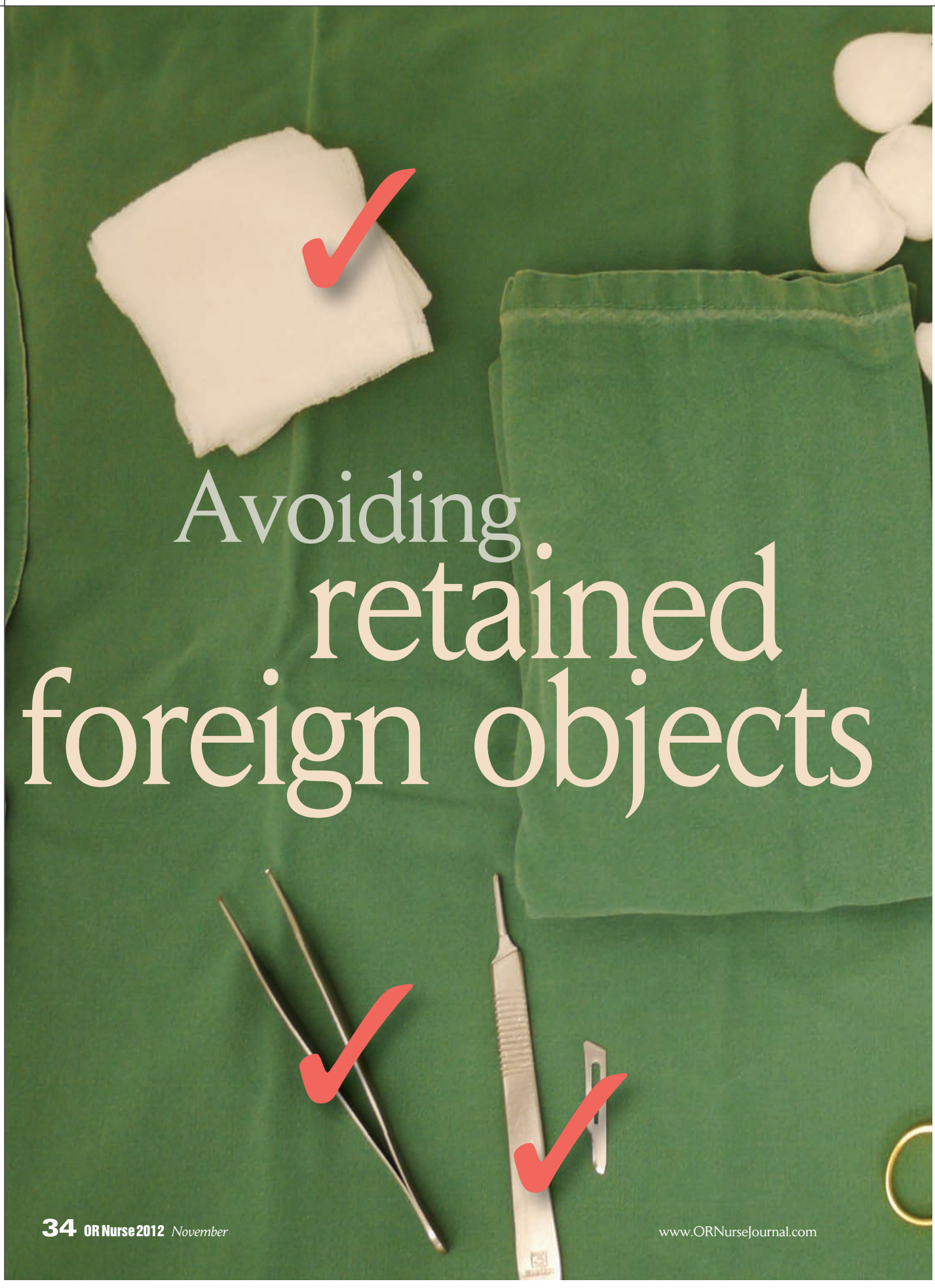


Avoiding retained foreign objects

By Kyung Jun, RN, MSN, CNOR, and Jennifer Blaha, MBA

A standardized process developed by an interdisciplinary team was the key to preventing retained foreign objects (RFOs).

In October 2008, the Centers for Medicare and Medicaid Services (CMS) stopped reimbursing healthcare providers for 11 "never events"—preventable adverse outcomes that should never occur in a healthcare setting.[1] CMS's refusal to reimburse for never events has become a burning platform to prevent RFOs in surgery. It's estimated that 44,000 to 98,000 events occur in hospitals every year and result in patient harm.[2] The prevalence of RFOs is approximately 1 out of every 1,000 abdominal procedures, or up to 1 out of every 18,000 surgeries performed.[3,4] There's an increased risk of RFOs in surgeries that include unplanned changes during the procedure, an emergency, a patient with a body mass index (BMI) greater than 40, when more than one surgical team is involved, and having multiple changes in nursing staff.[3,4]

Cedars-Sinai Health System took an interdisciplinary approach to reducing RFOs. The taskforce included surgeons, anesthesiologists, nurses, surgical technologists, radiologists, clinical engineers, and performance improvement facilitators. The goal was to reduce RFOs, and in order to achieve it, the team needed to know why it was occurring. An internal survey and review of the literature offered insight into the common causes of failures within the counting process. The statistics were unsettling: in 62% to 80% of all RFO cases, the final counts were noted to be correct.[3,5,6] The team wanted to get the perspective from those who work in the OR every day, with a goal of uncovering the root causes of the problem. Over 100 people, including nurses, surgical technology staff, surgeons, and anesthesiologists were surveyed (see *OR survey: Retained foreign objects*). Survey topics were geared toward discovering the processes that prevented staff from counting correctly. The survey results revealed three primary reasons for incorrect counts: interruptions, multitasking, and distractions.

The nurses were frequently interrupted during their count process by surgeons to obtain additional

OR survey: Retained foreign objects February 2009

Your answers are completely anonymous. Please be as detailed as possible to help uncover improvement opportunities.

1.) What is your role in the operating room?

☐ Anesthesiologist
☐ Nurse
☐ Scrub Technician
☐ Surgeon / OBGYN
☐ Other: _____

Specialty (if applicable):
_____

2.) Current CSMC Policy states that needle, sponge, and instrument counts should occur with every procedure. In your experience, do you <u>always</u> count

Needles?	**Sponges?**	**Instruments?**
☐ Yes	☐ Yes	☐ Yes
☐ No	☐ No	☐ No

Briefly explain why you might not count_____

3.) Should other items be included in the counts (electrosurgical scratch pads, etc.)?

☐ Yes
☐ No

4.) If you answered Yes above, please list items that are not currently included in the counts that you believe should be included: _____

5.) The amount of time spent on the count is:

☐ Too little time
☐ Time is adequate
☐ Too much time

6.) What distractions interfere with the count? Please rank 1 - 5 [1 being the most distracting]

____ Multitasking
____ Music
____ SIS computer entry
____ Too many people in the room
____ Other: _____

7.) When a count is off, what happens? _____

8.) Do you feel comfortable addressing concerns with any member of the OR team (surgeons, nurses, etc)?

☐ Yes
☐ No

If you answered No, please explain _____

9.) Is it clear to you when an x-ray should be performed?

☐ Yes
☐ No

10.) How often do personnel changes happen during procedures?

☐ 0% to 25% of the time
☐ 26% to 50% of the time
☐ 51% to 75% of the time
☐ 76% to 100% of the time

11.) The hospital is required to report all retained foreign items to the Department of Health Services. This information is publicly reported, and available on the internet. Hospitals can be fined. The penalty can include which of the following (check all that apply)?

☐ Up to a $10,000 fine payable to the state
☐ Up to a $25,000 fine payable to the state
☐ Up to a $25,000 fine payable to the patient
☐ Free hospital care for the patient

12.) If you had one suggestion to reduce the risk of retained foreign objects in the OR, what would it be?

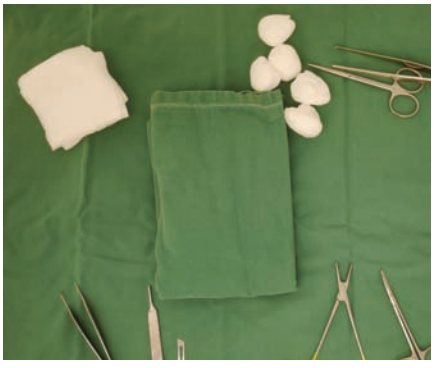
_____

_____

Thank you for your participation.

Example used with permission from Cedars-Sinai Health Systems.

sutures, to answer cell phones, and to prepare the next patient. After being interrupted, the nurse would pick up where he/she left off, which lead to counting errors. Additionally, the nurses are multitasking to keep up with computerized documentation, counting, and meeting the surgical team's additional needs. The surgical technologists are asked to count while handling instruments for surgeons. Multitasking while counting can be detrimental to the patient undergoing surgery. The survey also found that loud music and hand-offs were distractions that threw off sponge, needle, and instrument counts. Together, interruptions, multitasking, and distractions all divert attention away from the circulating nurse and the surgical technologist causing incorrect counts. Based on the survey results, a taskforce was formed to focus on solutions for these key areas.



The survey results revealed three primary reasons for incorrect counts: interruptions, multitasking, and distractions.

Knowing that physicians and staff are often resistant to changes on any improvement initiative, the team put together a core group of well-respected, experienced, and influential surgical technologists, nurses, and anesthesiologists. These individuals met regularly to assess the recommendations coming from the larger RFO taskforce. Were the recommendations practical? How would the staff react? What's the best way to introduce a new concept? This group helped determine whether or not the recommendation would impact the crucial areas noted by the staff; they were also key champions when new processes were introduced. The following is a summary of some of the successes.

The count board

The survey results showed a lack of standardization related to the counting system on the count board. Cedars-Sinai has 34 ORs on five different floors, so a lack of standardization added a lot of variation to the process. Staff members faced challenges as they moved from room to room. The team standardized the count board using the principles noted in the table (see *Count board*).

What goes in, must come out

The RFO Prevention Team started identifying all countable items in order to standardize the count board. The goal was to include a comprehensive list of countable items in the policy to ensure that nothing was missed. The list contained over 100 items that needed to be counted. The items weren't standard for every case, and the count board wasn't large enough for 100 magnets. After abandoning the quest to create a list of all countable items, the group instead turned to a new way of thinking: "What goes in must come out." Following the AORN guidelines for the counting process, staff were trained to always count in the same order.[6-8] The count begins with lap sponges, then moves to 4x4 gauze sponges, needles, case-specific items, and

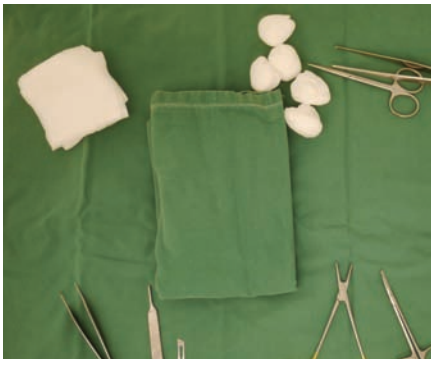
Count board

Elements	Details
Placement	• Easily viewed and accessible • Same location in every room
Size	• Large enough for all critical elements to be included
Items included	• Sponges • 4x4 • Needles and microneedles • Knife blade • Packed items
Packed items	• Surgeon calls out the item • RN writes item and number of item on the board • Once packed item is retrieved, item is crossed out and initialed
Needles	• Separated: larger than 13 mm and equal to and smaller than 13 mm
Standardized addition	• 2+2=4 versus $2^2/4$ (this standard will reduce math errors as well as prevent the "/" from being mistaken for a one)

finally, the instruments. The inspection process begins at the sterile field, moves to the mayo stand, then to the back table, and finally to the sponge counter bags.

Sponge counter bags

At the end of the case, it's easy for staff to think that they've accounted for all the sponges. The sponges get wrapped in the drape and tossed, and the entire team believes that all of the sponges were successfully removed from the patient. The concern is that the team can miss one, and a patient could return with a retained sponge. In order to reduce this risk, Cedars-Sinai uses sponge counter bags throughout all cases. The bags have been used at the hospital for many years, and now, the Nothing Left Behind initiative, led by Dr. Verna Gibbs, has been incorporated. Dr Gibbs is a surgeon who began a national surgical patient safety project to help hospitals prevent retained surgical items in the OR. One of the simplest solutions she supports is the use of sponge counter bags and visual inspection that the bags are full. The idea is to show the team all of the retrieved sponges rather than tell them that the count is correct. When the surgeon and the staff use the "show me" concept, both parties are accountable for knowing—with certainty—that all sponges were removed from both the field and the patient.[6]



Everyone in the room had to be accountable for the safety of the patient including the surgeon, the scrub technologist, the nurse, and the anesthesia provider.

Another new rule was to never pack 5 or 10 laps because the RN and surgical technologist are more likely to think they wrote an extra five on the board as opposed to thinking five lap sponges are unaccounted for. Instead, the practice is to pack a number different than what's contained in a package (6 or 4 laps, for example), so the surgical team doesn't lose track of entire packs.

The team uncovered another opportunity related to packed items. Patients requiring packed sponges must have the details documented in their electronic medical record and noted on the front of the chart. Noting the specifics (both the item packed and the number), allows the caregiver to quickly and safely obtain information, and ensure that everything is properly removed.

X-ray criteria

When the team looked at the X-ray criteria, they found it very vague. Not wanting to expose all patients undergoing surgery to radiation, the policy opted to take X-rays of only the patients who had an increased likelihood of an RFO. This was quite a challenge since "high likelihood" was very subjective and frequently led to disagreements between the nursing staff and surgeons. Since the policy didn't have clear rules that dictated when to call for an X-ray, the policy was simplified to the following four situations: when the count is incorrect and the search was fruitless; an inability to count for any reason such as trauma and emergency cases; after packed items are removed from patients returning to the OR; and when a member of the surgical team requests an X-ray for any reason.

When an X-ray is taken, the radiologist must speak directly to the surgeon to convey the result and to make sure that the wound isn't closed until a negative X-ray is confirmed. X-ray films are taken in the OR prior to the "last stitch" because the state of California defines RFOs as any object left in after the final stitch. The staff expressed confusion about the X-ray process for micro-needles, and a clarification was issued. When a microneedle (defined as 13 mm or smaller) is missing, it's at the surgeon's discretion whether an X-ray is needed;[6] this decision should be based on whether a search for the fine needle would cause harm to the patient and whether the needle could be detected by an X-ray. In addition, the surgeon must disclose to the patient and the family that a microneedle is missing.

Technology

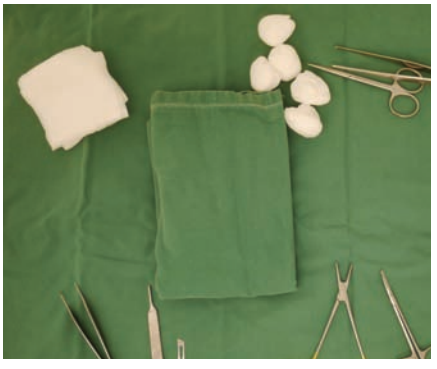
There are several technologies to assist in preventing retained sponges. The taskforce researched three types: a radio-frequency identification (RFID) wand, an RFID sponge counting bucket, and bar coding. The RF Surgical Detection System uses

RFID tags in the sponges and gauzes along with a wand that can detect sponges left inside a patient, hidden under a drape, or accidentally thrown out in the trash receptacle.[9] With the ClearCount Medical Solutions Smart Sponge System, sponges are scanned in at the beginning of the case and scanned out at the end. Throughout the case, the sponges are tossed into a bucket and automatically counted by the system. When one is missing, a wand is also available that can be used to scan the patient.[10] The SurgiCount Safety-Sponge System uses bar code labels and a scanner to record each sponge before and after the procedure. At the end of the procedure, the information is downloaded or printed for the medical record.[9] With any technology, the institution must weigh the benefits and risks of implementation. While the technologies could detect sponges, nothing on the market (to date) can detect everything including sponges, needles, and instruments. When evaluating technology, institutions should consider ease of use, cost, time added to the case, as well as the impact of the additional distraction of using the equipment.

Another technical possibility is to take an X-ray of every patient. The added risk of unnecessary radiation paired with the additional cost to the patient ultimately led to the decision not to trial or implement any technology system. Instead, the hospital chose to rely on the low-technology sponge counter bags.[6,7]

Accountability: Checkout process

At the start of the journey, the team interviewed many surgeons and learned that they get immersed in their procedures. Surgeons are busy trying to resect tumors, fix fractures, or control bleeding vessels. They're focused on the patient and often become unaware of the status of the count. If the surgical team tells them that the count is correct, that is what the surgeon will believe, as they are not thinking about where the sponges, needles, or instruments are. Prior to the taskforce, the scrub technologist and circulating nurse had sole responsibility of surgical items, however, this model didn't work. Everyone in the room had to be accountable for the safety of the patient including the surgeon, the scrub technologist, the nurse, and the anesthesia provider.



Approximately 3 in 1,000 internal fixation cases result in drill bit failures.

To minimize distractions during the count process and to increase accountability of all team members, a check out process was introduced. The team adapted the Surgical Safety Checklist created by the World Health Organization on the basis that it had been shown to reduce complications in surgery including death.[12] The goal was to introduce a safety process at the end of the case that mirrored the Time-Out at the beginning. Elements of the checkout process include a pause while the surgeon announces closure; a methodical wound exam (MWE) completed by the surgeon, uninterrupted counts completed by nursing personnel, and finally, an attestation of completion of the MWE along with the count. The nurse holds the closing suture until the count is completed. Distractions must be minimized during the check out process, including turning off music and avoiding hand-offs.

The MWE is a visual and manual inspection of the area explored during surgery; its sole purpose is to confirm that no items have been left in the wound.[7] Each surgical division chief was responsible for defining an MWE for their specialty.

Cedars-Sinai has over 300 surgeons on staff, so educating them about process changes is a challenge. In order to inform the surgeons about the required MWE, a web-based education module was created and required the user to complete a post test. Surgeons must complete the training module every 2 years to retain privileges. Additionally, posters were placed in the ORs as a constant reminder to leave nothing behind. Finally, an RFO Prevention video with participation from surgeons, anesthesiologists, OR staff, and labor/delivery was developed as an additional educational tool.

Reinforcement

The nursing staff and technologists should be educated on surgeries and circumstances that contribute to a higher probability for an RFO. Unplanned changes in procedures, emergent cases, increased BMI, multiple surgical specialty involvement, and multiple

nursing hand-offs are all scenarios that staff must proactively anticipate as high risk. In these cases, hand-offs by staff should be minimized, the scrub and circulating nurses should not be given breaks at the same time, cell phones should be turned off, and excessive noise and music should be avoided. The Time-Out and checkout must be done with a deliberate pause and mindful communication.

Retained failed devices

During the journey to reduce RFOs in surgery, the team uncovered increased reporting of retained failed devices. This can result from an instrument breaking during a case. Approximately 3 in 1,000 internal fixation cases result in drill bit failures.[13] These items can include broken drill bits that become imbedded in the bone and broken tips of screwdrivers; these events are most common during orthopedic and spine procedures. When these events occur, the staff must be encouraged to retrieve all pieces of the item. When an instrument has broken inside the patient, an X-ray must always be taken to ensure there is nothing left behind. The incident should be disclosed to the vendor in order to uncover patterns and, hopefully, reduce the risk to other patients. When the risk of retrieving broken bits and pieces of a drill bit outweighs the benefit, the surgeon must disclose this event to the patient. The incident is documented in the medical record, and the Significant Adverse Event Team, which includes the CNO, Patient Safety Officer, and Risk Manager, is notified within the hour. Careful analysis of these occurrences at Cedars-Sinai led to some process changes. We now ensure that single-use drill bits are not reprocessed and that the scrub personnel inspect the drill bits and screwdrivers after each use.

Lessons learned

It's important not to assume that everyone understands the problems or the solutions. Surveying the end users not only helped uncover the root causes of RFOs, but it also helped gain buy-in from the staff. In addition, leadership involvement is critical to success. During this initiative, the Chief-of-Surgery, Chief Medical Officer, Chief Operating Officer, CNO, Chief of Anesthesia, Operating Room Director, and Manager were behind the staff offering full support. The last key lesson was that education alone isn't enough. Education is a weak intervention that can't be the foundation of improvement work. Mistake-proofing processes and adding standardization whenever possible (along with keeping solutions as simple as possible) are keys to making change that lasts.

Results and next steps

Through the interdisciplinary taskforce, Cedars-Sinai was able to reduce RFOs related to sponges, needles, and instruments by 90%. The latest work has centered on failed devices. The team is diligently working with orthopedic and spine instrument companies to devise better tools to prevent breakage—the work is certainly not finished. **OR**

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