthetic procedures require a procedure verification process and Time-Out separate from the operative verification process.

(2) Regional anesthesia procedures followed by an operative procedure will follow the TJC Universal Protocol. A second clinical verifier is required during the regional procedure Time-Out.

(3) Regional anesthesia procedures performed on patients not going to the operating room can be documented on either MEDCOM Form 741 or MEDCOM Form 741-1.

b. Concurrent or sequential surgeries in the same operative event.

(1) If the surgeries are concurrent, the Time-Outs will occur immediately one after the other with both Time-Outs documented.

(2) If the surgeries are sequential, upon completion of the first surgery, a second Time-Out will take place before the start of the second procedure. Document each separately.

(3) Regional anesthetic procedures require a procedure verification process and Time-Out separate from the operative verification process.

c. Spinal surgery additional Time-Out. An intra-operative x ray with placement of immovable markers will be used to determine the exact location and level of surgery. Once marked in this way, a second Time-Out will occur and may be documented on page 2 of MEDCOM Form 741 or equivalent.

10. Documentation

a. MEDCOM Form 741 or equivalent documentation will be used for all operating room settings.

b. Invasive procedures performed in the clinic and those not occurring in the operative area must document the elements of MEDCOM Form 741-1. This information may be documented into the electronic medical record. Documentation that a Time-Out was completed will, as a minimum, include the following information:"

(1) Patient was identified using two patient identifiers.

(2) The correct site was marked and confirmed with patient.

(3) The correct procedure to be done and confirmed with patient.

c. Documentation of the Time-Out occurs as soon as possible after performing the Time-Out using one of the two forms as described in paragraphs *a* and *b*, above.

d. The Time-Out must be documented by a licensed staff member or may be completed by a clinical non-licensed staff member only if normal and customary practice involves a non-licensed assistant.

e. All discrepancies that occur during the Time-out must be resolved prior to the initiation of the procedure and the Time-out process re-started. The Time-out must also be repeated if there is an interruption in the procedure or the provider leaves the room and then returns to resume the procedure.

11. Compliance. Recommended measures for compliance include: Review of site marking compliance before a procedure is performed, quality review to ensure approved provider marks the surgical site, and/or quality review of the Time-Out procedure and documentation.

12. Policy discrepancies. In the event of a discrepancy among MEDCOM Regulation 40-54, TJC Universal Protocol, National Patient Safety Goals, local facility policies, or other related standards, the strictest of policies will be followed.

*MEDCOM Reg 40-54

Appendix A References

Section I Required Publications

AR 40-68
Clinical Quality Management

MEDCOM Regulation 40-41
The Patient Safety Program

Section II Related Publications

A related publication is a source of additional information. The user does not need to read the publication in order to understand this regulation.

The Joint Commission, National Patient Safety Goals Universal Protocol.
(Available at http://www.jointcommission.org/standards_information/up.aspx .)

The World Health Organization, Implementation Manual WHO Surgical Safety Checklist and Implementation Manual.
(Available at http://www.who.int/patientsafety/safesurgery/ss_checklist/en/index.html.)

Section III Prescribed Forms

MEDCOM Form 741
Medical Record - Universal Protocol: Procedure Verification Checklist

MEDCOM Form 741-1
Universal Protocol: Non-OR Procedure Verification Checklist

Section IV Referenced Forms

OF 522
Medical Record - Request for Administration of Anesthesia and Performance of Operations and Other Procedures

Glossary
Section I
Abbreviations

APRN

advanced practice registered nurse

DENCOM

United States Army Dental Command

GME

graduate medical education

GP

general purpose

MEDCOM

United States Army Medical Command

PA

physician assistant

PACU

post-anesthesia care unit

TJC

The Joint Commission

Section II
Terms

Consent. A patient's approval to have a specific procedure or surgery performed following counseling by the operating provider. All references to "consent" in this document will include "informed consent," if applicable.

Invasive/interventional procedure. Procedures requiring consent and involving insertion of objects into the body in order to provide treatment, study function, or deliver or remove fluids (for example, central line placement, chest tube placement, stent placement, cardiac catheterization, and so forth).

Laterality. The side of the body identified as "right" or "left."

Level. Position along a vertical axis.

Licensed staff member. A military treatment facility staff member with a professional healthcare license.

Operating provider. As used in this regulation, includes the individual performing the procedure, regardless of the setting. Examples of operating providers include but are not limited to anesthesiologists, nurse anesthetists, surgeons, dentists, pulmonologists, endocrinologists, podiatrists, intensivists, emergency physicians, radiologists, advanced nurse practitioners, and physician assistants.

Outpatient clinic. Ambulatory clinic settings, including but not limited to family practice, general surgery, gynecology, orthopedic, or podiatry clinics.

Patient identification. Full name and date of birth.

Pre-operative/pre-procedural medication. Any narcotic, analgesic, sedative, hypnotic, or amnesiac medication administered prior to a surgery or procedure.

Procedural area. An operating room, cardiac catheterization or interventional suite, radiation or nuclear medicine area, treatment or procedure room, patient room, emergency room, clinic room, or any other location where surgical or invasive procedures may occur.

Provider. Military (Active Army/Army Reserve National Guard/United States Army Reserve) and civilian (General Schedule and those working under contractual or similar arrangement) personnel who are engaged in the delivery of healthcare and are—

a. Privileged – Granted privileges to diagnose, initiate, alter, or terminate healthcare treatment regimens within the scope of his/her license, certification, or registration.

b. Non-privileged – Authorized to provide healthcare and services within the scope of practice designated by his/her license, certification, or registration.

Regional anesthesia. The rendering of a specific area of the body insensate to stimulus of surgery or other instrumentation. Types of regional anesthesia may include topical, local/field, intravenous blocks, peripheral, plexus, or central neuraxial. Example of these blocks include but are not limited to local infiltration, digital, retrobulbar, upper/lower extremity, interscalene, femoral sciatic, lumbar plexus, cervical plexus, subarachnoid block, and epidural.

Verification. A process that involves checking for consistency among patient identification, information contained on the procedural consent form, any diagnostic study reports, the pre-operative checklist, the marked anatomical site, confirmed with the response of the patient or guardian.

Wrong-site/wrong-patient procedure. Any procedure that is performed on a body part that was not the originally anticipated or intended site or performed on a patient for whom that procedure was not scheduled or intended. Categories of “wrong-site

surgery” include wrong-side surgery, wrong-level/part surgery, and surgery/procedure on the wrong patient are shown below:

- Wrong-side surgery/procedure. Any surgery or procedure in which the operative area was not the correct or intended laterality. Typically involves extremities or distinct sides of the body.
- Wrong-level/part surgery/procedure. Any surgery or procedure that is performed at the correct site but at the wrong level or part of the operative field. The correct part of the body was prepared for surgery, but the surgical procedure is performed on the wrong level or area of the patient’s anatomy.
- Wrong patient surgery/procedure. Any surgery or procedure that is performed on a patient who was not scheduled for that procedure.

*MEDCOM Reg 40-54

The proponent of this publication is the Clinical Performance Assurance Directorate. Users are invited to send comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications and Blank Forms) to Commander, U.S. Army Medical Command, ATTN: MCHO-CP-A, 2748 Worth Road, JBSA Fort Sam Houston, TX 78234-6054.

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