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A Qualitative Content Analysis of Retained Surgical Items - Learning from Root Cause Analysis Investigations

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ABSTRACT

Objective

To describe incidents of retained surgical items, including their characteristics and the circumstances in which they occur.

Design

A qualitative content analysis of root cause analysis investigation reports.

Setting

Public health services in Victoria, Australia, 2010 – 2015.

Participants

Incidents of retained surgical items as described by 31 root cause analysis investigation reports.

Main Outcome Measures

The type of retained surgical item, the length of time between the item being retained and detected, and qualitative descriptors of the contributing factors and the circumstances in which the retained surgical items occurred.

Results

Surgical packs, drain tubes and vascular devices comprised 68% (21/31) of the retained surgical items. Nearly one-quarter of the retained surgical items were detected either immediately in the post-operative period or on the day of the procedure. However, about one-sixth (5/31) were only detected after six months, with the longest period being 18 months. Contributing factors included:

complex or multi-stage surgery; the use of packs not specific to the purpose of the surgery; and design features of the surgical items.

Conclusion

Retained drains occurred in the post-operative phase where surgical counts are not applicable, and clinician situational awareness may not be as great. Root cause analysis investigation reports can be a valuable means of characterising infrequently occurring adverse events such as retained surgical items. They may detect incidents that are not detected by other data collections, and can inform the design enhancements and development of technologies to reduce the impact of retained surgical items.

KEYWORDS: patient safety, retained surgical items, root cause analysis, surgery

INTRODUCTION

The operating room is a complex environment where technology, team dynamics and technically difficult operations create a high potential for harm to patients (adverse events).(1) One such type of adverse event is a retained surgical item (RSI) which is any material object related to an operative or invasive procedure that is unintentionally left inside a patient.(2) The Joint Commission identified RSIs resulting in death or permanent loss of function as the most frequently reported sentinel events (“any unexpected occurrence involving death or serious physical or psychological injury or risk”),(3) surpassing wrong patient, wrong site, and/or wrong procedure events.(4, 5) RSIs have been reported to occur at a rate of 0.3 per 1,000 abdominal operations, and approximately 1 in 10,000 of all inpatient operations.(6) No surgical specialty or procedure is immune from the problem.(1)

RSIs can be associated with significant harm to patients including: readmission (59%); second surgery to remove the RSI (69%); sepsis or infection (50%); fistula or small bowel obstruction (15%); and visceral perforation (7%).(7) About half of RSIs are discovered prior to discharge with some RSIs not discovered until many months or even years later.(8) Given the harm associated with RSIs, their prevention has been identified by the Association of periOperative Registered Nurses (AORN), the American College of Surgeons, and The Joint Commission as a US national patient safety priority.(4)

A systematic review of RSIs (to 2014), identified a large number of contributing factors.(6) These include factors associated with: the case or patient, such as emergency or gynaecological procedures, unexpected intraoperative events, long procedure durations, and a large patient body mass; staff, such as poor communication between staff including failure to communicate suspicions and incompletely documented, non-standardised or incorrect counts; and policies, such as unclear criteria for obtaining post-operative radiographs.(6)

The authors of the systematic review suggested that aggregating the findings of root cause analysis (RCA) investigations will assist in determining the relative importance of these contributing

factors.(6) RCAs are commonly used in an attempt to prevent the recurrence of adverse events by undertaking a review of care, to find out what went wrong and why.(9) Despite their limitations,(9-14) due to their structured exploration and depth of qualitative data, aggregating RCAs can be a valuable source of information to characterise infrequently occurring adverse events such as RSIs.

The results of an individual RCA related to a RSI was published prior to the systematic review.(15) This found that the main contributing factors were not performing the standard protocol of counting sponges before, as well as after, the procedure.(15) An aggregated review of 308 RSIs from the US published in 2018 found contributing factors related to human factors including fatigue and distraction, disruptive and unacceptable behaviours, inadequate or non-compliance with policies and procedures, and communication between staff.(6)

There are methodological challenges that impede the analysis of these rare but potentially devastating events, however, RCAs are well suited to address these challenges.(6) The aim of this paper is to describe RSIs and their characteristics and circumstances in an Australian public health system, using RCA reports as the data source.

METHODS

Data source

The origins of the RCAs were sentinel events. These are adverse events that infrequently occur in health services and “commonly reflect hospital system and process deficiencies”.(16) In Australia there are eight nationally agreed sentinel events,(16) one of which is RSIs. In Victoria, an Australian state, public health services report sentinel events occurring in their facilities to the Department of Health and Human Services (DHHS), then conduct an RCA, and report their findings and recommendations.(16)

The Victorian DHHS provided our research group with 227 RCA de-identified paper-based reports from sentinel events that occurred between the years 2010 to 2015 in 48 health services. Of these, 31 reports related to RSIs and form the basis of the analysis presented in this paper. The 31 RSI reports were between 4 and 16 pages in length. The Victorian DHHS also provided the researchers with de-identified demographic information relating to the RCA reports including hospital codes, region and patient age.

Analysis

Due to the low number and wide variety of types of RSIs in this study, medical specialties, and anatomical locations,(8) a pre-defined patient safety classification framework was not used to extract and classify information from the RCA reports. Instead, a qualitative content analysis was undertaken,(17) which allows both deductive and inductive analytic approaches to be incorporated. For this analysis, we followed the items in the Standards for Reporting Qualitative Research: A Synthesis of Recommendations.(18)

Two researchers (PH, AD) undertook the analysis. Both researchers have over 15 years experience in analysing patient safety data sources including incident reports, coroner's reports, RCA reports and medico-legal claims. They read the 31 reports and classified them according to the type of RSI, and the time to detection. Each reviewer developed a list of type of RSIs iteratively and independently, compared their findings, and then developed a consensus list. The researcher then undertook a separate analysis for each type of RSI by re-reading the RCA reports and analysing them as a group. The researchers iteratively extracted themes or concepts from the text of the RCA reports related to the circumstances, types of surgery, contributing factors, and methods of detection.(19)

Ethics

Ethics approval was granted by the Victorian DHHS' Human Research Ethics Committee (05/16).

RESULTS

There were 20 health services who provided the 31 RCA reports with a range of 1-5 RCA reports per health service. There were 23 RSI incidents which occurred in health services in metropolitan areas, five in regional, and three in rural areas. The genders of the patients involved in the incidents were 17 males, 12 female and two unknown.

Of the 31 RCA reports related to RSIs, surgical packs, drain tubes and vascular devices comprised 68% (21/31) (Table 1). Because of the low numbers of incidents and their heterogeneity in types of devices involved, only those relating to surgical packs and drain tubes are presented thematically below in the results with summaries of some other incidents outlined.

Nearly one-quarter of the RSIs were detected either immediately in the post-operative period or on the day of the procedure (Table 2). However, about one-sixth (5/31) were detected after six months, with the longest period being 18 months. In all cases, except one involving a central venous catheter (CVC) guidewire, patients were subjected to a further procedure.

Surgical packs

The procedures associated with the nine retained surgical packs were two total hip replacements, two below knee femoral popliteal bypasses, an open hemicolectomy, a total laryngectomy, a laparotomy, an emergency caesarean section, and an episiotomy. The post-operative surgical counts were discrepant in five of the nine cases. X-rays detected two of these, but image intensifiers (II) did not detect the other three cases.

For one incident related to lack of detection by the II, as the images were not kept, the explanations for why the II did not detect the pack were speculative: poor image quality associated with inadequate software; the required anatomical area was scanned incompletely; and inadequate interpretation. In this incident, the fact that the surgical count was discrepant was then “lost” over

time in the patient's medical record and was not mentioned in the discharge summary. Therefore, a retained surgical pack was not considered as a possible explanation when the patient subsequently presented with symptoms of abdominal pain and was admitted to the same hospital. In the second SE where the II did not detect the surgical pack, the radiologist mis-interpreted an x-ray as the surgical pack was assumed to be external to the wound. In this case, the presence of pain and dysfunction during the admission and videofluoroscopic images subsequently detected the pack. In the third RSI where the II did not detect the surgical pack, the surgical pack was sandwiched between two components of the total hip joint prosthesis and was not visible on the view obtained.

Other themes or contributing factors related to surgical pack retention included:

- complex or multi-stage surgery using a large numbers of packs (>20) can lead to mis-counts or confusion (two cases). Multiple surgical teams can lead to inconsistency in how counts are conducted when large numbers of surgical packs are used;
- the use of packs that is not specific to the purpose of the surgery, in one case, abdominal packs were used for obstetrics surgery; and
- the surgical wound being closed prior to the surgical counts being performed, and then additional packs being used after the count. Although not stated in the RCA report, the safe surgical checklist(20) was deemed unlikely to have been used.

Drain tubes

Two of the retained eight drain tube incidents were nearly identical. They both involved patients having abdomino-perineal resections of rectal cancer with a Penrose Drain. These both slipped undetected into the patient's bodies. One of these was not detected for three months and was presumed to have fallen out. The mechanism of both RSIs was that a safety pin was not used to secure the drain in the perianal area for comfort reasons. Both RCA investigations teams recognised the need to develop a safe and comfortable method of securing tubes for these patients. A third

incident involved an unsecured Penrose Drain related to a hip arthrotomy. The role of radiology was highlighted in this incident, where a radiologist noted a possible retained tube in multiple X-ray reports, however these potentially abnormal findings were not highlighted. A surgeon who viewed the X-rays did not read the reports. This drain was in situ for 16 months.

There were two RSIs involving Yeates Drains. These comprise of multiple lumens that can be broken off. In one RSI, the lumens inadvertently separated. There was no standardised documentation that stated the number of Yeates Drains lumens being used. In the other, a registrar was left unsupervised to complete a surgical procedure without being familiar with the process for securing the drain. There was also no information on the drain packaging stating that it required fixation.

Another two drain incidents may have been detected earlier, although not prevented, by having the lengths inserted marked on the drains:

- A drain tube being inadvertently sutured to rectus femoris fascia; when the drain was being removed it broke and it was not recognised that the whole drain had not come out;
- Needlestick damage to a drain tube at time of insertion caused it to fracture, but staff did not recognise that part of the tube was missing.

The final drain incident involved use of a type of drain tube that staff were unfamiliar with i.e. a low suction drain tube which is slightly thicker than the more familiar non-suction drain tubes.

Other item and incident types

Examples of other item and incident types include:

- Weck vascular clips: the count record showed only the number of cartridges, not the number of individual clips. These clips are generally used as permanent clips, however in this case they were used as temporary, which is potentially confusing for staff. The white board, which was

used for displaying pertinent information on the surgical case at hand, was not visible to the scrub nurse and therefore did not provide a reminder to remove the clips.

- Temporary aneurysm clip: there was no requirement for this clip to be included in the surgical count. Therefore, monitoring was reliant on the tracking of the Time-On and Time-Off of each clip, which was not recorded nor verbalised.
- A “Fish” closure device was not included in the count, nor were artery forceps attached to the tail of the device when it was inserted, which meant that it was not visible.
- A microvascular clamp was retained with the main contributing factors identified as a long theatre time - ten hours with two teams (i.e., orthopaedics and plastics) and three separate counts for different components of the operation. This was compounded by short staffing with seven scrub nurses on personal leave, and confusing handovers between scouts.
- In two of the three CVC line incidents, retrospective review of X-rays revealed the presence of CVC lines, however they were not noted in the radiologists’ reports.
- A piece of plastic was used to cover a hernia repair mesh when it was being inserted. This plastic was not included in the count as it was a technique only used by one surgeon and staff were unaware of its purpose.
- A multiple site procedure but only one count done; and then the lack of availability of a rectal probe resulting in an additional curette being used as a rectal probe with subsequent count failure.

Other broad findings and contributing factors

Surgical checklist: Although not stated in the relevant RCA reports, it was unclear whether the “Sign Out” section of the Surgical Checklist was completed. This section contains a question “Instrument, Sponge and Needle counts are correct (or not applicable)”. As the checklist is meant to be a mechanism for common understanding across staff, its use may have led to detection of the retained packs.

Standardisation where possible: in a small number of cases, it was noted that a contributing factor was non-standardisation, for example, different types of drain being stocked or use of a surgical technique by one surgeon only. This meant that staff were less likely to know how to use the device appropriately or to have appropriate counting templates.

Communication: there were numerous occasions where inadequate communication between surgical team members was a contributing factor, particularly when the surgical procedure involved an unusual or unplanned step.

DISCUSSION

Principal findings

We analysed 31 RCA investigation reports related to RSIs from an Australian State health system. About two-thirds of these involved surgical packs, drains, and vascular devices including one-quarter (8/31) involving post-surgical management of drains. A significant contribution of the study is to re-emphasize the potential risk not just of items used during surgery, but also in the post-surgical period, such as drains. Nearly 20% of the RSIs were not detected for over six months. Contributing factors to these incidents occurring or not being detected in a timely manner include design of the operating theatre such as whiteboard positioning and surgical devices, documentation of devices used, standardisation of devices and techniques, counts not including all devices, communication and complex surgery.

Surgical counts, human factors and situational awareness

For surgical packs and instruments, counts are an important preventive measure. An incorrect count means that the chance of a RSI are at least 20 times greater.⁽¹⁾ However, the counting process is an inexact and error prone process.⁽²¹⁻²³⁾ Multiple studies have shown that count discrepancies are not fully protective, with one study showing that counts only detected 77% of RSIs.⁽²⁴⁾ The AORN

guidelines emphasise that distractions, noise, and interruptions during counts should be minimised.(25) Our study found that there are some examples of devices, such as temporary aneurysm clips, which are not ordinarily included in the count. We also found, in line with other studies, that complex or lengthy procedures were more likely to lead to RSIs.(1, 26, 27) Another study found that intraoperative process omissions or systems errors were also associated with RSIs.(28) Given these human factors, the importance of team briefings, handovers and the proper team-based completion of the surgical checklist are critical to maximise communication and situational awareness.(22, 29, 30)

Can technology improve RSI detection?

Technological ways to improve RSI detection and to supplement counts include radiofrequency labelling on surgical packs, product numbering or tagging, and magnetised products to supplement item counts.(31, 32) A review in 2017 found that radio frequency labelling technology could detect RSIs with high accuracy rates, reducing the risk of counting errors and improving workflow, but the evidence base was limited.(31) Given the infrequency of RSIs, evaluation of these technologies will be challenging and to be affordable may need to focus on the usability of the technologies, measuring process indicators such as surgical counting errors, rather than outcomes.(6)

Retained drains and the role of design changes

One of the main findings of the study and contributions to the literature was that a quarter of the sample involved retained drains. This is not too dissimilar to a review of RSI Sentinel Events from the US which found approximately one-sixth involved drains or catheters.(8) These RSIs occurred in the post-operative phase where surgical counts are not applicable and clinician situational awareness may not be as great. Contributing factors included poor design and documentation, and lack of knowledge of how best to manage them. Design factors included lack of safe and comfortable mechanisms of securing Penrose drains and a lack of lengths marked on drain tubes. There were also

documentation issues with Yeates drains, related to the number of lumens and their fixation requirements. Changing the design of these drains (or other surgical items) or their accompanying documentation are likely to be more effective types of recommendations rather than exhorting staff to be more careful.

However, these types of design changes require gaining agreement and support from external manufacturers or suppliers. Agreement on and support for such changes may not be likely given that RCAs are generally undertaken at health service level, and are often constrained by their rules and norms that their recommendations should pertain only to their own health service which may mitigate against design solutions being proposed.(33) The two highly similar Penrose drain RSI incidents in this study illustrate the value of the potential role of Departments of Health in identifying similar serious adverse events occurring at different health services, communicating these to the health services, and developing system-wide recommendations aimed at their prevention.(33, 34) Departments of Health, with their large market share, are more likely than individual health services to be successful in requesting changes from manufacturers or suppliers.

Using a checklist for investigations

Given that “Retained Materials” are “Sentinel Events” in Australia and “Never Events” in other jurisdictions such as the US and UK,(35, 36) a detailed investigation such as an RCA is generally mandated. However, from our study and others,(1, 6, 8) there are common features that could be combined into an investigation template checklist (Box 1). The benefits of such a checklist are to collect the information more efficiently and to promote solutions that are more focussed on the design features of surgical items and less likely to focus on errors on the frontline.

Box 1: The questions template for an investigation of retained surgical items could include the following:

- What was the type of retained surgical item?
- What was the surgical procedure involved?
- How long post surgery or procedure was the retained surgical item detected?
- How was the retained surgical item detected? (for example, staff immediately post-operatively, routine investigation, patient symptoms followed by clinical investigations)
- Were there any design features of the retained surgical item that increased the likelihood of the material either being retained or not detected?
- Was the surgery complex, long or did it involve multiple teams?
- Were distraction or fatigue contributing factors?
- What was the role of communication, including whether staff felt comfortable speaking up?
- Was the post-surgical count right, or wrong, or not applicable?
- If the count was incorrect, what were the types of actions taken after the count?
- If applicable, was the surgical safety checklist adequately completed?

Strengths and limitations

Limitations of the study include that, although sentinel event reporting is meant to be mandatory, they are generally under-reported. The RCA investigations were often hampered by the time between the occurrence of the adverse events and its detection, which was often months later. Given this time lapse, staff recall of the relevant surgical procedure may be poor. There were only 31 incidents in this study meaning that results must be viewed cautiously. Given the disparate nature and infrequency of RSIs, analysing low numbers of them is not unusual. For example, Moffatt-Bruce et al (2014) states that 52 case reports had been published.(27) On the other hand, a strength is that RCAs can provide information on RSIs that may not be detected by other methods. In a study of 30

RSIs that were detected using ICD9 codes in one US hospital over a ten-year period, there were none involving drains.(37) This is contrast to our study in which one-quarter were drains.

CONCLUSION

Although rare, RSIs can cause significant harm to patients. This analysis of 31 reports found that surgical packs, drains, and vascular devices make up over two-thirds of RSIs. Contributing factors included complex or multi-stage surgery, the use of packs that are not specific to the purpose of the surgery, using non-standardised equipment and techniques and sub-optimal design of the items. RCA investigation reports can be a valuable means of characterising and understanding infrequently occurring adverse events such as RSIs. They may detect adverse events that are not detected by other data collections, and can inform the design enhancements and development of technologies to reduce the impact of RSIs.

COMPETING INTERESTS

The authors have no competing interests.

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Table 1: Types of retained surgical items

Type of retained material	n
Surgical packs	9
Drain tubes	8
Vascular devices	4
Central venous catheter guide wire	3
Surgical instrument	1
Transvaginal tape - plastic sheath	1
Plastic around a hernia repair mesh	1
Silicon sheet	1
Cholangiogram catheter fragment	1
Cochlear implant stainless steel template	1
Green gauze	1
Total	31

Table 2: The length of time between surgical item being retained and detected

When detected	n
Immediately post-operative	6
Day of procedure	1
2 – 8 days	11
2 weeks - 3 months	8
>=6 months	5
Total	31