

ENSURING CORRECT SURGERY AND INVASIVE PROCEDURES IN AND OUT OF THE OPERATING ROOM

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive provides the policy on what steps must be taken to ensure that all surgery and invasive procedures performed in and out of the operating room are performed on the correct patient, at the correct site, and, if applicable, with the correct implant.

2. SUMMARY OF CHANGES:

a. Amendment dated December 23, 2019, replaces the non-accredited TMS training number with the accredited TMS training number (see paragraphs 6 and 8).

b. This VHA directive clarifies the procedure for ensuring correct surgery and invasive procedures both in the operating room (OR) and outside of the OR setting. The changes focus on ensuring provider staff understands their responsibilities to follow procedure established by this policy when performing an invasive procedure in a clinic, procedure room, Intensive Care Unit, Emergency Department, or any clinical setting outside the OR. For the purpose of this directive, the Interventional Radiology (IR) Suite and the Interventional Cardiology Suite (Cath Lab) are considered an OR.

3. RELATED ISSUES: VHA Directive 1026, VHA Enterprise Framework for Quality, Safety, and Value, dated August 2, 2013, VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, dated August 14, 2009, and VHA Handbook 1400.01, Resident Supervision, dated December 19, 2012.

4. RESPONSIBLE OFFICE: The National Surgery Office (10NC2) is responsible for the contents of this directive applying to the OR. Questions may be referred to the National Director of Surgery at (202) 461-7130 or vhaco.national.surgery.office@va.gov. The VA National Center for Patient Safety (NCPS) is responsible for contents of this directive applying to the out of OR setting. Questions may be referred to the Chief Officer, VA National Center for Patient Safety, (734) 930-5890 or ncps@va.gov.

5. RESCISSIONS: VHA Directive 1039, Ensuring Correct Surgery and Invasive Procedures, dated July 26, 2013, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of November 2023. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

Steven L. Lieberman, MD, MBA, FACHE
Executive in Charge

NOTE: All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.

November 28, 2018

VHA DIRECTIVE 1039(2)

DISTRIBUTION: Emailed to the VHA Publications Distribution List on November 29, 2018.

CONTENTS

**ENSURING CORRECT SURGERY AND INVASIVE PROCEDURES IN AND OUT
OF THE OPERATING ROOM**

1. PURPOSE..... 1

2. BACKGROUND..... 1

3. DEFINITIONS 2

4. POLICY 3

5. RESPONSIBILITIES 3

6. TRAINING REQUIREMENTS 11

7. RECORDS MANAGEMENT..... 11

8. REFERENCES..... 11

ENSURING CORRECT SURGERY AND INVASIVE PROCEDURES

1. PURPOSE

a. This Veterans Health Administration (VHA) directive provides policy on the steps that must be taken to ensure all surgery and invasive procedures performed in and out of the operating room (OR and non-OR) are performed on the correct patient, on the correct side, at the correct site, and, if applicable, with the correct implant.

b. **AUTHORITY:** Title 38 United States Code (U.S.C.) 1710, 7301(b) and 7331.

c. This policy **does not** apply to invasive procedures that do not require written informed consent; examples include venipuncture, auricular acupuncture, diagnostic tests with intravenous injections, intra-oral imaging, dental intraoral local anesthetic injections, joint aspirations, or intravenous therapy in any setting.

2. BACKGROUND

a. Surgery and other invasive procedures performed on the wrong site, to the wrong patient, or with the wrong implant are uncommon adverse events in health care, but are potentially devastating when they occur. Specifically, this directive provides policy regarding steps that must be taken when invasive procedures are performed.

b. In 2008, NSO and NCPS collaborated with the Employee Education System to create a mandatory training video for all VHA employees engaged in the performance of invasive procedures in OR and non-OR settings.

c. Specific examples of surgical and invasive procedures requiring written informed consent to which this directive applies include, but are not limited to:

(1) Injections of any substance into a body cavity or space;

(2) Percutaneous aspiration of body fluids through the skin; for example, bone marrow aspiration, lumbar puncture, paracentesis, thoracentesis, suprapubic catheterization; chest tube insertion;

(3) Biopsy; for example, breast, liver, muscle, kidney, genitourinary, prostate, bladder, vulva, skin;

(4) Invasive cardiac procedures; for example, cardiac catheterization, cardiac pacemaker implantation, angioplasty, stent implantation, intra-aortic balloon catheter insertion; trans-esophageal echocardiography and cardioversion;

(5) Central vascular access device insertion; for example, Swan-Ganz catheter, percutaneous intravascular catheter line, Hickman catheter; and central lines;

(6) Electrocautery or laser ablation of skin lesion;

(7) Endoscopy; for example, colonoscopy, bronchoscopy, upper endoscopy, cystoscopy, percutaneous endoscopic gastrostomy, J-tube placements, and nephrostomy tube placements;

(8) Laparoscopic surgical procedures; for example, laparoscopic cholecystectomy, laparoscopic nephrectomy, laparoscopic oophorectomy;

(9) Invasive radiology procedures; for example, angiography, angioplasty, percutaneous biopsy; including invasive radiation oncology procedures, which include interstitial or intracavitary placement of radiation sources, fiducial markers or other devices;

(10) Laser therapy; for example, eye, uterus, and ear, nose, and throat;

(11) Dermatology procedures (biopsy, excision and deep cryotherapy for malignant lesions – excluding cryotherapy for benign lesions); recommend using photographs to document skin lesion location to aid care coordination in case subsequent treatment (such as Mohs surgery) is needed;

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

(13) Oral surgical procedures, including tooth extraction and hard and soft tissue dental surgical procedures (does not include non-surgical dental procedures such as dental restorations dental procedures such as periodontal, oral diagnostic and prosthodontic procedures and endodontic treatment);

(14) Podiatric invasive procedures; for example, removal of ingrown toenail;

(15) Regional nerve block; for example, for pain control, surgical procedure;

(16) Gynecology procedures; for example, colposcopy with or without biopsy, cervical cone biopsy, cervical cryoablation, hysteroscopy, and hysterosalpingogram;

(17) Electro Convulsive Therapy;

(18) Lithotripsy; and

(19) All procedures requiring moderate sedation or monitored anesthesia care.

3. DEFINITIONS

a. **Invasive Procedure.** Invasive procedures are those involving a skin incision or puncture, including, but not limited to, percutaneous aspiration, selected injections, biopsy, percutaneous cardiac and vascular diagnostic or interventional procedures, laparoscopies, and endoscopies.

b. **Operating Room.** An operating room (OR) meets the space design criteria established by the Office of Construction and Facility Management, is located in an inpatient surgical suite or ambulatory surgery center, and is supported by the OR nursing staff. For the purpose of this policy, an OR also includes the IR suite and the Cath Lab.

c. **Surgical Procedure.** A surgical procedure is a surgical or invasive diagnostic procedure performed by qualified providers in an OR. For the purpose of this policy, surgical procedures include procedures performed in the IR suite and the Cath Lab.

d. **Simultaneous Surgery.** Simultaneous surgery occurs when the attending surgeon utilizes providers not credentialed and privileged to perform all or a critical portion of the surgical procedure (examples include, but are not limited to, physician residents, physician assistants, physician and non-physician surgical assistants) in order to leave the OR and actively participate (including resident supervision) in a surgical or invasive procedure in another OR or procedure room, inside or outside of the OR, at a time when there is any reasonable chance for the attending surgeon to be called to actively participate in the procedure. **NOTE:** *Simultaneous surgery is never permitted.*

e. **Special Purpose Wristband.** A special-purpose wristband can substitute for a marked site for patients that refuse to have a procedure site marked or when the procedure site makes marking problematic; for example, endoscopy or procedures on the perineum. 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.

f. **Staggered Surgery.** Staggered surgery occurs when the attending surgeon utilizes providers not credentialed and privileged to perform all or a portion of the surgical procedure; for example, physician residents, physician assistants, physician and non-physician surgical assistants, in order to leave the OR and actively participate, including resident supervision, in a surgical or invasive procedure in another OR or procedure room, in or out of the OR, at a time when there is no reasonable chance for the attending surgeon to be called to actively participate in the procedure. **NOTE:** *Staggered surgery is permissible.*

4. POLICY

It is VHA policy that any VHA health care provider and the team performing surgery or an invasive procedure which requires a written informed consent must complete the 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.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Deputy Under Secretary for Health for Operations and Management.** The Deputy Under Secretary for Health for Operations and Management is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Services Networks (VISN);

(2) Ensuring that each VISN Director has the sufficient resources to fulfill the terms of this directive in all of the VHA medical facilities within that VISN; and

(3) Providing oversight of VISNs to assure compliance with this directive, as well as the relevant standards, and applicable regulations as referenced.

c. **National Director of Surgery, National Surgery Office.** The National Director of Surgery. National Surgery Office is responsible for monitoring VA surgical programs for wrong site, wrong patient, and wrong implant procedure events that occur in the OR.

d. **Chief Officer, National Center for Patient Safety.** The Chief Officer, National Center for Patient Safety is responsible for monitoring VA medical facilities for wrong site, wrong patient, and wrong implant procedures events that occur outside the OR. **NOTE:** *Tracking of incorrect procedures occurring in non-OR settings is dependent upon self-reporting for peer review, root cause analysis, and issue briefs to Veterans Integrated Service Network (VISN) and the Deputy Under Secretary for Health for Operations and Management.*

e. **Veterans Integrated Service Network Director.** Each Veterans Integrated Service Network (VISN) Director is responsible for ensuring that each VA medical facility Director is compliant with this directive.

f. **VA Medical Facility Director, Facility Chief of Staff, and Associate Director for Patient Care Services.** The VA medical facility Director, Chief of Staff, and Associate Director for Patient Care Services must ensure that:

(1) The health care team performing a surgery or invasive procedure in the OR 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 health care team may include the physician, nurse, and any other support clinicians. **NOTE:** *Surgery in the OR includes invasive procedures performed in the IR Suite or Cath Lab.* The five steps for ensuring correct surgery **in the OR** are:

(a) **Step One: The Consent Process is Conducted, 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 procedure in language that the patient can understand and before the invasive procedure begins. 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, Informed Consent for Clinical Treatments and Procedures, published May 22, 2017, or subsequent policy, and VHA Handbook 1004.05, iMedConsent, dated December 10, 2014, or subsequent policy.*

(b) **Step Two: 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 surgical procedure;
2. A member of the operating team (ex. resident, nurse practitioner, physician assistant) assigned to be present in the operating 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 during the procedure.

a. The operative site must be marked prior to the anesthesia provider proceeding with performance of a regional nerve block. **NOTE:** *The anesthesia provider must perform a separate time out for the performance of the 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) Step Three: 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 an 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 operating 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 operating room. **NOTE:** *The reliability of the second identification process is enhanced by assigning one category of team member; for example, circulating nurse or anesthesia provider) to always perform this function in the operating room.*

(d) Step Four: All Pertinent Medical Images are Reviewed by Two Members of the Surgical Team Prior to Commencing the Surgical Procedure to Verify That the Images Are Available, Properly Labeled, and Properly Presented. The physician performing the surgical 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) Step Five: A Time-out Must Be Facilitated by a Checklist and Occur Immediately Prior to the Start of the Surgical Procedure.

1. 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.

2. 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.

3. If two or more procedures are to be performed on the same patient and the person performing the procedure changes, a time out must be performed before each procedure.

4. The Time-out checklist must include, but not be limited to the following relevant information:

- a. Correct patient identity;
- b. Procedure to be performed;
- c. Site of the procedure, including laterality if applicable;
- d. Valid consent form, containing information consistent with paragraph 5.f.(1)a;
- e. Patient position;
- f. Procedure site has been marked appropriately and that the site of the mark is visible after prep and draping;
- g. Pertinent medical images have been confirmed, if applicable;
- h. Correct medical implant(s) is available, if applicable;
- i. Appropriate antibiotic prophylaxis;
- j. Appropriate deep vein thrombosis prophylaxis;
- k. Blood availability, if applicable;
- l. Availability of special equipment, if applicable; and
- m. Accuracy of the specimen labels if specimen collection is planned. NOTE: All unused specimen labels must be destroyed or removed from the operating room at the completion of the procedure and the patient exiting the OR.

(2) Except when clinically necessary, the patient must not be sedated or anesthetized until the three steps found in paragraphs 5.f.(1)a, 5.f.(1)b., and 5.f.(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 including the expiration date. 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 Surgical Procedures. For emergency surgical procedures the five steps to ensure correct surgery in the OR 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.

(c) 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 must include the additional steps as follows:

1. The surgeon must place a fixed spine marker and take an intra-operative radiograph (fluoroscopy alone is not sufficient) to confirm the position of the spine marker with another member of the procedure team before continuation of the procedure. If there is any ambiguity regarding the location of the correct spinal level, it is recommended that the surgeon consult with a radiologist intraoperatively.

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 policy on resident supervision. **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.

(d) For Ophthalmologic Intraocular Lens Implant Procedures. In ophthalmologic intraocular lens implant procedures performed in the OR, the five steps to ensure correct surgery 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 Surgery 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. When lens calculation is performed in the OR using newer technology, the surgeon, and one other member of the team must agree that the selected lens appropriately matches the intraoperative calculation prior to implant. The implant expiration date must also be confirmed at this time.

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. During the surgical procedure an "intra-operative pre-implant read-back" is performed. The intra-operative pre-implant read-back must include verification of the 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*

[https://www.aao.org/patient-safety-statement/recommendations-of-american-academy-ophthalmology-\).](https://www.aao.org/patient-safety-statement/recommendations-of-american-academy-ophthalmology-)

(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) Simultaneous surgery is not performed. **NOTE:** *Staggered surgery is acceptable.*

(8) The health care provider performing an invasive procedure outside the OR 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 invasive procedure **outside the OR** are as follows:

(a) Step One: 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 in language that the patient can understand and before the invasive procedure begins. 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.

(b) Step Two: The Operative Site is Marked.

1. The site is marked to clearly indicate the site of the planned invasive procedure; 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.

2. The mark must be applied by one of the following individuals:

a. The licensed independent provider scheduled to perform the invasive procedure;
or

b. A member of the clinical team (ex. resident, nurse practitioner, physician assistant) assigned to be present in the procedure room during the invasive procedure, and appropriately privileged or practicing on a qualifying scope of practice.

3. A special-purpose wristband can substitute for a marked site for patients that refuse to have a surgical site marked or when the site of the procedure makes marking problematic; for example, dental procedures, endoscopy, or procedures on the perineum.

4. Marking the site of the invasive procedure performed outside the OR is not required when the invasive procedure immediately follows the informed consent process and the informed consent and invasive procedure are performed by the same practitioner. **NOTE:** *Any break in the flow of this process, such as the patient transferring to another unit or location between informed consent and procedure will require the site to be marked or a special purpose wristband to be applied.*

(c) Step Three: 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 an approved unique identifier.

2. The process of patient identification must occur twice, at the time the invasive procedure site is marked and in the procedure room if the two locations are different.

(d) Step Four: All Pertinent Medical Images are Reviewed by Two Members of the Surgical Team Prior to Commencing the Surgical Procedure to Verify that the Images are Available, Properly Labeled, and Properly Presented.

1. The physician performing the surgical 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.

2. Dental procedures should have the site identified using digital imaging or radiographs or intraoral chart.

(e) Step Five: A Time-out Must be Facilitated by a Checklist and Occur Immediately Prior to the Start of the Invasive Procedure Performed Outside the OR.

1. The participants of the time-out must include the privileged provider performing the procedure and a member of the nursing staff, associate health care staff, or another member of the medical staff. A member of the anesthesia staff must be included in the time-out if participating in the procedure.

2. The time-out participants must concur verbally to each item on the checklist and the time-out must be documented in the patient's electronic health record.

3. If two or more procedures are to be performed on the same patient and the person performing the procedure changes, a time-out must be performed before each procedure.

4. The Time-out Checklist for invasive procedures performed outside the OR must include the following:

- a. Correct patient identity;
- b. Procedure to be performed;
- c. Site of the procedure, including laterality if applicable;
- d. Valid consent form, containing information consistent with paragraph f.(1)(a);
- e. Procedure site has been marked appropriately and that the site of the mark is visible after prep and draping; and
- f. Patient position.

5. The Time-out Checklist for invasive procedures performed outside the OR may include but not be limited to the following if applicable:

- a. Pertinent medical images have been confirmed;
- b. Correct medical implant(s) are available;
- c. Appropriate antibiotic prophylaxis,
- d. Availability of special equipment, if applicable; and

e. Accuracy of the specimen labels if specimen collection is planned. **NOTE:** *All unused specimen labels must be destroyed or removed from the procedure room at the completion of the invasive procedure and the patient exiting the procedure area.*

(9) Except when clinically necessary, the patient must not be sedated or anesthetized until the three steps found in paragraphs 5.f.(1)a., 5.f.(1)b., and 5.f.(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.

(10) An additional step is performed immediately prior to the implantation of the medical device; for example, intraocular lens. The privileged provider performing the procedure must confirm the correct implant with a team member, including a “read-back” of all relevant information including expiration date. Documentation of the correct medical implant must be placed in the health record.

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

(a) Emergency Invasive Procedures. For emergency invasive procedures performed outside the OR, the five steps to ensure correct invasive procedure 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) A special-purpose wristband can substitute for a marked site for patients that refuse to have a surgical site marked or when marking of the procedure site is problematic; for example, endoscopy or procedures on the perineum.

(c) For Ophthalmologic Intraocular Lens Implant Procedures. In ophthalmologic intraocular lens implant procedures performed in a procedure room, the five steps to ensure correct surgery 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 Surgery 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. When lens calculation is performed in the procedure room using newer technology, the surgeon and one other member of the team must agree that the selected lens appropriately

matches the lens calculation at the time of the procedure and prior to implant. The implant expiration date must also be confirmed at this time.

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

3. A “pre-implant read-back” is performed during the procedure and prior to implant. The pre-implant read-back must include verification of the 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: <https://www.aao.org/patient-safety-statement/recommendations-of-american-academy-ophthalmology->*

(12) 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.

(13) 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.

(14) There is appropriate documentation of the five steps in the patient’s electronic health record for all surgery and invasive procedures performed in any clinical setting.

NOTE: *Although responsibilities are assigned to the VA medical facility Director and Chief of Staff for all steps for ensuring the correct site for surgery and invasive procedures, potential accompanying special conditions, and ancillary matters, this directive does not anticipate that the Director or Chief of Staff will personally perform any of these functions. The direct responsibility for these actions lies with the members of the health care team performing the surgery or invasive procedure. The VA medical facility Director is responsible for ensuring that health care teams fulfill these responsibilities.*

6. TRAINING REQUIREMENTS

Ensuring Correct Surgery and Invasive Procedures Video. Talent Management System (TMS) number VA 39094, is required (see paragraph 8.f.). Target audience is anyone performing an invasive procedure in or out of the OR. Training is a one-time requirement.

7. RECORDS MANAGEMENT

All records regardless of format (paper, electronic, electronic systems) created by this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule 10-1. If you have any questions regarding any aspect of records management you should contact your facility Records Manager or your Records Liaison.

8. REFERENCES

- a. 38 U.S.C. 1710, 7301(b), 7331.

b. VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, dated August 14, 2009.

c. VHA Handbook 1004.02, Advance Care Planning and Management of Advance Directives, dated December 24, 2013.

d. VHA Handbook 1004.05, iMedConsent, dated December 10, 2014.

e. VHA Handbook 1400.01, Resident Supervision, dated December 19, 2012.

f. Ensuring Correct Surgery and Invasive Procedures Video. Talent Management System (TMS) number VA 39094. **NOTE:** *This is an internal VA Web site that is not available to the public.*

g. American Academy of Orthopedic Surgeons (AAOS) and the North American Spine Society Position Statements. Available at:

<https://www.spine.org/Documents/ResearchClinicalCare/SMAX2014Revision.pdf>

h. Alspach JG. The checklist: Recognize Limits but Harness its Power. Crit Care Nurse. 2017; 37(5):12-18. Doi: 10.4037/ccn2017603. Available at:

<http://ccn.aacnjournals.org/content/37/5/12.full?sid=3328450b-3ba6-42f8-9eb1-fcac79318e26>

i. American College of Surgeons (2016). Statements on Principles. Concurrent or Simultaneous Operations. Available at <https://www.facs.org/about-acs/statements/stonprin>.

j. Association of periOperative Registered Nurses (2018). Guidelines for Perioperative Practice. Available at: <http://www.aornstandards.org>.

k. Creating a Culture of Safety in the Ambulatory Surgery Environment: Implementation Guide: Implementing the Surgical Safety Checklist. Agency for Healthcare Research and Quality. Available at:

<http://www.ahrq.gov/professionals/quality-patient-safety/hais/tools/ambulatory-surgery/sections/implementation/implementation-guide/guide-implement.html>.

l. Haynes AB, Wieser TG, Berry WR, Lipsitz SR, Breizat AH, Dellinger EP, Herbosa T, et al. A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population. N Engl J Med. 2009; 360(5):491-9. Doi: 10.1056/NEJMsa0810119. Available at: <http://www.nejm.org/doi/full/10.1056/NEJMsa0810119>.

m. Patient Safety Primer: Checklists. AHRQ PSNet Patient Safety Network. Available at: <https://psnet.ahrq.gov/primers/primer/14>.

n. Stanford Hospital and Clinics (2018). Patient Safety Refresher. Universal Protocol. Boarding Pass. Available at:

<http://med.stanford.edu/shs/update/archives/DEC2006/boardpass.pdf>.

o. The Joint Commission 2018 National Patient Safety Goals, Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery™ available at http://www.jointcommission.org/standards_information/npsgs.aspx