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## Overview: Retained Foreign Objects During Vaginal Deliveries and Caesarian Sections

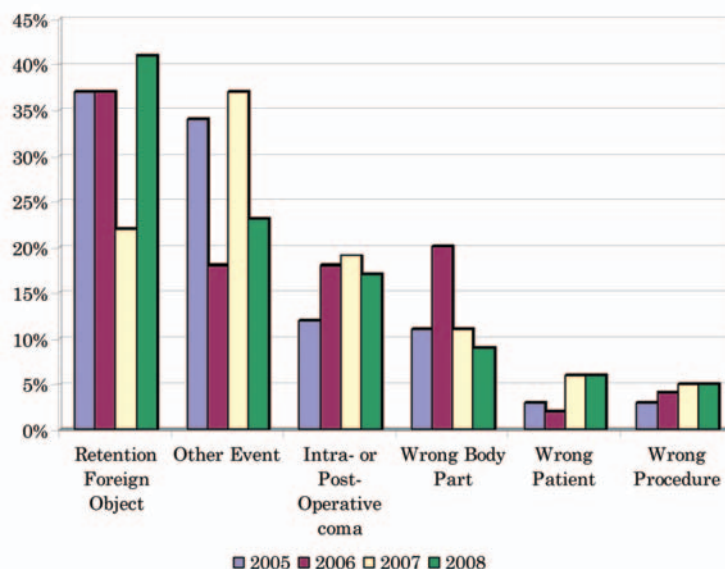
Retention of foreign objects, such as, sponges and instruments is considered by the National Quality Forum and other national organizations to be a preventable adverse event that should never happen. The Centers for Medicare and Medicaid Services includes the retention of foreign objects in its list of non-reimbursed hospital-acquired conditions. In 2005, The Joint Commission added retained foreign objects to its list of sentinel events. Nationally, it is the seventh most frequently reported sentinel event and the fourth most frequently reported event in 2008.<sup>1</sup>

A retained foreign object can result in post procedure infections, bowel perforations, abscess, undue pain, return to surgery and even death.<sup>1</sup> A retrospective case-control study was conducted on patients with retained instruments or sponges following a procedure. Sixty cases were identified with 54 of these cases confirmed to have a retained object. Sixty-nine percent of these cases identified the retained objects as sponges. Over half of these objects were retained in the abdomen or pelvis and 22% were retained in the vagina.<sup>2</sup>

In the four years that the New Jersey Department of Health and Senior Services (NJ DHSS) has been collecting serious preventable adverse events, retention of foreign objects has been the most frequently reported surgery-related event type. Since 2005, there have been 111 retained foreign object events, 64 (58%) of them occurring in female patients. Of these 64 events, 36% were related to obstetrical procedures, generally caesarian sections and vaginal deliveries.

Many facilities do implement counting protocols for surgical procedures that occur in the operating room. However, after review of the root cause analyses (RCAs) for the retained object events reported to NJ DHSS following a vaginal delivery or caesarian section, 50% of the events did not include a count of the sponges, pads, or gauze for these types of procedures. Upon review of the RCAs another trend emerged. Frequently visual inspection of the vagina or a gauze count after a repair of the vaginal area is not required. Thirty-one percent of the RCAs did report a documented correct count, however it later turned out that these counts were incorrect. In some facilities (13% of the events) the count was conducted as the surgeon was closing the incision. In one case, the surgeon was made aware of the missing instrument and decided to close anyway. Most of these retained objects were discovered within two weeks of the event. However, one retained object was not discovered for three years and was calcified.

### Surgery-Related Events



## Dependability of Counts

There have been several studies conducted on the reliability of surgical counts. Generally, the labor and delivery team rely on discrepancies in the count to screen for the possibility of retained objects.<sup>3</sup> However, many studies have found this practice to be unreliable or insufficient. One study on retained objects discovered that the majority of the retained objects were associated with a count that was erroneously thought to be correct, which is consistent with NJ DHSS's findings.<sup>2</sup> The incorrect counts were due to limitations in the counting procedures, such as, additions, incorrect documentation, or miscounting. These studies concluded that manual counts are not reliable enough to be used without concurrent manual visual checks. Any count discrepancy should prompt a thorough search and reconciliation and should never be ignored.<sup>4</sup>

There is technology available to help assist in the detection and prevention of retained objects. To augment the manual count, radio-frequency (RF), radio-frequency identification (RFID) and bar coded detectable sponges, gauze, and laparotomy pads are available.<sup>3</sup> Use of this technology will help with early detection of retained objects, prevention of additional surgery to retrieve the objects, and the need for x-rays to locate retained objects.

## Human and Environmental Factors

Many different human and environmental risk factors can result in retained objects. These include communication failures, distractions from the various competing interests and lack of staff.<sup>3</sup> According to The Joint Commission, the number one causal reason identified in all the root cause analyses was miscommunication or lack of communication.<sup>5</sup> The Joint Commission has designated communication as one of its national patient safety goals.

There is a hierarchical structure in many facilities that contribute to communication failures: cross-cultural (physician to nurse), gender-related (male to female), captain-crew (surgeon to OR team) and structural (medical staff to hospital staff).<sup>6</sup> Other cultural aspects include levels of education, training, and experience. Those with less education or training may feel intimidated by those with more and may not feel comfortable speaking up about issues such as a discrepancy in the counts. Another

factor in miscommunication is the different styles of communication; closed or harsh communication can limit the exchange of information. Many facilities have implemented Situation, Background, Assessment, and Recommendations (SBAR) as one way of improving communication.

Environmental factors also contribute to retained objects.<sup>5</sup> Noise in the procedure room (i.e. music, conversations, and equipment noise) traffic in and out of the room and interruptions can all cause distractions during the counting process.<sup>6</sup> Noise can and should be controlled. Traffic and interruptions should be at a minimum, especially while counting, to avoid errors in the process.

Other causes of retained objects include abbreviated or omitted counts during emergency situations, additional unexpected surgical procedures, transvaginal surgery or vaginal emergencies.<sup>6</sup> A patient's higher body mass is another risk factor that can make it difficult to visually determine if an object is still in the patient. Sponges sticking together and the use of a poor counting system are additional risk factors.

## Second Look: Review of Events and RCAs

*1. An emergency caesarian section was performed. A sponge count was done and documented as correct following the surgery by the circulating nurse. During one of the counts a lap sponge fell to the floor and when it was found it was not certain if it was placed with the other soiled sponges. This sponge was included in the count and may have been counted twice, resulting in the count being correct. Post operatively, the patient experienced abdominal pain and x-rays were taken. The x-rays detected a lap sponge in the abdomen.*

**Response:** As a result of the RCA process, the facility has revised its protocols to have both the scrub and circulating nurse count the instruments and sponges. The circulating nurse will stretch out all of the lap sponges on a blue pad in the room for visualization, count all the items aloud, confirm the number with the scrub nurse and document the number on the count

sheet. This will be repeated at set intervals during the procedure and at the end of the procedure. Both nurses will sign off on the count sheet when the counts are correct.

- A female patient presented to the emergency department with complaints of abdominal and pelvic pain. Two weeks earlier the patient had a vaginal delivery of a healthy infant with no complications. Upon examination, surgical gauze was found and removed from the vagina.*

**Response:** Although the patient suffered no lasting physical harm, the facility revised its vaginal delivery checklist to include post delivery digital vaginal inspection and a sponge count. Documentation that this inspection was completed is now required and will be completed by both a physician and a nurse. Also, a sponge count will now be conducted on **all** labor and delivery cases.

- A patient underwent a caesarian section for a pre-term delivery. During surgery a large ovarian mass was removed. At the end of the lengthy procedure the instrument and sponge count was incorrect. An x-ray was performed and a nurse was informed by radiology that it appeared that something was on the film, probably drains. The nurse asked the anesthesiologist and another nurse if the patient had drains, to which they replied yes. It was then assumed that this was what was showing up on the x-ray. The attending surgeon did not speak to the radiologist and accepted the information given by the nurse that the x-ray was negative. The missing lap pad was never accounted for. Approximately one month after the surgery the patient returned for follow-up and x-rays were taken, which revealed the lap pad. The patient underwent exploratory surgery and the pad was removed.*

**Response:** A break down in communication was the primary cause of the retained object. To improve communication, a new process was developed. When there is an incorrect count, the nurse will document the incorrect count in the chart and complete an OR x-ray request form. The x-ray technologist will sign off on the form and complete the x-ray. The form is then scanned to radiology and the times of the order, when the x-ray was completed, when the radiologist was notified and the time that the radiologist spoke to

the surgeon will be entered on the form, similar to a chain of custody form. Also, the ability to remotely read the x-ray on the labor and delivery unit will allow interactive communication between the radiologist and the surgeon.

## Effective Corrective Actions/ Recommendations

There are several issues involved in preventing retained objects, especially during vaginal deliveries or caesarian sections. The first issue is making sure that there are policies and protocols in place for counting sponges/soft goods during these procedures. Other issues include ensuring the reliability of surgical counts, recognizing, evaluating, and controlling the human and environmental factors during the counting process.

### Counting Procedures and Protocols

- The Institute for Clinical Systems Improvement (ICSI) believes that active support from administrative and medical leadership for counting sponges/soft goods during vaginal deliveries and caesarian sections is crucial.
- ICSI recommends 3 rules that should be included in the protocol:
  - All sponges and sharps will be counted for **every** vaginal delivery
  - Only radiopaque sponges/soft goods will be present on the labor and delivery trays or enter the delivery field
  - If the count can not be reconciled imaging must be done
- The count process should be performed at the following times:
  - Immediately before the delivery pack is used
  - At the end of the delivery
  - Any time a member of the labor and delivery team is concerned about the accuracy of the count
  - Whenever there is a permanent change of the labor and delivery nurse
- Other recommendations for counting protocols include:<sup>5,7</sup>
  - Use of audible and visual aids such as, having a count worksheet or a white board in labor and delivery to keep track of baseline and final counts

- A dedicated receptacle for all used sponges/soft goods. This should be in a location where staff can retrieve and count these items and not be mixed with the waste bucket
- Allow sufficient time for the count
- Counting process should include a registered nurse and another person trained in the counting process
- Unless absolutely necessary, avoid disturbing the nurse during the count
- Inform the labor and delivery team about additional items added to the count
- Actively ask if the count procedures have been conducted at the end of the procedure
- Verify the final count before any items are removed from the labor and delivery area
- Countable items that accompany the infant out of the labor and delivery area will be communicated to the labor and delivery nurse and documented
- After all the counts have been reconciled, all the items should be removed from the labor and delivery area
- Have a policy in place for when the count does not reconcile, including accountability for initiating this policy

## Minnesota's SAFE COUNT

In 2008 the Minnesota Hospital Association (MHA) started its "Safe Count" campaign to eliminate retained sponges in labor and delivery. Since this campaign started the number of these cases has almost been eliminated.<sup>8</sup> In 2009, Buffalo Hospital Birth Center was recognized by MHA for putting the "Safe Count" into action and reducing the number of retained sponges following vaginal births to zero for 2008 and into the present.<sup>9</sup>

### Safe Count <sup>7</sup>

- S** Safe Count Teams
- A** Access to information
- F** Facility expectations
- E** Educate staff
- C** Count sponges, sharps, and miscellaneous items
- O** Obtain post-delivery imaging
- U** Use of white board/other visual documentation
- N** Never use anything but radiopaque
- T** Time-out "pause for gauze"

## Resources on Prevention of Retained Objects

Minnesota Hospital Association "Safe Count" available at

<http://www.mnhospitals.org/index/tools-app/tool.385?view=detail>

ICSI "Prevention of Unintentionally Retained Foreign Objects During Vaginal Deliveries" available at:

<http://www.icsi.org/forms/feedback.aspx?catID=12818&itemID=12847>

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