Strategies to prevent inadvertent retained surgical items: An integrative review

Supplement 1: Characteristics of included studies

Author (year) Country of origin	Aim	Design Sample Setting	Key findings	Limitations
Cima et al. (2008)[1] USA	To investigate incidence and characteristics of potential and actual retained foreign object (RFO) events in surgical patients.	Retrospective study All RFO events, near misses and actual reported on an adverse event line from 2003–2006. Mayo Clinic, Rochester. 98 main ORs, 3 obstetrical ORs and 8 labour and delivery rooms.	• The more times the count is performed, the incidence of a possible error increases exponentially. • Compounded by performing simple counting process in complex environment. • Important component of problem is non-modifiable human factor; therefore, technological solution to sponge counting might be desirable. • Intra-operative imaging is poor for certain items such as needles (13% detection of needles < 13mm, no detection of needles < 10mm). • Barcode and radiofrequency identification technology have been incorporated to improve reliability of counting products. • Because majority of RFOs occurred in setting of a correct count, routine X-ray (using high-resolution radiographic equipment in a dedicated imaging area, not a portable X-ray intra-op) in all patients is a very important safety process.	Nature of practice and high number of complex cases that involve multiple specialties and large blood loss means staff and support systems might be more sensitised to the risk associated with procedures and might contribute to increased vigilance and avoidance of RFO. Findings might not be representative of the more general surgical practices throughout the country.
Cima et al. (2011)[2] USA	To assess the impact of the implementation of a data-matrix-coded sponge (DMS) system after 18 months.	Randomised controlled trial Surgical practice at Mayo Clinic Rochester.	• Cotton sponges are the most commonly retained item despite the national standards for sponge counting. • No retained sponge events in 18 months and no increase in operative time. • Use of DMS identified more count discrepancies. • Increased sponge counting time but not overall case length. • Targeted screening for RSIs on the basis of risk factors. • DMS was most cost-effective technology.	Represents only a single institution's experience with the technology.
Edel (2021)[3] USA	To review current count policy practices and identify any necessary improvements; define a new count policy based on the assessment of staff member practices.	Qualitative study n = 120 staff members St Luke's Episcopal Hospital, 46 ORs, 3 surgical departments.	• Interpretation of count policy varied widely among staff. • Obstacles affecting accurate counting: unfamiliar with policy, anaesthetists needs and counting while they are preparing infusion lines, poor communication between OR nurses, interruptions, inconsistent passing of sharps, death in the OR, multitasking, equipment (instrument set wrong), need for count to be completed before time out. • Identified need for standardisation of the count.	Did not assess all staff members' practices.
Freitas et al (2016)[4] Brazil	To analyse the surgical count process according to reports of nurses working in surgical centres.	Cross-sectional study n = 55 nurses 15 hospitals across São Paulo, 16 surgical centres across these 15 hospitals.	• A range of procedures and customisation of practices occurred in the OR, even within the same hospital. • Circulating technician was person responsible for counting. • Literature recommends standardisation of the surgical count. • Evidence indicating new technologies may help reduce frequency of retained surgical items.	Size of the sample and development of the study in a single city may be inferred. Data analysis was based on reports of nurses and relevant aspects of the surgical count process may not have been considered.
Greenberg et al (2008)[5] USA	To evaluate a computer-assisted method for counting sponges using a barcode system.	Randomised controlled trial n = 56 nurses / surgical technicians, 36 surgeons Brigham and Women's Hospital in Boston.	• Computer-assisted counting with a barcode sponge system significantly increased the detection of misplaced and miscounted sponges, compared with traditional manual counting protocol. • Increased time devoted to sponge counts by approximately three minutes per case.	Unable to determine whether the barcode system could decrease the rate of retained sponges because of the impossibly large sample size required. Current analysis limited to elective general surgery operations and did not test emergency operations which are recognised at higher risk of retained sponges.

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Kertesz et al (2020)[6] USA	To investigate prevalence and description of surgical count interruptions.	Prospective, observational study n = 50 surgeries, 150 surgical counts Large tertiary teaching hospital in New York.	• Initial count has highest number of people entering/exiting due to room preparation, schedule changes, consultations. • Surgical counts warrant undivided attention with high cognitive demands – high levels of interruption interfere with and impact patient safety. • Growing evidence that distractions add to length of surgery.	Individual coping strategy in response to distraction or interruption cannot be measured through observation. Did not include emergency cases, which may have more frequent interruptions.
Moffatt-Bruce et al (2012)[7] USA	To identify risk factors for intravascular retained surgical items (ivRSIs).	Retrospective, multi-centre study n = 83 ivRSI events 5 tertiary referral academic medical centres.	• All but one patient in this study had to undergo an additional procedure to remove the ivRSI. • Many ivRSIs were missed on the confirmatory post-procedure films, but were found within 48 hours. • No patient's outcome was ultimately affected by retention of ivRSIs. But was a significant patient dissatisfier to have to undergo an additional invasive procedure to remove ivRSI.	Retrospective nature of study and small sample size. Lack of intra-procedural details pertaining to unexpected events and equipment malfunctions/failures.
Primiano et al. (2020)[8] USA	To compare incidence of retained sponges before and after routine integration of radiofrequency (RF) technology and compare patient outcomes.	Quality improvement project Incident reports for adult patients from September 2013 to 2015. Main OR of 641-bed academic medical facility in northeast Ohio.	• Use of RF technology was associated with 68% fewer reports of near misses and unresolved miscounts. • Average length of time for extensive count resolution process was 18 minutes, costing US$1162 per occurrence. • 34 fewer occurrences in post-implementation period, estimated US$39 508 savings. • Cost to resolve counts is US$226 per procedure. • With 29 fewer incidences of radiography to resolve counts, saving of US$6554. • Total cost savings US$424 292 after implementation costs.	Lack of control for our risk factors or specific diagnosis types associated with miscounted sponges. Project design did not allow for inferences of causation between RF technology and patient-related outcomes.
Regenbogen et al. (2009)[9] USA	To estimate cost-effectiveness of standard counting against alternative strategies such as universal or selected X-ray, barcoded sponges and radiofrequency (RF) tagged sponges.	Decision-analytic model For base case, data used from 4-year study of 200 000 operations performed in institution that routinely screens all patients undergoing operations involving a body cavity with high-resolution post-operative radiography.	• Standard counting detects 82% of retained surgical sponges (RSS). • Barcoding prevents 97.5% for an additional US$95 000 per RSI averted. • If RF were as effective as barcoding, would cost US$720 000 per additional RSS averted. • Universal and selective X-rays for high-risk operations are more costly but less effective than barcoding.	Effectiveness estimates for each of the new preventative strategies are crude and somewhat uncertain because of limited clinical evidence to inform estimates.
Rupp et al. (2012)[10] USA	To evaluate the effectiveness of a radiofrequency detection system (RFDS) as an adjunct to manual counting protocols for tracking surgical sponges.	Prospective clinical study. All patients undergoing surgery from September 2009 to August 2010. University of North Carolina (UNC) hospitals.	• Majority of procedures during the study were confined to the abdominal cavity (58%), with 13% chest (cardiac and thoracic) and 9% 'other cavity' such as spinal column, perineum or breasts. • Most frequent type of procedure performed was open, elective surgery (61%) followed by laparoscopic, elective (21%), open emergency (7%) and endoscopic (5%). • 36 action events identified during study period with no true RSIs identified. • Reliance on manual counting, which has a low but inherent error rate, is a circumstance that lends itself to potentially devastating consequences.	Budget prevented developing a study arm to compare our RFDS findings against the gold standard. While high-resolution X-rays were obtained after all surgical invasive procedures in Cima, it is not the institutional policy at UNC to obtain X-rays for every patient unless clinically indicated. Lack of long-term patient follow-up. Average institutional follow-up of 20 months for study but some papers report RSIs being discovered up to 40 years post-operatively.

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Stawicki et al. (2014)[11] USA	To determine clinical signs, symptoms, diagnostic evaluation, anatomic locations and intra-operative characteristics associated with RSIs.	Post hoc examination of data from retrospective study 71 RSI occurrences 7 teaching institutions	• Plain imaging and computerised tomography (CT) were the most common localising modalities. • Human errors (single individual, not team error) in 7/71 cases (<10%). • Team or system errors (no single individual could be pinpointed) 50/71 cases (70%). • Combination of individual and team error in 14/71 cases (20%). • Combined, 90% RSI events were associated with some type of team/system error.	Retrospective design, relatively small patient sample size, lack of uniform data availability for all variables across all reported cases. Categorisation of clinical signs/ symptoms and pathologic findings into narrowly define groups limits the overall resolution of the reported data. Intra-operative events reported here are limited by availability and inherent bias of retrospectively recorded documentation. Likely reporting bias for subjective variables such as imaging/tagging interpretation, team communication or adherence to protocols.
Steelman (2011)[12] USA	To evaluate the sensitivity and specificity of the detection of surgical sponges embedded with a radiofrequency (RF) chip through the torsos of subjects of varying body habitus.	Prospective, crossover, observer blinded study n = 210 subjects Large midwestern academic medical centre and US Department of Veterans Affairs medical centre.	• RF sponge technology found to be much more sensitive than a previous report of the surgical count. • In a recent study, sensitivity of surgical counts was only 77%. • Studies show between 62% and 88% RSIs occur when counts were correct. • Failure modes and effects analysis found 57 potential failures in surgical counts; distraction, multitasking, time pressure. • RF sponge technology is a highly accurate way to mitigate these failures in the surgical setting.	Sponges placed behind the backs of subjects, rather than in the abdominal cavity – may not accurately approximate the intra-abdominal assessment. Density of the additional tissue may pose a greater challenge for sponge detection.
Steelman and Cullen (2011)[13] USA	To describe perioperative processes to prevent retained sponges, identify potential failures in these processes and to rate causes, probability and severity of these failures.	Observational study 10 RNs and 6 surgical technologists 593-bed veterans affairs hospital that serves eastern Iowa and western Illinois.	• Surgical count has long been considered a standard of care, but retained sponges continue to occur in the presence of the count. • Intra-operative radiography is suboptimal – failing to identify 33% RSIs later found in one study – and two overlapping films are needed for morbidly obese patients, exposing patient to unnecessary radiation. • Barcode technology: each sponge has unique matrix barcode affixed to it, initial research showed it identified more count discrepancies than traditional counting including misplaced and miscounted sponges. • Radiofrequency (RF) technology: RF chip sewn into sponge and wand connected to console to detect sponges – 100% detected in tests. • RF identification detection: counts sponges and detects sponges left in the patient, can also be used affixed to bins to receive sponges directly from sterile field.	Surgeries observed for process mapping routine were colon resections – no change in personnel involved and studying more complex procedures with changes of personnel may identify additional steps not discussed in this study. Sample for focus group was one of convenience and may not be generalisable to all settings. Surgeons were not included in the focus group.
Steelman and Alasagheirin (2012)[14] USA	To evaluate the sensitivity and specificity of radiofrequency (RF) mats for detection of surgical sponges through torso of patient and compare sensitivity of RF mat to RF wand.	Prospective, crossover, double-blinded study 320 partcipants: Phase one 203 Phase two 117. Large midwestern academic medical centre.	• Use of the RF wand is preferable to use of the RF mat in patients with a high BMI, due to RF mat being narrow and abdominal cavity can exceed width of mat, likely causing false negatives. • Count discrepancies require additional searching time which can easily add more than 15 minutes to operation time. • RF scanning detects the presence of a sponge in less than 1 minute. • Can also be used to locate a sponge in linen or trash receptacle.	Sponges were placed outside of the abdominal cavity – may not accurately approximate the intra-abdominal assessment.

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Steelman et al. (2019)[15] USA	To describe reports of unintentionally retained foreign objects (URFOs) including the types of objects, anatomic locations, contributing factors and harm, in order to make recommendation to improve perioperative safety.	Descriptive study 308 events reported to Joint Commission's Office of Quality and Patient Safety from October 2012 to March 2018.	• 307 URFO events including instruments, catheters, drains, needles, blades, packing, implants and specimens. • 1516 contributing factors were identified including human factors, leadership and communication. • Human factor issues included distraction and multitasking. • Inadequate policy or no policy for prevention of URFOs were identified in 160 cases. • Found surgical count only had 77.2% sensitivity and time-consuming.	Reporting to the Joint Commission is voluntary, so all URFO events may not be reported. Definition of URFO varies, so those discovered while patient is still in OR may not have been reported or may be underreported. List of keywords for search was not comprehensive.
Steelman et al. (2019a)[16] USA	To estimate time spent searching for sponges and using radiography to rule out the presence of retained sponges; incidence of unreconciled final closing counts and estimated costs of searching for sponges and using radiography to rule out the presence of retained sponges.	Observational study Operative and other invasive procedures from nine months before implementation and nine months after implementation. Large midwestern academic medical centre and Level 1 trauma centre.	• Estimated annual reduction in cost of OR time to be US$3803.04 per 1000 procedures, or US$57 045.60 per annum in a hospital performing 15000 procedures per year. • Count process is time consuming and only partially effective. • Number of searches for missing sponges was reduced by 77%.	Relied on perioperative nurses to record the number of minutes spent searching for sponges in their documentation, may have underreported because of documentation fatigue. Sample size in study was too small to evaluate appropriately the effect of the RF sponge detection system on retained surgical sponges. Results cannot be generalised to other similar technology.
Walter et al. (2015)[17] USA	To determine performance of a protocol for locating surgical items after a miscount, in which intra-operative radiography included a radiograph on an unaccounted-for item.	Retrospective study Sets of intra-operative patient and overlooked-item radiographs for surgical miscounts between January 2011 and April 2013. Large, urban, tertiary-care hospital.	• In 2/3 cases of false-negative intra-operative radiographs for suture needles, missing needles were not detectable on intra-operative radiographs even in retrospect but were visible on post-operative portable radiographs or other modalities such as CT. • Suboptimal intra-operative radiographic imaging quality decreases sensitivity for detecting surgical items, particular small items such as needles. • Counting protocols for surgical items have been found to be important but imperfect methods of prevention. • More sophisticated interventions to improve perioperative safety have emphasised the detectability of surgical items as a means to prevent both miscounts and retention e.g. standard, embedded radiopaque markers in surgical sponges. • Barcoding systems and radiofrequency technology create easier location and cataloguing of surgical items.	Cases identified only by review of radiographs obtained for miscounts did not identify cases of retained items in which the manual count was erroneously correct. Small number of cases of RSI in study group so rigorous statistical analysis could not be performed – such an analysis would require combined data from multiple health care centres.
Warwick et al. (2021)[18] Australia	To measure and describe perioperative nurses' surgical count practices using the Surgical Count Observation Tool (SCOT), to measure conformity with standardised processes and identify barriers and enablers influencing nurses' practices.	Observational study 83 nursing staff over 57-hour period. Large public tertiary hospital in Western Australia.	• Instrument and circulating nurse were observed counting aloud and together during 17 cases in initial count but only the instrument nurse counted aloud in final count, indicating lack of consistency. • Count process was interrupted on many occasions. As per behavioural indicator, count should be recommenced from the beginning but it was often commenced from the point of interruption. • Inconsistency in who notifies surgeon of count outcome. Was often the circulating nurse, but not always acknowledged before proceeding with surgical duties. • Tray lists were often discarded and therefore not used to count and check off instrumentation. • Accountable items being removed from the OR may occur depending on procedure but was not observed by researcher in this study. • Overall compliance rate to ACORN Standards was 60%. • Observations suggest perioperative nurses often under pressure to complete surgical count quickly by the surgery finishing quickly and by the surgeon themselves or anaesthetic team pushing drapes off to wake patient up. • Knowledge enabled perioperative nurses to question and challenge practices – junior nurses may have found it easier to follow others instead of the correct process.	Use of single hospital – practices undertaken may be different to the general perioperative nursing population. Possibility of a Hawthorne effect – changing practice or behaviour while being watched. During observations, participants were aware of the researcher being present but tended to revert to normal activities once procedures commenced.

Supplement 2: Quality appraisal table

	Author (year) country	Clear research question	Addresses research question	Approach is appropriate to answer question	Data collection methods adequate to address question	Findings adequately derived from data	Interpretation of results substantiated by data	Coherence between qualitative data sources, collection, analysis and interpretation
Qualitative studies	Edel (2021) USA[3]	✓	✓	✓	✓	✓	✓	✓
	Freitas et al (2016) Brazil[4]	✓	✓	✓	✓	✓	✓	✓
	Kertesz et al. (2020) USA[6]	✓	✓	✓	✓	✓	✓	✓
	Rupp et al. (2012) USA[10]	✓	✓	✓	✓	✓	✓	✓
	Stawicki et al. (2014) USA[11]	✓	✓	✓	✓	✓	✓	✓
	Steelman and Cullen (2011) USA[13]	✓	✓	✓	✓	✓	✓	✓
	Steelman et al. (2019a) USA[16]	✓	✓	✓	✓	✓	✓	✓
	Walter et al. (2015) USA[17]	✓	✓	✓	✓	✓	✓	✓

	Author (year) country	Clear research question	Addresses research question	Appropriate randomisation	Groups comparable at baseline	Complete outcome data	Outcomes assessors blinded to intervention provided	Participants adhere to assigned intervention
Quantitative RCTs	Greenberg et al. (2008) USA[5]	✓	✓	✓	✓	✓	Can't tell	✓
	Cima et al. (2011) USA[2]	✓	✓	✓	✓	✓	✓	✓

Quantitative non-randomised	Author (year) country	Clear research question	Addresses research question	Participants representative of target population	Measurements appropriate regarding both outcome and intervention	Complete outcome data	Confounders accounted for in design and analysis	Intervention administered as intended during study period
	Steelman (2011) USA[12]	✓	✓	✓	✓	✓	✓	✓
	Steelman and Alasagheirin (2012) USA[14]	✓	✓	✓	✓	✓	✓	✓

Quantitative descriptive	Author (year) country	Clear research question	Addresses research question	Sampling strategy relevant to address question	Sample representative of target population	Measurements are appropriate	Low risk of nonresponse bias	Statistical analysis is appropriate to answer the question
	Moffatt-Bruce et al. (2012) USA[7]	✓	✓	✓	✓	✓	✓	✓
	Primiano et al. (2020) USA[8]	✓	✓	✓	✓	✓	✓	✓
	Regenbogen et al. (2009) USA[9]	✓	✓	✓	✓	✓	✓	✓
	Steelman et al. (2019) USA[15]	✓	✓	✓	✓	✓	✓	✓

Mixed methods	Author (year) country	Clear research question	Addresses research question	Adequate rationale for using this design	Different components effectively integrated to answer question	Outputs of integration of qualitative and quantitative components adequately interpreted	Divergences and inconsistencies between quantitative and qualitative results addressed	Different components of study adhere to quality criteria of each tradition of methods involved
	Cima et al. (2008) USA[1]	✓	✓	✓	✓	✓	✓	✓
	Warwick et al. (2021) Australia[18]	✓	✓	✓	✓	✓	✓	✓

Supplemental material references

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