

PREVENTION OF RETAINED SURGICAL ITEMS

- 1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) Directive provides policy to prevent incidents of surgical items being retained in a patient following surgery.
- 2. SUMMARY OF MAJOR CHANGES:** Content updated to include drains and guidewires as retained surgical items. The updated policy also describes the Critical Incident Tracking Notification (CITN) process for the field to document retained surgical item events using a secure web-based intranet tool. The National Surgery Office (10NC2) works with the National Center for Patient Safety (10A4E) to reconcile all retained surgical items events to ensure complete capture and evaluate lessons learned. An amendment, dated October 19, 2020, updates content to reflect the Department of Veterans Affairs (VA's) transition to a new electronic health record (EHR) and enable implementation of this directive at VA medical facilities using Cerner Millennium (see paragraphs 3 and 5.b.(5-6)).
- 3. RELATED ISSUES:** None.
- 4. RESPONSIBLE OFFICE:** The National Surgery Office (10NC2) in the Office of the Assistant Deputy Under Secretary for Health for Operations and Management for Clinical Operations is responsible for the content of this Directive. Questions may be directed to the National Director of Surgery at 202-461-7130.
- 5. RESCISSIONS:** VHA Directive 2010-017, Prevention of Retained Surgical Items, is rescinded.
- 6. RECERTIFICATION:** This VHA Directive is due for recertification on or before the last working day of March 2021.

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1. PURPOSE

This Veterans Health Administration (VHA) Directive provides policy to prevent incidents of surgical items being retained in a patient following surgery. **AUTHORITY:** 38 USC 7301(b).

2. BACKGROUND

a. Surgical items are defined as instruments, sharps, soft goods, drains, guidewires, or any materials used by the surgical team to perform an operative procedure. Sharps are surgical needles, aspirating needles, blunt needles, scalpel blades, or any items with a sharp or pointed edge that pose a risk for skin puncture by members of the surgical team. Soft goods include cotton gauze sponges of various sizes, laparotomy pads, surgical towels, or any absorbent materials not intended to remain in the patient's body after the surgical procedure is completed.

b. A surgical item is considered to be retained if it is an item or parts thereof not intended to remain and is found in any part of the patient's body after the patient has been taken from the operating or procedure room. Drains are retained if placed intentionally in the operating room (OR) for subsequent removal (example Penrose drain, chest tube, ureteral stent) but upon attempted removal outside the OR, all or a portion of the drain is unintentionally retained requiring an invasive procedure with informed consent for removal.

c. The National Surgery Office (NSO) and the National Center for Patient Safety (NCPS) collect data for retained surgical items. For Fiscal Year 2014, the VHA incidence estimated rate of retained surgical items was determined to be 1 in 17,200 surgical procedures. This rate compares favorably to the national incidence rate for retained surgical items reported to range from 1 in every 8,000 to 18,000 procedures.

d. The occurrence of a retained surgical item is considered a sentinel event, requires Root Cause Analysis (RCA), and must be reported to the NCPS. The NCPS aggregates RCA data and reports quarterly to the National Director of Surgery. **NOTE:** *VHA Handbook 1050.01, VHA National Patient Safety Improvement, provides further guidance regarding sentinel event reporting and requirements for patient disclosure.*

e. Beginning in August 2010, the NSO established the Critical Incident Tracking Notification process to collect retained surgical item events using a secure web-based intranet tool. On a quarterly basis, the NSO and NCPS reconcile all retained surgical item events to ensure complete capture, evaluation and determination of lessons learned.

3. DEFINITIONS

Electronic Health Record. Electronic health record (EHR) is the digital collection of patient health information resulting from clinical patient care, medical testing, and other

care-related activities. Authorized VA health care providers may access EHR to facilitate and document medical care. EHR comprises existing and forthcoming VA software including Computerized Patient Record System (CPRS), Veterans Information Systems and Technology Architecture (VistA), and Cerner platforms. **NOTE:** *The purpose of this definition is to adopt a short, general term (EHR) to use in VHA national policy in place of software-specific terms while VA transitions platforms.*

4. POLICY

It is VHA policy that the surgical team must apply a standard approach to the prevention of retained surgical items when the operative procedure being performed is one in which there is any possibility for retention of a surgical item.

5. RESPONSIBILITIES

a. **Facility Director.** The facility Director is responsible for ensuring compliance with this Directive at the local level.

b. **Facility Chief of Surgery.** The Chief of Surgery is responsible for ensuring that the surgical team performing an operative procedure in which there is any possibility for retention of a surgical item (including laparoscopic procedures) adheres to the following standards:

(1) **Soft Goods.** All soft goods that are placed in the surgical field must be left in their original configuration and must not be cut or altered in any way, or used for dressings.

(2) **Radiopaque Surgical Items.** Surgical items intended for placement in the surgical wound or are placed peripheral to the operating field and have the potential to be placed in the surgical wound must be radiopaque (detectable by a radiograph).

(3) **Non-Radiopaque Surgical Items.** Non-radiopaque surgical items that are used in the operating room, for example, sponges used during IV line insertion, must be disposed of in a separate waste receptacle designated for that purpose and never in the same space with counted surgical items.

(4) **Methodical Wound Exploration.** A methodical wound exploration must be performed before closing the surgical wound in every case to ensure that all surgical items are accounted for and extracted.

(a) The space to be closed must be carefully examined. Special focus must be given to closure of a cavity within a cavity (e.g., heart, major vessel, stomach, bladder, uterus, and vagina).

(b) A methodical wound exploration must be performed before removing stationary or table mounted retractors.

(c) The surgeon must visually and manually explore the operative field, making every effort to remove any and all surgical items left within a body cavity.

(d) A methodical visual inspection of the body cavity is required when performing a minimally invasive laparoscopic, thoracoscopic, or arthroscopic procedure.

(e) A methodical wound sweep is required for cataract procedures utilizing the microscope.

(f) If at any time during wound closure, the surgeon is informed of an inaccurate count of surgical items the surgeon must stop closing the wound and perform a repeat methodical wound examination while OR staff continues to look for the missing surgical item.

(5) **Count of Surgical Items.** All surgical items must be counted in every case.

(a) A count of surgical items must occur:

1. Before the procedure has begun or the incision is made to establish a baseline count;

2. When new soft goods and/or sharps are added to the field

3. When a drain or other miscellaneous item is cut, all pieces must be accounted for and counted.

4. Before the closure of a cavity within a cavity;

5. Before wound closure begins;

6. At skin closure or end of procedure; and

7. At the time of permanent relief of either the scrub person or the RN circulator.

(b) OR staff must be allowed sufficient time for a count of surgical items to be performed.

1. All surgical counts are performed using a standard two-person practice; the items are counted audibly and viewed concurrently by the scrub person and RN circulator.

2. Any time there is a question by any member of the surgical team regarding the count, an additional count must be performed.

3. Perioperative personnel must never assume that the count on prepackaged sterilized items is accurate. The contents of each package must be counted individually by the scrub person and RN circulator using the standard two-person practice. If the package has an incorrect number of items and the procedure has not

begun, the entire pack must be removed from the OR. If the procedure has begun, the pack must be bagged, properly labeled, and isolated from the other counted items.

4. Counts must be performed in the same sequence each time. The count needs to begin at the surgical site and the immediate surrounding area, proceed to the instrument stand and back table, and finally to the counted items (soft goods, sharps, or instruments) that have been discarded from the field. **NOTE:** *The use of assistive technologies, including radiofrequency tags to detect technology-enabled soft goods and radio frequency identification (RFID) systems, are adjunct technologies to supplement the manual counting process but not replace the requirement to perform a count of surgical items in every case.*

5. All relief personnel must be documented in the EHR in intraoperative nursing documentation.

(c) The surgeon must be informed by OR staff at the time a discrepancy in a count of surgical items is discovered. It is imperative that a reasonable and appropriate search of the operative field and surrounding area be undertaken to recover the item in question and resolve the discrepancy.

(d) When soft goods are used as therapeutic packing and the patient leaves the operating room with packing in place, the number and types of items placed must be documented in the EHR in the intraoperative nursing documentation. If and when the patient returns to the operating room for a subsequent procedure including the remove of the therapeutic packing, the number and type of radiopaque soft goods must be similarly documented and excluded from subsequent counts of surgical items.

(6) Use of Intraoperative Radiograph.

(a) An intraoperative radiograph of the surgical field is not required if a methodical wound exploration is performed and a count of all surgical items is correct at the completion of the procedure.

(b) A radiograph of the entire surgical field to rule out a retained surgical item must be performed and interpreted by a physician at the completion of the surgical procedure, prior to the patient's transfer from the OR, in the following circumstances:

1. When the surgical count is "incorrect" (i.e., the preoperative surgical item count plus surgical items added during the procedure is greater or less than the postoperative surgical item count) and the surgical item in question is not recovered following a methodical wound exploration.

a. A radiologist must interpret the radiograph and notify the surgical team by verbal or written communication when the missing surgical item is not found. The radiologist's report must be made available to the surgical team in a timely fashion recommended to be less than 30 minutes from the time the radiograph is

requested. Consideration should be given to obtaining additional views, for example, an oblique view of the operative site when initial radiographs do not reveal the missing item and the item still has not been found. **NOTE:** *The surgeon has the discretion to close the surgical wound prior to receiving a report from the radiologist regarding a missing surgical item if delaying wound closure would substantially increase risk for the patient.*

b. There is no requirement for a radiologist to interpret the radiograph if the surgical team subsequently finds the missing object, thereby establishing the surgical count as correct.

c. When the surgical wound does not involve a body cavity and the entirety of the wound is visible to the surgical team, the attending surgeon may determine that an intraoperative radiograph is not required when a count of surgical items is "incorrect." All members of the surgical team must be in agreement. The attending surgeon must document the circumstances and reason for not obtaining an intraoperative radiograph in the patient's EHR.

2. Radiography will be substituted for an instrument count when the surgeon, scrub person, and RN circulator unanimously agree that the number of surgical instruments utilized during the operative procedure prohibits an expeditious and timely count. This situation is typically encountered with major joint replacements. **NOTE:** *A methodical wound exploration and count of all sharps and soft goods must still be performed even though a radiograph is substituted for the surgical instrument count in such circumstances.*

3. When the clinical circumstances dictate the patient requires emergency care and the counting of surgical items may not be in the best interest of the patient. This divergence or omission from standard protocol (i.e., methodical wound exploration and complete surgical item count) must be documented in the intraoperative documentation in the following manner:

a. The surgeon must include a statement in the operative report describing the emergent nature of the procedure, the clinical condition of the patient, and the reasons for divergence from or omission of standard protocol.

b. The circulating nurse must describe in the intraoperative nursing documentation the emergent nature of the surgical procedure, the clinical condition of the patient, and the aspects in which standard protocol was omitted or modified.

c. In such cases, a radiograph must be obtained in the Post-Anesthesia Recovery Unit or Intensive Care Unit and interpreted by a radiologist to rule out a retained surgical item unless contraindicated by the patient's clinical condition.

4. When the operative procedure being performed is one determined by any member of the surgical team to be at high risk for retained surgical items, even though a methodical wound exploration has been performed and the surgical item count is

correct. **NOTE:** *The following operative procedures should be considered at high risk for retained surgical items: emergency procedures involving a body cavity; unexpected change in the conduct or scope of the operative procedure; operative procedures involving more than one surgical team; operative procedures of considerable duration particularly those that require a nursing staff shift change; unexpected transfusions defined as greater than 4 units of packed red blood cells; and high patient body mass index (BMI > 35).*

6. REFERENCES

- a. VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook. March 4, 2011.
- b. Cima, R.R., Kollengode, A., Garnatz, J., Storsveen, A., Weisbrod, C., Deschamps, C., "Incidence and Characteristics of Potential and Actual Retained Foreign Object Events in Surgical Patients," *Journal of the American College of Surgeons*, July; 207 (1): 80-87, 2008.
- c. The Joint Commission Sentinel Event Alert 51: Preventing unintended retained foreign objects. Published October 17, 2013, available at http://www.jointcommission.org/sea_issue_51/
- d. Association of Perioperative Registered Nurses. *Guideline for Prevention of Retained Surgical Items*. 2015, available at: <http://www.aornstandards.org>