NoThing Left Behind®

Differential Count Contributions in Retained Surgical Sponge Cases: Examination of Administrative Penalty Cases from the California Department of Public Health (CDPH), Health and Safety Code Section 1280.1 Enforcement Reports from 2007-2014

A NoThing Left Behind® tenet is that Retained Surgical Item (RSI) cases are surgical patient safety problems and safety problems, in a simplistic view, are the result of failed practice and/or communication processes. Practices are the way the providers of care work and communication is the way in which knowledge and information is exchanged between multiple stakeholders. All RSI cases are not the same. It is important to identify the work performance errors and failed communication strategies of the stakeholders involved, so practice improvements can be employed and enhanced ways of sharing information developed.

As a way of approaching a categorization of RSI cases, this analysis will look at retained surgical sponge cases because there is more public data available on this class of retained surgical item. Many state-based reporting systems were designed to require reporting of cases where there was severe patient harm. Retained surgical sponges usually require an unplanned second operation for sponge removal. The necessity for a second operation is considered harmful to the patient (even though necessary) so there has been little conflict over whether or not these types of retained sponge cases should be reported.

It turns out that the predominate problem with retained sponge cases are practice problems NOT communication problems. The errors in practice are committed by all stakeholders; surgeons, nurses, anesthesiologists and radiologists. Nursing staff, registered nurses and surgical technologists, are the "content experts" on surgical item management and performance of surgical counts is within their primary professional domain of care. From the nursing care practice perspective, in the case of a retained surgical sponge, it's not that the nurses perform sponge counts and recognize that something is missing (call an "incorrect sponge count"), speak up and are ignored or nothing is done further to reconcile the incorrect count; it's that they don't even know something is missing (call a "correct sponge count") and the patient is taken from the OR. This failure to recognize error is because the sponge management practices they use are unreliable.

How do we know this? What data was examined to substantiate this assertion?

As a consulting entity we sought to avoid violation of any client business associate or confidentiality agreements we had and recognized the reluctance of hospitals to divulge RSI cases or participate in research and policy studies that might cause exposure, elicit shame or reputational insult. To gather frontline RSI case information, we sought a public source and examined a state patient safety harm-based reporting system. In 2007 California hospitals began mandatory reporting to CDPH in compliance with newly enacted Health and Safety Code legislation. Hospitals were assessed administrative penalties after a determination that the facilities noncompliance with licensing requirements had caused serious injury or death to patients. Types of events which required reporting included, medication errors, wrong surgery cases, child abduction cases, and unplanned retention of a surgical item, among others. After cases were reported and investigated, each hospital submitted a plan of correction (POC). The CDPH made public the hospitals which received administrative penalties. Three or four times a year, along with the individual POC, they published this information on their website. We conducted an analysis of the California administrative penalty cases publicly reported from 2007-2014.

A frequent finding in the retained sponge cases was that the final sponge count was wrong. This observation, made at the end of the case investigation, was a conclusion that the sponge count obtained must have been incorrect because there was a retained sponge. To understand why the sponge counts were wrong

requires a deeper analysis of the policies and practices being used. Actually, there are different types of RSI cases based on the final count that was "called" and documented in the nursing intraoperative report at the end of the operation. The count documentation indicates actions that were taken during the case (or should have been taken) and what policy violations or difficulties, if any, were present.

There are basically three surgical count documentation options: The final Count is entered as a Correct Count; an Incorrect Count or that No Count was performed. The final count is taken when items are no longer in use and have been removed from the surgical field. The final count can only be recorded as correct or incorrect. As a general principle when surgical items are opened and added to the field they are counted IN and when they are removed from the field they are counted OUT. The count IN = count OUT for a correct final count to be documented. An incorrect final count is when the IN and OUT counts do not match. When an incorrect count is identified, nursing communication strategies are employed to inform the surgeon that something is wrong, so actions can be taken to find the missing item or understand why there is an extra item. The most common remedial action is then re-counting and the taking of intraoperative x-rays to determine if the radiopaque item can be visualized within the patient. When re-counting and examination reconciles the incorrect count, when there is an extra item, or when x-rays identify a missing item, which is "found", the final count is documented as "correct". Any final count that is incomplete, unsubstantiated, uncertain, pending or unresolved is documented as incorrect.

Cases in which No Counts will be performed are specifically outlined in hospital OR policies. Special circumstances or items that will not or cannot be "counted" are written in policies e.g. extreme emergency conditions or large numbers of instruments and trays. Other options, such as the taking of x-rays or using alternative management practices can then be employed to insure no items have been retained. All hospital intraoperative records have surgical count documentation areas and during an operation it is the professional responsibility of the circulating OR Nurse to supervise, manage and document the practice of performing the surgical count. The professional responsibility of the surgeon, related to the prevention of retained surgical items, is to perform a methodical wound examination before closing the wound to do their part to ensure no unintended items have been left in the patient. It should be apparent that these nursing and surgeon actions are a team-based activity that requires cooperation, knowledge and expertise.

With this background, since RSI cases have an incorrect count, one might expect that the surgical count would be documented as "incorrect" and identification of the whereabouts of the missing sponge were unsuccessful or removal actions were not taken or if attempted were unsuccessful. The actual data tells a different story.

Administrative Penalty Retained Surgical Sponge Cases

Mandatory reporting to CDPH began in 2007 and in this review, examination of cases was stopped in 2014. During this time period, within the administrative penalty cases, there were forty-six cases of retained surgical sponges. This number is not indicative of any incidence or prevalence rates.

Of the 46 cases, 39 (85%) involved sponge retention in the abdomen or pelvis. In 31 cases (67%) lap pads (18x18" cotton woven surgical sponges) were retained, in 11 cases (24%) "raytex" (4x4" cotton gauze surgical sponges) were retained and in 4 cases (9%) OR towels (blue drape towels or white surgical towels) were retained. In 41 of the 46 cases (89%) sponge counts were performed. Examination of the final sponge count, as documented at the end of the case in the operative record (which is how cases in this report are being categorized); there is one (2%) Incorrect Count Retention Cases; five (11%) No Count Retention Cases and forty (87%) Correct Count Retention Cases.

The Incorrect Count Retention Case (ICRC) represents a True Positive count (#1). The counting practice recognized that a sponge was missing yet the patient left the OR without sponge removal. ICRCs are often the result of communication failures and are at least not counting practice errors. In the manual counting case in the data set, there was an incorrect count, a lap pad was missing, an x-ray was taken but instead of having radiologists review intraoperative x-rays (who are the content experts in image interpretation) the surgeon "read" the image and did not correctly identify the presence of the lap pad on the x-ray. In spite of the lap pad never being found, the patient was taken from the OR. Later review of the x-ray by radiologists correctly identified the lap pad marker and the patient was taken back to the OR for sponge removal. Another case (#2), which is included with the correct count cases because the case was documented as having a correct count, involved the use of a sponge counting device. The device registered that a sponge was missing, and indicated that the count was incorrect but the manual count performed by the nursing staff was documented in the medical record as correct. There was no reconciliation during the operation between the two different information sources and it turns out that the machine data was indeed correct because there was a retained lap pad. Here in discussion, I have included it with the ICRC because it demonstrates communication and knowledge failures albeit between nursing staff and a device but is "counted" with the correct count cases because the actions of the stakeholders were consistent with that belief. The ICRC also illustrates the multi-stakeholder errors which are involved and ways that hospitals have to provide muti-layered resources and education.

The more common outcome of an incorrect count called at the end of the case, when good communication between the nurses and surgeons has taken place, is the recovery of the missing sponge and the count is reconciled and now "correct". Cases with reconciled incorrect counts are False Positive counts and are often categorized as miscounts or near miss cases. These near miss cases actually represent sponge count practice success and are what nurses remember most often because they are frequent and because the nurses were "right".

No Count Retention Cases (NCRC) (#3-7) are practice failures either because there is no written policy or more commonly, because of longstanding "usual practices", some surgical items are "not counted". This phenomenon is evident among the retained OR towel cases. The blue drape towels are used in multiple ways to set up a sterile field, cover and protect instruments and wipe and dry things. They are part of the surgical packs of drapes and are not supposed to be inserted inside of patients and are not "counted" as a part of usual and customary practice. When a larger soft good is desired by a surgeon as part of their practice, the safer alternative is to use a white surgical towel (surgical sponges and towels have radiopaque markers sewn within them, so they can be identified on x-ray images). White surgical towels can be distinguished by color from the blue drape towels so the surgical towels can be managed by counting them just like the white surgical sponges (lap pads and raytex). In the four towel cases in the data base, in one case there was a towel management policy in place which was ignored and in other cases there was no written policy for how towels were to be managed so since they "didn't count" drape towels, when they were put inside patients during operations, there was no plan how team members (both the surgeons and the nurses) were going to ensure the towels were removed. The NCRC that involved the retained raytex in the spine was the result of a specific policy for spine cases that required an x-ray be taken at the end of the case instead of counting sponges during the case, but in the reported case, no x-ray was obtained.

The Correct Count Retention Case (CCRC) is the most common scenario for a retained sponge case. At the end of the operation in 98% (40/41) of the database cases when a sponge count had been performed (41/46 cases, 89%), the sponge counts had been called "correct", yet there was a sponge retained in the patient. These cases would be considered False Negative counts and are the greatest source of error and contributing factor in retained sponge cases. They represent practice errors in how sponge counts are

conducted. There is no one reason in the 40 CCRCs but the common finding is that while there is a policy for the performance of sponge counts, the actual practices for how the sponge counts are performed lack specificity. Counting practices were executed with variation and usually with consensual agreement among operating room peers. In all the cases there was surprise with the knowledge that a sponge had been retained and absolute certainty that "the counts were correct" even knowing there was a retained sponge. There was little evidence of critical thinking, acceptance of error or consideration of viable hypotheses about how the count practice failed, which is not surprising but is detrimental to practice improvement.

The recognition that manual sponge counting practices needed improvement has stimulated the creation of technological adjuncts to manual counting. These devices are additions to the manual handling of the sponges not substitutes for the practice. The first technological adjunct was developed using bar-code technology, where a matrix label is applied to each type of sponge when they are manufactured and a bar code reader is employed in the operating room to "count" each sponge and record it on the machine. This system still requires the manual handling by the nurses of the sponges and the machine readers and actually adds a degree of complexity to the sponge management process. The system was available for purchase in the late 2000's. Within the database there are two retained "technology" lap pad cases (#2, #27). In both cases the final sponge counts were documented as "correct". The errors in practice were identified to be in the human/machine interface where the humans either mis-interpreted or didn't believe the device information. It is evident that even though hospitals had purchased the device, their addition to work practices did not prevent sponge retention.

Table

Case #	Operation; year of report	Retained Soft Good type	End Case Count documentation	Comments
1	Left nephrectomy, radical lymphadenectomy, orchiectomy; 2012	Lap Pad	Incorrect	Intra-op x-ray read by Surgeon called negative
2	Hysterectomy, tumor debulking, colectomy, omentectomy; 2013	Lap Pad	Incorrect on machine; Correct in electronic medical record (EMR)	Machine result ignored, EMR result believed, Surgicount bar code sponge retained
3	Lumbar laminectomy; 2009	Raytex	No Count	Mandatory x-ray not performed
4	Partial gastrectomy; 2010	Drape Towel	No Count	No management policy
5	Hartmann procedure; 2012	Drape Towel	No Count	No management policy
6	Laparoscopic cholecystectomy converted to open; 2012	Drape Towel	No Count	Drape towel inserted for liver exposure
7	Colostomy takedown; 2011	Surgical Towel	No Count	Ignored policy directive
8	Damage control laparotomy; 2009	Lap Pad	Correct	Actually 3 lap pads and 2 surgical towels = 5 "sponges" retained
9	Cesarean section; 2008	Lap Pad	Correct	
10	Takeback for bleeding after open appendectomy; 2009	Lap Pad	Correct	Actually 5 laps retained

11	Damage control laparotomy; 2009	Lap Pad	Correct	Trauma case with multiple take backs
12	Bilateral ovarian cystectomy; 2009	Lap Pad	Correct	
13	Exploratory laparotomy, lysis of adhesions; 2009	Lap Pad	Correct	
14	Paraesophageal hernia repair; 2009	Lap Pad	Correct	
15	Peritoneal dialysis catheter removal; 2009	Lap Pad	Correct	
16	Exploratory laparotomy, small bowel resection; 2009	Lap Pad	Correct	
17	Vaginal hysterectomy; 2009	Lap Pad	Correct	In abdomen, not vagina
18	Total gastrectomy; 2009	Lap Pad	Correct	
19	Sigmoid colectomy; 2010	Lap Pad	Correct	
20	Cesarean section; 2010	Lap Pad	Correct	
21	Cesarean section; 2010	Lap Pad	Correct	
22	Cesarean section, hysterectomy; 2010	Lap Pad	Correct	
23	Vaginal hysterectomy, bilateral salpingo-oopherectomy (HBSO); 2011	Lap Pad	Correct	In abdomen, not vagina
24	Exploratory laparotomy, lysis of adhesions; 2011	Lap Pad	Correct	
25	Cesarean section; 2011	Lap Pad	Correct	
26	Esophagectomy; 2011	Lap Pad	Correct	
27	Exploratory laparotomy, small bowel resection; 2011	Lap Pad	Correct	Surgicount bar code sponge retained
28	Laparoscopic cholecystectomy converted to open; takeback for bleeding; 2012	Lap Pad	Correct	Unknown in which operation lap pad retained
29	Cesarean section; 2012	Lap Pad	Correct	
30	Takeback for bleeding after cesarean section; 2012	Lap Pad	Correct	
31	Takeback for evisceration after laparotomy for lysis of adhesions; 2012	Lap Pad	Correct	Kerlix wound dressing counted as a lap pad
32	Cholecystectomy, pancreatic resection; 2013	Lap Pad	Correct	
33	Bladder operation; 2013	Lap Pad	Correct	
34	Partial gastrectomy; 2013	Lap Pad	Correct	
35	Cesarean section; 2014	Lap Pad	Correct	

36	Laparoscopic right ovarian cystectomy converted to open; 2014	Lap Pad	Correct	
37	Liver transplant; 2009	Raytex	Correct	
38	Hysterectomy; 2010	Raytex	Correct	In abdomen, not vagina
39	Abdominal HBSO, colectomy; 2010	Raytex	Correct	Extruded through vagina
40	Coronary artery bypass graft (CABG), aortic valve replacement; 2010	Raytex	Correct	In right pleural cavity
41	CABG; 2012	Raytex	Correct	In pericardium
42	Partial sacrectomy; 2012	Raytex	Correct	
43	Laminectomy; 2012	Raytex	Correct	Dressing sponge put in holder instead of raytex
44	Vaginal hysterectomy; 2012	Raytex	Correct	In abdomen not vagina; discovered four years after operation
45	Anterior cruciate ligament reconstruction; 2012	Raytex	Correct	3 cm incision
46	Permanent pacemaker; 2014	Raytex	Correct	20 minute operation

Summary data conclusion

The counting of surgical sponges is a foundational operating room nurse practice but in actuality, counting sponges is not a single practice and it's not a practice performed the same way by all users. The ways in which nurses count sponges has a lot of variability within it and there is variation in how different users employ and execute practice policies and guidelines in different environments of care. Compounding the variation that makes the practices unreliable is a lack of transparency and critical thinking when trying to decipher what actually happened and why it happened after a retained sponge case occurs which impedes learning from the event and application of practice improvements.

The current versions of all the technological inventions still require human use and aren't replacements or substitutes for "counting". Since much of the difficulty with the problem of retained surgical items is with the human factors involved in the work and the still present "hands-on" aspect of surgical care, no "absolute-zero" solutions are yet apparent.

REFERENCE:

California Department of Public Health website: Licensing and Certification Program
Hospital Administrative Penalties by Year. Accessed September 8 2024
https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/Hospital-Administrative-Penalties-by-Year.aspx

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NoThing Left Behind®: A National Surgical Patient Safety Project to Prevent Retained Surgical Items
December 2023; September 2024