

DEPARTMENT OF THE ARMY  
HEADQUARTERS, UNITED STATES ARMY MEDICAL COMMAND  
2050 Worth Road Fort Sam Houston, Texas 78234-6010

MEDCOM Regulation  
No. 40-54

23 February 2009

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-CL-Q.

**1. History.** This issue, formerly MEDCOM Circular 40-17 (Surgical/Procedural Site Verification), publishes a revision. Because the publication has been extensively revised, the changed portions have not been highlighted.

**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 veni-puncture, 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's (TJC) Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery has been incorporated into this regulation.

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\*This regulation supersedes MEDCOM Circular 40-17, 29 May 2008.

**3. Applicability.** This policy applies to all U.S. Army Medical Command (MEDCOM) and Dental Command (DENCOM) 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. Documentation of the surgical/procedural verification process is required using MEDCOM Form 741 (Universal Protocol: Procedure Verification Checklist) (see app B) or MEDCOM Form 741-1 (Non-OR Procedure Verification Checklist) (see app C) as described in paragraph 10.

(1) For documentation of the surgical/procedural verification process performed in the operating room, MEDCOM Form 741 is required (see app B and para 10a).

(2) Documentation of procedure verification process done outside of the operating room (for example, in a clinic) may be documented on MEDCOM Form 741 (app B) or MEDCOM Form 741-1 (app C and para 10b).

## **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) 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, MEDCOM Form 741 (app B) or MEDCOM Form 741-1 (app C) will be used to review and 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 surgeon 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 may mark the site as permitted by the military treatment facility (MTF), if present and actively involved in the procedure.

(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—

1. Sites shall be marked according to the Universal Protocol unless contraindicated.

2. 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—

1. Interventional procedures for which the insertion site is not predetermined, such as cardiac catheterization or central line placement; or,

2. The procedure will be performed on a midline structure or single organ; or,

3. The procedure is without intended laterality such as endoscopy, cystoscopy, colposcopy, or trans-nasal esophagoscopy; or

4. 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.)

(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:

1. When it is technically or anatomically impossible or impractical to mark the site (mucosal surfaces and perineum).

2. With premature infants.

3. 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 may use the alternative marking method as permitted by the MTF if the resident will be present and actively involved in the procedure.

(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 collocated 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. Team members include (but are not limited to) the operating provider, anesthesia provider, circulating nurse, and operating room technician. 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 (that is, the provider must be gowned and scrubbed).

(4) All members of the healthcare team have the responsibility to stop the procedure and request clarification if there is any question, difference, or discrepancy.

(5) 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 provider's initials are visible, and the correct side/site is marked or alternate marking method is used.

(d) The patient's position is appropriate for the planned procedure.

(e) Relevant images and test results are properly labeled and appropriately displayed.

(f) The required items are available (equipment, implants, blood products, and so forth).

(g) The need to administer antibiotics and/or fluids for irrigation purposes has been addressed.

(h) Safety precautions based on patient's history or medication use have been identified.

(6) Each team member is accountable for speaking up and working toward reconciling any discrepancy with the information exchanged during the Time-Out. If a discrepancy can not be reconciled, the procedure will be aborted and appropriate documentation completed.

## **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) All pre-procedural verifications must be completed and documented prior to performing the regional procedure Time-Out.

(3) All the operative site(s) must be marked prior to the placement of regional anesthesia.

(4) Regional anesthetic procedures require a second clinical verifier. Examples of a second verifier include but are not limited to another anesthesia provider, a registered nurse, an operating room technician, an anesthesia technician, or a pain technician.

(5) The Time-Out should be documented by a licensed staff member. This may be completed by a clinical non-licensed staff member only if normal and customary practice involves a non-licensed assistant.

(6) Regional anesthesia procedures followed by an operative procedure will follow the Universal Protocol - Procedure Verification process on page 2 of MEDCOM Form 741. A second clinical verifier is required during the regional procedure Time-Out.

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

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

(1) If a patient is undergoing concurrent or sequential surgeries during the same operative event, all surgeries must be listed MEDCOM Form 741 (app B). The second operating provider will document the pre-verification processes on page 2 of this form prior to the patient being transported to the procedural area.

(2) If the surgeries are concurrent, the Time-Outs will occur immediately one after the other with the second Time-Out documented on page 2 of MEDCOM Form 741 (app B) (for example, a trauma case with an orthopaedic team and an oral maxillo facial team).

(3) 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 (for example, a mastectomy followed by reconstructive surgery).

*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 documented on page 2 of MEDCOM Form 741 (app B).

## 10. Documentation

- a. MEDCOM Form 741 (app B) must be used in all operating room settings.
- b. Invasive procedures performed in the clinic and those not occurring in the operative area may use MEDCOM Form 741-1 (app C) for documentation. This form may be overprinted on the consent form, inserted into the electronic record, or duplicated as a stamp for non-electronic documents.
- c. Documentation of the Time-Out occurs as soon as possible after performing the Time-Out using one of the two forms 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.

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

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## **Appendix A References**

### **Section I Required Publications**

**AR 40-68**  
Clinical Quality Management

**DENCOM Policy 06-46**  
Correct Site Surgery

**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.

**Agency for Healthcare Research and Quality, Patient Safety Net, Glossary of Terms**

**American Association of Orthopedic Surgeons, Advisory Statement, Wrong-Site Surgery, On-Line Service**

**American Academy of Ophthalmology, Eliminating Wrong Site Surgery**

**American Academy of Orthopaedic Surgeons Advisory Statement**

**American Dental Association Recommendations to the Joint Commission on the Accreditation of Healthcare Organizations, Universal Protocol Frequently Asked Questions**

**American College of Surgeons: ACS Endorses Universal Protocol for Preventing Wrong-Site, Wrong-Procedure, Wrong-Person Surgery**

**Association of periOperative Nurses (AORN), Guidelines to Eliminate Wrong Site Surgery**

**AORN Correct Site Surgery Position Statement**

**Joint Commission on Accreditation of Healthcare Organizations, Sentinel Event Alert, Lessons Learned: Wrong Site Surgery**

**OTSG Memorandum, Mandatory Use of Full Patient Name and Date of Birth for Patient Identification**

**The Joint Commission Resources, Compliance Strategies for the Universal Protocol**

**The Joint Commission, National Patient Safety Goals**

**The World Health Organization, Implementation Manual WHO Surgical Safety Checklist**

**Wrong Site Surgery Summit, Chicago, IL**

**Section III  
Prescribed Forms**

**MEDCOM Form 741**  
Universal Protocol: Procedure Verification Checklist

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

**Section IV  
Referenced Forms**

**OF 522**  
Medical Record – Request for Administration of Anesthesia and Performance of Operations and Other Procedures.

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**Appendix B**  
**MEDCOM Form 741**

Appendix B contains the MEDCOM Form 741, Universal Protocol: Procedure Verification Checklist, beginning on the next page.

<b>MEDICAL RECORD - UNIVERSAL PROTOCOL: PROCEDURE VERIFICATION CHECKLIST</b> <small>For use of this form, see MEDCOM Reg 40-54; the proponent agency is MCHO-CL-Q</small>	
List of Procedure(s):	# of Consents: <span style="border: 1px solid black; display: inline-block; width: 20px; height: 15px;"></span>
<b>PRE-PROCEDURAL AREA</b> <small>With patient involvement (when possible) prior to pre-op medication administration</small>	
<b>Clinical Staff</b> I have verified ALL of the following: a) Patient's full name and birth date are consistent with consent(s). b) Consent is complete (including side/level/site), accurate and is signed and dated by provider, patient and witness. Additional procedure consents for this operative event are acknowledged.	<b>Clinical Staff Signature:</b>  Date: _____ Time: _____
<b>Operating Provider</b> List Procedure(s): I have verified ALL of the following: a) Patient identification, consent, H&P/progress note, relevant diagnostic and radiologic tests are accurate, readily available and properly labeled. b) I have marked at or near the procedural site with my initials (or used Alternate Marking Method). c) Required blood products, implants, devices and/or special equipment are available.	<b>Provider Signature:</b>  Date: _____ Time: _____
<b>Verifications Immediately Prior to Patient Transfers to Procedure Area (After above verifications have been completed)</b>	
<b>Circulating Nurse / Holding Area Nurse / Procedural Assistant</b> I have verified ALL of the following: a) Patient identification confirmed, consent(s), and H&P/progress note are consistent with plan of care. b) The provider's initials are visible at or near the procedural site(s) (or Alternate Marking Method is used) and consistent with the operative plan. c) Required implants, devices and/or special equipment are available.	<b>Nurse/Assistant Signature:</b>  Date: _____ Time: _____
<b>Anesthesia Provider</b> <input type="checkbox"/> <i>Not Applicable</i> I have verified ALL of the following: a) Patient identification confirmed with ID band; consent(s) and H&P/progress note are consistent with plan of care. b) The operating provider's initials are visible at or near the procedural site(s) (or Alternate Marking Method is used) and consistent with the operative plan. c) Required blood products and special equipment are available.	<b>Anesthesia Provider Signature:</b>  Date: _____ Time: _____
<b>PROCEDURAL AREA TIME-OUT</b>	
The operating provider led the operating team using interactive verbal communication and confirmed the following:	
a) Patient identification confirmed with the ID band; consent is consistent with planned procedure. b) Provider's initials are visible and the correct side/site is marked (or Alternate Marking Method is used). c) Patient's position is appropriate for the planned procedure. d) Required items are available (images, equipment, implants, blood products, etc.). e) The need to administer antibiotics or fluids for irrigation purposes has been addressed. f) Safety precautions based on patient history or medication use have been identified. g) Team agrees on procedure to be done. or <input type="checkbox"/> <b>Discrepancy noted and procedures aborted. Signature:</b>	<b>Licensed Staff Signature:</b>  Date: _____ Time: _____
<b>PATIENT'S IDENTIFICATION</b> (For typed or written entries give: Name - last, first, middle; grade; date; hospital or medical facility)	<b>Notes:</b>



**Appendix C**  
**MEDCOM Form 741-1**

Appendix C contains the MEDCOM Form 741-1, Universal Protocol: Non-OR Procedure Verification Checklist, beginning on the next page.

<b>UNIVERSAL PROTOCOL: NON-OR PROCEDURE VERIFICATION CHECKLIST</b> <small>For use of this form, see MEDCOM Reg 40-54; the proponent agency is MCHO-CL-Q</small> <b>Used for Procedures Performed Outside of the Operating Room</b>	
<div style="border: 1px solid black; padding: 10px; margin: 0 auto; width: 80%;"> <p style="text-align: center; margin: 0;"><b>Universal Protocol Checklist</b></p> <p><b><u>Pre-procedure verification</u></b> confirmed correct patient, procedure, consent, positioning, side/site, blood products and special equipment (as applicable).</p> <p><b><u>The procedure site was marked</u></b> (or used alternate marking method). Note: not required for obvious wound/lesion, midline, single organ procedures, procedures without intended laterality (e.g., endoscopes and colposcopies) or procedures in which there are no predetermined sites of insertion.</p> <p><b><u>A Time -Out was performed</u></b> immediately before the procedure noting the above as well as confirming the patient's position, relevant images and labs, antibiotics, fluids, and safety precautions IAW MEDCOM Reg 40-54.</p> <p><b>Team agrees on procedures to be done:</b></p> <p>By: <input style="width: 100%;" type="text"/></p> <p>And: <input style="width: 100%;" type="text"/></p> <p>Date/Time: <input style="width: 100%;" type="text"/></p> </div>	
<p>Instructions for completing the Non-OR Procedure Verification Checklist.                      Conducting the TIME-OUT prior to incision/procedure</p> <p><b><u>By:</u></b> Should be signed by the licensed team member who performed the TIME-OUT.</p> <p><b><u>And:</u></b> Should be the name(s) of at least one member of the team present that participated in the TIME-OUT.                      If there was no one else present mark "NONE".</p> <p><b><u>Date/Time:</u></b> The date and time the TIME-OUT occurred.</p>	
<p><b><i>PATIENT'S IDENTIFICATION</i></b> (For typed or written entries give: Name - last, first, middle, grade, date, hospital or medical facility)</p>	<p><b>Notes:</b></p>

## **Glossary**

### **Section I Abbreviations**

#### **AORN**

Association of periOperative Registered Nurses

#### **DENCOM**

U.S. Army Dental Command

#### **GME**

graduate medical education

#### **MEDCOM**

U.S. Army Medical Command

#### **MTF**

military treatment facility

#### **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.** An MTF 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 and civilian (GS and those working under contractual or similar arrangement) personnel granted privileges to diagnose, initiate, alter, or terminate healthcare treatment regimens within the scope of 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.

a. 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.

b. 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.

c. Wrong patient surgery/procedure. Any surgery or procedure that is performed on a patient who was not scheduled for that procedure.

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**The proponent of this publication is the Quality Management 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-CL-Q, 2050 Worth Road, Fort Sam Houston, TX 78234-6010.**

FOR THE COMMANDER:



HERBERT A. COLEY  
Chief of Staff

JOSE L. LOPEZ  
Colonel, MS  
Assistant Chief of Staff for  
Information Management

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