

ENSURING CORRECT SURGERY AND INVASIVE PROCEDURES

1. REASON FOR ISSUE. This Veterans Health Administration (VHA) Directive provides specific policy on what steps must be taken to ensure that all surgery and invasive procedures performed in the clinical setting are performed on the correct patient, at the correct site, and if applicable, with the correct implant. **AUTHORITY:** 38 U.S.C. 1710, 7301(b) and 7331.

2. SUMMARY OF CHANGES. This VHA Directive defines the policy for steps to be taken to ensure that all surgery and invasive procedures in the clinical setting are performed on the correct patient, at the correct site, and with the correct implant. Revisions have been made to the existing Directive to:

a. Emphasize that this policy applies to invasive procedures both in and outside of the operating room,

b. Update the policy to include the process for ensuring correct surgery in ophthalmologic intraocular lens implants, and

c. Reinforce the policy that only documents for the current patient are present in the operating room or procedure room at the time of the procedure.

3. RELATED ISSUES. None.

4. RESPONSIBLE OFFICE. The National Surgery Office (10NC2) is responsible for the contents of this Directive. Questions may be referred to the National Director of Surgery at (202)-461-7148.

5. RESCISSIONS. VHA Directive 2010-023, Ensuring Correct Surgery and Invasive Procedures, is rescinded.

6. RECERTIFICATION. This VHA Directive is scheduled for recertification on or before the last working day of July 2018.

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ENSURING CORRECT SURGERY AND INVASIVE PROCEDURES

1. PURPOSE: This Veterans Health Administration (VHA) Directive provides policy on the specific steps that must be taken to ensure all surgery and invasive procedures performed in the clinical setting are performed on the correct patient, at the correct site, and if applicable, with the correct implant. *NOTE: This policy applies to invasive procedures both in and outside of the operating room, but does not apply to venipuncture or intravenous therapy in any setting.*

AUTHORITY: 38 U.S.C. 1710, 7301(b) and 7331.

2. BACKGROUND

a. Wrong site, wrong patient, and wrong implant procedures are uncommon adverse events in health care, but have the potential to be devastating when they occur. Specifically, this Directive provides policy regarding the steps that must be taken when invasive procedures are performed in the clinical setting.

b. In addition to surgical procedures, specific examples of invasive procedures to which this Directive applies include:

- (1) Injections of any substance into a joint space or body cavity;
- (2) Percutaneous aspiration of body fluids through the skin (e.g., arthrocentesis, bone marrow aspiration, lumbar puncture, paracentesis, thoracentesis, suprapubic catheterization);
- (3) Biopsy (e.g., breast, liver, muscle, kidney, genitourinary, prostate, bladder, vulva, skin);
- (4) Cardiac procedures (e.g., cardiac catheterization, cardiac pacemaker implantation, angioplasty, stent implantation, intra-aortic balloon catheter insertion);
- (5) Central vascular access device insertion (e.g., Swan-Ganz catheter, percutaneous intravascular catheter line, Hickman catheter);
- (6) Electrocautery or laser ablation of skin lesion;
- (7) Endoscopy (e.g., colonoscopy, bronchoscopy, esophagogastric endoscopy, cystoscopy, percutaneous endoscopic gastrostomy, J-tube placements, and nephrostomy tube placements);
- (8) Laparoscopic surgical procedures (e.g., laparoscopic cholecystectomy, laparoscopic nephrectomy, laparoscopic oophorectomy);
- (9) Invasive radiology procedures (e.g., angiography, angioplasty, percutaneous biopsy);
- (10) Laser therapy (e.g., eye, gynecology, and ear, nose, and throat);
- (11) Dermatology procedures (biopsy, excision and deep cryotherapy for malignant lesions - excluding cryotherapy for benign lesions);

(12) Invasive ophthalmic procedures, including miscellaneous procedures involving implants;

(13) Oral surgical procedures, including tooth extraction and gingival biopsy;

(14) Podiatric invasive procedures (removal of ingrown toenail, etc.);

(15) Regional nerve block (e.g., for pain control, surgical procedure);

(16) Skin or wound debridement performed in an operating room; and

(17) Gynecology procedures (colposcopy with biopsy, cervical cone biopsy, cervical cryoablation, endometrial biopsy, hysteroscopy diagnostic or operative, dilatation and curettage, hysterosalpingogram).

NOTE: Procedures similar in scope to those listed in the preceding must be considered invasive procedures and are subject to the requirements of this Directive.

b. **Definition of Surgical or Other Invasive Procedures.** Surgical or other invasive procedures are those involving a skin incision or puncture, including, but not limited to: open surgical procedures, percutaneous aspiration, selected injections, biopsy, percutaneous cardiac and vascular diagnostic or interventional procedures, laparoscopies, and endoscopies.

3. POLICY: It is VHA policy that any VHA health care provider performing a surgery or invasive procedure must complete the five specific steps set forth in this Directive to ensure that the procedure is performed on the correct patient, at the correct site, and, if applicable, with the correct implant.

4. RESPONSIBILITIES

a. **National Director of Surgery.** The National Director of Surgery is responsible for monitoring VHA Surgical Programs for the occurrence of wrong site, wrong patient, and wrong implant procedures.

b. **Facility Director.** The facility Director must ensure that:

(1) The health care provider performing a surgery or invasive procedure completes specific steps to ensure that the procedure is performed on the correct patient, at the correct site, and, if applicable, with the correct implant. The five steps for ensuring correct surgery and invasive procedures are performed in the clinical setting. *NOTE: The clinical setting includes, but is not limited to, the: operating room, interventional suite, intensive care unit, patient room, or outpatient clinic.* The five steps are:

(a) **The Consent Process is Administered and Informed Consent Obtained for the Appropriate Procedure.** A valid consent form must be obtained in writing, after the patient has been informed of the procedures and in language that the patient can understand. The form must include identification of the procedure site, including laterality if applicable; the name and brief

description of the procedure; and the reason (condition or diagnosis) for performing the procedure. **NOTE:** For details regarding the informed consent process, see VHA Handbook 1004.01 and VHA Handbook 1004.05.

(b) The Operative Site is Marked. The site is marked to clearly indicate the procedure site; this needs to be done with the involvement of the patient, whenever possible. Indicating the site with appropriate precision must be the primary consideration when placing the mark and the mark must be unambiguous. The operative site mark must be applied by one of the following individuals:

1. The physician provider scheduled to perform the operation or invasive procedure;
2. A member of the operating team assigned to be present in the operating room or procedure room during the procedure, and appropriately privileged or practicing on a qualifying scope of practice; or
3. The anesthesia provider assigned to be present in the operating room or procedure room during the procedure.
 - a. The operative site must be marked prior to the anesthesia provider proceeding with performance of a regional nerve block.
 - b. When the operative site mark is applied by the anesthesia provider, the anesthesia provider must review the site mark with another member of the operating team prior to the patient entering the operating room or procedure room.

(c) The Patient and Procedure Site is Identified Using a Standardized Approach. This approach is as follows:

1. The staff must ask the patient to verbally state (not confirm) the patient name, location of the procedure on the patient's body, and a facility-approved unique identifier.
2. The process of patient identification must occur twice; at the time the operative site is marked; and again in the immediate environment outside the procedure room where the patient is again identified and the presence of the mark at the operative site is confirmed.
3. Once the second identification process is performed, the staff member who has performed the identification must stay with the patient until the patient is in the procedure room. **NOTE:** The reliability of the second identification process is enhanced by assigning one category of team member (e.g., circulating nurse or anesthesia provider) to always perform this function in each clinical setting (e.g., operating room or catheterization laboratory).

(d) All Pertinent Medical Images are Reviewed by Two Members of the Procedure Team Prior to Commencing the Operation or Invasive Procedure to Verify that the Images are Available, Properly Labeled, and Properly Presented. The physician performing the procedure bears the primary responsibility for image verification. The role of the second check is

performed by another member of the team is to confirm the process and therefore, can be performed by a non-physician.

(e) A Time-out Must be Facilitated by a Checklist and Occur Immediately Prior to the Start of the Procedure. The participants of the time-out must include the privileged provider performing the procedure, a member of the participating nursing staff, and a member of the participating anesthesia staff, if an anesthesia provider is participating in the procedure. The team members must concur verbally to each item on the checklist and the time-out must be documented in the patient's electronic health record. The checklist must include, but not be limited to the following relevant information:

1. Correct patient identity;
2. Procedure to be performed;
3. Site of the procedure, including laterality if applicable;
4. Valid consent form, containing information consistent with preceding subparagraph 4b(1)(a);
5. Patient position;
6. Procedure site has been marked appropriately and that the site of the mark is visible after prep and draping;
7. Pertinent medical images have been confirmed, if applicable;
8. Correct medical implant(s) is available, if applicable;
9. Appropriate antibiotic prophylaxis;
10. Appropriate deep vein thrombosis prophylaxis;
11. Blood availability, if applicable; and
12. Availability of special equipment, if applicable.

(2) Except when clinically necessary, the patient must not be sedated or anesthetized until the three steps found in subpars. 4b(1)(a), 4b(1)(b), and 4b(1)(c) have been completed so that the patient can actively participate. The patient is not expected to participate in the time-out briefing if sedated or unconscious.

(3) An additional step is performed immediately prior to the implantation of the medical device. The privileged provider performing the procedure must confirm the correct implant with a team member, including a "read-back" of all relevant information. Documentation of the correct medical implant must be placed in the health record.

(4) The following special conditions and circumstances of the five steps are modified, if needed, to ensure correct surgery and invasive procedures:

(a) Emergency Procedures. For emergency procedures the five steps to ensure correct surgery and invasive procedures must be applied to the extent possible. The justification for the decision to deviate from any of the five steps must be documented in the health record.

(b) Patients that Refuse to Have the Surgical Site Marked. A special-purpose wristband can substitute for a marked site for patients that refuse to have a surgical site marked. The wristband must be affixed by the practitioner; who will perform the procedure, or be initialed by the practitioner after being affixed by another member of the team, and must identify the patient and the procedure, the anatomic site of the procedure, and laterality, if applicable. The wristband must be visible when the time-out occurs.

(c) When Marking the Procedure Site is Problematic (for Example, Endoscopy or Procedures on the Perineum). In those instances when marking the site is deemed to be inappropriate, a special purpose wrist band must be used as a substitute for a marked site. The wristband must be affixed by the practitioner; who will perform the procedure, or be initialed by the practitioner after being affixed by another member of the team, and must identify the patient and the procedure, the anatomic site of the procedure, and laterality, if applicable. The wristband must be visible when the time-out occurs.

(d) For Spine Surgery when Marking the Operative Site is Inadequate to Indicate the Appropriate Vertebral Body or Inter-vertebral Space for the Procedure. In spinal surgery, when marking the operative site is inadequate to indicate the appropriate vertebral body or inter-vertebral space, the five steps to ensure correct surgery and invasive procedures must include the additional steps as follows:

1. The surgeon must place a fixed spine marker and take an intra-operative radiograph to confirm the position of the spine marker with another member of the procedure team before continuation of the procedure.

2. The attending (supervising) surgeon must be present for the marking of the spine and confirmation that the correct spine level has been identified and marked if performed by the resident surgeon (see VHA Handbook 1400.1). **NOTE:** *These steps are consistent with guidance from the American Academy of Orthopedic Surgeons (AAOS) and the North American Spine Society (see <http://www.aaos.org/about/papers/advistmt/1015.asp>).*

3. Confirmation that the correct spine level has been identified and marked must be documented in the patient's electronic health record.

(e) When the Invasive Procedure is Performed Outside the Operating Room by a Single Practitioner. The practitioner must conduct, with a staff nurse, associate health care staff or another member of the medical staff, the five steps to ensure correct surgery and invasive procedures. In this situation, the second individual who confirms the pertinent medical images (see subpar. 4b(1)(d)), need not be involved in the procedure and the confirmation process may occur outside the presence of the patient. When the invasive procedure immediately follows the

consent process and is performed outside the operating room, the requirement to mark the site or apply a special purpose wrist band is waived when consent and invasive procedure are performed by the same practitioner.

(f) For Ophthalmologic Intraocular Lens Implant Procedures. In ophthalmologic intraocular lens implant procedures, the five steps to ensure correct surgery and invasive procedures must include the following additional steps:

1. All pre-procedure measurements, calculations, desired post-operative refraction, and selected lens implant style and power using original source data are reviewed by two members of the Procedure Team prior to commencing the intraocular lens implant procedure. The physician performing the procedure bears the primary responsibility for verification of this information. The role of the second check by another member of the team is to confirm the process and therefore can be performed by a non-physician.

2. The time-out and checklist must include confirmation of the pre-procedure measurements, calculations, desired post-operative refraction, and selected lens implant style, power, and expiration date.

3. The immediate intra-operative pre-implant “read-back” must include intraocular lens implant style, power and expiration date. *NOTE: These steps are consistent with guidance from the American Academy of Ophthalmology (see Recommendations of the AAO Wrong-Site Task Force, available at http://one.aao.org/ce/practiceguidelines/patient_content.aspx?cid=d0db838c-2847-4535-baca-aebab3011217).*

(5) Only documents (paper charting, labels, specimen containers, etc.) for the current patient are present in the operating room or procedure room at the time of the procedure.

(6) With the exception of a surgical or medical emergency, any action required by this Directive found not to have been accomplished delays the performance of the procedure until the discrepancy is corrected.

(7) There is appropriate documentation of the five steps in the patient’s electronic health record.

5. REFERENCES

a. VHA Handbook 1004.01. Available at: <http://www1.va.gov/vhapublications>.

b. The Joint Commission Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery. Available at: http://www.jointcommission.org/standards_information/up.aspx

c. The Joint Commission 2012 and 2013 National Patient Safety Goals. Available at: http://www.jointcommission.org/standards_information/npsgs.aspx