

Ensuring Correct Surgery and Invasive Procedures

By Noel Eldridge, MS, NCPS executive officer

IN JUNE 2004, a new directive on Ensuring Correct Surgery and Invasive Procedures (2004-028) was issued to update the initial, groundbreaking directive that went into effect January 2003.

Visit the NCPS Web site to review the new directive: <http://www.patientsafety.gov/CorrectSurg.html> or <http://www.ncps.med.va.gov/CorrectSurg.html>. This article is just a summary. *The entire directive should be reviewed and understood by those who implement relevant facility policies, or participate in performing surgical or other invasive procedures.*

In the new and old directive, NCPS worked with the VA National Director of Surgery and a number of VA medical centers to develop a national policy — based on a straightforward, five-step process — which includes filling out a consent form, marking the site, identifying the patient, holding a time-out, and checking pertinent images.

The initial directive was focused on surgical procedures conducted within the operating room (OR). The new directive was developed to adapt the five-step Ensuring Correct Surgery Directive to healthcare settings outside the OR, such as at the bedside or in the intensive care unit.

The new directive also addresses JCAHO's requirements noted in the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™, effective July 1, 2004, and available at www.jcaho.org (click on "Universal Protocol").

To establish a procedure and policy for ensuring correct invasive procedures outside the OR, we focused on two main requirements:

- Modification of existing processes to recognize the variations in practice that are associated with out-of-OR invasive procedures
- Development of a list of invasive procedures to which the directive applies

A list of procedures that apply to the directive appears below in figure 1, and a flowchart showing the process is provided in figure 2 (see page 4). In general, the criteria for whether the processes must be followed are simple: Is the procedure one that requires signature consent? If so, is it invasive? If yes to both questions, then a form of the five steps applies.

To meet the requirements of the JCAHO Universal Protocol, the practices described in figures 1 and 2 must be followed.

The new directive includes one specific change to meet the requirements of JCAHO's Universal Protocol for surgery performed *within* the OR: During the time-out, the position of the patient must be checked and confirmed in addition to the other requirements. In OR settings, the initial directive that took effect in 2003 meets or exceeds all other requirements of the universal protocol.

To address miscellaneous issues and questions that have come up since the implementation of the initial directive, several adjustments or additions were included in the new directive. The most important ones are the following:

- For surgery on the spine, a mark on the skin is sometimes inadequate to indicate the intervertebral space or other specific location to be operated upon. Because of

Figure 1: 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, and excluding venipuncture or intravenous therapy. To clarify the types of procedures that are subject to this directive — in addition to open surgery and other unambiguously surgical procedures — specific examples of other invasive procedures are provided as follows:

- Injections of any substance into a joint space or body cavity
- Percutaneous aspiration of body fluids through the skin
- Biopsy
- Cardiac procedures
- Central vascular access device insertion
- Electrocautery of skin lesion
- Endoscopy
- Laparoscopic surgical procedures
- Invasive radiology procedures
- Laser therapy
- Dermatology Procedures
- Invasive ophthalmic procedures, including miscellaneous procedures involving implants
- Oral surgical procedures including tooth extraction and gingival biopsy
- Podiatric invasive procedures
- Skin or wound debridement performed in an operating room

NOTE: Procedures similar in scope to those listed above need to be considered invasive procedures and subject to the requirements of this directive. See Directive 2004-028, Attachment E, for examples.

Reducing the Vulnerability of Retained Surgical Sponges

By Carol Samples, BGS, NCPS program analyst, and Ed Dunn, MD, MPH, director of policy and clinical affairs

LEAVING SPONGES inside patients who undergo surgical procedures is a serious and persistent problem in health-care throughout the world. The estimated incidence of retained sponges or instruments is one out of every 1,500 operative procedures that involve an open abdomen or open chest.^{1,2} Such incidents may result in major injury. The retention of surgical sponges is avoidable and thus an important opportunity for reducing harm to patients served by the VHA.

The Association of periOperative Registered Nurses, AORN, recommends counting sponges on all procedures in which the likelihood exists that a sponge or instrument could be retained in a body cavity. They advise sponge counts to be taken:

- ✓ before the procedure to establish a baseline,
- ✓ before closure of a cavity within a cavity,
- ✓ before wound closure begins,
- ✓ at skin closure or end of the procedure, and
- ✓ at the time of permanent relief of either the scrub person or the circulating nurse.³

Background RCA Data

In our search of the NCPS SPOT database for surgical procedures involving retained sponges, more than 70 cases were identified: 58 percent were adverse events; 42 percent were close calls. Our search spanned 2000 to 2004. We defined “sponges” to include: peanut sponges, various sizes of gauze pads (4x4 in., 2x3 in.), laparotomy pads, surgical towels, and folded surgical drapes.

RCA Case Data

In cases of adverse events due to retained sponges, 41 percent of sponge counts were reported as incorrect and 21 percent were reported as correct. In 38 percent of these cases, no counts were documented.

Sponges were left in the neck, chest, peritoneum, knee, groin, mediastinum, retroperitoneal cavity, and pelvis. Gauze sponges have been discovered in a patient’s airway after a tra-

cheostomy, defecated following use as a throat pack during a maxillectomy, and found visibly extruding from an abdominal incision.

Retained sponges were discovered before and after wound closure and were also found when searches were initiated after incorrect sponge counts were reported. In some cases, evidence of a retained sponge was not apparent until days, weeks or years later, when X-rays were taken of patients with symptoms of pain, swelling, or signs of occult infection. Radiologists also observed sponges in unrelated routine X-rays and pathologists discovered them during autopsies.

The time elapsed from the original surgical procedure to reoperation for removal of a retained sponge ranged from an immediate response to eight years after the operation.



Radiographs are often inconclusive when they are done for incorrect sponge counts. Radiopaque markers imbedded in sponges may be confused for pacing wires and artificial cardiac valves or valve rings. Material such as Surgicel® has been mistaken for a sponge. Sponges have been obscured because of their proximity to bone or their position deep within the recesses of the chest or abdominal cavities. The quality of images from portable X-ray equipment in the OR is often suboptimal and limited by a narrow range of possible views. To improve detection skills, it has been suggested that radiology residents review films with various foreign objects, including sponges, as part of their training.

Root Causes and Contributing Factors from RCA teams

Reports from RCA teams taken from our SPOT RCA database have suggested possible root cause contributing factors in cases with retained surgical sponges:

- Incorrect sponge counts are commonplace and usually not associated with an actual retained sponge.
- Radiopaque sponges were not used consistently; counts were not recorded.
- Local norms may interfere with the adoption of AORN standards for counting surgical sponges — i.e., “This isn’t the way we’ve done things around here.”
- Suboptimal communication between members of the surgical team increases the likelihood of incorrect sponge counts.
- Productivity pressures to increase throughput may compromise implementation of AORN standards (re: sponge counts).
- Feelings that socialization, music and conversation are acceptable because the patient is asleep can contribute to lapses in concentration.
- The stressful environment of the OR, with many people coming and going, requires multiple hand-offs of responsibility.
- Urgency is experienced with changes or complications in surgical procedures.
- Inconsistent policies and practices when sponge counts are incorrect, or when a missing sponge is not visualized on X-ray, leave staff without clear direction.
- Lack of clarity in X-ray requests leads to incomplete interpretation by the radiologist reading the film.
- Inability to obtain stat X-ray readings from the radiology department reduces the likelihood that incorrect counts are promptly validated.

- Audits of the count process focus on count documentation rather than direct observation of the count process.
- A surgeon's role in sponge and instrument counts is not clearly defined.
- Varying levels of physician orientation to OR practices (especially residents who come and go on monthly rotations) contribute to practice violation of AORN standards. Attending physicians are often not completely familiar with the process.

NCPS Observations & Suggested Actions

Please note:

* Indicates that "better than before" was documented in the outcome measure table of the RCA. In all others, there was no indication of follow-up.

- ◆ *Use AORN sponge and instrument count guidelines consistently.
- ◆ Without exception, all sponges and towels should have radiopaque markers.
- ◆ Sponge and instrument counts are critical regardless of the type and size of the incision.
- ◆ A "throughput focus" for managing patient flow through the OR can hinder accurate and effective sponge and instrument counts. Designate an OR supervisor or team leader to control movement and flow of patients through the OR.
- ◆ In collaboration with radiology, arrangements must be made for stat images whenever a surgical case is in progress.
- ◆ Observational studies of the counting process in the OR should be done periodically for quality control. The actual counting process is more important than the documentation of that process.
- ◆ Ensure that portable X-ray machines can provide adequate imaging data to meet needs for assisting with identification of retained items.
- ◆ Recognition of retained foreign bodies after surgical procedures should be an integral part of residency training in radiology.

- ◆ Consider routine intraoperative radiographic screening in selected, high-risk categories of surgical procedures (obese patients, closed-to-open procedures, emergent cases, and unexpected change in surgical procedures).⁴
- ◆ Without exception, all attending surgeons should know and adhere to the institution's policies and practices for sponge and instrument counting.
- ◆ Staff cannot rely on vigilance. They require physical reminders such as cognitive aids to ensure that they are conducting the correct procedure for sponge and instrument counting.
- ◆ OR staff must be empowered to "speak up" during a surgical case if they are uncomfortable with the sponge or instrument count. The mindset should always be: "If you're not sure it's safe, it's not safe."

Additional actions recommended by RCA teams included:

- Annually, assess staff competencies on the management of sharp instruments and sponges.
- All medical and nursing staff should be educated and trained in the appropriate and standardized sponge and instrument count procedures. Without exception, all attending surgeons should know the institution's count procedures.
- *Evaluate sponge-counting aids or devices such as plastic compartmented counting bags that could improve the accuracy and efficiency of the process.
- Consider the elimination of small sponges (2x3 in. and 4x4 in.) from surgical cases when possible.
- *Purchase radiopaque towels for use in thoracic and abdominal cavities.
- Use whiteboards in the OR suites to document counts.
- *Maintain continuity whenever possible by having the same team of OR staff start and complete a case. Whenever possible, lengthen assignments for consistency.

- Conduct observational study of count process to learn vulnerabilities, identify specific distractions, and improve process design.
- Enforce quiet or dedicated time during final counts so nurses performing them are not disturbed.
- *Requests for stat X-rays in the OR for surgical cases with an incorrect count should include: type of procedure, surgical site, surgeon, and nature of missing item. Stat intraoperative X-rays should be jointly or sequentially reviewed and discussed by the surgeon and the radiologist.
- *Check kick-buckets and trash before initiating sponge and instrument counts.
- Sponge wrappers should not be discarded until the final count is complete and accurate to corroborate initial and final counts.

In the future, Electronic Article Surveillance (EAS) may play a role in sponge and instrument counting. Radio Frequency Identification (RFID) sensors are becoming increasingly miniaturized, some recently cited as being the size of a grain of sand. This technology has the potential to facilitate dramatic changes to the practice of sponge counting and detection.

For additional information see:

Gawande, A. et al. Risk Factors for Retained Instruments and Sponges after Surgery. *N Eng J Med* 2003;348:229-235.

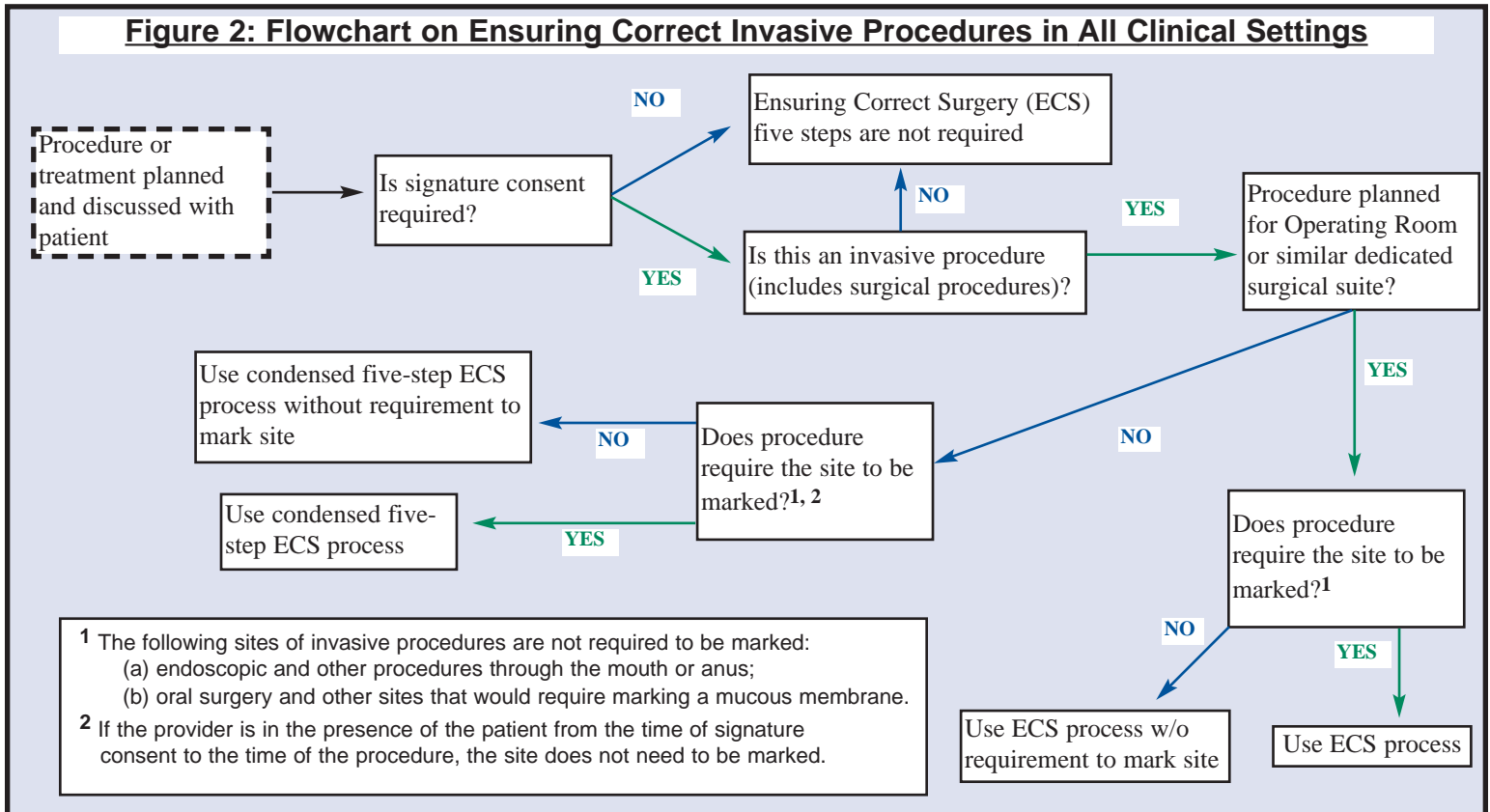
AORN web site: www.aorn.org

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- 2 Hyslop, J. Maulm i, K. Natural history of the retained surgical sponge. *South Med Journal* 1982; 75:657-60.
- 3 AORN, Inc. (2004) *Standards, Recommended Practices, and Guidelines*.
- 4 Gawande, A. et al. Risk Factors for Retained Instruments and Sponges after Surgery. *N Eng J Med* 2003;348:234.



Figure 2: Flowchart on Ensuring Correct Invasive Procedures in All Clinical Settings




this, the American Academy of Orthopaedic Surgeons developed additional guidance that is incorporated into the new directive as follows: In spine surgery, or when the bone or level is not identifiable visually, the surgeon takes an intraoperative X-ray using markers that do not move to confirm the site.

- In some cases, procedures performed outside of the OR may be performed by an individual practitioner working alone. In these cases, the requirement for two practitioners to perform the step requiring an imaging check, as well as for a time-out, will not apply. The sole practitioner should pause to review the relevant information, as would be done in a time-out; the imaging data should be reviewed in the same manner as would be done were the sole practitioner with another practitioner.
- In some cases, a special purpose wristband may be used instead of marking the site. JCAHO's FAQs state that an alternative method for visually identifying the correct side should be used (e.g., a temporary unique wristband or other similar device) when it is technically or anatomically impossible or impractical to mark a site. For example, JCAHO has OK'd the use of a wrist-

band instead of a mark for operative sites on the genitalia or perineum, but has also made it clear that an operative site that can be marked easily, such as a site on a breast, must be marked unless the patient refuses a mark. A wristband can also be used whenever a patient refuses a mark.

- The requirement to mark the site is waived for endoscopic procedures performed through the mouth or anus. The requirement to mark the site is also waived for oral surgery, tooth extractions, and other procedures where marking the site would require marking a mucous membrane rather than skin. For dental extractions, a radiograph or diagram of the mouth showing the tooth (or teeth) planned for extraction should be marked and reviewed with the patient, and with any participating assistant (e.g., dental technician) prior to the procedure.

In summation, the biggest difference between the two directives is that the 2004 update adds out-of-OR processes and allows for the use of a wristband instead of a mark in limited situations. We have had multiple reports of adverse events being prevented by the five-step procedure and the results will be the subject of a future *TIPS* article. 

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