

**BY ORDER OF THE COMMANDER
59TH MEDICAL WING**

59TH MEDICAL WING INSTRUCTION 44-128

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Medical

**UNIVERSAL PROTOCOL: PROCEDURE
AND SURGICAL SITE VERIFICATION**

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This instruction implements Air Force Policy Directive 44-1, *Medical Operations*. This instruction establishes proactive, interdisciplinary guidelines directed to prevent wrong-site, wrong procedure, wrong patient surgery within the 59th Medical Wing (MDW). It applies to all operative and other invasive procedures, outpatient, including procedures done in settings other than the operating room such as a special procedures area, the Urgent Care Clinic, endoscopy clinic, or interventional radiology. This facility has set a goal of zero-tolerance for surgeries on the wrong site, on the wrong person, or the performance of the wrong surgical procedure. This instruction does not apply to the 359th Medical Group and 959th Medical Group. This instruction does not apply to the Air National Guard or Air Force Reserve. The authority to waive requirements is the publication approval authority. Refer recommended changes and questions about this publication to the Office of Primary Responsibility using the AF Form 847, *Recommendation for Change of Publication*. This publication requires the collection and maintenance of information protected by the Privacy Act of 1974 authorized by 10 U.S.C. 55, *Medical and Dental Care*, and E.O. 9397 (SSN). The applicable SORN F044 AF SG D, and Automated Medical/Dental Record System is available at: <http://dpclo.defense.gov/privacy/SORNs/SORNs.htm>. Ensure that all records created as a result of processes prescribed in this publication are maintained in accordance with (IAW) Air Force Manual 33-363, *Management of Records*, and disposed of IAW Air Force Records Information Management System Records Disposition Schedule.

SUMMARY OF CHANGES

This document has been substantially revised and must be completely reviewed. Major changes include: updated references and removed spinal surgery marking procedural site.

1. Overview.

1.1. The purpose of this instruction is to describe the process for procedure/site verification in all settings where procedures are performed to ensure the correct patient has the correct procedure at the correct site. The Universal Protocol applies to all surgical and non-surgical invasive procedures including procedures done in settings other than the operating room (OR) such as a clinic, special procedures unit, endoscopy unit, or interventional radiology.

2. Goal.

2.1. To ensure the correct patient is getting the correct procedure at the correct procedure site.

3. Scope.

3.1. This instruction provides the necessary guidance for a pre-procedure/preoperative verification process, a process to mark surgical/invasive procedure sites and a process by which to perform a final verification or “time-out” to confirm the correct patient, procedure and site prior to the beginning of any operative/invasive procedure.

3.2. There is no specified period between steps; if a step required by this instruction has not been performed, the next step must be delayed until the previous step has been completed. In rare cases where the steps are not all followed, the justification for the deviations must be documented in the notes section of the used form (see paragraph 3.4.) or in a progress note if the space is not sufficient. The final time-out, however, must be conducted *immediately* before starting the invasive procedure or making the incision.

3.3. Routine minor procedures such as venipuncture, peripheral intravenous line placement, insertion of nasogastric tube, or Foley catheter insertion are not within the scope of this instruction.

3.4. The 59 MDW Form 97, *Universal Protocol: Procedure Verification Record* will be used for all applicable procedures in the OR. The 59 MDW Form 123, *Universal Protocol: Non-OR Procedure Verification Record* will be used for all procedures outside of the OR; with the exception of procedures requiring conscious sedation and those performed in the Dental Clinics and other clinics which already have an equivalent documentation process for timeouts. Procedures requiring conscious sedation will use 59 MDW Form 35, *Procedural Sedation Record* instead of 59 MDW Form 123.

4. General.

4.1. Wrong-person, wrong-site, and wrong-procedure surgery can and must be prevented.

4.2. Each member of the procedural team is essential to this process. Any member of the team may question the decision of any other member of the team, at any time, regarding the surgical/procedural site, the type of procedure to be performed or the identity of the patient.

4.3. If the patient/guardian cannot participate in the verification process, but the consent matches the pre-operative progress note or history and physical (H&P), then the verification process can be accomplished by two qualified health care providers.

4.4. Inconsistencies will be reported immediately to the involved provider and corrective actions taken before the procedure continues. All discrepancies will be resolved prior to progressing to the next verification process. All discrepancies and their resolution will be reported via the web based Department of Defense (DoD) Patient Safety Reporting (PSR) application which can be accessed via the 59 MDW SharePoint or a desktop PSR Outlook icon.

4.5. Surgeries/procedures that require multiple procedures on different sites by different staff to be performed on the same patient during one encounter will follow each of the verification steps for each of the procedures/surgeries; e.g., a patient having knee surgery and a cholecystectomy will undergo a pre-op site marking and final verification by a member of each surgical/procedure team performing a procedure on a different part of the body. The 59 MDW Form 97 has two surgeon site verification areas and two time-out sections for this occurrence. If additional procedures by additional teams are required, supplemental 59 MDW Form 97 may be used, filling out the additional areas as needed. Multiple procedures by the same staff in succession do not require multiple time-outs or verifications; all appropriate site markings should be visible at the time of the time-out.

4.6. All personnel will ensure that x-rays are properly marked with the correct patient name and date of birth and that all references to the pertinent sites are correctly and clearly indicated in the patient's records. Procedures for ensuring correct site radiographic films are addressed in radiology flight operating instructions.

4.7. For all parts of this instruction indicating verification of correct patient, 59 Medical Wing Instruction (MDWI) 44-165, *Patient Identification*, will be followed using the two patient identifiers as indicated, the patient's full name (including suffix, Jr, Sr, III, etc) and date of birth as the standard for non-emergency events. For any questions about patient identification, use 59MDWI 44-165 as a reference.

4.8. 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.

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

4.8.1.1. At the time the procedure is scheduled.

4.8.1.2. At the time of pre-admission testing and assessment.

4.8.1.3. Upon admission or entry into the facility.

4.8.1.4. Any time a caregiver transfers responsibility of the patient to another clinical staff member.

4.8.1.5. Before the patient leaves the preoperative area or enters the operating/procedural room.

4.8.1.6. Immediately before the provider begins the procedure, as part of the time-out.

5. Pre-Procedure Verification or First Verification for OR procedure verification, 59 MDW Form 97. The intent of this process is to verify that all appropriate documents pertinent to the procedure are available and consistent.

5.1. Each area that performs invasive procedures is responsible for performing and documenting a pre-procedure verification that will include, at a minimum, the following items:

5.1.1. Verification of the correct person, procedure site and side (if applicable) must occur with the patient involved, awake and aware, if possible or using a parent or guardian (as applicable) by licensed personnel. Have the patient point to the site and state the expected procedure.

5.1.2. Use 59 MDW Form 1202, *Disclosure and Consent-Medical and Surgical Procedures*, for all procedures where written consent is indicated. If the provider or procedure has changed from the original consent, a new 59 MDW Form 1202 will be completed. The surgery site/level/side will be written on the consent form by the operating provider, it will be signed and dated by the provider, the patient and witnessed. The witness must not be a part of the procedure team, IAW 59MDWI 51-302, *Informed Consent Refusal of Treatment, Diagnostics and Blood or Blood Products*.

5.1.3. Ensure that the informed consent note is documented and placed in the patient's medical record in accordance with IAW 59MDWI 51-302.

5.1.4. Service appropriate history and physical must be accomplished and will include the diagnosis and procedure to be accomplished which will be consistent with the surgical/procedure consent. Any "add-on" procedure or surgery requires a new consult from the requesting service to the operating service. This consult may be electronic. A new 59 MDW Form 1202 will be accomplished IAW 59MDWI 51-302.

5.1.5. All necessary medical information will be available to include x-rays and lab results. With the exception of emergent procedures, radiology films used to determine the site of a procedure, i.e. which lung, can only be utilized after a radiologist has read them.

5.1.6. Documentation. In cases performed in the OR (excluding those performed under conscious sedation) the staff member who verifies the above processes are complete will sign, date and time the first row of the 59 MDW Form 97 in the '1st verification' section. Procedures performed under conscious sedation will have the time-out procedure documented on 59 MDW Form 35.

5.2. Verification/Documentation Exception. If the patient/parent/guardian is unable to state/point to the surgical/procedural site for any reason, enter "not able to confirm with patient" in the margin to the right of the first block of the '1st verification' section' and affix your signature with a date and time and proceed to the second verification. Document the issue with patient confirmation in the lower right corner of the 59 MDW Form 97 and state whether the H&P and/or progress notes and consent match intent for the indicated procedure.

6. Second Verification OR procedure verification 59 MDW Form 97 or Marking of Site.

6.1. Marking the Operative/Procedural Site.

6.1.1. Each area performing the procedures will establish a process to accomplish, at a minimum, the following. Prior to the administration of pre-operative or pre-procedural medication such as sedatives, hypnotics or anesthetic drugs, a licensed independent practitioner (LIP) who will be performing the procedure (or designated resident) will place his/her initials on or adjacent to the site. In cases where the patient will be moved to another procedure area (such as in the OR) the site marking must be done prior to moving the patient to the procedure area. In the instance when a patient cannot participate (and a guardian is not available) document the issue with patient confirmation in the lower right corner of the 59 MDW Form 97 and state whether the H&P and/or progress notes and consent match intent for the indicated procedure.

6.1.2. A skin marker will be used; the mark is made at or near the procedure site and is sufficiently permanent to be visible after skin preparation and draping. The mark should not be covered up by any drapes that may be applied at the time of the procedure unless the drape material is transparent.

6.1.3. There is no evidence that markers transmit disease from one patient to another as long as there is intact skin. If the patient has a known contagion, dispose of the marker after used. With a patient with broken skin which cannot be avoided and a site marking is required, use a fresh marker or the alternate armband method used for patient refusal.

6.1.4. Do not mark any non-operative sites unless necessary for some other aspect of care (such as to warn against using a particular extremity for venous access because of a prior surgical procedure). The mark for this facility is the signer's initials. **Note:** If the operating LIP/designated resident's initials are "N.O.", utilize three initials.

6.1.5. Marking the site is required for procedures involving right/left distinction, multiple structures (such as fingers and toes), or levels (as in spinal procedures) to identify the intended site of incision or insertion.

6.1.6. Procedures done through a mid-line incision or port which are intended to treat a paired organ, that is "right" or "left", must have a site mark indicating the side. This mark, as for other site marks, must be positioned to be visible after the patient is prepped and draped unless it is technically or anatomically impossible or impractical to do so.

6.2. Exemptions from Site Marking.

6.2.1. Procedures/interventions at/near a natural body orifice (e.g., GI endoscopy, tonsillectomy, hemorrhoidectomy, or procedures on the genitalia) and other situations in which marking the site would be impossible or technically impractical do not need a site marking.

6.2.2. Site marking is not required (nor is it prohibited) for cases such as midline sternotomy, and other interventional procedures that the site of incision is not pre-determined.

6.2.3. Obvious surgical sites do not require marking. Site marking is not required if there is an obvious wound or lesion that is the site of the intended procedure (e.g., removal of external fixator). If there are multiple wounds or lesions and only some are to be treated, the specific site markings are required before the start of the procedure.

6.3. Dental/Oral Surgery Procedures. There does not appear to be a practical or reliable method to actually mark surgical sites or teeth to be extracted or restored. Therefore, dental procedures will be considered exempt from the site-marking requirement (as are other procedures done through or immediately adjacent to a natural body orifice) on the tooth/tissue. Dental Group personnel involved with orofacial surgery, extraction or restoration of teeth will follow Air Force Medical Service Dental Clinical Practice Guidelines and local operating instructions discussing correct-patient/correct-site procedures in our efforts to ensure safe site surgery.

6.4. For Ophthalmologic procedures; the surgeon will initial the patient's skin adjacent to the surgical eye.

6.5. Alternate Marking Method. For use when patients refuse site marking or when it is technically or anatomically impossible or impractical to mark the site.

6.5.1. 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 graduate medical education programs may use the alternative marking method if the resident will be present and actively involved in the procedure.

6.5.2. The operating provider will place the procedure identification band on the patient (typically on the patient's wrist). For patients who are not candidates for the procedure identification band placement on their body (for example, missing limbs), the band will be collocated with the patient during the pre-procedure verification and the time-out.

6.5.3. The operating provider will annotate alternative marking use in the notes section of the 59 MDW Form 97 located on the lower right corner of the page.

6.6. For OR procedures, after the LIP (or designated resident) has verified the procedure and appropriately marked the surgical site with the non-sedated patient or guardian participation, they will sign the 59 MDW Form 97 in the Operating Provider signature block with the date and time.

6.7. The perioperative nurse/licensed staff member will verify: patient identification, presence of H&P which corresponds with consent and availability of blood products, implants, devices or equipment needed for the procedure prior to the administration of pre-operative or pre-procedural medication such as sedatives, hypnotics or anesthetic drugs. This will be documented on the 59 MDW Form 97 in the Perioperative Registered Nurse (RN) signature block with the date and time.

6.8. Anesthesia Provider. Prior to administration of pre-operative or pre-procedural medication such as sedatives, hypnotics or anesthetic drugs, the anesthesia provider will verify: patient identification, presence of H&P which corresponds with consent, availability of blood products, presence of pertinent tests, and appropriate marking of the site and verification by the LIP (or designated resident). This will be documented on the 59 MDW Form 97, in the 2nd verification section Anesthesia Provider Signature block section with the date and time.

7. Third Verification for 59MDW Form 97 and/or Final Time-Out.

7.1. The time-out is required for all invasive procedures and must be completed by the operating or procedural team immediately prior to the incision, insertion, or start of the procedure. This generally occurs after the prep and drape, in most cases.

7.2. In cases when a local anesthetic is injected for block or surgical purposes prior to prepping and draping, a verification of patient identity, procedure and site verification will occur before the injection. This pause will not count as the final time-out unless at least one surgeon is already scrubbed in, and does not leave the room before the start of the procedure.

7.3. The time-out is consistently led by the designated member who is the operating provider and involves the entire team but may be initiated by any member of the team at the appropriate time. It is done using active verbal communication conducted in a "fail-safe" mode, i.e., the procedure is not started until any questions or concerns are resolved. All team members must be actively engaged in the time-out and all other activity is stopped. Team members include (but are not limited to) the operating provider, anesthesia provider, circulating nurse, and the operating room technician. 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 in the OR).

7.4. The time-out confirms that: the correct patient is in place, the correct procedure and site verified by the consent is the plan and team members agree on the planned procedure.

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

7.6. Once all team members are in complete agreement that all elements of the time-out are complete, the surgical scrub technician will hand the knife blade or initiating instrument to the operating LIP (or designated resident).

7.7. Documentation. In the OR the perioperative nurse/licensed staff member will document completion of the third site verification process/final time-out on the 59 MDW Form 97, by signing, dating, and timing the Licensed Staff (or designated resident) signature block in the 3rd verification section. The nurse is ensuring that all prescribed processes have been completed and verified.

7.8. Regional Anesthesia Procedure Verification.

7.8.1. Regional anesthesia procedures performed in conjunction with other procedures are subject to the following:

7.8.1.1. Regional anesthetic procedures require a procedure verification process and time-out separate from the operative verification process.

7.8.1.2. The perioperative nursing and anesthesia pre-procedural verifications must be completed and documented prior to performing the regional procedure time-out. In the instance when the site marking and verification by the surgical provider has not yet occurred, the anesthesia provider performing the block will initial the block site with patient participation before the patient has sedation and is moved to the block location.

7.8.1.3. 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.

7.8.2. The regional time-out should be documented by a licensed staff member (or designated resident). This may be completed by a clinical non-licensed staff member only if normal and customary practice involves a non-licensed assistant. Regional procedures followed by an operative procedure will be documented in the Regional Anesthesia Procedure Verification Process section of the 59 MDW Form 97. Regional anesthesia procedures performed on patients not going to the OR may be documented on 59 MDW Form 97.

7.9. Emergency Procedures. The overarching goal is patient safety; therefore no precautions should interfere with the timely care of the patient in an emergency situation. During emergencies, marking the site may not be necessary, although the “time-out” to verify the correct patient, procedure, and site would still be appropriate (unless it was such an emergency that even the time-out would add more risk than benefit).

8. 59 MDW Form 123, *Universal Protocol: Non-OR Procedure Verification Record.*

8.1. For procedures outside of the operating room, the time-out is required for all invasive procedures and must be completed by the operating provider immediately prior to the incision, insertion, or start of the procedure except in an emergency/resuscitation situation. For procedures in which a written consent is accomplished, time-out documentation will be accomplished either on 59 MDW Form 35 (if performed under conscious sedation), or on 59 MDW Form 123 for all other invasive procedures in clinics which don't already have their own unique process for time-outs such as the dental (SF 603/603a, *Health Record—Dental*) and dermatology clinics. For procedures in which verbal consent is deemed appropriate, time-out verification should be documented in the Armed Forces Health Longitudinal Technology Application procedure note.

8.2. 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 usually performed by a sole provider. The operating provider must remain in the procedure room between the time-out and the start of the procedure.

8.3. Site marking is not required when the individual doing the procedure is continuously with the patient from the time of the decision to do the procedure through to the performance of the procedure. If the person performing the procedure leaves the presence of the patient for any amount of time during that interval, then the site should be marked before leaving the patient.

8.4. Procedures/interventions at/near a natural body orifice (e.g., endoscopy, tonsillectomy, hemorrhoidectomy, or procedures on the genitalia) and other situations in which marking the site would be impossible or technically impractical do not need a site marking.

8.5. Site marking is not required (nor is it prohibited) for interventional procedures that the site of incision is not pre-determined.

9. Discovery that a Wrong-Site Surgery has occurred.

9.1. In all situations of wrong-site surgery the staff surgeon should notify Risk Management at 292-6004 or Wilford Hall Ambulatory Surgical Center pager 594-1116 and the chain of

command. An actual wrong site surgical procedure should be reported immediately but no later than 24 hours after the event to the Risk Management Office. If possible, consult with Risk Management prior to discussing the issue with the patient/family. Disclosure of information will be done in accordance with 59MDWI 44-130, *Patient Safety Program*. The surgeon will document the facts of the event in the progress note to include a course of action and the patient's stated wishes. This event will be reported via the web based DoD PSR application which can be accessed via the 59 MDW SharePoint or a desktop PSR Outlook icon.

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Attachment 1

GLOSSARY OF REFERENCES AND SUPPORTING INFORMATION

References

AFPD 44-1, *Medical Operations*, 1 September 1999

59MDWI 44-130, *Patient Safety Program*, 16 July 2013

59MDWI 44-165, *Patient Identification*, 14 November 2011

59MDWI 51-302, *Informed Consent/Refusal of Treatment, Diagnosis and Blood or Blood Products*, 12 March 2010

DoD 6025.18-R, *DoD Health Information Privacy Regulation*, 24 January 2003

Accreditation Association for Ambulatory Health Care (AAAHC) *Accreditation Handbook* (current issue)

The Joint Commission *Patient Safety Goals* Current Year

Prescribed Forms

59 MDW Form 97, *Universal Protocol: Procedure Verification Record*

59 MDW Form 123, *Universal Protocol: Non-OR Procedure Verification Record*

Adopted Forms

SF 603/603A, *Health Record—Dental*

AF Form 847, *Recommendation for Change of Publication*

59 MDW Form 1202, *Disclosure and Consent—Medical and Surgical Procedures*

59 MDW Form 35, *Procedural Sedation Record*

Abbreviations and Acronyms

DoD—Department of Defense

H&P—History and Physical

IAW—In Accordance With

ICU—Intensive Care Unit

LIP—Licensed Independent Practitioner

MDW—Medical Wing

MDWI—Medical Wing Instruction

OR—Operating Room

PACU—Post-Anesthesia Care Unit

PSR—Patient Safety Reporting

RCA—Root Cause Analysis

RN—Registered Nurse

Terms

Active Communication—Means an affirmation, orally that the patient, procedure, and site are correct. The members of the team will signal their agreement by a brief oral acknowledgement. Absence of a response should not be interpreted as agreement. It is not mandatory for the patient to participate in the final verification process although it may occur.

Correct Site—A procedure or surgery upon an organ or body part where the approach is specific to a particular location of the body.

Discrepancy—Variance in the planned procedure.

Invasive Procedure—Any procedure exposing patient to more than minimal risk. Includes, but not limited to, surgical entry, puncture or insertion of an instrument or foreign material into tissues, cavities or organs.

Laterality—Any anatomical structure that occurs on both sides of the body, both internally and externally identified as “right”, “left”, “bilateral”, or “midline”.

Level—Any anatomical structures that include multiples linearly (e.g. spinal vertebrae, ribs).

Licensed Independent Practitioner—Any physician, dentist or allied health provider (audiologists, dieticians, nurse anesthetists, nurse mid-wives, nurse practitioners, occupational therapists, optometrists, pharmacists, physician assistants, physical therapists, psychologists, social workers, and speech pathologists) permitted by law and by the organization to provide care and services, without direct supervision, within the scope of the individual’s license/certification and consistent with individually granted clinical privileges.

Licensed Staff Member—An example would include the DDS, MD, or RN.

Near Miss—Any process variation or error or other circumstance that could have resulted in harm to a patient but through chance or timely intervention did not reach the patient or did not harm the patient. Such events or circumstances have also been referred to as “close calls.” Examples include a procedure almost being done on the wrong patient but being “caught” before patient injury; a medication almost given to the wrong patient/wrong route/wrong dose, etc, but being “caught” before reaching the patient.

Patient Involvement in Marking the Procedure/Surgical Site—Every effort will be made to mark the surgical/procedure site with the patient’s involvement, prior to the patient receiving pre-procedure sedation. If the patient cannot be involved due to sedation, metabolic or physiologic processes, the provider will mark the intended site in accordance with this policy.

Procedure—A diagnostic or therapeutic intervention.

Procedural Area—An operating room, cardiac/angiographic catheterization or interventional suite, gastroenterology suite, radiation or nuclear medicine area, treatment or procedure room, patient room, emergency room, and any other location where procedures may occur.

Verification—A process that involves validating consistency between various sources, such as the information contained on the consent form, diagnostic study reports, the preoperative checklist, the marked anatomical site and the response of the patient and /or guardian.

Wrong—Site Surgery—Any surgery or invasive procedure that is performed on a site that was not the originally anticipated or intended site, or performed on a patient for whom that procedure was not intended. Categories of “wrong-site surgery” include wrong-side surgery, wrong-level/part surgery, and wrong patient.