

**Patient safety**

## Getting the whole team on board to prevent retained foreign bodies

**A** case of an item left behind after surgery can be like a canary in a coal mine—a signal that an OR department has systems problems. Retained items often happen as a result of poor communication and faulty processes. Perhaps nurses aren't using a standardized counting procedure in all ORs. Maybe surgeons are using towels without radiopaque markers. Surgeons and nurses may not be working together to resolve incorrect counts. Intraoperative x-rays may be poorly taken or misread.

As Medicare and other insurers prepare to stop paying for care of patients with retained items and other preventable complications, facilities are redoubling efforts to prevent this “never event.”

A project called NoThing Left Behind is working to bring the disciplines together and develop evidence-based guidelines and best practices to prevent this rare event. The effort, started in 2004, has involved more than 20 hospitals and many surgeons, nurses, and radiologists, notes the project leader, Verna C. Gibbs, MD, FACS, professor of clinical surgery at the University of California, San Francisco (UCSF), and staff general surgeon at the San Francisco Veterans Affairs Medical Center. She spoke at the Perioperative Care Symposium April 29 to 30 in Chicago sponsored by Joint Commission Resources.

“All parts of the system have a job to do to prevent our tools from being left behind,” says Dr Gibbs. She adds that the NoThing Left Behind guidelines are meant to supplement existing guidelines and recommended practices, such as those of AORN and the American College of Surgeons.

### Three principles

NoThing Left Behind advocates 3 principles at a minimum to prevent retained items, which apply to all OR personnel in nonemergency situations:

1. Use only items with radiopaque markers within the operative site and perform a methodical wound exploration before closing every time.
2. Use standardized practices for accounting for surgical items in all ORs, and allow time to perform them—take a “pause for the gauze.”
3. Call for an x-ray early when there is a discrepancy. Get a quick response, a good-quality study, and expert read back.

Specific steps for surgeons, nurses, and radiologists, called “Easy as 1, 2, 3,” are in the sidebar.

### Use only radiopaque items

Items placed in the surgical wound, such as sponges, towels, laparotomy pads, and gauze patties, should have radiopaque markers, NoThing Left Behind advises. Towels used for packing or retraction should also have radiopaque markers and should be a different color than towels used for drapes. These towels should be sterilely packaged separately and if used in the wound, should be added to the surgical count. This is also a recommendation of the 2006 Veterans Health Administration (VHA) directive on prevention of retained surgical items, authored by Dr Gibbs and the VHA's National Center for Patient Safety and adopted by the VHA's 165 surgical facilities.

### Perform a methodical wound exploration

The typical “swish and a sweep” a surgeon performs before closing the incision



## Steps to prevent retained items



### Surgeons

1. Use only x-ray detectable sponges or towels. Don't alter them.
2. Perform a methodical wound exam while the nurses perform the closing count. Take a "pause for the gauze." Call out, "All sponges are out." Then ask for the closing suture.
3. At the end of the case before leaving the OR, look at the hanging sponge holders and say, "Show me that all of the sponges are there." Dictate, "A methodical wound exploration was performed, and I saw that all sponges were accounted for."

### Nurses

1. **In-count:** Use a standardized and transparent process. Record the count for all personnel to see.
2. **Closing count:** While the surgeon does the wound exam, perform a focused 2-person count, using the sponge holders to get the sponges in one place. Check back: "We think the count is correct."
3. **Final count:** Performed before the patient leaves the OR. Verify that all sponges (used and unused) are in the hanging sponge holders.

### Radiologists

1. X-ray the complete operative field with proper technique; consider oblique/lateral views.
2. Know what is being looked for; eg, the kind of sponge, the size of needle.
3. Report the findings directly to the surgeon of record.

Source: Verna C. Gibbs, MD, FACS.

isn't enough, Dr Gibbs says. "The surgeon has to examine and explore, or as we say, do a methodical wound exam."

This step is especially important in cases involving the chest, abdomen, pelvis, or vagina. This recommendation is also in the VHA directive and is audited quarterly by the National Center for Patient Safety.

After exploring the wound, the surgeon should call out, "I believe all of the sponges are out" and then ask for the closing suture, Dr Gibbs says.

### Use standardized practices

Accounting for all surgical items takes focused attention and time, she notes. After completing the wound exploration and saying all of the sponges are out, the surgeon can allow the "pause for the gauze" while closing the fascia, a time for the nurse and scrub person to complete their closing count.

"This is a critical juncture in the procedure, and in many states is the last opportunity to prevent an item from being considered retained," she says.

When the count is finished, they should say either the counts are correct, or they are missing an item.

## ***Surgical counts: Should we be asking a different question?***

In the effort to prevent retained foreign bodies, are we asking the wrong question? Instead of asking, "What's the count?" we should be asking, "Where are the sponges?" advocates Verna C. Gibbs, MD, FACS, a surgeon who leads a project called NoThing Left Behind to help prevent retained surgical items.

Asking, "Where are the sponges?" puts the emphasis in the right place, she suggests.

"It is not about whether nurses count accurately. It is about being able to account for all of the sponges at the end of a case."

This question also makes clear that accounting for sponges is not solely a nursing responsibility but also involves surgeons and radiologists.

"The surgeons need to give their best effort to get the sponges out of their operative field—that's the methodical wound examination piece—and verify with the nurses that all sponges are accounted for at the final count," which NoThing Left Behind recommends.

Nurses account for sponges by making sure they are all in plastic hanging sponge counters, a method she recommends. If a sponge is missing, radiology is called in to find out if the sponge is in the patient.

### **Accounting for sponges**

Dr Gibbs has worked with nurses to implement the plastic counter bags at 2 hospitals. A counter bag holds 10 sponges (illustration). A separate counter bag is used for each type of sponge. One sponge is placed per pocket, and 2 are placed per pouch, with 10 per counter bag. The bags are similar to hanging racks nurse used for sponges years ago, she notes.

The goal is to have a visible repository for sponges, she says.

"If you have 30 sponges out, at the final count you should have 3 full hanging counter bags. By the time the surgeon has finished the wound exploration, the only place the sponges should be in is the hanging counter bag."

At the end of the case, before leaving the room, instead of asking if the count is

correct, the surgeon would say, "Show me the sponges have been accounted for."

The nurse would show the surgeon the completed counter bags.

If a pocket is empty, the nurses and surgeons would know a sponge is missing, she says. "Then the question is, 'Where is the sponge?' not 'How many sponges are there?' Counting is irrelevant at this point—you need to know where the sponges are."

The hanging bags can become cumbersome if there are more than 5 full bags. In that case, she says, "We recommend that you take down one counter bag, verify that it has 10 sponges, roll it up, have the circulator initial it, and put it in a clear plastic bag in the room." If there is permanent relief of staff, the circulator going off duty reviews the hanging counter bags with the circulator coming on duty.

### **Technology may have an answer**

Technology may eventually help answer the question, "Where are the sponges?" Two technologies that use RFID technology are on the market: the RF Surgical Detection System, distributed by Medline, and the SmartSponge System from ClearCount Medical Solutions, distributed by Cardinal Health.

The systems use sponges with RFID tags plus a wand that can detect sponges left in the patient or lost elsewhere in the room. (See table, p 18.)

"With new technology, we may have a greater capacity to answer that question, 'Where are the sponges?'" Dr Gibbs says. "That is really the goal—nothing left behind in the patient."



*A hanging sponge counter is a visible way to account for sponges.*

### **Use a standardized counting process**

Though all surgical facilities follow the AORN guidelines, Dr Gibbs says most don't have specific standardized processes that are applied uniformly in all of a facility's ORs and labor and delivery suites. NoThing Left Behind recommends:

- Develop a standardized method that must be used by all OR personnel for all ORs and all cases in the facility. "These counting practices can be specific to the type of sponge, as long as all OR personnel are doing it the same way in all rooms, all the time," she says.
- For manual sponge counting of lap pads and x-ray-detectable 4 x 4s, use a single method. "We recommend the use of plastic hanging sponge holders," she says. "Counting out of kick buckets and ring stands makes it difficult to reconcile easily that all sponges have been accounted for." She says she has worked with multiple hospitals to develop a standardized method using the hanging sponge holders (sidebar).
- Develop a standard nomenclature for all sponges used in the OR as a communication tool.
- Develop a standardized, visual way to record and display the surgical count in each OR. "We recommend a dry-erase board because it is inexpensive, multipurpose, and provides a visual record anyone in the OR can see," she says.
- Ensure the sponge count is written in a standardized format. One suggestion is to use the same notation used for the atraumatic needle count:

Laps: 10 20 25 30 35

Ray-Tecs: 10 20 30

"We trained OR personnel in this method in over 100 cases to study the utility of the change," Dr Gibbs says.

Initially, some nurses were concerned about confusing the needle and sponge counts. She says confusion can be minimized if labeling on the count board is clear, and sponge and needle counts are kept in different positions on the board. After evaluating the new method, she says the nurses now question why they had 2 systems in the first place and why they hadn't been doing it this way all along.

### **Verify sponges are accounted for**

At the time of the final count, before the surgeon leaves the room, all sponges should be in the hanging sponge holders, Dr Gibbs notes. This includes unused as well as used sponges.

The surgeon can look at the sponge holders with the nurses and see that all of the sponges have been accounted for.

"In 80% of cases where there has been a retained sponge, the count has been incorrectly called 'correct,'" she says. "With this visual verification method using the hanging sponge holders, the count will be proven correct. This provides a powerful reassurance to the team that they have properly accounted for all of the sponges."

### **If there is an incorrect count**

If the count is incorrect, NoThing Left Behind recommends the following steps:

- If the nurses tell the surgeon there is a missing sponge, the surgeon should stop closing the wound. "Concerns about a discrepancy should not be dismissed," she says. "In cases where a sponge has been retained when there was an incorrect count, the most frequent error is that the surgeon failed to stop closing the wound and do a thorough exploration."
- If the body cavity has been closed, the surgeon should remove enough sutures to allow a visual and tactile exploration.
- If the item is not found immediately, additional nursing personnel should be called to help.
- It saves time to call for an x-ray early.
- The missing item must be found or confirmed not to be in the patient before the

## Sponge counting and detection technologies

	Bar code	Radiofrequency	Radiofrequency
<b>Brand name</b>	SurgiCount Medical Safety-Sponge System	RF Surgical Detection System	ClearCount SmartSponge System
<b>Web site</b>	www.surgicountmedical.com	www.rfsurg.com	www.clearcount.com
<b>Distributor</b>	Cardinal Health	Medline Industries	Cardinal Health
<b>FDA cleared?</b>	Yes	Yes	Yes
<b>Description</b>	The system has 2 components: surgical sponges and towels with data-matrix bar code labels and a scanner to record each sponge before and after the operation.	The system has 3 components: a micro RF tag embedded in gauze, sponge, and towels and a sterile handheld wand connected to the third component, a self-calibrating console.	The system has 3 components: A scanning pad, sponges with attached RFID tags, and a wand device.
<b>What it does</b>	Using the scanner, each sponge is scanned and recorded during the initial and final counts. At the end of a procedure, the information can be downloaded to a desktop database or a printed report can be produced.	By passing the wand over the patient, personnel can detect retained disposables before surgical closure.	Sponges are scanned in at the beginning of the case and scanned out at the end. If there is a discrepancy, a wand is used to scan the patient.
<b>Cost</b>	\$12 to \$14 per procedure (estimated)	\$50 to \$55 per open procedure	\$35 to \$50 per case on average
<b>Evidence</b>	In randomized controlled trial, bar-coded sponge system detected significantly more counting discrepancies than traditional counting. The system also introduced new technical difficulties and increased counting time. <i>Greenberg C C, Diaz-Flores R, Lipsitz S R, et al. Ann Surg. 2008;247:612-616.</i>	Hospitals collecting data; not yet published.	Wand scanning device had 100% success rate in detecting sponges with RFID tags in an experimental study. <i>Macario A, Morris D, Morris S. Arch Surg. 2006;141:659-662.</i>

patient leaves the OR. "This gives the team the chance to get it right while the patient is still in the OR, preventing a repeat operation to remove a retained item," she says.

- The surgeon should dictate in the operative report what actions were taken in response to the incorrect count and the results of the search.

"Ideally, all incorrect counts are rectified, and the final counts are recorded as correct," she says. "But we know that in some circumstances, items are never found, especially missing needles."

### Call early for x-ray

Radiology policies for preventing retained items are a “systems issue—you have to get the hospital administration engaged,” Dr Gibbs says.

Regarding radiology practices to prevent retained items, NoThing Left Behind recommends that facilities:

- Require an x-ray of the operative field in the event of an incorrect count, assuming the patient is stable.
- Develop a standardized process for requesting intraoperative x-rays to look for missing surgical items.
- Develop a standardized process for the radiologist’s read back of requested intraoperative films.
- Ensure radiology technicians are trained in performing intraoperative portable x-rays, especially films of the entire operative field, of obese patients, and lateral/oblique films on the OR table.
- X-ray technicians should be available during the times ORs are available. Response to the OR should be less than 20 minutes. Radiologist read-back confirmation to the OR should be available within 20 minutes.
- If no radiologist is immediately available to review the x-rays, films should be read by the surgeon but reviewed within 12 hours by a radiologist.
- Training and annual competency review for radiologists should include recognition of surgical items. Though one might think identifying sponges and other surgical implements is easy, it isn’t, says Dr Gibbs.

“There is no radiology specialty called ‘foreign body detection,’ so radiologists don’t usually have specific training in recognizing these objects,” says Dr Gibbs. UCSF has a teaching tool for use by faculty and residents website at [www.radiology.ucsf.edu/instruction/abdominal](http://www.radiology.ucsf.edu/instruction/abdominal).

She thinks that as new radiofrequency technologies are perfected for detecting sponges, the need for radiology for this purpose may become obsolete.

### What about needles?

Retained needles may account for up to 50% of retained objects. How well are needles detected in x-rays?

Dr Gibbs and her group recently published a study that tested x-ray detection of 39 needles of various sizes randomly placed in a pig cadaver. Eight films were taken and independently read by 5 radiologists. Results showed detection was strongly associated with needle size and was under 50% for needles smaller than 10 mm.

The authors concluded that plain films are accurate for detecting needles over 10 mm retained in the abdomen. They suggest that x-rays continue to be used following incorrect needle counts when the size of the needle is known. They also suggest that the physician tell the radiologist the size of the lost needle. For needles smaller than 10 mm, use of plain abdominal films is more debatable, they note. These needles can’t be seen on x-ray, are unlikely to be found, and there is no evidence that these small needles cause injury. ❖

For more on *NoThing Left Behind*, visit [www.nothingleftbehind.org](http://www.nothingleftbehind.org).

### References

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## ***Surgical count policy must-haves***

- Address issue of surgical "drape" towels.
- Replace "surgeon's choice" with mandatory x-ray in situation of incorrect count.
- Outline how surgical counts are to be performed. Let there be time for the count.
- Require miscount reports and give review and feedback as soon as possible.

### **Radiology**

- Radiologists read radiographs better.
- X-ray technician will take image; image is reviewed by on-call radiologist; radiologist will call back to the OR and orally report findings, with readback and documentation in OR.
- Patient can't leave room until x-ray is reviewed by surgery or radiology experts.

*Source: Verna C. Gibbs, MD, FACS.*

## Questions to ask about RF sponge-detection systems

RF sponge-detection systems, fairly new to the market, are intended to detect sponges that may have been left behind before the wound is closed. The systems include sponges with RF tags and a wand for detecting the sponges.

These are questions to ask if you're considering such a system, suggested by Erick Jones, PhD, independent RFID researcher, University of Nebraska-Lincoln.

### 1. Does the vendor use an open or closed RFID technology?

If the company goes out of business, is this system compatible with other companies' RFID tools? Does the system use a standard RFID frequency that other manufacturers can write to (that is, the Gen 2 ISO-approved RFID standard)?

### 2. What is your objective? Do you want to track, trace, or locate sponges?

- Tracking is the ability to track sponges as they move from one reader antenna to another (eg, one room to another, one shelf to another).
- Tracing means tracing the sponge from the nurse to the surgeon to the patient and back again.
- Locating means being able to locate a sponge wherever it is in the room.

Basically, the more functions you want the system to perform, the more expensive it will be. Tracking is least costly, tracing is more costly, and locating is the most costly.

### 3. What is the reliability of the RFID tags the company is using?

Can the company provide results of reliability studies by an independent testing lab? Was the testing performed under conditions that simulate an OR environment rather than in a pure laboratory setting?

### 4. What about electromagnetic interference?

A Dutch study published in the June 25 *JAMA* found RFID systems have the potential to cause malfunctions in critical patient equipment. The researchers tested 2 types of RFID systems with 41 medical devices in a nonclinical setting. There were 34 electromagnetic interference incidents, with 22 classified as hazardous. The hazardous incidents occurred at a median distance of about 10 inches between the RFID system and medical device.

Jones notes that most studies on frequency conclude that RFID overall has less effect on medical devices than cellular phones. Still, he advises testing before buying or implementing RFID equipment.

His advice:

- Be aware of the tag frequency ranges.
- Ask vendors to provide information on what equipment their system has previously had interference with. If they do not know, have them run a test showing that all the OR's equipment will work when using their products.
- Have the vendor or an independent lab use a spectrum analyzer to document and identify the frequencies used in your OR.
- Document the equipment used in your ORs, the frequency at which it operates, and how long it operates.

### 5. How does the company's software work?

Will the software integrate with the OR information system and other hospital information systems? You may want to run a trial to upload the company's data to your system.

### 6. Will the system save costs?

You need to do a cost analysis. A rule of thumb: If the system costs less than \$100,000 to purchase and \$25,000 in annual maintenance, it will allow you to be more

productive. If the purchase price is over \$100,000, you should bring in others to assist in decision making, such as the hospital administration and/or the IT department.

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## **Reference**

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