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What does integrated care look like in a perioperative service?

The traditional approach to planning care based on surgical procedures rather than patient needs is no longer fit for purpose. The typical surgical patient has grown increasingly more complex over the past decade due to a combination of clinical and social factors. If this complexity is poorly managed, it can result in substantial and avoidable increases in length of hospital stay, post-operative complications, hospital readmissions, delayed recovery and reduced quality of life.

Integrated care is a growing movement in health service reform that has emerged as a response to managing the complexities of health care delivery. The World Health Organization defines integrated care as 'an approach to strengthen people-centred health systems through the comprehensive delivery of quality services designed according to the multidimensional needs of the population and the individual and delivered by a coordinated multidisciplinary team of providers working across settings and levels of care'.[1]

Integrated care has been widely adopted in chronic disease, where significant efforts have been made to create a seamless health service for complex medical patients. High-quality perioperative care also requires communication and collaboration across primary, secondary and social care sectors that would benefit from an integrated approach. Unfortunately, this philosophy has not been successfully adopted in surgery services, particularly in Australia. In contrast to the patient-centred integrated care approach, many surgical services remain fragmented and structured around the needs of health professionals rather than those of the patient.

Ideally, integrated perioperative care involves the individualised care of patients from referral for surgery through to complete recovery. A multidisciplinary perioperative care team delivers the care, incorporating all individuals involved in a patient's perioperative journey, including doctors, nurses, other health professionals and family members or other carers. The multidisciplinary team works collaboratively with the primary care team, social services and family and carers to provide safe, effective and efficient care.[2]

The emergence of perioperative frailty clinics is an excellent example of effective integrated, perioperative care that could be more widely adopted. As the population ages, increasing numbers of frail older people undergo elective and emergency surgery. Frailty is a significant risk factor for surgical complications. As a response, some services have developed a dedicated multidisciplinary perioperative frailty clinic that addresses patients' medical, psychological, functional and social needs.[3] Frailty clinics have been highly successful where they have been trialled. One of the key outcomes is an increase in shared decision-making about surgical and non-surgical options.

Perioperative medicine is an emerging field dedicated to optimising care for patients prior to surgery and minimising the risk of and managing perioperative complications. The field has been established to provide optimal

pre-operative, intra-operative, and post-operative care for all patients, particularly those at high risk of adverse outcomes. The multidisciplinary perioperative medicine team performs risk and needs assessment, coordinates pre-operative care, helps prevent and manage post-operative medical complications and supports functional recovery. The Australian and New Zealand College of Anaesthetists has recently released a perioperative framework to help facilities develop a perioperative medicine service.[4]

Enhanced Recovery after Surgery (ERAS) refers to a patient-centred, evidence-based pathway delivered by a multidisciplinary team. ERAS protocols aim to reduce patients' surgical stress response, optimise their physiologic function and facilitate recovery. These care pathways form an integrated continuum as the patient moves from home through the preadmission, pre-operative, intra-operative, and post-operative phases of surgery to home again.[5] Unfortunately, ERAS has not been systematically adopted in Australia and, where it has been adopted, it is often in a specific area of care (pre-operative, intra-operative, or post-operative) and not integrated.[6]

Integrated perioperative care is essential for achieving a seamless patient-centred surgical service. We can learn from the above examples, but I fear that widescale change will not happen without a paradigm shift from health care staff, health services and government. If you have an example of a successful integrated perioperative service, please consider sharing it in the *Journal of Perioperative Nursing*.

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Development and psychometric evaluation of a questionnaire for measuring distraction due to mobile phone use in operating rooms

Abstract

Aim: Use of mobile phones in health care centres can distract care providers and consequently disrupt the care procedure and risk patient safety. This study aims to develop and evaluate the psychometric properties of a questionnaire for measuring distraction caused by mobile phone use in operating rooms.

Sample and setting: 208 operating room nurses and doctors from five hospitals affiliated to Shiraz University of Medical Sciences participated in the study.

Method: This methodological study was conducted in two stages. In stage one, through a review of relevant texts, articles and books, the different dimensions of distraction as caused by mobile phone use were determined, and the items of the questionnaire were developed after several meetings with experts. In stage two the researchers used the two tests of content and face validity to determine the validity and internal consistency (Cronbach's alpha) and stability (test-retest) to evaluate the reliability. Also, the construct validity of the instrument was determined using exploratory factor analysis.

Results: In the first stage of the study, distraction due to mobile phone use was defined and 29 items on a five-point Likert scale were developed. In the second stage, after face and content validity assessments, 17 items remained. Evaluations of the reliability of the questionnaire using internal consistency and test-retest reliability yielded a Cronbach's alpha of 0.743. The Spearman–Brown correlation coefficient of the instrument was found to be 0.994. The construct validity of the instrument was examined through factor analysis.

Conclusion: The findings show that the developed instrument has enough validity and reliability to measure distraction due to mobile phone use in operating rooms.

Keywords: distraction, mobile phone, operating room, psychometric evaluation

Introduction

Recent studies show that distractions in the operating room contribute to 50 per cent of medical errors. Distractions may happen as often as once every three minutes and, on average, 13.5 times per case.[1] Distraction and attending to several tasks simultaneously result in work overload, adverse effects on perception and an increase in the incidence of errors.[2] Minimising the possibility of distraction in such environments as clinics and hospitals, where there is a constant need for communication and coordination between the personnel, is essential.[3] Computers are used widely in health care centres and there has been a rapid increase in the use of mobile phones in hospitals recently. Mobile phones are becoming

increasingly indispensable to everyday activities, for example using the internet, accessing bank services and entertainment.[2] Use of computers and other personal electronic devices in clinical environments is quickly growing.[3] This fact is especially alarming in operating rooms where distraction on the part of care providers can disrupt the therapeutic procedure and risk patients' safety.[4]

In 2013, distraction due to mobile phone use was ranked ninth on the list of the ten technologies threatening health care systems.[5] The seriousness of distraction can vary according to many factors, including the features of the tasks one should perform (main job), the source of distraction and the environment.[3] A major source of distraction at work, mobile phone use can increase one's reaction time and adversely affect concentration and performance.[6] Distraction in medical environments is defined as inconsistency or interruption in the performance of one's main medical tasks.[7,8] The members of a surgical team can be the source or recipient of distraction due to use of communication devices. Distraction can even be caused by loud music or conversations which are not related to the condition of the patient.[8] In an operating room, distraction can be due to internal sources (e.g. alarms of surgical equipment, conversations related to the surgery) and external sources (e.g. ringing phones, phone calls, contacting personnel from other wards).[4] Known as major sources of distraction, communication devices can reduce concentration and increase the possibility of clinical mistakes.[3] Distraction can affect all the members of a surgical team, including anaesthetists, nurses, surgeons and surgical technicians, thereby reducing the effectiveness of teamwork, increasing surgeon stress and leading to extra workload.[3,8]

As distraction can influence one's clinical performance,[7] it must be controlled in order for care providers to concentrate on patients and their work.[9] Development of policies to reduce or eliminate sources of distraction can prove very effective.[1] The Association of periOperative Registered Nurses (AORN) in the United State of America (USA) believes that a team-based interdisciplinary approach is needed to reduce distraction and noise levels to create a safer environment for patients and surgical teams. It is vital that during the critical stages of surgery, surgical teams work in an environment where unnecessary conversations and activities are forbidden.[9]

A review of the articles available in the databases of Medline, CINAHL, PubMed, Scopus and Elsevier showed that a valid and reliable tool exclusively designed to measure distraction caused by mobile phone use of operating room doctors and nurses has never been developed. In view of the seriousness of distraction in operating rooms and the urgency of studying distraction due to mobile phone use in the operating room, a valid instrument to measure distraction in the operating room is required.

The validity of the instrument/s used in a study is an indication of the significance of the subject under study. Therefore, development of a questionnaire should be followed by a psychometric evaluation.[10] Researchers who are involved in the development of research instruments should design and develop instruments with satisfactory validity and reliability. Accordingly, in view of the lack of a measurement tool, the present study aimed to develop and subsequently evaluate the psychometric properties of a questionnaire for measuring distraction caused by mobile phone use in operating room doctors and nurses.

Method

The present study is a methodological work undertaken to develop and determine the psychometric properties of an instrument for measuring distraction caused by mobile phone use in operating rooms. The current study was designed based on the STROBE guidelines for observational studies. The study was conducted in two stages. In stage one, the various dimensions of distraction due to mobile phone use in operating rooms were identified, based on a review of the relevant literature, and the researchers developed the items of the questionnaire, based on the definition of the concept and the objectives of the study. The questionnaire items were evaluated by experts (a surgeon, an epidemiologist and an operating room nurse) at several meetings. In stage two, the questionnaire was validated. There are various views about the numbers and types of validity and reliability of questionnaires. Norbeck, for example, believes that in the development of a research instrument, at least the following must be validated: content or face validity, predictive validity, construct validity, test-retest and internal consistency.[11] The researchers used the two methods of content and face validity to determine the validity of the instrument, and internal consistency (Cronbach's alpha) and constancy (test-retest) to evaluate the reliability. Also, exploratory factor analysis was used to determine the construct validity of the instrument. The questionnaire included questions about distraction, the patterns of mobile phone use, respondents' personal views and attitudes, respondents' knowledge

and awareness, respondents' activities, use of mobile phones, the advantages and disadvantages of mobile phone use, policies on mobile phone use at work, and use of social networks during clinical work.

The inclusion criteria for participants were being an operating room nurse or surgeon, owning at least one smartphone or tablet, and willingness to participate in the study.

Exclusion criteria included being unwilling to participate in this study, not returning the questionnaire, returning an incomplete questionnaire and lack of fluency in Persian language.

To evaluate the validity of the questionnaire, the researchers provided three professors, four faculty members of the university and three operating rooms nurses with copies of the questionnaire. Based on the factors which the questionnaire was intended to measure and the feedback of the consulted professors, faculty members and nurses, some items were eliminated or revised and some new items were added. The two indexes of face validity and content validity were used to assess the validity of the questionnaire. Face validity was assessed first, as a change in the statements and items of a questionnaire can lead to a change in its total validity.[12]

To determine the face validity of the instrument, the researchers used both qualitative and quantitative approaches. For qualitative evaluation of face validity, five operating room nurses and five surgeons were interviewed separately, face-to-face and the levels of difficulty, relevance and ambiguity of items were discussed. That is, how difficult the statements and words were to understand, how relevant the items were to the dimensions of the questionnaire, and how ambiguous words were as well as the possibility of items being misunderstood. After the unsatisfactory items had been revised, the quantitative method of item impact testing was used to determine the significance of each item so that the irrelevant items could be identified and eliminated. In item impact testing, those items whose impact score is 1.5 or more are considered as valuable and kept for later analysis.[13,14] Statistical analysis software SPSS version 22 was used, together with descriptive and analytical statistics, for analysing the collected data.

Both quantitative and qualitative approaches were used to determine the content validity of the instrument. The evaluation of the content validity of the questionnaire was based on the judgment of experts in the fields of instrument development, medicine, epidemiology and nursing who were consulted. For the qualitative evaluation of content validity, 15 experts (five surgeons, six faculty members of the university and four operating room nurses) were asked to read the items and give feedback about the grammatical structure of the statements, the appropriateness of the words, and the arrangement of the items. For the quantitative evaluation of content validity, the two measures of content validity ration (CVR) and content validity index (CVI) were used. First, for determination of CVR, ten experts (three surgeons, four faculty members of the university and three operating room nurses) were asked to rate each item on a three-point scale: 'necessary', 'helpful but not necessary' and 'unnecessary'. According to Lawshe's table, to determine the minimum value of CVR, the items whose CVR score (based on the evaluation of the ten experts) was over 0.62 were regarded as significant (P-value<0.05) and kept in the questionnaire.[15] Subsequently, CVI was assessed according to Waltz and Bausell's content validity index.[14] The 15 experts were asked to score each item in the questionnaire in terms of its relevance, clarity, simplicity and specificity; thus, the four indexes were scored individually on a four-point Likert scale. In the present study, the CVI score of each item was calculated by dividing the number of experts who had scored the item 3 or 4 by the total number of experts.[16] Hyrkas et al. recommend a score of 0.79 or above for accepting items according to their CVI scores.[17]

To determine the construct validity of the instrument, the researchers used factor analysis, which addresses the relationships between items, to identify and categorise the items which had the closest inter-relation. Construct validity can be evaluated in a variety of ways, including convergent validity, divergent validity, discriminant analysis and factor analysis. Factor analysis is regarded as a major step in the development of new instruments.[18] In the present study, the researchers executed exploratory factor analysis using the Kaiser–Meyer–Olkin (KMO) measure of sampling adequacy, Bartlett's test of sphericity, a scree plot, principal component analysis and varimax rotation. In the present study, factor loading of 0.5 was considered as the lowest factor loading required for an item to remain in the factors obtained from factor analysis. After the items in each factor had been established, the relevance of the factors to the concept and main dimensions of distraction due to mobile phone use in operating rooms was examined. Researcher opinion about the minimum number of samples required for factor analysis to evaluate construct validity ranged from five to ten samples per item.[19] In the present study, the sample of operating room nurses and surgeons selected was more than ten times the number of items in the questionnaire.

In the final stage of the study, the two methods of internal consistency analysis and stability analysis (test-retest) were used to determine the reliability of the questionnaire. Internal consistency was measured using Cronbach's alpha. A Cronbach's alpha of between 0.7 and 0.8 indicates a satisfactory level of internal consistency.[20] The stability of the instrument was evaluated using the test-retest method. An important factor in this method is the length of the interval between the two tests: according to Fox, the interval should be long enough for the respondents to forget the items of the instruments, but not so long enough for the phenomenon under study to change.[19] Grove et al. suggest two weeks to one month as an appropriate interval.[21] In the present study, the retest was carried out two weeks after the initial test. Subsequently, the correlation between the scores obtained from the two tests was examined using Spearman–Brown's test. For evaluation of construct validity and reliability, the operating room nurses and surgeons in the five large hospitals affiliated to Shiraz University of Medical Sciences in Shiraz, the largest city in the south of Iran, were sampled based on the random sampling method. The participants selected according to stratified sampling consisted of experts, operating room nurse, and anaesthetists assistants who met the inclusion criteria of the study.

Statistical analysis

SPSS software version 22 was used for data analysis. In all analyses, the significance level was considered as $p<0.05$. the researchers executed exploratory factor analysis using the KMO measure of sampling adequacy, Bartlett's test of sphericity, a scree plot, principal component analysis and varimax rotation. In the factor

Table 1: Demographic characteristics of the participants

Variable		Absolute frequency	Relative frequency (%)
Age (years)	under 25	34	16.3
	26–30	68	32.7
	31–35	46	22.1
	36–40	52	25
	over 40	8	3.8
Gender	male	102	49
	female	106	51
Marital status	married	109	52.4
	single	96	46.2
	divorced	3	1.4
Professional experience (years)	under 5	131	63
	6–10	42	20.2
	over 11	35	16.8
Organisational position	operating room nurse	95	45.7
	anaesthetist assistant	47	22.6
	surgeon	66	31.7
Type of employment	permanent	34	16.3
	contractual	27	13
	temporary (extendable)	30	14.4
	trainee	47	22.6
	student	70	33.7
Education	associate degree in operating room nursing	18	8.7
	bachelor degree in operating room nursing	70	33.7
	bachelor degree in nursing	5	2.4
	associate's degree in anaesthetics	2	1
	bachelor degree in anaesthetics	44	21.2
	masters degree in nursing	4	1.9
	resident	57	27.4
	specialist	6	2.9
	super specialist	1	0.5
	fellowship	1	0.5

Table 2: The results of the evaluations of the items of the questionnaire in terms of content validity

No.	Item	Relevance (CVI)	Clarity (CVI)	Simplicity (CVI)	Specificity (CVI)	Necessity (CVR)
1	In the operating room, I use my mobile phone only for urgent calls.	0.93	0.93	1	0.87	0.8
2	During clinical work, if my mobile phone rings, I will answer it.	0.87	1	1	0.87	0.8
3	I always turn off my mobile phone before I begin my shift.	0.87	1	1	0.87	0.8
4	I always set my mobile phone to silent mode before I begin my shift.	0.87	1	1	0.87	0.6
5	Using my mobile phone in the operating room reduces my awareness of my surroundings.	1	0.93	0.93	1	1
6	The ringing sound of my mobile phones disturbs my concentration on my clinical duties in the operating room.	1	1	1	1	1
7	The ringing sound of the doctors' and my co-workers' mobile phones has a disruptive effect on my work.	0.93	0.87	0.93	0.93	0.8
8	The ringing sound of my co-workers' mobile phones distresses me.	0.93	1	1	1	0.8
9	Use of mobile phones (by myself or my co-workers) has made me forget matters about patients which needed to be attended to.	1	0.81	0.93	1	0.8
10	During clinical work, I use my mobile phone for professional purposes or to improve treatment of patients.	0.75	0.87	0.93	0.81	0.8
11	My using my mobile phone during work in the operating room has caused problems at the cost of patients (waking up patients during surgery, failure to check supplies of gauze or other essentials, administration of the wrong drug, failure to monitor patient's conditions etc.).	1	0.93	0.87	1	0.8
12	During clinical work, I listen to music or take calls by headset.	0.87	0.93	1	0.87	0.8
13	Do you use the internet on your phone in the operating room?	0.81	0.93	1	0.81	0.8
14	During clinical work, I surf social networks (WhatsApp, Telegram, Instagram etc.) on my mobile phone.	0.87	1	1	0.87	0.8
15	When I am on my shift, I check my mobile phone regularly for new messages.	0.81	1	1	0.87	0.8
16	In the operating room, I download and install new apps and games.	0.81	1	1	0.87	0.4
17	In the operating room, I use my mobile phone to entertain myself.	0.87	1	1	0.87	0.8
18	In the operating room, I use my mobile phone to read and send personal emails.	0.75	1	0.93	0.87	0.6
19	I support a ban on the use of mobile phones in operating rooms.	0.81	1	1	0.81	0.8

analysis, items with the loading factor of 0.5, Eigen values of greater than 1 and variance of 60.886 determined the dimensions of the questionnaire. In the last stage of the study, the reliability of the instrument was measured using the two tests of internal consistency (Cronbach's alpha coefficient) and constancy (test-retest).

Ethical considerations

The present study was approved by the ethics committee of Shiraz University of Medical Sciences (Ethical code: IR.SUMS.REC. 1395. S1221) before it was conducted. All the participants were informed about the objectives of the study and participants' names were replaced with codes to ensure confidentiality. Moreover, all the participants signed an informed consent form.

Results

In the present study, 208 operating room nurses and surgeons with the average age of 31.8±6.5 and average experience of 6.2±5.7 years participated in the study. Table 1 shows the distribution of the participants according to age, gender, marital status, education, professional experience, type of employment and organisational rank.

At the beginning of the study, the definition of distraction was established based on a review of literature: distraction due to mobile phone use means dividing one's attention between one's tasks and a mobile phone during clinical work. In the first stage of the study, 29 items were developed based on a review of related literature. After separate, face-to-face interviews with ten operating room nurses and surgeons, the questionnaire was revised several times and the number of items was reduced to 19 (see Table 2). Based on the results of the content validity

Table 3: The factor loading of the items of the questionnaire about distraction due to mobile phone use in operating rooms based on rotation matrix

	Factor				
	1	2	3	4	5
Q1 before			0.715		
Q2 before		0.644			
Q3 before			0.562		
Q5 before					
Q6 before	0.642				
Q7 before	0.798				
Q8 before	0.802				
Q9 before	0.821				
Q10 before					0.892
Q11 before	0.668				
Q12 before				0.811	
Q14 before		0.598			
Q15 before		0.749			
Q17 before				0.756	
Q20 before		0.672			
Q21 before			0.639		

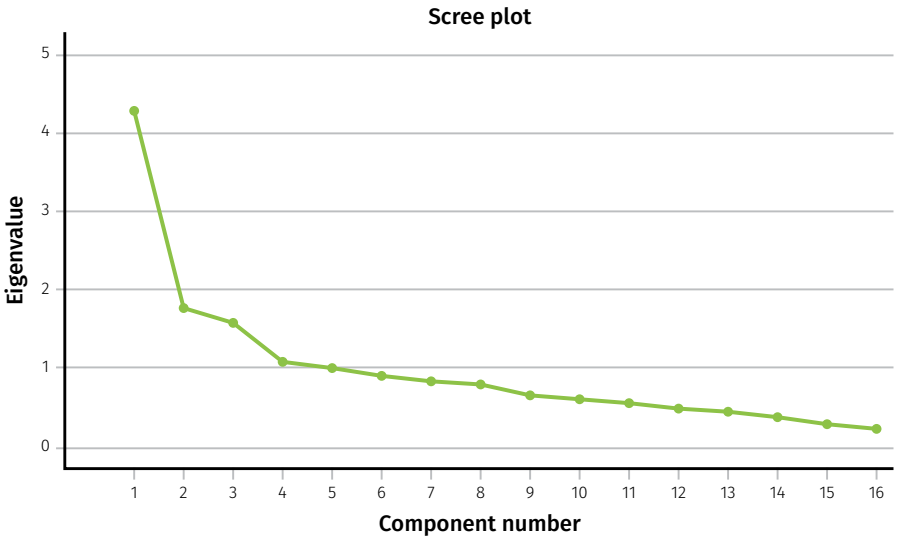

Figure 1: The factor analysis scree plot

evaluation and several meetings of the research team, items 9, 10, 11 and 15 were revised and corrected.

Furthermore, items 4, 16 and 18 were eliminated due to their CVR values of under 0.62 and two new items were added (see items 20 and 21 in Table 4) bringing the number of questionnaire items to 18. Of the 18 items, 16 items had five-point Likert scales and two items had two possible answers – 'I agree' and 'I disagree'. Since factor analysis can only be used for items which are answered on a Likert scale, items 13 and 19 which had only two possible answers, were not analysed in exploratory factor analysis with the principal items approach; exploratory factor analysis was performed for 16 items.

After performing exploratory factor analysis on 16 items, item 5 was deleted due to insufficient exploratory factor load. The final questionnaire had 15 items that were designed to be scored on a five-point Likert scale and two items (13 and 19)

Table 4: The items of the questionnaire grouped into the three categories as obtained from the factor analysis test

Categories	Items	Factor loadings
Category 1: Lack of concentration	6. The ringing sound of my mobile phone disturbs my concentration on my clinical duties in the operating room.	0.64
	7. The ringing sound of the doctors' and my co-workers' mobile phones has a disruptive effect on my work	0.79
	8. The ringing sound of my co-workers' mobile phones distresses me.	0.82
	9. Use of mobile phones (by myself or my co-workers) has made me forget matters about patients which needed to be attended to.	0.80
	11. My using my mobile phone during work in the operating room has caused problems at the cost of patients (waking up patients during surgery, failure to check supplies of gauze or other essentials, administration of the wrong drug, failure to monitor patient's conditions etc.).	0.66
Category 2: Patterns of mobile phone use	12. During clinical work, I listen to music or take calls by headset.	0.81
	2. During clinical work, if my mobile phone rings, I will answer it.	0.64
	14. During clinical work, I surf social networks (WhatsApp, Telegram, Instagram etc.) on my mobile phone.	0.59
	15. When I am on my shift, I check my mobile phone regularly for new messages.	0.74
	17. In the operating room, I use my mobile phone to entertain myself.	0.75
	20. In the operating room, I put my mobile phone where I can easily notice when I have a new message.	0.63
Category 3: Responsible use of mobile phones	1. In the operating room, I use my mobile phone only for urgent calls.	0.71
	3. I always turn off my mobile phone before I begin my shift.	0.56
	10. During clinical work, I use my mobile phone for professional purposes or to improve treatment of patients.	0.79
	21. I am aware of the consequences of professional mistakes that mobile phone use during work can cause.	0.67
Questions with two possible answers	19. Do you support a ban on the use of mobile phones in operating rooms?	–
	13. Do you use the internet on your phone in the operating room?	–

with only the two possible answers of 'I agree' and 'I disagree'. The final total number of questionnaire items was 17 (see Table 4).

The factor analysis results showed the KMO measure of sampling adequacy to be 0.754. Moreover, Bartlett's test of sphericity yielded the value of 987.234 which was significant at 0.001 (see Table 3). The factor analysis scree plot showed that by considering the special values of greater than 1 and the slope of the scree plot, three factors with the predictive power of 60.886 per cent determined the dimensions of the questionnaire (see Figure 1).

Kaiser–Meyer–Olkin measure of sampling adequacy = 0.754; Bartlett's test of sphericity = 987.234, P<0.0001; test–retest correlation coefficient = 0.994; Cronbach's alpha = 0.734.

The factor analysis yielded five factors which were grouped into three categories (see Table 4):

- Factor 1 consisted of five items (6, 7, 8, 9 and 11) and accounted for 20.046 per cent of the total variance. As these items dealt with such concepts as disruption or lack of concentration during clinical work and forgetting to attend to patients' needs, the category was labelled 'Lack of concentration'.
- Factor 2 consisted of four items (2, 14, 15 and 20) and accounted for 14.162 per cent of the total variance. These items addressed how mobile phones were used during clinical work; therefore, the category was labelled 'Patterns of mobile phone use'.
- Factor 3 consisted of three items (1, 3, 21) and accounted for 10.372 per cent of the total variance. These items addressed such issues as not using mobile phones during clinical work and being aware of the hazards of using mobile phones during clinical work; therefore, the category was labelled 'Responsible use of mobile phones'.
- Factor 4 consisted of two items (12 and 17). The researchers agreed to transfer these items, which were related to patterns of mobile phone use, to category two.
- Factor 5 consisted of one item (item 10). Due to its conceptual similarities to the items which addressed responsible use of mobile phones, item 10 was transferred to category three.

One item of the questionnaire (item 5) was eliminated due to not having sufficient loading factor.

To determine internal consistency, after factor analysis, the researchers used a sample consisting of 208 surgeons and nurses and found the Cronbach's alpha coefficient of the whole questionnaire to be 0.743. Evaluation of the stability of the questionnaire was conducted through the test-retest approach with a two-week interval. Spearman's correlation coefficient of the results was found to be 0.994 for the whole instrument, which was an indication of the high stability of the questionnaire.

Initially, 29 items were developed for the questionnaire but, after several revisions by a team of experts and researchers and evaluation of the validity of the instrument, the questionnaire was reduced to 17 items. With regard to the scoring of the instrument, 15 items were designed to be scored on a five-point Likert scale – 'never', 'rarely', 'sometimes', 'often' and 'always', scored from 0 to 5 with 'never' and 'always' being assigned 0 and 5 points respectively – and two items had only two possible answers – 'I agree' and 'I disagree' that would be given a score of 0 or 1.

Discussion

The present instrument was developed to measure distraction caused by mobile phone use by operating room nurses and surgeons and addresses a variety of factors, including perception, awareness, performance and patterns of mobile phone use. The definition of distraction due to mobile phone use in operating rooms as provided in the present study is based on a literature review; however, the development and psychometric evaluation of the instrument is an innovation in Iran and the world. In the present study, the face and content validity (qualitative and quantitative), construct validity (factor analysis), internal consistency (Cronbach's alpha coefficient), and stability (test-retest) of the instrument were verified.

The initial version of the questionnaire consisted of 29 items that were developed based on a review of related literature and views of experts. To evaluate the face validity of the instrument, in addition to a qualitative evaluation which resulted in the merger of some items, the researchers used the quantitative approach of item impact. As the impact score of the entire items was over 1.5, none of the items was eliminated.

The content validity of the instrument was evaluated using the CVR and CVI, one of the strengths of the study, which resulted in the elimination of four items and revision of another four. The construct validity of the instrument was examined through factor analysis. The results of the KMO measure and Bartlett's test,

0.754 and P<0.001 respectively, showed the factor analysis model to be valid and satisfactory. The results also showed the instrument to be multifactorial in the domains of lack of concentration, patterns of mobile phone use and responsible use of mobile phones during clinical work. The results proved that the factors derived from the factor analysis were consistent with the definition of distraction, thus confirming the construct validity of the instrument.

The Cronbach's alpha coefficient of the instrument was found to be greater than the acceptable minimum of 0.7, which points to the high internal consistency of the items.[16] Likewise, the results of the test-retest with a two-week interval showed the stability of the instrument to be high.

The score range of the instrument is between 15 and 77, with higher scores indicating a greater degree of distraction due to mobile phone use in operating rooms. Fifteen of the items on the questionnaire are scored on a five-point Likert scale. For 13 of these items 'never' = 1, 'rarely' = 2, 'sometimes' = 3, 'often' = 4, 'always' = 5; the other two items (3 and 21) are scored reversely, i.e. 'never' is scored as 5 and 'always' is scored as 1. Two items (13 and 19) are scored as 1 or 0 as they have two possible answers: 'I agree' and 'I disagree'. For item 13, 'I agree' = 1 and 'I disagree' = 0 points, for item 19 it is vice versa.

There are not many instruments that measure distraction due to mobile phone use in Iran or elsewhere in the world. One example is the checklist developed and used by Sevdalis et al. to study the effects of distraction during surgery on patient safety. There are two possible answers to the items on the checklist, 'done' and 'not done', which are checked by the researcher as they observe surgery. The factors addressed in the checklist include electronic communication, telephones, pagers, equipment, regulations and the environment.[22] The items are derived from the study of Wu et al. which addresses the safety and effectiveness of task performance in operating rooms.[23] Sevdalis's instrument has only been subjected to content validity and its CVI has been calculated; its CVR, however, is unknown.[22]

In the existing instruments, the Likert scale used is for agreement, ranging from 'I completely agree' to 'I completely disagree'; therefore, it is possible that a respondent agrees with an item but does not actually practice it. In the present questionnaire, however, the Likert scale, ranging from 'always' to 'never', reflects what respondents actually do.

McBride et al. have designed a questionnaire to measure nurses' non-work-related use of mobile phones in hospitals. Consisting of 30 items, the questionnaire has been subjected to face and content validity analyses – Cronbach's alpha and test-retest with a one-week interval have been used to determine its reliability – however, its construct validity has not been examined. Moreover, this instrument addresses only non-work-related use of mobile phones during clinical practice, which includes reading the news, playing games, surfing social networks, online shopping and reading and sending emails and text messages.[24] The present questionnaire, on the other hand, covers all the factors that can contribute to distraction, among them internet-related mobile phone use, making phone calls, individuals' awareness, regulations and work-related as well as non-work-related use of mobile phones.

To study the rate, patterns and potential of distraction due to mobile phone use during clinical rounds, Katz-Sidlow et al. used a self-made questionnaire, observation and interview with the participants. Their questionnaire consisted of 12 items which have only been subjected to face validity evaluation; the content validity, construct validity and reliability of the instrument have not been tested. The strength of the study is its use of several methods to measure distraction.[4]

Cho et al. have developed an instrument to measure distraction caused by mobile phones during clinical practice and the policies that limit use of mobile phones by nursing students. Consisting of 13 items, the instrument addresses distraction in nursing students and nurses, policies that restrict use of mobile phones, the amount of time mobile phones are used during clinical work and the main reasons for using mobile phones. The researchers use exploratory factor analysis to assess the construct validity of this questionnaire, but there is no mention of its face validity, content validity, or reliability. Cho's questionnaire measures distraction in clinical areas, while the present instrument has been developed exclusively for evaluating distraction in operating rooms.[5]

The questionnaire developed by Smith et al. has assessed the views and concerns of perfusionists about mobile phone use during clinical practice. The questionnaire consists of 19 items and addresses the three dimensions of communication devices, patterns of mobile phone use during work with the cardiopulmonary machine, and views about mobile phone use and safety of patients. Some of the items in the questionnaire are scored on a Likert scale and the others are open-ended questions. The reliability and validity of the instrument are not reported.[25].

Avidan et al. conducted a study on distraction caused by mobile phone

calls of operating room nurses during elective surgery. To collect data, the researchers used direct observations which focused on the length and topic (patient-related, work-related or personal) of calls. Lengths of distraction were also recorded through observation. This study evaluated the extent of distraction caused by mobile phone calls, while the present study addresses all aspects of mobile phone use, including visiting social networks, receiving and sending text messages as well as making and receiving phone calls.[26]

In a review study, Dala-Ali et al. examined doctors' responsible use of iPhones.[27] Wu et al. conducted a study to determine how mobile phones are used to make clinical communication in general wards and how they can affect the effectiveness of teamwork and communication — their study is a mixed methods work where data has been collected based on the frequency of calls and emails on smart phones, interviews with doctors, and observation of clinical interactions.[23] Another example is the review study by Ruskin et al.[28] Most of the above-mentioned studies focus on the benefits of mobile phones and how they can improve care providers' efficiency; the present study, however, addresses not only the benefits of mobile phone use, but also the aspects of distraction and patterns of mobile phone use.

The instrument developed in the present study was subjected to validity and reliability tests. Also, it addresses most aspects of mobile phone use including patterns of use, performance, awareness, knowledge, attitude and distraction. One of the advantages of the instrument is that it can be easily used: operating room nurses and surgeons can complete it in approximately ten minutes.

Furthermore, the majority of the above-mentioned instruments are intended for collection of general data and do not examine the causes of distraction. Also, most of the instruments in this field lack satisfactory validity and reliability and are not fit for use in operating rooms.

Limitations of the study

Because the views of culture of Iranian society have been used in the process of developing the present instrument, it is possible that the results may not be applicable to all societies. However, since the initial content of the questionnaire was derived from an extensive review of international literature, it seems likely that the present instrument can be applied to operating room personnel in other countries.

Conclusion

Based on the results of the study, the present instrument is sufficiently valid and reliable to measure distraction due to mobile phone use in operating rooms. The present instrument can be used to study distraction due to mobile phone use so that more effective steps can be taken to eliminate the problems that can occur as a result of this in operating rooms.

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Hospital costs of post-operative delirium: A systematic review

Abstract

Aims: In this systematic review, the primary aim is to investigate the hospital cost burden attributed to post-operative delirium (POD). A secondary aim is to examine how patient length of stay (LOS) in hospital varies across the selected studies.

Background: POD is a common occurrence after major surgery and leads to serious medical complications. It is associated with increased morbidity and double the risk of mortality from surgery compared to non-delirious patients. POD increases patient LOS in hospital and increases the economic burden on patients and the health system.

Design: A systematic review was conducted.

Method: Published articles in English over the period 2010 to 2020 were searched using the PubMed and MEDLINE databases. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were followed. The study quality and risks of bias of included studies were assessed using the Newcastle–Ottawa Quality Assessment Scale (NOS).

Results: A total of 2539 published records were initially screened and ultimately ten studies were found to be relevant to the review criteria. Six studies were from the United States of America (USA) and the others from South Korea, Australia, and Canada. The additional costs for patients with POD ranged from a minimum of US$1551 to a maximum of US$23 698 compared to non-delirious patients. Costs were higher in the USA than other countries. Studies reported most surgical patients experiencing POD were aged 70 years or older which dramatically increases the risk of its occurrence and increases LOS and hospital related costs. The difference in LOS between POD and non-delirious patients ranged from 0.8 to 7.3 days and this increased significantly if POD patients were in intensive care.

Conclusions: Increased LOS and increased hospital costs are strongly associated with POD after major surgery.

Keywords: post-operative delirium, POD, length of stay, LOS, costs, systematic review

Introduction

Among post-operative medical complications, delirium is common and characterised by cognitive dysfunction, inattention and thinking disorder.[1,2] Delirium has two states – hyperactive and hypoactive.[3] Post-operative delirium (POD) is significantly associated with higher risk of morbidity and mortality, inferior functional recovery and extended immobilisation.[3,4] The major factors in developing POD are advanced age, previous history of mental dysfunction, multiple medical comorbidities, acute injuries and pain.[1,5–8] Recent reviews of its incidence reveal a wide range from 3.3 to 77 per cent among surgical and intensive care unit (ICU) patients.[9–12] Studies report that POD also leads to prolonged length of stay (LOS) in hospital and ICU, and associated increased cost of health care treatment both in hospital and after discharge.[13–19]

The overall additional estimated cost for delirium was reported as ranging from US$806 to US$24 509 in 2019.[20] In 2021, a study in the USA reported the health care costs attributed to POD after major elective surgery for delirious patients in one year had a mean of US$146 358 (SD: US$140 469) which is significantly higher than US$94 609 (SD: US$80 648) for non-delirious patients. The annual national health care costs in the USA due to POD were estimated at US$32.9 billion (CI 95%: US$25.7 billion–US$42.2 billion).[21] An Australian study described that the cost index of hospital episodes for post-operative delirious patients was 51 per cent higher than the non-delirious patients. Post-operative delirious patients also had a higher 28-day rehospitalisation rate than their counterparts.[22] Total cost due to delirium was about AU$8.8 billion in 2016–2017 and this severe neuropsychiatric syndrome causes about 10.6 per cent of cognitive impairment (i.e. dementia) in Australia.[23]

POD also increases LOS in hospital and ICU and can lead to other post-operative complications. Increased LOS in hospital and ICU attributed to POD after major surgery is significantly higher than for non-delirious patients.[24–27] Further, hospital readmission after initial discharge was also higher among patients with cognitive impairments like POD.[28] As the prevalence of POD in ICU is upwards of 80 per cent, an investigation of the cost of POD and the resultant extended LOS is needed.[29]

Research evidence shows that POD is a potentially preventable medical condition.[30–32] The occurrence of delirium could be avoided for 30 to 40 per cent of medical emergency patients.[33] Considering the severe impact on patient's morbidity and mortality, the prevention of POD is essential to minimise the risks to the individual surgical patient and to mitigate the economic burden on the patient, health system and society.[34,35]

Aims

The primary aim of this study was to systematically review the literature on the hospital costs of POD over the period 2010 to 2020. A secondary aim was to examine how patient LOS in hospital varies across the selected studies.

Methods

Review design

This review involved a systematic search of studies in the PubMed, PubMed Central and Medline databases and followed the standard Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[36] All published research articles related to delirium and post-operative delirium (POD) including reviews and meta-analysis were taken into consideration based on MeSH terms and keywords related to cost and hospital stay.

Search strategy

Of the published journal articles from 2010 to end of 2020, articles were only included if they were peer-reviewed research articles, available as full-text, written in English and reported on one or more of the following: the post-operative delirium condition, any associated direct or indirect hospital costs, the length of stay in hospital or ICU.

The systematic literature searching occurred in two electronic databases of PubMed, and PubMed Central, and Medline. MeSH terms, key words and subject headings were used which are conceptually synonyms of delirium, POD and the direct or indirect hospitalisation cost. The OR/AND operator was used to create the combination of searching key words. The following MeSH terms and key words with a combination of delirium and POD were used to search the literature: "economics"; "health care economics and organizations"; "cost of illness"; "cost evaluation"; "cost-benefit analysis"; "health care costs"; "cost Analysis"; "cost effectiveness"; "statistics and numerical data"; "economic outcome"; "economic impact"; "medical expenditure"; "cost utility"; "costs and cost analysis"; "hospital costs"; "medical care cost"; "delirium/statistics and numerical data"; "emergence delirium/statistics and numerical data"; "care, post-operative"; "length of stay". All the outcomes were recorded and assessed through the various filtration steps according to PRISMA guidelines and the final articles were selected.

Eligibility/inclusion criteria

The preliminary outcomes of interest were increased LOS in hospital and ICU due to POD and the additional costs of hospitalisation related to POD.

Studies that did not satisfy the inclusion criteria were excluded. Moreover, published articles not in English, systematic reviews, meta-analyses, editorials, conference proceedings, commentaries and research protocols related to delirium were also excluded.

Screening process

For this systematic review, the direct and indirect cost data and the LOS information of delirious patients were collected from selected full-length research articles written in English. To perform this, the outcome records from the database search were evaluated by two independent researchers screening the title, abstract and the full-length articles to select the most relevant studies. This was done using the PRISMA guidelines. The first researcher

(MPM) did the primary extraction and selection and discussed these with KA and JG to resolve if any conflict arose. The final selected papers were shared and evaluated by KA and JG independently. One study was excluded at the last stage due to disagreement among the researchers. This procedure ensures selection reliability and reduces the risk of bias. For each of the ten finally selected articles, the authors, publication year, types of surgery, data collection period, places/settings/country, all hospitalisation costs, LOS, and currency were extracted.

Quality appraisal

To ensure the quality of the selected studies and reduce the risk of bias, the Newcastle-Ottawa Quality Assessment Scale (NOS)[37] was used to assess the studies. The NOS is a well-established tool for cohort study evaluation in systematic reviews and meta-analyses. The NOS not only checks the study quality (i.e. study selection and comparability between the populations) but also measures the risk of bias in study outcomes or exposure variables. A score-based evaluation, with maximum NOS score of 9, was used to assess the risk of bias and indicate the study quality with 7 or higher indicating high quality, 5 or 6 indicating fair or moderate quality and less than 5 indicating high risk of bias.

Cost values and currency conversion

The extracted cost information from the articles were in different currency values and over various time periods. To make an easy, presentable and scientific comparison, the cost data was converted by using a well-established conversion method, namely, purchasing power parity (PPP), using US dollars in 2020 as the conversion year for comparison purposes.[38]

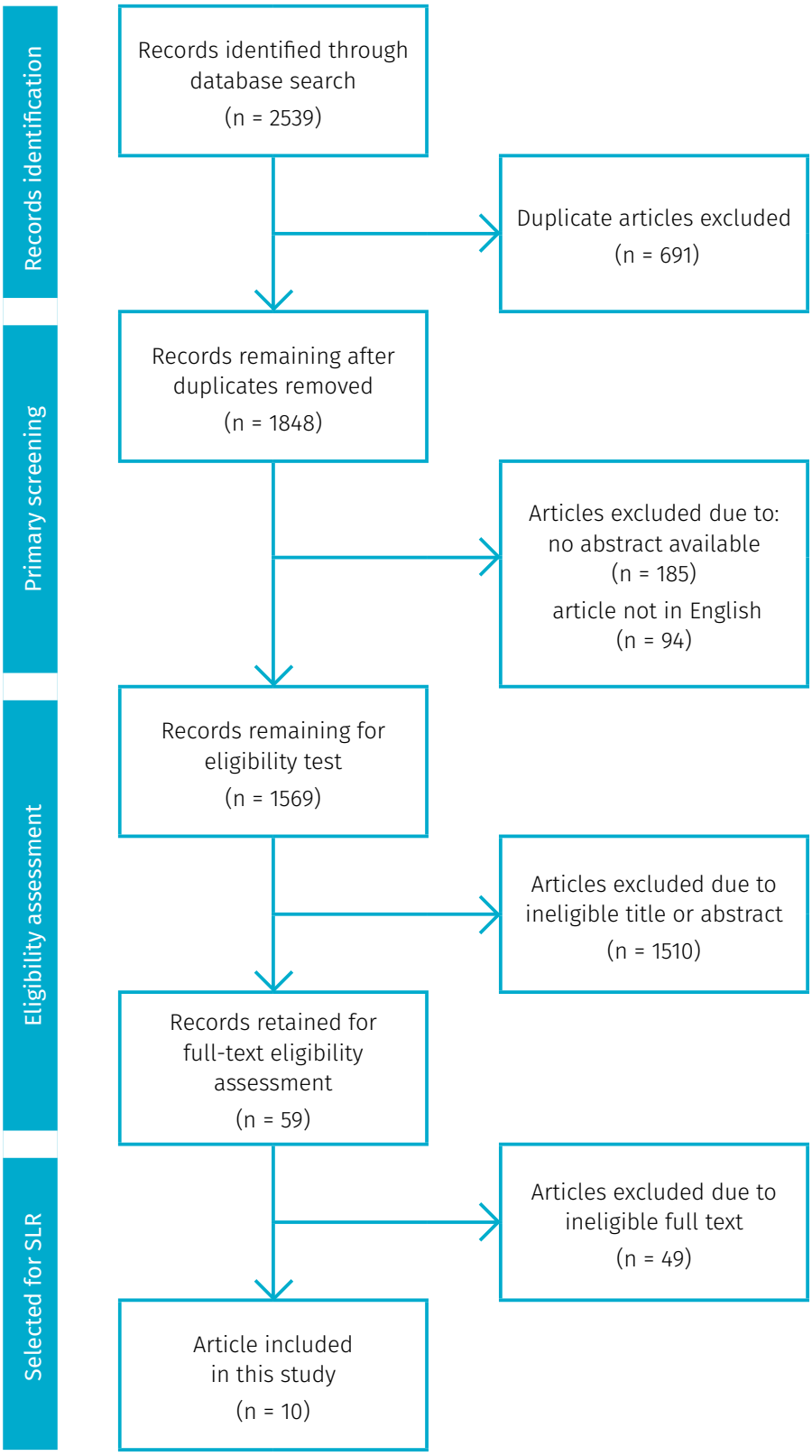

Figure 1: The PRISMA framework flowchart for this systematic literature review

Results

Literature search outcomes

The search results were collected from the electronic databases using MeSH terms and POD-related keywords. The comprehensive literature search revealed a total of 2539 published records over the period from 2010 to 2020. The final selection strategies of the eligible studies are described in Figure 1 using the PRISMA framework. After excluding duplicates and articles with missing or non-English abstracts, 1569 studies continued to the next investigation step. Subsequently, these articles' titles and abstracts were screened considering the inclusion criteria and 1510 articles were excluded. Only 59 abstracts were found to fully or partly meet the inclusion criteria and the full texts of those articles were further assessed. Eleven articles were found to satisfy the inclusion criteria with one article excluded from the analysis after discussion with all researchers. Finally, ten full-text articles met the criteria and were selected for this review (see Figure 1).

Characteristics of identified studies

All ten studies included cost information and the length of hospital stay for major surgery patients. Table 1 shows the basic characteristics of the included studies. The sample size of the selected studies varied from 66 to 1389526 for distinct major surgeries where the number of affected delirious patients ranged from 37 to 54615. The proportion of POD occurrence among patients varied widely from 0.8 to 78.5 per cent and these two extremes were for lumbar fusion (LF) or lumbar decompression (LD) surgeries and respiratory failure or shock in surgical or medical ICU patients, respectively. Most of the studies were conducted in the USA (six studies),[4,39–42,45], two studies were conducted in South Korea[43,44] and one study from each of Australia[22] and Canada[24] (see Table 1).

Most of the selected studies were retrospective studies. They reported upon distinct types of major surgeries while one study[22] did not declare directly any particular surgery type. The studies only considered the medical or surgical acute inpatient, not their further treatment (if any) after discharge.

For the majority of post-operative patients, delirium was assessed by well-established methods, notably, confusion assessment method (CAM), confusion assessment method for the ICU (CAM-ICU), International Classification of Diseases (9th revision) Clinical modification (ICD-9-CM) codes and International Classification of Diseases and Related Health Problems (10th revision) Australian modification (ICD-10-AM) codes.

The NOS scores for the selected studies show minimal risk of bias and all but one study[39] had a score of seven or higher which indicates high quality (see supplementary material).

The age distribution of POD patients for the various major surgeries indicates that they were mostly elderly people of over 50 years. The mean age of POD and non-delirious patients varied from 49 to 87 years and 36 to 87 years, respectively. In two studies, the age distribution showed that POD also developed among young people under 40 years of age.[4,40]

The gender ratio of POD patients in seven studies showed that males made up more than 50 per cent of patients. Overall, the proportion of males experiencing POD ranged from 29 to 84 per cent. A significant number of women had POD after the fragility hip fracture operation (82%) and lumbar fusion (LF) or lumbar decompression (LD) operations (55.5%).[24,41]

Length of stay

The LOS after major surgeries was represented in two ways, namely, hospital stay and ICU stay (see Table 2). Seven studies reported inpatient LOS for hospital only, one study reported LOS for ICU only and two studies reported LOS for both hospital and ICU.

The LOS in most of the studies was represented using the mean and median along with variance/spread measurements, notably, interquartile range (IQR), standard deviation (SD) and range. Two studies reported only the mean LOS[41] and frequency distribution of LOS[40] without any other dispersion/variance measurements.

The day difference of LOS in hospital between POD and non-delirious patients ranged from to 0.8 to 7.3 days (see Figure 2). The maximum mean LOS in hospital was found to be 20.2 days (SD ±13.6 days) for osteoporotic hip fractures surgeries for POD patients.[44]. Median LOS in hospital was 7.0 days (IQR 4–11 days) for major urologic cancer surgeries.[4]

The LOS in ICU for delirious patients was reported in three studies and the lowest mean ICU stay was 54.4 hours (range 7–714 hours) and the highest median LOS was 75.6 hours (IQR 43.6–136.8 hours) for cardiac and major abdominal surgeries, respectively.[42,43]

Table 1: Basic information about the included studies (n = 10)

Author (year) Country	Type of surgery / medical facility used	Type of study	Sample size Total (delirious; per cent)	Time of data collection	Sex		Age (year) Mean (±SD or range)		Diagnostic tools for POD
					delirious	non-delirious	delirious	non-delirious	
Brown et al. (2016)[42] USA	cardiac surgery	Prospective observational study	N=66 (37; 56.1%)	October 2012 to February 2014	M: 28 (75.7%)	M: 23 (79.3%)	70 (±7)	69 (±8)	CAM/CAM-ICU
Fineberg et al. (2013)[41] USA	lumbar fusion (LF) or lumbar decompression (LD) surgeries	Retrospective database analysis	N=578 457 (4857; 0.8%)	2002 to 2009	F: 55.5%	F: 50.6%	70	55	ICD-9-CM
Ha et al. (2018)[x] USA	major urologic cancer surgeries – radical prostatectomy (RP), radical nephrectomy (RN), partial nephrectomy (PN) and radical cystectomy (RC)	Retrospective cohort study	RP: N=630 353 (5,986; 0.9%)	2003 to 2013	RP: M: 0.9%	RP: M: 99.1%	RP: 63.01	RP: 62.50	ICD-9-CM
			RN: N=305 503 (14 431; 4.7%) 291 072		RN: M: 60.6%	RN: M: 58.2%	RN: 72.12	RN: 64.27	
			PN: N=104,214 (3377; 3.2%)		PN: M: 59.1%	PN: M: 57.2%	PN: 67.01	PN: 61.00	
			RC: N=57,261 (6268; 10.9%)		RC: M: 84.3%	RC: M: 81.5%	RC: 74.04	RC: 70.07	
Kim et al. (2017)[44] South Korea	osteoporotic hip fractures	Follow-up study	N=221 (37; 16.7%)	2010 to 2014	M: 12 F: 25	M: 11 F: 26	81.8 (±6.8)	80.8 (±6.7)	CAM
Park et al. (2019)[43] South Korea	major abdominal surgery	Retrospective study	N=1061 (194; 19.1%)	January 2014 to December 2016	M: 126 (64.9%)	M: 567 (65.4%)	74.6 (60–91)	69.0 (60–95)	CAM
Patel et al. (2018)[40] USA	neuro-AIDS patient cohort	Cohort study	N=1 389 526 (54 615; 3.9%)	2005 to 2014	M: 70.06% F: 29.94%	M: 67.07% F: 32.93%	49	36	ICD-9-CM
Potter et al. (2018)[45] USA	transcatheter and surgical aortic valve replacement (TAVR and SAVR)	Retrospective study	TAVR: N=12 114 (195; 1.6%)	2015	TAVR: F: 5931 (48.96%)		TAVR: 87.06 (±3.77)		ICD-9-CM
			SAVR: N= 8974 (323; 3.6%)		SAVR: F: 3532 (39.36%)		SAVR: 84.20 (±2.67)		
Tropea et al. (2017)[22] Australia	medical or surgical acute inpatient	Retrospective cohort study	N=93 300 (6459; 6.9%)	July 2006 to June 2012	F: 3177 (49.2%)	F: 37 582 (43.3%)	80 (±9)	70 (±11)	ICD-10-AM
Vasilevskis et al. (2018)[39] USA	surgical or medical ICU for respiratory failure or shock	Prospective cohort study	N=479 (376; 78.5%)	2013	M: 248 (52%)		57 (±15)		CAM-ICU
Zywiel et al. (2015)[24] Canada	fragility hip fracture		N=242 (126; 52.1%)	January 2011 to December 2012	M: 34 (29%) F: 82 (71%)	M: 40 (32%) F: 86 (68%)	85.3 (65-103)	79.8 (65-101)	CAM

CAM = Confusion Assessment Method; CAM-ICU = Confusion Assessment Method for the ICU; ICD-9-CM = International Classification of Diseases (9th revision) Clinical Modification codes; ICD-10-AM = International Classification of Diseases and Related Health Problems (10th revision) Australian Modification codes.

Table 2: Length of stay (LOS) in hospital and/or ICU of delirious and non-delirious patients

Author (year) Country	Type of surgery / medical facility used	Statistics	Length of stay in ICU and/or hospital		
				delirious (SD, IQR or range)	non-delirious (SD, IQR or range)
Brown et al. (2016)[42] USA	cardiac surgery	median (IQR)	ICU stay	75.6 hours (43.6–136.8)	29.7 hours (21.7–46.0)
			hospital stay	9 days (6–16)	7 days (5–8)
Fineberg et al. (2013)[41] USA	lumbar fusion (LF) or Lumbar decompression (LD) surgeries	mean	hospital stay	7.9 days	3.4 days
Ha et al. (2018)[4] USA	major urologic cancer surgeries	median (IQR)	hospital stay	7 days (4,11)	3 days (2,4)
Kim et al. (2017)[44] South Korea	osteoporotic hip fractures	mean (SD)	hospital stay	20.2 days (±13.6)	16.7 days (±6.9)
Park et al. (2019)[43] South Korea	major abdominal surgery	mean (range)	ICU stay	54.4 hours (7–714)	27.5 hours (8–460)
			hospital stay	19.1 days (5–60)	14.2 days (4–94)
Patel et al. (2018)[40] USA	neuro-AIDS patient cohort	frequencies	hospital stay		
			1–3 days	22.74%	35.89%
			4–6 days	24.20%	28.66%
			7–9 days	16.93%	14.21%
			10–12 days	9.81%	6.91%
			13–15 days	6.71%	4.48%
			≥ 16 days	19.60%	9.84%
Potter et al. (2018)[45] USA	transcatheter and surgical aortic valve replacement (TAVR and SAVR)	mean (CI)	hospital stay		
			for all AVR	15.1 days (12.0–18.0)	7.9 days (7.8–8.0)
			for TAVR	11.9 days (10.3–13.5)	6.1 days (6.0–6.2)
			for SAVR	17.0 days (12.2–21.7)	10.4 days (10.2–10.5)
Tropea et al. (2017)[22] Australia	medical or surgical acute inpatient	median (IQR)	hospital stay (unadjusted)	9 days (5–16)	5 days (2–8)
			hospital stay (adjusted)	7.4 days (6.7–10.0)	6.6 days (5.7–8.3)
Vasilevskis et al. (2018)[39] USA	surgical or medical ICU for respiratory failure or shock	median (IQR)	ICU stay	11 days (7–18)	
Zywiel et al. (2015)[24] Canada	fragility hip fracture	mean (range)	hospital stay	18.5 days (4–137)	11.2 days (3–107)

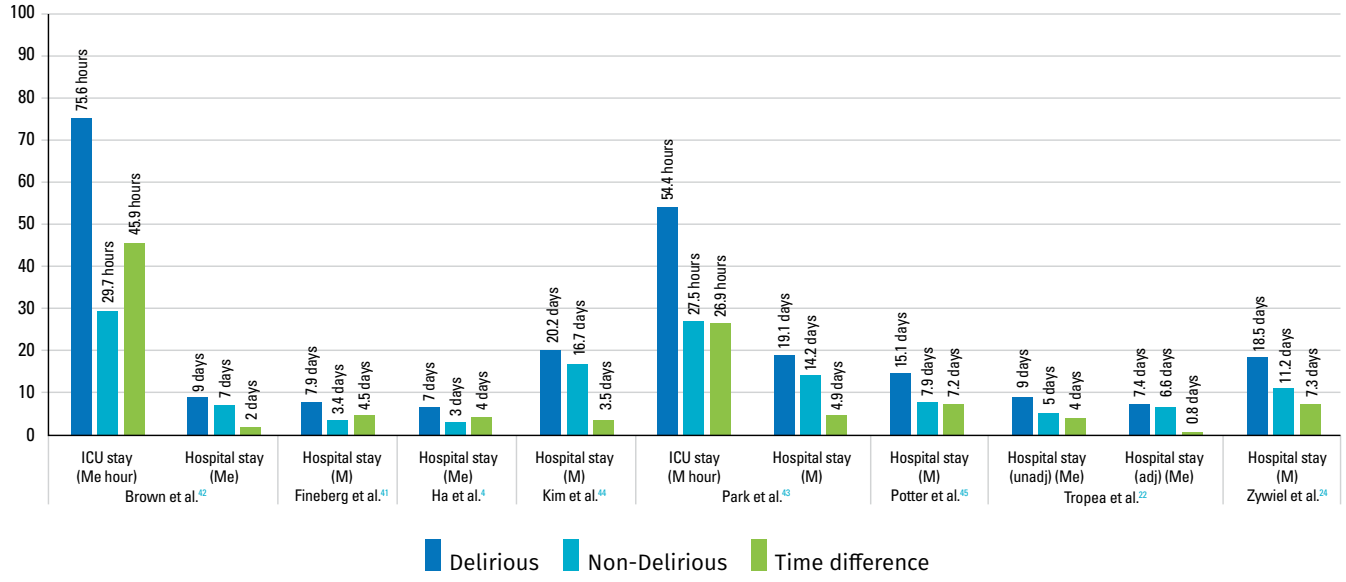

Figure 2: Length of stay (LOS) in hospital and/or ICU for delirious and non-delirious patients

M = mean; Me = median
Note: Patel et al. presented LOS as frequencies and Vasilevskis et al. did not compare LOS for delirious and non-delirious patients.

Costs due to POD

Eight studies used the mean[4,24,39–41,43–45] and two studies showed median costs.[22,42] Studies also reported 95 per cent confidence interval (CI), IQR and SD. One study reported the standard error with the mean cost[40]. Interestingly, three studies did not report any variance measurement and only reported mean cost.[4,41,43]

Costs associated with POD after major surgeries and severe medical conditions were reported in several ways, notably, total or overall cost, hospitalisation and hospitalisation admission cost, index hospitalisation and admission cost and care cost (see Table 3).

There was a significant heterogeneity among the cost reporting for POD. Six studies reported 'total' or 'overall' cost[39–44] which indicated the total cost of hospitalisation without any breakup into direct or indirect treatment costs. Four studies also reported hospitalisation or hospital admission costs.[4,40,44,45] Two studies reported the costs as index hospitalisation and index admission cost[22,45] and one study represented the costs as care cost[21].

The overall cost for POD patients ranged from median US$7396 (IQR US$3250 – US$15,005)[22] up to US$57 306 (IQR: US$48 718 – US$88 759)[42] for medical or surgical acute inpatient and cardiac surgery, respectively. The mean hospitalisation cost and hospital admission cost varied from US$8558 (SD US$3260.78) to US$20 940 (SE ± US$483.40) for osteoporotic hip fractures and neuro-AIDS patient cohorts.

Two studies conducted in Australia[22] and the USA[45] reported index hospitalisation costs and the index admission costs coded for medical or surgical acute inpatient and the trans-catheter and surgical aortic valve replacement surgeries, respectively. The unadjusted mean index hospitalisation cost for POD patients was reported as US$82 403 (95% CI US$70 816 – US$93 991) and median index admission cost as US$13 167 (IQR US$10 512 – US$17 299).

One study examined hip fracture surgeries[24] and reported mean care cost for POD patients as US$24 416 (IQR US$8141 – US$10 945). Another study[39] reported costs for POD as total cost and its components – pharmacy; laboratory; diagnostic radiology; respiratory, physical therapy and occupational therapy; central supply; professional, bed expenses and dialysis. That study reported that the total 30-days cumulative incremental cost due to POD was US$20 105 (95% CI US$12 547 – US$26 484) and the incremental cost effect of mortality was US$5245 (95% CI US$2317 - US$8869) for surgical or medical ICU patients suffering from respiratory failure or shock.[39]

The cost differences between POD and non-delirious patients ranged from US$1551 to US$23 698 (see Figure 3) for osteoporotic hip fracture surgery[44] and transcatheter and surgical aortic valve replacement surgeries,[45] respectively.

Table 3: Cost data for delirious and non-delirious patients (n = 10)

Authors (year)	Year of cost data	Currency	Statistics	Outcome measures	Original costs	PPP 2020 USD values
Brown et al. (2016)[42]	October 2012 to February 2014	USD	Median (IQR)	Overall charges	45 459 (36 607–67 807)	50 286.83 (40 494.73–75 008.22)
				Total charges with delirium	51 805 (44 041–80 238)	57 306.78 (48 718.23–88 759.42)
				Total charges without delirium	41 576 (35 748–43 660)	45 991.44 (39 544.5–48 296.77)
Fineberg et al. (2013)[41]	2002 to 2009	USD	Mean	Overall cost with delirium	29 970	36 180.47
				Overall cost without delirium	16 578	20 013.34
Ha et al. (2018)[4]	2003 to 2013	USD	Mean	Admission cost with delirium	30 859	34 782.07
				Admission cost without delirium	26 607	29 989.52
Kim et al. (2017)[44]	2010 and 2014	USD	Mean (IQR) Mean (SD)	Overall hospitalisation cost	6973 (3924–17 222)	7713.99 (4340.74–19051.01)
				Hospitalisation cost with delirium	7736 (2947.73)	8558.19 (3260.78)
				Hospitalisation cost without delirium	6333 (1698.24)	7006.65 (1878.6)
Park et al. (2019)[43]	January 2014 to December 2016	KRW (x10^3)	Mean (range)	Hospital costs with delirium	12 816 (755–73 168)	16 375.50 (964.69–93 489.57)
				Hospital costs without delirium	9292 (498–75 270)	11 873.77 (636.31–96 175.38)
Patel et al. (2018)[40]	2005 to 2014	USD	Mean ± SE	Total cost of hospital admission for patients with HIV-associated cognitive impairment	18 930 ± 436.99	20 940.4±483.40
				Total cost of hospital admission for patients without HIV-associated cognitive impairment	15 328 ± 216.97	16 955.86±240.01
Potter et al. (2018)[45]	2015	USD	Mean (95% CI)	Unadjusted index hospitalisation cost with delirium	82 403 (70 816–93 991)	90 189.64 (77 507.73–102 872.65)
				Unadjusted index hospitalisation cost without delirium	58 705 (58 294–59 116)	64 252.31 (63 802.47–64 702.15)
Tropea et al. (2017)[22]	1 July 2006 to 30 June 2012	AUD	Median (IQR)	Unadjusted median cost with delirium	9504 (4176–19 280)	7396.66 (3250.05–15 005.01)
				Adjusted median cost with delirium	15 640 (12 678–21 096)	12 172.12 (9866.89–16 418.35)
				Unadjusted median cost without delirium	5588 (2661–12 256)	4348.96 (2070.97–9538.46)
				Adjusted median cost without delirium	10 422 (8927–12 946)	8111.11 (6947.6–10 075.46)
				Cost of the index admission with delirium	16 919 (13 507–22 228)	13 167.52 (10 512.07–17 299.35)
				Cost of the index admission without delirium	11 069 (9677–14 068)	8614.65 (7531.3–10 948.68)

Authors (year)	Year of cost data	Currency	Statistics	Outcome measures		Original costs	PPP 2020 USD values
Vasilevskis et al. (2018)[39]	2013	USD	Mean (95% CI)	*Estimates of the 30-day cumulative incremental effects of ICU delirium*			
				Incremental cost attributed to intensity of utilisation:	Total cost	17 838 (11 132–23 497)	20 105.73 (12 547.20–26 484.15)
					Pharmacy	4 018 (2582–5020)	4528.80 (2910.25–5658.19)
					Laboratory	1185 (539–2047)	1335.65 (607.52–2307.23)
					Diagnostic radiology	665 (373–1028)	49.54 (420.42–1158.69)
					Respiratory, physical therapy and occupational therapy	904 (520–1339)	1019.26 (586.11–1509.23)
					Central supply	2434 (1592–3229)	2743.43 (1794.39–3639.50)
					Professional, bed expenses and dialysis	13 965 (8698–19457)	15 740.35 (9803.77–21 930.55)
				Incremental cost attributed to mortality:	Total cost	4654 (2056–7869)	5245.66 (2317.38–8869.38)
					Pharmacy	843 (334–1396)	950.17 (376.46–1573.47)
					Laboratory	270 (14–604)	304.32 (15.78–680.79)
					Diagnostic radiology	142 (45–244)	160.05 (50.72–275.02)
					Respiratory, physical therapy and occupational therapy	324 (138–536)	365.19 (155.54–604.14)
					Central supply	399 (-47–766)	449.72 (-52.98–863.38)
					Professional, bed expenses and dialysis	4564 (1666–7872)	5144.22 (1877.80–8872.76)
Zywiel et al. (2015)[24]	January 2011 to December 2012	CAD	Mean (IQR)	Care cost with delirium		26 272 (8760–117 769)	24 416.84 (8141.42–109 452.91)
				Care cost without delirium		17 703 (5113–122 246)	16 452.93 (4751.95–113 613.77)

PPP = purchasing power parity; AUD = Australian dollar; CAD = Canadian dollar; KRW = Korean won; USD = US dollar; CI = confidence interval; IQR = interquartile range; SD = standard deviation; SE = standard Error

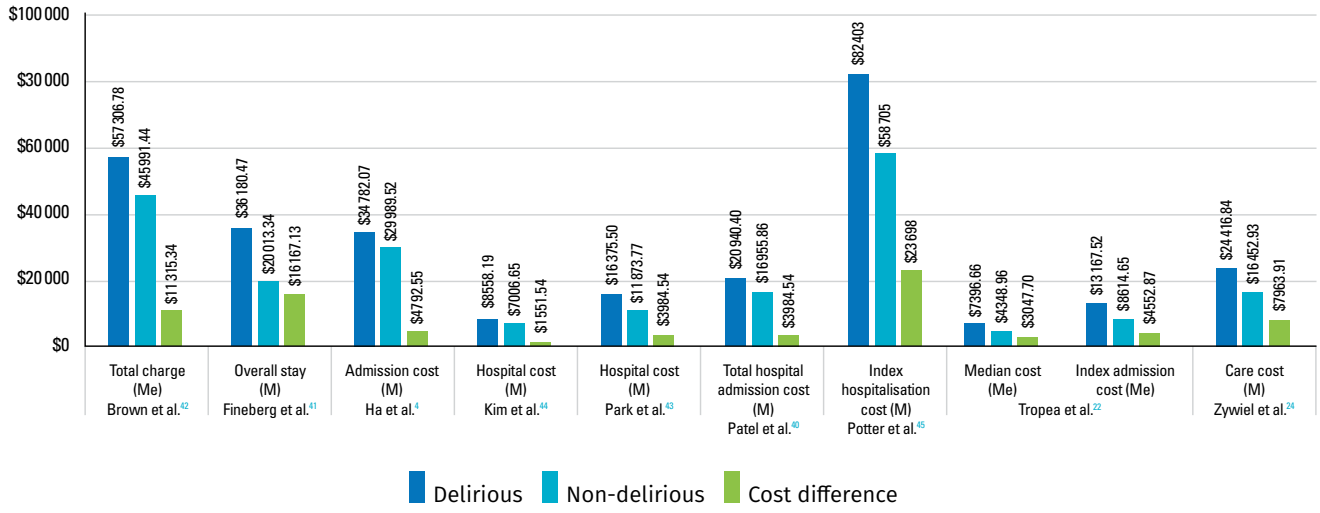

Figure 3: Cost comparison (PPP values, in US$) for delirious and non-delirious patients

M = mean; Me = median
Note: Vasilevskis et al. did not compare costs for delirious and non-delirious patients.

Discussion

In this systematic review a total of ten studies that met the inclusion criteria were reviewed. These studies had information about the extra LOS in hospital and ICU after major surgery and the associated hospital costs for an episode of POD. The studies reported the incidence of POD varied widely from 0.8 to 78.5 per cent which, in part, is explained by different study settings, study population characteristics, types of surgeries as well as the delirium diagnostic methods used after surgery. The delirium assessment method employed to identify POD might also have an impact on the extent of diagnosis of POD. The studies which used CAM as a POD diagnostic tool had greater numbers of delirious cases (16.7 to 78.5 per cent) compared to other methods like ICD-9-CM codes and ICD-10-AM codes (0.8 to 10.9 per cent). These outcomes demand a deeper investigation of POD assessment methods.

Age has been identified as a predominant factor for the occurrence of POD.[46,47] An age of 70 years or more is a well-recognised risk factor for POD which influences post-operative comorbidities and recovery.[47–52] It was observed that the older patients were the more likely they were to experience POD. Most studies reported on patient groups older than 70 years. Conversely, Patel[40] reported that a significant number of young neuro-AIDS patients (<44 years) also experienced POD (~31%). It was also observed in five studies[4,22,40,42,43], that male patients were more affected by POD that female patients. Therefore, gender specific interventions for aged people who undergo major surgery should be undertaken to minimise the risk of POD.

All the costs reported in the studies were found to be significantly higher in POD patients compared to those who were not delirious. Kim,[44] in Korea, reported the lowest cost difference between delirious and non-delirious patients at US$1551.54. Potter et al.,[45] in their USA study, reported the highest cost difference between the groups at US$23 698 which is significantly higher than in other countries and for other types of surgeries. Also, the six USA studies exhibited significant cost variation ranging from US$3984 to US$23 698[45] for different types of surgeries and hospital settings. The reported hospitalisation cost for POD of hip fracture surgeries in Canada[24] suggested that the cost is higher there than in Asia and Australia. A single study conducted in Australia[22] reported that delirious patients cost US$3047 extra compared to the non-delirious patient, which is lower than the USA and Canada but about two times higher than Korea.

The study results show that POD significantly increased the costs of procedures and recovery in all clinical settings and in all surveyed countries by an average of US$8105. Comparatively, the costs were lower in Asia and higher in the USA with Canadian and Australian costs in between. Unlike other studies, Vasilevskis[39] reported a comprehensive distribution of the incremental costs regarding the intensity of utilisation and mortality for the ICU delirious versus non-delirious patients. The study showed that the 30-day cumulative incremental cost due to POD was significantly higher

than for non-delirious patients and the incremental cost attributed to intensity of utilisation is higher than that attributed to mortality, for all cost classes**.**

The LOS in hospital and/or ICU was investigated for all the selected studies and it was found that delirious patients needed to stay more days in hospital and more hours in ICU than other patients. The maximum days of hospital stay for delirious patients was 20.2 days after osteoporotic hip fractures surgery in Korea,[44] followed by 19.1 days after major abdominal surgery in the USA[43] and 18.5 days after hip fracture surgery in Canada.[24] Although the costs reported by Korean studies were lower than in other countries, the LOS in hospital was higher in many instances. The greatest difference in LOS was reported by Zywiel et al. in patients who experienced POD after hip fracture surgery – on average POD patients stayed 7.3 days longer than non-delirious patients.[24] However, this study considered older patients than the other studies and this may be a reason for longer stays in hospital after surgery. Tropea[22] reported the lowest LOS day difference between delirious and non-delirious medical or surgical acute inpatients, while Vasilevskis[39] reported the median LOS in ICU for surgical or medical ICU patients for respiratory failure or shock was 11 days (IQR 7–18 days) for the both delirious and non-delirious patients. Patel[40] presented the distribution of the hospital stay after surgery for neuro-AIDS patients – 22.74 per cent of delirious patients stayed one to three days compared to 35.89 per cent of non-delirious patients, 24.20 per cent of delirious patients stayed four to six days compared to 28.66 per cent of non-delirious patients, and 53.05 per cent of delirious patients stayed seven days or longer compared to 35.44 per cent of non-delirious patients. The other studies also showed significant differences in LOS between the delirious and the non-delirious cohorts. Regarding LOS in ICU, studies in the USA reported that LOS in ICU after major abdominal surgery was 26.9 hours longer for POD patients than non-delirious patients[43] and after cardiac surgery was 45.9 hours longer for POD patients than non-delirious patients.[42] Four studies were conducted in the USA in same year, 2018, and reported distinct costs and LOS for different surgeries.

All studies reflected that LOS in hospital after major surgery was increased for POD patients compared to non-delirious patients.

Study limitations

First, the studies were selected from the PubMed and MEDLINE databases only. The number of studies might increase if other databases had been explored. Secondly, the timeframe for searching the studies covered only the past ten years (2010–2020) which might be a limitation to finding more studies based on the inclusion criteria. The results show that most of the studies were conducted very recently (i.e. 2017–2019) and were mainly (six out of ten) from the USA. A few studies were conducted in Asia and Australia and no studies were found from Europe and Africa. Finally, most of the studies adopted a retrospective study setup and considered the costs and LOS data from 2002 to the most recent year 2016. Furthermore, only peer-reviewed and publicly available English articles were considered. This study only focused on the cost and LOS due to POD, therefore further in-depth investigation of other factors associated with POD will be informative.

Conclusions

This systemic review revealed ten studies captured the cost burden and LOS in hospital and ICU for surgical patients who developed POD. The selected studies were conducted mostly in the USA with two in South Korea and single studies in Australia and Canada. Surprisingly, no Europe studies were sighted. The present review clearly identified and summarised that hospital costs and LOS significantly increase due to POD. Although the cost increment/quantum because of POD was lower in Asia, it was extremely high in the USA studies. The highest cost due to POD was reported for the trans-catheter and surgical aortic valve replacement in USA and lowest cost in South Korea for osteoporotic hip fractures. Further clinical investigations are needed to decipher the detailed and distinct cost drivers related to POD. The present findings clearly indicate that total costs of treatment are increased with the occurrence of POD after major surgeries. This review also suggests that a gender specific investigation could be warranted as well as a deeper investigation of POD assessment methods. The outcomes of this review should be helpful for policy development regarding the different health care settings and specific cost drivers aimed at diminishing the overall costs of POD and the risk of its occurrence in surgical and hospital settings.

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Hospital costs of post-operative delirium: A systematic review

Supplemental material

Table S1: Study evaluations and Newcastle-Ottawa Quality Assessment Scale (NOS) score

	Selection				Compara-bility	Outcome			
	Representativeness of the exposed cohort	Selection of the non-exposed cohort	Ascertainment of exposure	Demonstration that outcome of interest was not present at start of study	Comparability of cohorts based on the design or analysis	Assessment of outcome	Was follow-up long enough for outcomes to occur	Adequacy of follow-up of cohorts	Total score
Study (year)	Reviewer	Reviewer	Reviewer	Reviewer	Reviewer	Reviewer	Reviewer	Reviewer	Reviewer (NOS)
Brown et al. (2016)[42]	1	1	1	1	1	1	1	1	8
Fineberg et al. (2013)[41]	1	1	1	1	1	1	1	1	8
Ha et al. (2018)[4]	1	1	1	1	1	1	1	1	8
Kim et al. (2017)[44]	1	1	1	1	1	1	1	1	8
Park et al. (2019)[43]	1	1	1	1	1	1	1	1	8
Patel et al. (2018)[40]	1	1	1	1	1	1	1	1	8
Potter et al. (2018)[45]	1	1	1	1	1	1	1	1	8
Tropea et al. (2017)[22]	1	1	1	0	1	1	1	1	7
Vasilevskis et al. (2018)[39]	1	0	1	1	0	1	1	1	6
Zywiel et al. (2015)[24]	1	1	1	1	1	1	1	1	8

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The effect of an enhanced recovery after surgery protocol on opioid consumption, pain and length of stay among patients undergoing prostatectomy and nephrectomy

Abstract

Objective: To examine the effect of the Baptist Health Lexington Urology ERAS Protocol (BHLEX-UEP) on opioid consumption, pain and length of stay among patients undergoing prostatectomy and nephrectomy.

Methods: A quasi-experiment (N=303) was conducted in a 434-bed Magnet® re-designated community hospital in the south-eastern United States of America (USA). Data on all adult patients who underwent prostatectomy or nephrectomy surgery were retrieved over a 19-month period. Group differences related to morphine equivalents consumed, mean pain score on the day of surgery, and length of stay were examined between patients who experienced the traditional recovery protocol (n=133) and those experiencing the BHLEX-UEP (n=170).

Results: Significant differences for the three variables of interest were found between the groups.

Conclusions: Results of this study indicate that the use of the BHLEX-UEP for patients undergoing prostatectomy or nephrectomy could lead to a decrease in opioid consumption and patients' pain and a shorter length of stay in hospital.

Keywords: enhanced recovery after surgery, urology, opioid, pain

Introduction

Enhanced recovery after surgery (ERAS) is a comprehensive approach to surgery that places the patient at the centre of a multidisciplinary team. Using a multimodal approach to pain management, one of the goals of ERAS is to diminish post-operative pain and opioid consumption.[1] An ERAS protocol is designed to create optimal patient care from the physician's office through to post-operative discharge to home.[1] ERAS protocols used among patients undergoing many types of surgery have led to positive post-operative outcomes.[2] These outcomes include decreased opioid consumption during hospitalisation, effective pain management and decreased length of stay.[2,3] There is evidence to suggest that ERAS protocols can effectively manage pain while diminishing opioid intake in patients by using a multimodal, scheduled approach to pain management.[2] The Baptist Health Lexington Urology ERAS Protocol (BHLEX-UEP) was initiated pre-operatively with patient education to explain how non-opioid analgesics are highly effective in managing pain. The goal of this education was to provide informed

patients with the expectation that they would experience effective non-opioid pain management with the ERAS approach.

Chronic opioid misuse frequently begins post-operatively as a result of opioids prescribed related to surgery.[4,5] ERAS protocols can minimise opioid exposure while effectively managing pain.[6] For example, findings from a recent study of patients undergoing head and neck surgery that compared patients who experienced the ERAS protocol to patients having the same surgery in a traditional recovery pathway showed that both pain scores and post-operative opioid consumption were lower in the ERAS group.[3]

Similar positive outcomes related to opioid consumption, pain management and length of stay have been found in surgical fields such as gastroenterology and orthopedics. To date, however, there is little research regarding ERAS protocols with patients undergoing prostatectomy and nephrectomy. The BHLEX-UEP developed for this study was based on ERAS protocols used in radical cystectomy surgery or the removal of the entire bladder.[7,8] The purpose of this study was to examine the effect of the BHLEX-UEP on opioid consumption, pain and length of stay, among patients undergoing prostatectomy and nephrectomy.

Materials and methods

Sample

This quasi-experimental study (N=303) was conducted at a 434-bed Magnet® re-designated community hospital in the south-eastern United States of America (USA). Data on all adult patients who underwent prostatectomy or nephrectomy surgery were retrieved over a 19-month period.

An a priori power analysis revealed a minimum sample size of 118 (59 per group) with an alpha of 0.05 and power of 0.85 was required to reach significance. Participants were divided into two groups based on recovery protocol followed, either traditional recovery or BHLEX-UEP. Research team members reviewed patient charts using initiation of the BHLEX-UEP as the division of study groups. Working backward from the initial day of BHLEX-UEP implementation, traditional recovery group patients were selected in a sequential manner until a sample, allowing for missing data, was achieved (n=133). Similarly, working forward from BHLEX-UEP implementation, patients were identified sequentially for the BHLEX-UEP group (n=170).

Data collection

The following data were collected from patient charts: age, sex, type of surgery (prostatectomy or nephrectomy), length of stay in hours, mean pain score in the first 24 hours after surgery and opioid consumption (measured in morphine equivalents). Opioid consumption was recorded at three stages: the day of surgery (first 24 hours after arrival to the recovery floor), post-operative day one (24–48 hours after arrival to the recovery floor) and post-operative day two (48–72 hours after arrival to the recovery floor). Morphine equivalents were calculated using an online opioid conversion calculator.[9]

Ethical review statement

The Institutional Review Board of the hospital approved the study (IRB# BHL-20-1611). As a retrospective chart review with de-identified data, the requirement for patient consent was waived.

Intervention

This intervention consisted of two phases: phase 1, the BHLEX-UEP (see Table 1), and phase 2, extensive education of nurses. The protocol was designed by a multidisciplinary team consisting of a pharmacist, nurse anaesthetist, surgeon, nursing director, two charge nurses and the hospital ERAS coordinator. A continuous focus on training nurses to understand and use the protocol occurred during daily huddles with the ERAS coordinator, shared governance meetings, staff meetings and mandatory education sessions led by the hospital ERAS coordinator. These education sessions were offered during annual nurse competency training. The protocol was presented to nurses in poster format with verbal instruction. In addition, an ERAS team member visited 14 staff meetings to deliver a 15-minute presentation regarding the benefits of enhanced recovery protocols, the BHLEX-UEP and order set, and the importance of clearly explaining to patients the terms used when their care is based on the BHLEX-UEP (e.g. 'around the clock' dosing of non-opioid analgesics). Anecdotal evidence from multiple interactions in meetings suggests that nurses were unaware of how a combination of scheduled non-opioid analgesics could effectively control pain.

Data analysis

Data analysis was conducted using SPSS v25. Demographics of the sample were analysed using frequencies and percentages. Independent t tests were calculated to detect differences in means between traditional recovery and BHLEX-UEP groups for the variables of interest: morphine equivalents consumed, length of stay (in hours) and pain score on the day of surgery.

Table 1: Baptist Health Lexington-Urology Enhanced Recovery After Surgery Protocol

Stage	Protocol	Details
Pre-operative	Patient and family education	• ERAS brochure and educational tool at pre-admission testing or surgeon's office
	Prehabilitation	• nutritional counselling • smoking cessation education • alcohol abstinence
	Carbohydrate loading and elimination of NPO ('nil by mouth')	• clear liquid diet day before surgery • 20 oz. oral electrolyte solution (sugar-free if diabetic)
	Multimodal analgesia	• Acetaminophen 1000 mg oral • Gabapentin 600 mg oral • Meloxicam 15 mg oral • Scopolamine patch 1.5 mg (contraindicated in patients with glaucoma or >65 years) • antibiotics
Intra-operative	Transversus abdominis plane block	• also used with traditional recovery group
Post-operative	Nutrition	• clear liquids two hours after surgery, advance as tolerated
	Analgesia	• Gabapentin 100 mg three times per day for 48 hours • Acetaminophen 650 mg orally every 6 hours for 48 hours • Opioids as needed
	Mobilisation	• Out of bed on arrival to floor (walk from stretcher to bed) • Out of bed evening of surgery (ambulate or up to chair) • Out of bed and walking five times per day (post-operative day 1 through to discharge)

Results

Participants (N=303) in this study had surgery before (n=133) or after (n=170) BHLEX-UEP was implemented at the health service organisation. Both males (n=247, 82%) and females (n=55, 18%) were included. Participants in this sample had nephrectomy (n=122, 40%) or prostatectomy (n=180, 60%) surgery. Of patients undergoing nephrectomy, both full and partial were included. Given that differences in the variables of interest were non-significant between full or partial nephrectomy groups (probability value range 0.054–0.822), data from all nephrectomy patients were included. Significant differences between the traditional recovery and BHLEX-UEP were found for the three variables of interest. Total morphine milligram equivalents (MME) consumed by day and for the duration of the post-surgical hospital stay, mean pain scores on the day of surgery and length of hospital stay (measured in hours) were significantly lower in the BHLEX-UEP group when compared to the traditional recovery group (see tables 2, 3, 4).

Discussion

Clinical and statistical differences for each variable in this study were meaningful. In relation to opioid use, mean opioid consumption on the day of surgery decreased from 46.3 MME to 12 MME. A reduction in hospital-based opioid consumption can diminish both short-term and long-term complications.[4] Short-term complications related to opioid dose include sedation, respiratory depression and paradoxical worsening of pain despite higher opioid doses. Long-term complications can include opioid

Table 2: Total morphine milligram equivalents consumed (N=303)

		Mean	SD	t-value	*p*-value
Day of surgery	Traditional recovery	46.3	32		
	Enhanced recovery	12	15.0	11.3	<.01
Day 1 post-surgery	Traditional recovery	35.9	29.2		
	Enhanced recovery	7.2	13.8	10.45	<.01
Day 2 post-surgery	Traditional recovery	12.2	21.3		
	Enhanced recovery	2.2	7.6	5.1	<.01
Entire duration of post-surgical hospital stay	Traditional recovery	97.2	71.5		
	Enhanced recovery	21.6	30.7	5.08	<.01

Table 3: Mean pain score day of surgery (on a scale of 0–10)

	Mean	SD	t-value	*p*-value
Traditional recovery	4	2		
Enhanced recovery	2.2	1.9	7.8	<.01

Table 4: Length of stay in hours (N=303)

	Mean	SD	t-value	*p*-value
Traditional recovery	57.4	25.4		
Enhanced recovery	44.5	16.8	5.07	<.01

dependence, immunosuppression, depression and diversion.[5] As adverse effects of short-term opioid use tend to accrue over time, decreasing the total MME consumed over the length of stay, as occurred in this study (97.2 MME to 21.6 MME), could reduce the risk of opioid-related, long-term adverse outcomes.

Mean pain scores on the day of surgery differed from 4 (on a scale of 0–10) in the traditional recovery group to 2.2 in the BHLEX-UEP group. In the presence of decreased opioid consumption, patients in the BHLEX-UEP group consistently rated their pain lower than those who received traditional care. This finding may reflect several factors integral to the BHLEX-UEP. For example, patients in the BHLEX-UEP group received scheduled non-opioid analgesic medications such as acetaminophen and gabapentin. Scheduled administration of these medications provided patients with continuous analgesic therapy, preventing pain from flaring to a level that could require opioid intervention.[10]

Another component of the BHLEX-UEP that likely contributed to lower pain scores was early and frequent mobility. Clinical nurses on the unit where this study was conducted reported that prior to implementation of the BHLEX-UEP, patients commonly complained of abdominal gas pain resulting from anaesthesia. Patients undergoing full nephrectomy or prostatectomy who experienced the BHLEX-UEP were encouraged to walk as soon as one hour after surgery. Patients undergoing partial nephrectomy who experienced BHLEX-UEP, however, were restricted to walking until the morning after surgery, given the safety concern for bleeding. Walking as soon as permitted following surgery promotes gastric motility and is associated with decreased length of stay and decreased pain.[11]

Length of stay changed from a mean of 57.4 hours in the traditional recovery group to 44.5 hours (approximately half a day) in the BHLEX-UEP group. Reducing the

length of stay for the 170 BHLEX-UEP patients saved 92 days and a supply cost of over US$15 000. While financial savings are important, the reduction of pain and opioid use are clearly the most meaningful findings in this study.

Nurse and patient education is an important component of the BHLEX-UEP and findings may not have been as meaningful without it. Nurses caring for patients recovering from prostatectomy or nephrectomy surgery received information regarding the pharmacological attributes of scheduled non-opioid analgesics. This education helped nurses to understand that continuous pain management using non-opioids can lead to a decreased need for opioid analgesia. Patient education is also crucial to providing effective pain management, given society's present understanding that opioids are best for pain control. Prior to surgery, patients are educated regarding what to expect during recovery with a focus on scheduled non-opioid pain medication. The intent of educating patients regarding medications is to help them understand that their post-operative pain can be managed effectively without opioids. That knowledge can help them to accept non-opioids as the major component of their pain management plan.

Study limitations

Findings are limited in that the BHLEX-UEP was tested in one community hospital in the south-eastern USA.

Conclusion and recommendations

Results of this study suggest that implementing the BHLEX-UEP in urology surgery for patients undergoing prostatectomy or nephrectomy may lead to a decrease in opioid consumption, patients' pain and length of stay in hospital. Findings are in agreement with prior research with other patient populations. Overall, there is growing evidence to suggest that the use of ERAS protocols promote positive surgical outcomes related to pain and opioid use.

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Uncertainty in post-anaesthesia nursing clinical reasoning: An integrative review in the light of the model of uncertainty in complex health care settings

Abstract

Problem identification: Post-anaesthesia nursing plays an important role in the early detection and treatment of clinical deterioration after surgery and/or anaesthesia. Concomitantly, the effectiveness of post-operative care is highly dependent on the accurate analysis, synthesis of patient data and quality of diagnostic decisions through clinical reasoning. Given the dynamic processes required to come to a diagnosis, uncertainty is common in clinical reasoning and expected during practice. Nevertheless, uncertainty may permeate the foundations of clinical reasoning, which can jeopardise diagnostic accuracy and consequently the quality and safety of health care.

Literature search: The objectives of this review are to identify available evidence related to uncertainty in post-anaesthesia nursing clinical reasoning and to analyse the results from the perspective of the Model of Uncertainty in Complex Healthcare Settings (MUCH-S). A comprehensive search strategy using CINAHL (EBSCO), Cochrane Library (EBSCO), Medline (PubMed), ProQuest and Google Scholar databases was used to find published and unpublished relevant studies. Studies published in English and Portuguese were included. There was no temporal restriction, nor geographical or cultural limitation for the studies included.

Data evaluation synthesis: All papers were reviewed by the authors to extract key information about purpose, sample and setting, research design and method, key findings and limitations. The literature search identified a total of 248 studies, 22 of which were retrieved for full reading. A total of four articles were included in this review.

Implications for practice: Three main themes were identified: nurses' intuition to reason, feelings of uncertainty related to lack of nursing knowledge and clinical (in)experience to deal with uncertainty. These findings are encompassed within the MUCH-S taxonomy: personal, scientific and practical. This review offers post-anaesthesia nurses' greater levels of understanding of this phenomenon and may support more informed and reflexive clinical reasoning.

Keywords: clinical reasoning, patient safety, post-anaesthesia nursing, post-operative care, uncertainty

Introduction

Post-operative nursing care occurs in an uncertain and changing environment and post-operative nursing practice is complex, highly challenging and demands quick and efficient decision making.[1] This period of critical care, and of great vulnerability for the person being cared for, comes with the risk of complications associated with surgery and anaesthesia. Complications occur in 40 per cent of cases[2] with half of these occurring during the first hour after admission to the Post Anaesthesia Care Unit (PACU)[3] and 16.5 per cent being adverse events after discharge.[4] The reality is that patients' presentations in PACU are often obscure, uncertain and ill-fitting with a model of linear causality.[5] This means there may not be a straightforward relationship between causes and effects.[5]

It is also important to consider the attributes of the post-anaesthesia clinical scenario where nurses' work is highly influenced by interpersonal and interdisciplinary professional relationships,[6] diplomacy and collaborative competence are critical,[7] a highly specialised performance is necessary to manage complex clinical cases,[8] quick and distinct discernment is required when making decisions,[9] patients are vulnerable and dependent on nursing care[10] and environmental conditions and occupational exposure increase professional risk.[11]

Up to 70 per cent of adverse events are related to lapses in anaesthetists' non-technical skills, such as communication, teamwork, leadership, decision-making and risk assessment. Experience and observation are factors influencing situational awareness,[12] another non-technical skill. Situational awareness is the perception of environmental elements and events with respect to time or space, the comprehension of their meaning, and the projection of their future status.[12] Errors associated with medical diagnoses are related to more than ten per cent of all health care costs.[13] Direct costs accrue from failure to treat, inappropriate testing and treatments for incorrect diagnoses.[13] Given these facts, awareness of uncertainty increased physicians' anxiety which translated to a 17 per cent increase in average health care costs.[14]

The conceptualisation of uncertainty, which partly comes from maturity, appears as a professional gains experience in practice.[15] In relation to nursing discipline, uncertainty is described as a cognitive and emotive component, interrelated with stress and coping[16] derived from and related to ethical decision-making.[17] Nursing uncertainty research is mainly focused on a person's illness experience[18] but is hazy in regards to a nurse's reactions in clinical practice and their adaptive behaviours.

Diagnosis usually occurs under a veil of uncertainty so that those who identify it must develop advanced probabilistic reasoning skills given the well-known fact that intuitive probabilistic arguments are very likely to be biased. This also relates to the nature of the diagnostic framework, namely the normative criterion, the temporal structure and the teleological component.[19] Authentic clinical reasoning requires nurses to collect and interpret imperfect clinical data in real time. Learning how to successfully navigate uncertainty in this complex and ambiguous setting is essential for patient safety and high-quality care.[20] For this reason, clinical reasoning becomes relevant to gain an understanding of the phenomenon of uncertainty in post-anaesthesia nursing.

The Model of Uncertainty in Complex Health care Settings (MUCH-S),[21] based on Han's Model,[22] will be the guide to enhancing the understanding of the phenomenon in this review. MUCH-S is a recent three-dimensional model, or conceptual taxonomy, and characterises uncertainty in three broad categories: personal, scientific and practical. Specific issues are gathered into these categories: psychosocial, existential and ethical issues in the personal category; diagnosis, prognosis, causal explanations and treatment recommendations in the scientific category; and structures of care, processes of care and systems in the practical category.

Review methods

Following the methodology of an integrative review,[23] the research questions are:

- What is the available evidence related to uncertainty in post-anaesthesia nursing clinical reasoning?
- How does available evidence related to uncertainty in post-anaesthesia nursing clinical reasoning fit with the MUCH-S?

The literature search was conducted in the CINAHL (EBSCO), Cochrane Library (EBSCO), Medline (PubMed) databases and ProQuest and Google Scholar, in October 2021, using the natural language and index terms adapted for each included information source (See Figure 1). To ensure the hypothetical inclusion of recently published articles, we performed an additional research on 21 January 2022, with no extra findings.

Reference details for all returned searches were downloaded into the reference manager software, Mendeley. Duplicates were removed, then title and abstracts were screened by the first author against the inclusion criteria: empirical output, context of the PACU setting

(((((‘Postanesthesia Nursing’[Mesh]) OR ‘Perioperative Nursing’[Mesh]) OR ‘Postoperative Care’[Mesh]) OR (‘postanesthesia nursing’[Title/Abstract] OR ‘perianesthesia nursing’[Title/Abstract] OR ‘postoperative care’[Title/Abstract] OR ‘postoperative period’[Title/Abstract])) AND ((‘Uncertainty’[Mesh]) OR (uncertainty[Title/Abstract] OR ‘personal uncertainty’[Title/Abstract] OR ‘scientific uncertainty’[Title/Abstract] OR ‘practical uncertainty’[Title/Abstract] OR ambiguity[Title/Abstract] OR ambiguous[Title/Abstract] OR unsure[Title/Abstract] OR unpredict[Title/Abstract] OR doubt[Title/Abstract] OR equivocal[Title/Abstract]))) AND (‘clinical reasoning’[Title/Abstract] OR ‘decision making’[Title/Abstract] OR ‘decision-making’[Title/Abstract])
Filters: English; Portuguese.

Figure 1: Search expression example

and experience(s) of uncertainty discussed from the nursing perspective. Reference lists of included articles were also screened to identify additional studies. Any geographical, cultural, temporal or study type limitations were applied. Search results and studies selection were summarised in a flowchart adapted from Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA)[24] (see Figure 2).

After removing duplicates and screening the remaining 248 studies by title and abstract, 22 were retrieved in full text and screened. Considering the inclusion criteria, four studies were included in the review.

Results

Studies originated from Sweden (n = 2), Canada (n = 1) and South Korea (n = 1). Clinical settings are general,[25] orthopedic[26] and surgical[27,28] caring for adult patients in the PACU. Nurses were recruited from mid-sized hospitals[25] and from major public hospitals[26,27,28]. All studies are qualitative and used semi-structured interviews for data collection. The number of participants varied from 9 to 20, with a ratio of 4:1 females to males. The participants’ clinical experience ranged from 1 to 32 years. The characteristics and key findings of the studies included are summarised in Table 1.

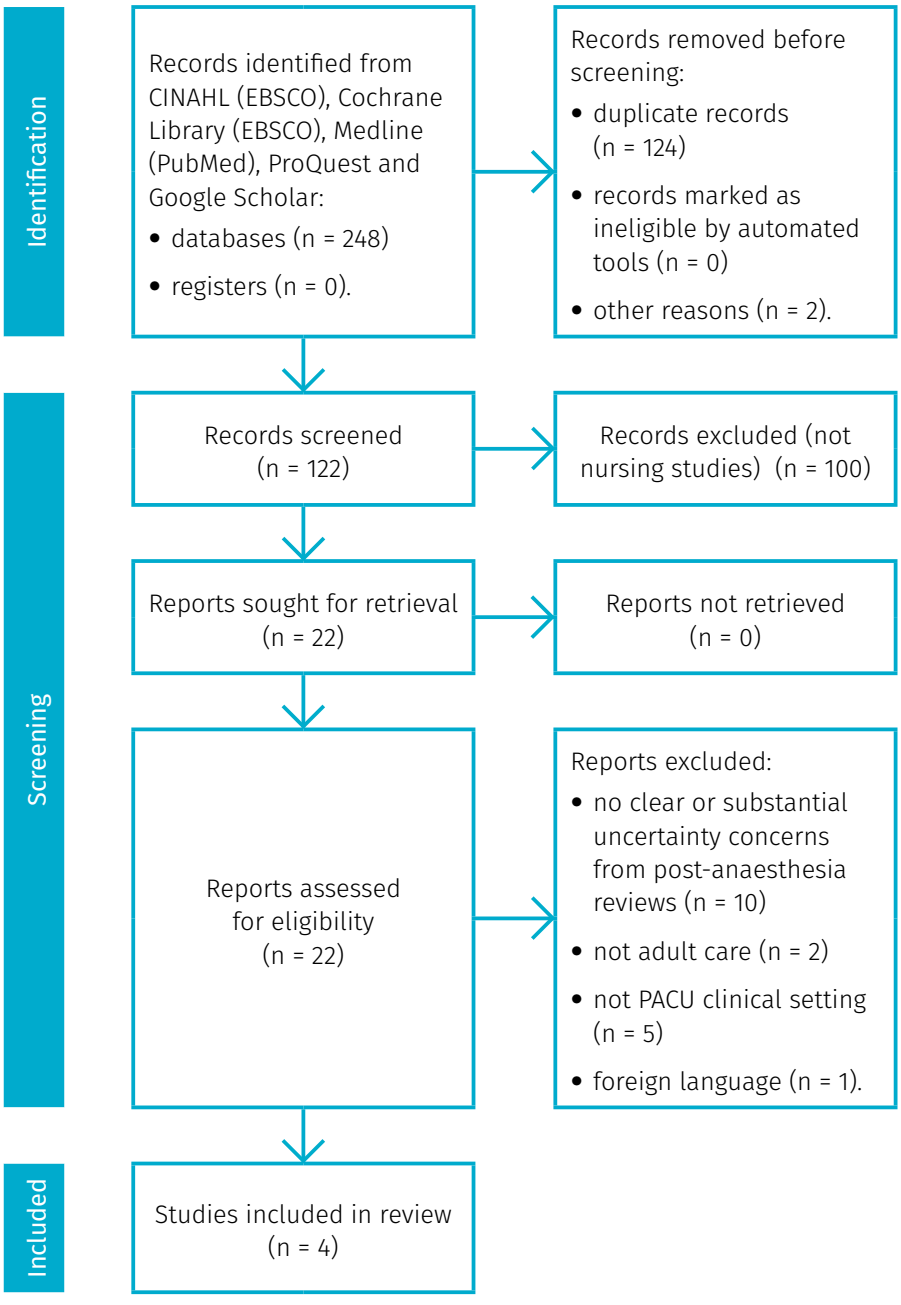

Figure 2: PRISMA flow diagram of review process

Table 1: Characteristics of included studies

Study (year)	Purpose	Sample and setting	Research design and method	Key findings
Calebrant et al. (2016)[28]	To determine the factors that affect how nurse anaesthetists in a county in Sweden decide how to manage perioperative fluid status.	n=16 nurse anaesthetists professionally qualified for at least two years	cross-sectional qualitative study through semi-structured interviews	Three categories emerged: 1. clinical criteria and thought processes that drive decision making 2. interdependence in decision making 3. uncertainty in decision making. They lacked guidelines and, at the same time, it was emphasised that each patient must be treated individually.
Forberg et al. (2017)[27]	To describe nurse anaesthetists' reflections on the provision of perioperative care to patients with previous substance dependence.	n=10 nurse anaesthetists from two surgical departments in Sweden	interpretative study with semi-structured interviews based on clinical vignettes	Nurses revealed a process of balancing between professionalism and preconceptions. This was based on three categories: 1. an anaesthesiological challenge of knowledge, experience and time 2. feelings of mistrust due to the difficulty in dealing with this group of patients 3. feelings of uncertainty because of lack of knowledge. The nurse anaesthetists experienced that these patients tended to react differently to anaesthesia and some nurses felt that their knowledge was not sufficient for taking care of patients. This requires skills, expertise, experience, time, open-mindedness and intuition. If guidelines were developed for this patient group, care could be made safer and nurses' sense of uncertainty minimised.
Jang et al. (2019)[26]	To identify nurses' experiences related to the reasoning methods employed during post-operative pain assessment.	n=20 nurses from the orthopaedic surgery ward of a university hospital in Seoul, South Korea	phenomenography Nurses were interviewed after post-operative pain assessments. A total of 60 patients who had experienced post-operative pain were discussed in the nurses' interviews.	The reasoning used by nurses in post-operative pain assessment was identified from two perspectives: 1. the frames of reference used to interpret a patient's perception of pain 2. the strategic efforts used to assess the pain. Holistic clinical pain assessment is the product of both the personal knowledge of the nurse involved and the practical knowledge that the nurse has developed through intuition. Nurses' own reasoning in post-operative pain assessment appears to reflect various forms of clinical knowledge, drawing from a variety of sources of information and taking into account multiple factors, some of which are unexplained by the research evidence.
Shannon et al. (2020)[25]	To explore PACU nurses' interactions with technology during the critical Phase I recovery period.	n=9 PACU nurses in three mid-sized hospitals in a Western Canadian province	interpretive description Nurse participants were interviewed using a semi-structured interview guide.	Nurses' interactions with technology are significantly influenced by the recovery room culture, as they constantly navigate through a level of uncertainty about the respiratory status of their patients. Three themes are described: 1. nurses' confidence and trust in a visual sensory respiratory assessment process and the influence of anaesthesia providers 2. PACU nurses' guarded trust or rationalised mistrust in technology 3. contextual influences on nurses' approach to respiratory assessment. Post-anaesthesia nurses practice their intuitive sensory assessments with a strong projected sense of expert practice and minimal reliance on technology.

The key findings were organised by the following themes, identified through deductive coding into MUCH-S taxonomy: 'nurses' intuition to reason' (personal), 'feelings of uncertainty related to lack of nursing knowledge' (scientific) and 'clinical (in)experience to deal with uncertainty' (practical). Firstly, the explicit empirical indicators of MUCH-S taxonomy were applied to the data analysis and confirmed that the codes appear in the data by finding examples. Secondly, themes were identified by pattern response and meaning and articulated with the propositions of the review. Finally, pattern matching was applied and compared the dataset with the MUCH-S framework through abductive inference.[29]

In 'nurse's intuition to reason as personal uncertainty', the psychosocial issue of communicating uncertainty manifests itself as a clinical assessment difficulty related to the influence of personal, practical knowledge and intuition factors.[26] The existential issue is due to the difficulty of understanding patient's behaviour and anticipating critical events.[27] The ethical issue is due to the difficulty in navigating through a more intuitive nursing practice.[25]

In 'feelings of uncertainty related to lack of nursing knowledge as scientific uncertainty' associated with diagnosis issues, nurses rationalised their mistrust in technology based on their personal beliefs about what clinical data readings are acceptable[25] and reported insecurity related to scientific knowledge deficit[27] and differences in practice related to clinical experience.[28] In the prognosis issue, nurses revealed difficulties in predicting patients' unexpected reactions to the anaesthesia and preventing adverse events.[27] In the causal explanations issue, nurses struggled to balance the relationship between patient's own needs assessment and nurse's assessment.[26] Related to treatment recommendations issues, nurses had difficulty challenging anaesthesia care due to insufficient knowledge[27] and lack of time to evaluate the impact of nurses' intervention.[28]

In 'clinical (in)experience to deal with uncertainty as practical uncertainty' related to structure of care, nurses adapted their evaluation priorities to the anaesthetist's preferences.[25] In processes of care, nurses reported feeling confused when there is variability in individual anaesthesia handover practises[25] (especially when they contradict evidence-based practises) and refer to peer counselling for evidence-based practice when difficult situations arise.[28] In the system's issues, nurses reinforce the need for clinical practice guidelines adapted to particular situations.[27,28]

Discussion

The aims of this review were to identify available evidence related to uncertainty in post-anaesthesia clinical reasoning and to analyse the results from the perspective of the MUCH-S model, which uses the taxonomy of personal uncertainty, scientific uncertainty and practical uncertainty. To our knowledge this is the first review study about the phenomenon of uncertainty in post-anaesthesia nursing clinical settings. The results were analysed using the MUCH-S model to facilitate understanding. The results presented in this paper highlight the complexity of this topic; additionally, nurses' difficulties were identified.

Nurses' intuition to reason as a personal uncertainty

Personal uncertainty is related to three main issues: psychosocial (communicating uncertainty), existential (effects of illness or treatment on life goals and quality of life) and ethical (inconsistency between self-values, sociocultural codes, the health care system and the organisation).[21]

Uncertainty is primarily managed through communicative practises, which emphasise communication in moderating the effect of uncertainty on health care decision-making.[30] As a matter of fact, pain assessment through personal knowledge, practical knowledge and intuition, allows the post-anaesthesia nurse to take clinical action leading to patient-centred care.[26] Coincidently, uncertainty affects a nurse's ability to maintain patient-centredness during patient–nurse conversation.[30]

Making predictions while uncertain is a challenge that nurses face daily in their practice. Nurses anticipate events based on experiences of past events in similar situations. Exposure to similar situations plays a decisive role in anticipating future events.[31,32] Safe work performance[33] cannot be expected from workers whose job designs involve multiple competing urgent priorities. Nurses need to develop skills to manage the unpredictable nature of their work, including dividing up care throughout the shift and redefining or adapting their care throughout.[33]

Given the mission of the PACU, nurses receive patients at high risk of complications, requiring close nursing clinical surveillance. If patient outcome may be maximised with guidelines,[27,28] an early recognition and intervention process is fundamental for preventing the occurrence of adverse events. Under certain circumstances and conditions of uncertainty (epistemic and random, tangible or not), deviations from reference situations can pose a specific threat to a given objective.[34] Patients' non-rational thinking and

behaviour (unnecessarily exposing themselves to factors that could be a direct threat to their life) made some nurses feel that patients with previous substance dependence were difficult to understand.[27] Nurses can apply simple strategies to recognise and effectively deal with existential uncertainty, including attending to emotions, slowing down clinical reasoning, exploring certainty within uncertainty and partnering with the patient.[35]

As we move towards more complex patient problems, we increasingly recognise the importance of non-analytical but integrative parts of clinical reasoning by recognising patterns and using clinical intuition.[25–27,36] Analytical and non-analytical reasoning[37] can operate separately but are mainly interconnected in clinical practice; to illustrate the complexity-based approach, the application of systemic thinking can benefit the understanding of clinical reasoning.[36] If, on one hand, nurses demonstrate confidence in their professional practice, on the other hand they demonstrate difficulties in articulating a subconscious and intuitive assessment approach.[25] This captures ethical uncertainty.[21]

In short, the collective consciousness of scientific knowledge is seen as the realm of absolute certainty and separate from the impressionistic knowledge of human intuition.[38]

Feelings of uncertainty related to lack of nursing knowledge as a scientific uncertainty

Scientific uncertainty includes issues related to diagnosis (classifying symptoms to abstract criteria), prognosis (regarding the longevity of disease), causal explanations (cause of illness) and treatment recommendations (regarding best mode of treatment).[21]

A study into post-anaesthesia nurses' reflections about caring for patients with previous substance dependence[27] reported that nurses feel uncertainty because of lack of knowledge and difficulty interpreting symptoms in these patients. The juxtaposition of nurses' desire to perform safe and good care with their preconceptions and inability to understand these patients affects both pre-operative and post-operative care.[27]

Clinical reasoning, as the process of applying knowledge and expertise to a clinical situation to develop a solution, involves the processes of cognition and metacognition.[39] Clinical reasoning in nursing revolves around the process of making professional judgements, evaluating the quality and contribution of available evidence to enhance problem solving and to consider to what extent the evidence available is sufficient to base decisions on and provide diagnosis and relevant treatment in regards to nursing care.[40] It also integrates meaningful phenomenological perceptions, experience, patient diversity and the uniqueness of the patient situation.[41] Nurses reported having insufficient knowledge of the pathophysiologic conditions associated with substance dependence during anaesthesia. This resulted in insecurity, especially in specific situations like determining the dosage of intravenous drugs.[27]

Clinical reasoning is viewed as a multidimensional, recursive cognitive process that employs formal and informal strategies to assemble and analyse patient information that is then evaluated relative to its significance and contribution to patient management.[42] Clinical reasoning allowed, for example, for nurses to rationalise their mistrust of technology based on their personal beliefs about what were acceptable respiratory data readings.[25]

Clinical reasoning competence is an essential nursing skill for providing safe and quality patient-centred care.[43,44] Effective clinical reasoning skills are found to be positively correlated with patient outcomes – nurses with poor clinical reasoning skills often fail to recognise impending patient deterioration or fail to prioritise appropriate interventions which may result in a failure to rescue or an irreversible situation. Post-anaesthesia nurses found it difficult to determine pharmaceutical dosage and know how to deal with patients' unexpected reactions to the anaesthesia and their behaviours.[27]

To address the inaccurate clinical reasoning associated with inappropriate interventions that could lead to increased and untimely patient mortality, Levett-Jones et al.,[45] created the Clinical Reasoning Model. This is represented as a circled eight-step diagram that reflects the ongoing and cyclical nature of clinical interventions and the importance of evaluation and reflection. When providing nursing care based on the reasoning cycle, nursing professionals learn to recognise, understand and work in each step, rather than just assuming they understand the patients' problems and perform interventions without adequately using higher order thinking. The recognition of the relationship between a patient's limited ability to express the intensity of their pain and the actual intensity of their pain is an important factor in nurses' post-operative pain assessments.[26] In this sense, effective clinical reasoning skills are a key factor in the prevention of iatrogenic harm.[43]

It is also important to mention research which measured the effects of guided clinical reasoning on the quality of the advanced nursing process in the knowledge and nurse's attitude. [46] Leoni-Scheiber et al., developed an educational approach aiming to improve nurses' diagnostic competencies to allow accurate nursing diagnoses and to link these with effective nursing interventions to achieve favourable patient outcomes.[46] Guided clinical reasoning data revealed improvement in nursing assessments, refinement of nursing diagnoses accuracy and effectiveness of nursing interventions.[46]

Post-anaesthesia nurses revealed that health care delivery becomes a challenge when their knowledge proves to be insufficient.[27] So, evaluating clinical reasoning in a context of uncertainty can also contribute to direct strategies for the teaching and learning of this competence.[47]

Clinical (in)experience to deal with uncertainty as a practical uncertainty

Practical uncertainty encompasses structures of care (absence of clarity regarding the expectations and responsibilities), processes of care (unclear procedures to access care) and systems (lack of clarity in system guidelines).[21]

Uncertainty is expressed in situations with distracting contextual factors, most of all in diagnosis and least in reflection.[48] Nurses' perceptions of inconsistent practises and processes of care of individual anaesthesia providers were often compromised by prioritising relationships over best practices.[25] In the absence of clarity regarding the expectations and responsibilities in care structure, post-anaesthesia nurses tend to adapt their assessment priorities to the preferences of the anaesthesia provider.[25] These results highlight how linguistic markers of uncertainty can shed light on the role contextual factors might play in uncertainty, which can lead to error, and why it is essential to find ways of managing it.

Research into uncertainty in health care has found that when there is lack of clarity in a system's guidelines nurses work to tame uncertainty, shape the environment and set boundaries around what can be tolerated and normalised.[49] This was highlighted by post-anaesthesia nurses who expressed a need for guidelines when caring for patients with substance dependence,[27] managing inotropic medication and applying restrictive fluid therapy.[28]

Nurses described confidence in their intellectual capacity based on their experience, perceptions and behaviours. Some of them referred to confidence in their ability to reason and described their base knowledge as tenuous, that is, accompanied by uncertainty and insecurity.[27,28,50] Thus, experienced post-anaesthesia nurses reported planning how they would act. The less experienced nurses used theoretical knowledge and comparison of different parameters to assess fluid requirements and later conferred with the anaesthetist.[28]

Feelings that can be attributed to nurses' uncertainty include anxiety, ambiguity, discomfort and stress. Additionally, their response to stress and uncertainty can directly impact patient care.[51] When in difficult situations related to fluid therapy, the post-anaesthesia nurses advised each other to use evidence-based practice.[28] Accordingly, some nurses found more clarity during times of uncertainty while other nurses reported negative emotional and physiological responses when faced with unresolved uncertainty. A positive response to a feeling of uncertainty may lead a nurse to seek trusted resources to work through the issue causing the uncertainty. Additionally, patients benefit when a nurse positively manages stress and uncertainty because the nurse finds more clarity or focus for patient care. Conversely, continuous practice in uncertain situations can negatively influence nurses' confidence, increase doubts and negatively impact satisfaction in practice.[51]

Practical knowledge of how a nurse perceives a patient's status in clinical settings and how a patient is assessed need to be fully explored to gain a practice-based understanding of clinical reasoning. How do nurses integrate scientific evidence into practical decisions? How are they taught the process of clinical reasoning in contexts of uncertainty in an era where it is believed that doubt can be resolved simply with the advent of evidence-based practice? Research concerning nursing clinical reasoning continues to be needed to understand nurse cognition in complex situations involving uncertainty. Increased knowledge and experience may decrease uncertainty in practice, but even with policies and resources in place, uncertainty may still occur.[52] Dealing with uncertainty requires humble reflection on our systems with an open mind to complex dynamics and emergent patterns.[53]

Conclusion

A significant gap remains in nursing scientific evidence related to uncertainty in complex clinical settings in health care. This integrative review briefly expresses the incipient understanding of post-anaesthesia clinical reasoning under uncertainty using the MUCH-S taxonomy of personal, scientific and practical uncertainty. The main themes identified were nurses'

intuition to reason (encompassed within personal uncertainty), uncertainty related to lack of knowledge (encompassed within scientific uncertainty) and clinical (in) experience to deal with uncertainty (encompassed within practical uncertainty).

For nurses, communicating uncertainty in clinical pain assessment, dealing with patient's behaviours and articulating intuitive professional practice are all associated with personal uncertainty. Related to scientific uncertainty, nurses struggle with balancing personal beliefs, lack of scientific knowledge and limited clinical experience with their clinical practice. The challenging relationship with patients impacts the recognition of causal explanations. Allied with practical uncertainty, the variability of individual anaesthesia providers' practises can induce uncertainty in nurses.

This review has some limitations. Only four studies met the inclusion criteria. Evaluation of the methodological quality of the included studies was not performed and, although reflexivity was considered for strengthening rigour and minimising potential bias in coding, the potential subjectivity in categorisation related to deductive coding into MUCH-S taxonomy is latent. Furthermore, due to the intrinsic characteristics of an integrative review, the scope is limited.

To support post-anaesthesia nurses to learn to manage complex clinical scenarios effectively, it is essential further research is conducted to understand the process of clinical reasoning. Analysing how personal, scientific and practical uncertainties shape clinical reasoning and lead to nursing outcomes also might be particularly important.

Despite the great benefits of uncertainty analysis and its application in certain contexts, it should not be considered as a panacea to guarantee absolute security. Notwithstanding, evidence suggests that uncertainty comprehension has in its favour the very positive fact that it places uncertain consequences or effects at the centre of decisions, thus being able to contribute to the improvement of safety in post-anaesthesia health care.

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Understanding the use of tympanic thermometry in the Post Anaesthesia Care Unit: A discussion paper

Abstract

Inadvertent perioperative hypothermia (IPH) is an uncomfortable, dangerous and costly but preventable complication of surgery. For perioperative nurses to treat this condition, they must first have an accurate means of detecting it. In making clinical decisions based on patients' temperature, an important vital sign, nurses must understand how different thermometers work and be competent in their use. It is vital that patients have accurate core body temperature recorded when admitted to the Post Anaesthesia Care Unit (PACU). Infrared tympanic thermometers are a non-invasive tool regularly used by PACU nurses and provide a quick and easily obtained measurement that is a reflection of core body temperature. Despite this, uncertainty remains about the accuracy of tympanic thermometer readings and their ability to accurately estimate core temperature, leading to questions being raised about their acceptability in clinical use. This discussion paper will evaluate the use of tympanic thermometers within the PACU and identify their benefits, limitations and alternatives, as well as the competency requirements of the nurse. Clinical trials give varying results and more research is needed into both the use of tympanic thermometers in the PACU and the competence of the user.

Keywords: tympanic thermometry, temperature measurement, post-operative

Introduction

Inadvertent perioperative hypothermia (IPH) is an uncomfortable, dangerous and costly but preventable complication of surgery.[1] For perioperative nurses to treat this condition, they must first have an accurate means of detecting it. The Post Anaesthesia Care Unit (PACU) nurse has a vital role in the management of patient thermoregulation.[1] Temperature is an important part of patient vital signs and to make accurate assessments and clinical decisions based on a patient's temperature nurses must have an understanding how different thermometers work and be competent in their use.

The ACORN standard for hypothermia states that a patient's temperature should be taken 'within the hour prior to transfer to the perioperative department, on arrival to the preoperative holding area, immediately preceding induction of anaesthesia, every 15 minutes when forced air warming is used and every 30 minutes for all patients' during the operative process.[2, p.129] The hypothermia standard also suggests that all patients should have their temperature taken on arrival to the PACU, at least every 15 minutes during their stay, before a decision is made about discharge to either stage 2 recovery or a surgical ward area and at the time of discharge.[2, p.129]

The ACORN standard further suggests perioperative nurses should also follow the National Institute for Health and Care Excellence (NICE) recommendations.[2] The NICE highly recommends prevention of IPH and states that a patient's temperature should be taken using a device or product that either directly measures core temperature or records a direct estimate of core temperature.[3] The NICE also reports that an accuracy to within +/- 0.5°C is acceptable in clinical use.[3] The most common thermometer used to estimate core body temperature in the PACU is an infrared tympanic thermometer.[4] Although tympanic thermometry use is widespread, the use is subject to discussion and debate because of doubt about accuracy and reliability in the acute clinical and critical setting.[5] Machin et al.[5] highlight the importance of accurately measuring core body temperature and acknowledge thermometry as a focal point in research findings that many clinicians distrust the performance of some commonly used peripheral thermometers.

From our reading on this subject four themes emerged – benefits of, limitations of and alternatives to tympanic thermometry and perioperative nursing competence. This discussion paper will explore the use of tympanic thermometry, under these themes, provide greater understanding of its current use and make recommendations for perioperative nursing practice.

Discussion

Measurement of a patient's temperature in the PACU is a performance indicator as outlined by the Australian Commission on Safety and Quality in Health Care.[6] The first important thing to understand is that there are two types of temperature readings, core and shell.[7] It is vital that patients have accurate core body temperature recorded when admitted to the PACU as this temperature reading provides important information to guide clinical judgment.[7] Core temperature refers to the temperature within the contents of the skull, the thorax and the abdomen and most notably the hypothalamus.[7] Shell temperature refers to the skin, subcutaneous tissue and the limbs and is completely expendable to ensure the core temperature is maintained.[7] In a haemodynamically unstable patient, or one that has experienced rapid thermal changes such as hypothermia, blood supply may be shunted away from vital organs making skin temperature a poor indicator of a patient's core temperature.[7]

It is also important to understand that these alterations to the vascular system may cause changes to blood pressure readings; thus, a hypothermic patient may be vasoconstricted which can elevate the blood pressure, even in the presence of hypovolaemia.[8] Similarly, a hyperthermic patient may be vasodilated; this can cause the blood pressure to fall.[8] Due to the connection between temperature and blood pressure, it is vital that normothermia be achieved prior to discharge to ensure accurate blood pressure readings have been obtained.[8]

During surgery, patients are frequently exposed to the cooler perioperative environment and in combination with body exposure and central nervous depression, due to general anaesthesia, this makes them prone to IPH.[1] Equally, patients undergoing surgery may develop hyperthermia while in the PACU due to malignant hyperthermia or sepsis; therefore, it is vital that temperature readings are accurate when outside the acceptable range of 36.0°C to 37.5°C.[1] Both the ACORN standard[2] and the NICE guidelines[3] recommend that temperature measurement be obtained at least every 15 minutes while the patient is in the PACU. The frequency of recording the patient's other vital signs should also be increased when a patient's temperature is outside of the clinically acceptable range.[6]

Rauch et al.[9] recommend that highly perfused anatomic structures such as the tympanic membrane, nasal pharynx and the distal oesophagus, which is adjacent to the left atrium, should be used for core temperature measurement. The gold standard of core body temperature measurement is the temperature obtained at the pulmonary artery[9]; however, a pulmonary artery catheter is very invasive and not present in PACU patients. Similarly, a temperature sensor positioned within the bladder and distal oesophagus provide accurate core body temperature but are also invasive and not always practical for patients emerging from anaesthesia in the PACU.[4] This has led to alternative methods for obtaining accurate estimates of core body temperature to be sought.

Benefits of tympanic thermometry

Tympanic thermometry has been embedded in clinical practice because of its ease of use and the speed with which measurements are displayed, allowing nurses to make clinical decisions and alterations to patient care based on accurate information.[7] Robertson and Hill[10] identify the benefits of tympanic thermometry including the ability to measure core temperature rapidly and close to the hypothalamus, convenience for patients and preservation of their dignity, and good hygiene when used with probe covers.

Jevon and Joshi[11] explain that the tympanic membrane blood supply is provided by the carotid artery, which also supplies blood to the hypothalamus. This allows the tympanic membrane to reflect core body temperature when other more invasive measures are not practical.[12] Modern tympanic thermometers measure the temperature at the tympanic membrane by sensing the infrared radiation emitted by the tympanic membrane and through algorithms that convert the measurement into a temperature reading.[13] Infrared tympanic thermometers used in a clinical environment must comply with the International Organization for Standardisation standard ISO 80601-2-56:2017[14] and comply with the Australian *Therapeutic Goods (Medical Devices) Regulations 2002*.[15]

Niven et al.[12] conducted a meta-analysis and systematic review of the accuracy of thermometers for estimating temperature. In their study they explored 75 studies (n = 8682) in which 52 studies were relevant to tympanic thermometers and concluded that peripheral thermometers, including tympanic thermometers, temporal artery thermometers and oral thermometers, did not have a clinically acceptable limit of agreement (LOA) when compared to pulmonary artery catheter temperature measurement.[12] However, Niven et al. did acknowledge an improvement in LOA between pulmonary artery temperature and tympanic measurement when the tympanic thermometers had been calibrated before use – the pooled mean difference in the calibrated group was -0.01 (-0.49°C to 0.47°C at 95% LOA) compared to -0.24 (-1.61°C to 1.13°C at 95% LOA) in the non-calibrated group.[12] As a result of this information, Niven et al. recommend that when a central invasive thermometer is impractical then a tympanic thermometer that has been calibrated was the best alternative for accurate temperature readings in both adult and paediatric patients.[12] Niven et al. also reported a +/-0.5°C correlation at 95 per cent for calibrated tympanic thermometers,[12] placing them within the NICE guidelines of accuracy and acceptability for clinical use.[3]

In their scoping review of 35 studies which included healthy adults and patients who had cardiovascular and neurological emergencies, Mase et al.[16] noted an accurate correlation between tympanic thermometry and central target temperature management during both local and whole-body cooling. The ability for tympanic thermometers to track temperature changes associated with active cooling and active warming is crucial in the PACU where treatment of IPH is required.[2–3]

Limitations of tympanic thermometry

While tympanic thermometers are commonly used due to their ease of use, they do have limitations to do with clinical accuracy. In their two prospective observational studies (n = 100), Aykanat et al.[4] explored the reliability of tympanic thermometers and temporal artery thermometers compared to urinary bladder temperature and nasopharyngeal temperature in the PACU. Aykanat et al.[4] concluded that neither tympanic thermometer or temporal artery thermometers were reliable compared to an indwelling catheter temperature sensor in the bladder, although they highlighted that the tympanic thermometers gave a marginal improvement with a mean bias of 0.13°C (95% LOA +/-0.54°C) versus a mean bias of 0.15°C (95% LOA +/-1.4°C) in the temporal artery thermometer group.

In 2018, Ryan-Wenger et al.[17] in their meta-analysis of 197 articles recommended removal of all peripheral thermometers including tympanic thermometers from their hospital and a change of hospital policy to reflect this because of the inaccuracies compared to central temperature measurement. It should be noted that this outright exclusion of peripheral thermometers is not practical, and the use of invasive devises as recommended by Ryan-Wenger et al. is unacceptable in the PACU environment, as previously mentioned by Aykanat et al.[4] There were also limitations within the study conducted by Ryan-Wenger et al.[17] in that 39 of the samples on tympanic thermometry were dated between 1994 and 2014, with only five being conducted after 2010. There have been several newer models of tympanic thermometers produced since this date range that were not included in the study conducted by Ryan-Wenger et al. The results may be different if the meta-analysis was repeated with these studies included.

More recent research comparing seven different commercially available thermometers (four digital infrared thermometers, one digital sublingual thermometer, one zero heat flux thermometer and one infrared thermal imaging camera) found that not all temperature monitoring techniques are equal, and recommended that tympanic thermometers are the most accurate commercially available system for the regular measurement of body temperature.[18]

Alternatives to tympanic thermometry

The variance in results obtained by studies researching the effectiveness of tympanic thermometers in accurately reflecting core body temperature leads to the question of whether alternative peripheral thermometers provide more accurate measurements. There are several different peripheral thermometers that exist that have been used in the PACU with varying levels of accuracy.[19] One such device that has made its way into the PACU is the temporal artery thermometer.[3]

In findings from research conducted by Fong et al.[20] (n = 106) temporal and forehead temperature readings were generally lower than tympanic readings and were unreliable in detecting fever. This was also supported by Minzola and Keele[21] who suggested that temporal artery thermometers had greater mean bias (-0.55 bias at 95% LOA -0.97 to 2.07) than tympanic thermometers (-0.37 bias at 95% LOA -0.79 to 1.54) when compared to rectal temperatures. Skin temperature, which depends on vasomotor tone and varies across the surface area, is affected by surgical procedures, central nervous system depression, environmental temperature and skin products such as alcohol-based skin preparation agents.[22] Alcohol-based skin preparation can often cool skin down and, if a temporal artery thermometer or contact-free infrared thermometer is used, may provide a lower temperature reading than tympanic.[22]

This limits the choice further to oral and axillary temperature measurements. While both are easy to use, results can vary significantly.[10] Oral temperature measurement is also contraindicated in the unconscious patient and is affected by salivation and therefore impractical in the PACU.[10] Axiliary temperature measurement, on the other hand, does not assess core temperature and is affected by ambient and environmental temperatures and has been found to provide a lower reading than other methods in febrile patients.[10] In hypothermic patients vasoconstriction occurs and thus axilla readings do not provide an accurate temperature measurement.[7, 23]

Competence of perioperative nurses

A common theme noted in the literature is the need for nurses to be competent in the use of different tympanic thermometers,[24, 25] and the need for regular calibration of these devices.[12] Despite passing approval for clinical use and having acceptable ranges in test settings,[5, 13, 25] accuracy when measuring tympanic temperature is dependent on the skill of the clinician and the technique they use. While there are several factors that may affect the reliability of tympanic thermometers, problems may be a result of user error.[24, 25] It is vital that nurses are assessed as competent in the use of tympanic thermometers and familiar with the individual manufacture guidelines when undertaking temperature assessment.[24, 25] Jevon[25] explains that the temperature difference between the tympanic membrane and the opening of the ear canal can be as much as 2.8°C which contributes to inaccuracy when incorrect technique is used. Yeoh et al.[26] explain the importance in understanding how tympanic thermometry works and emphasise that knowledge is required about the correct positioning and the anatomy of the tympanic membrane. Yeoh et al.[26] highlight that consistently obtaining the temperature at a specific focal spot on the tympanic membrane increased accuracy and gave a reliable measurement. Nurses should ensure that the ear canal is free from any visible debris and insert the tympanic probe at the correct angle in the ear canal to achieve accurate results.[27] Consideration should also be given to patients who arrive in the PACU in the lateral position and the tympanic temperature should be taken from the ear that is facing up as this will reflect core temperature.[28]

Conclusion

The literature presented in this discussion does not make a definitive recommendation about peripheral thermometers in measuring core temperature and fails to suggest alternative body temperature measurement strategies that are non-invasive for the PACU patient.

It does appear that when calibrated and used correctly by competent users tympanic thermometers are more reliable than temporal artery thermometers, axillary thermometers and oral thermometers for providing a best estimate of core temperature. It is therefore vital that all tympanic membrane thermometers are regularly calibrated and that PACU nurses are trained and assessed as competent in the use of the type of tympanic membrane thermometer used in their PACU. Several studies suggest that the newer generation of tympanic thermometers have a place in clinical practice, due to their ease of use and ability to provide an adequate estimate of core temperature, and these are recommended when invasive measurement is contraindicated.

Tympanic temperature measurement will continue to aid the PACU nurse to obtain a non-invasive core temperature measurement that is practical, cost effective and

minimally disruptive to patients' dignity. The accuracy of tympanic thermometers is still a focal point of research and there are minimal studies that measure the effectiveness of tympanic and other peripheral thermometers specific to the PACU environment; this highlights a need for more research into this aspect of perioperative practice.

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Excessive noise in the operating room: Can it be improved?

Abstract

Introduction: Excessive noise in the operating room has been a topic of interest since the early 70s. It has been recognised that excessive noise can affect cognitive behavior and impair memory function which can be a health and safety issue. Though different approaches have been explored there remains a deficit in research into the application of noise modification programs within the operating room to combat the issue of noise pollution. This project aimed to identify if a discussion about appropriate noise levels and the use of a safe phrase at 'time out' would reduce noise levels in the operating room.

Method: Several different approaches were used throughout this study, including a questionnaire to collect data before and after the project and two observational tools, one used to collect baseline data and the second used throughout the four-week trial period.

Results: The evidence gained from this project showed an overall improvement with noise during the surgical process reduced by 26 per cent. This was done by dicsussing appropriate noise levels at 'time out' and allowing staff to speak up using the non-judgmental safe words 'below ten thousand'.

Conclusion: This study aimed to see whether discussing appropriate noise levels at 'time out' could help reduce current noise levels within the operating room as, seen in other studies, reducing noise can be a challenge. Though small, the overall results of this study had a positive impact on reducing noise levels. It is, however, recommended that continued reinforcement and education about the issues surrounding noise are required.

Key words: noise, operating room, time out

Identified problem

This project was designed to identify a suitable approach to address the question of excessive noise in the operating room. The documented evidence suggests that noise in the operating room continues to be an issue with widespread implications.[1–3] However, limited attention has been allocated to the prevention or limitation of this issue.

Proposed solution

After reviewing the current literature, it could be seen that limited resources have been applied to address this problem. However, some recommendations have been made.[4] The proposed approach for this project was to use an adaptation of the health service organisation's current surgical safety checklist, as initiated by the World Health Organization in 2009. The adaptation of this checklist involved adding a discussion at 'time out' about appropriate noise levels during the patient's surgical journey and using a non-judgmental safe phrase if it was felt that the volume of noise was becoming a distraction at any time, especially during time critical moments.[5]

Project plan and implementation

Ethics approval was required and granted (ID:40698). Data collection for this project took the form of a questionnaire consisting of open and closed questions distributed throughout the department before and after the trial period. Two observational tools were designed to collect information about the practice within randomly selected operating rooms. The observations were undertaken by perioperative nurses who volunteered to help collect data.

The observation tools gathered a variety of information which included:

- surgical specialty
- number of staff present (surgical flow)
- noise at critical moments, including pre- and post-anesthesia, throughout the surgical procedure and during perioperative counts
- types of distraction
- use of safe phrase and success (second observational tool).

Prior to the start of the four-week trial, baseline information was collected which was followed by a departmental presentation. This presentation justified the project, including information from the baseline data, and described what would be involved during the trial. Also, concerns or issues surrounding the project were addressed, which included using an appropriate safe word or phrase as this has been found beneficial in reducing distraction at critical moments.[6] A reference sheet addressing the 'time out' discussion was made available in each operating room. The sheet helped to initiate a conversation about appropriate noise levels and identify a safe word or phrase for each 'time out'.

Project results and improvement strategies

The information gained from this quality project was both subjective and objective. The data analysis tools consisted of both descriptive and narrative analysis as these approaches are considered to complement each other and allow for flexibility within an open-ended enquiry.

The project results showed that before the trial commenced the noise levels in the operating room during surgery were high to moderate, on average. During the trial period noise levels improved too acceptable to moderate. Non-procedural communication was identified consistently as the contributing factor to excessive noise levels.

Survey results

The pre-trial survey identified that discussion about appropriate noise levels was rarely undertaken. During the post-trial survey, respondents agreed that it was an issue that should be addressed as inappropriate noise levels can be distracting at time critical moments. Using a non-judgmental safe word or phrase to draw attention to inappropriate noise levels was well received as some staff felt quite intimidated about speaking up.[7] The safe phrase used in this trial was 'below ten thousand' but it was felt to be too long and would need to be re-evaluated. Some of the general comments included:

- noise levels increased during teaching
- some specialties are significantly quieter than others
- the vocal tone of some staff can be higher than others.

Observation results

The results from the observational tool detected an overall reductio in noise levels of 26 per cent compared with the pre-trial data. As the operating rooms were randomly selected, not all specialties within the department were covered; however, it was generally observed that a discussion about appropriate noise levels was had at each 'time out'. On further observation, it was found that some surgical specialties were non-compliant throughout the trial period and this was reflected in the results. As with the departmental surveys, the main contributing factor to excessive noise levels remained non-procedural communication. However, it could be seen that a further contributing factor to excessive noise was surgical flow and the number of staff involved in some surgical procedures.

Since the project was conducted, a further survey was sent out to see whether noise in the operating room continues to be an issue. The feedback revealed that noise levels remain moderate but no further improvement has been seen since the trial. It was found that 60 per cent of the respondents still felt that discussing noise at 'time out' and using a safe word or phrase would be highly beneficial.

Implications to practice and future recommendations

For the continuation of appropriate noise levels to be addressed several strategies must be considered and implemented, as appropriate.

- Positive reinforcement of discussing appropriate noise levels at 'time out' and encouraging all team members to speak up if it is felt that the level of noise is becoming a distraction.

- Regular education and training programs to discuss the noise levels in the operating room and the long-term health and safety issues excessive noise can cause.
- Restriction of staff movement and the number of staff in an operating room at any one time.
- A requirement that communication devices be put on silent and any music played during surgical procedures is appropriate and at an acceptable volume.
- Keeping non-procedural communication to a minimum.

These small adjustments to our practice can provide a safe environment for the welfare of our patients, colleagues and ourselves.

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Exploring risk, antecedents and human costs of living with a retained surgical item: A narrative synthesis of Australian case law 1981–2018

Abstract

Objective(s): This study aimed to critically examine the circumstances contributing to, and the human costs arising from, the retention of surgical items through the lens of Australian case law.

Design, setting and participants: We reviewed Australian cases from 1981 to 2018 to establish a pattern of antecedents and identify long-term patient impacts (human costs) of retained surgical items. We used a modified four-step process to conduct a systematic review of legal doctrine, combined with a narrative synthesis approach to bring the information together for understanding. We searched LexisNexis, AustLII, Coroner Court websites, Australian Health Practitioner Regulation Agency Tribunal Decisions and Panel Hearings, Civil and Administrative Tribunal summaries, and other online sources for publicly available civil cases, medical disciplinary cases, coronial cases and criminal cases across all Australian jurisdictions.

Results: Ten cases met the inclusion criteria, including one coronial case, three civil appeal cases and six civil first instance cases. Time from item retention to discovery ranged from 12 days to 20 years, with surgical sponges the most frequently retained item. Five case reports indicated possible deviations from standard protocols regarding counting procedures and record-keeping. In the four cases that reported on count status, the count was deemed correct at the end of surgery. Case reports also showed the human costs of retained surgical items, that is, the long-term impacts on patients associated with a retained surgical item. In eight of the nine civil cases, ongoing pain was the most frequently reported physical symptom; in three cases, patients suffered psychosocial symptoms requiring treatment.

Conclusion: While there was little uniformity in the items retained or how items came to be retained, we identified significant time delays between item retention and item discovery, coupled with long-lasting physical and psychosocial harms suffered by patients living with a retained surgical item. Current prevention strategies, including national standards-based professional practices, are not always effective in preventing retained surgical items. An internationally standardised taxonomy and reporting criteria, more consistent reporting, and open access to event and risk data could inform a more accurate global estimate of risk and incidence of this hospital-acquired complication.

Keywords: unintended retained foreign object, retained surgical item, retained surgical instrument, retained surgical sponge, gossypiboma, sentinel event, adverse event

Introduction

The total global volume of surgical operations performed in 2012 was estimated at almost 313 million procedures,[1] and the rate is undoubtedly increasing as the burden of disease requiring interventional surgery increases.[2] In the same year, the International Surgical Outcomes Study Group estimated an in-hospital surgical complication rate of 16.8 per cent.[3] From this, we can extrapolate that over 50 million patients will suffer from a surgical complication in their lifetime. Comparatively, the incidence of in-hospital surgical complication in Australia and New Zealand was reported to be 20 per cent in 2013,[4,5] which was higher than the international average. More recently, a New Zealand study found that 40 per cent of patients reported experiencing a surgical complication,[6] another indication that surgical complication rates may be rising.

Although surgical complications seem ubiquitous, adverse events, which result in harm to a person receiving care, are potentially preventable. One such adverse event is when a surgical item is unintentionally left behind in the patient after surgery, also known as a retained surgical item (RSI). In most jurisdictions around the world, an RSI is a reportable adverse event. We previously reported findings from this review in our analysis of the key legal issues arising from RSI claims for compensation and the phenomenon of the vanishing trial in Australia.[7] In this paper, we focus our attention on understanding the risks, antecedents and human costs of living with a retained surgical item and make recommendations to improve detection, responses and reporting.

Background

Risk and prevention of retained surgical items

Over the last decade, common risk factors for RSIs have been reported in the international literature,[8–14] and the list is growing. For example, in 2018, Steelman et al. examined 319 event reports of retained surgical sponges submitted to the Joint Commission in the United States of America (USA) and identified more than 1400 contributing factors across eight broad categories, with most relating to human factors (interaction between humans, such as staff orientation and supervision, medical staff credentialing and peer review, staffing levels and skill mix), leadership (e.g. policies and procedures and compliance, nursing and medical leadership, and organisational culture) and communication (e.g. oral, written and electronic, and with doctors, with administration and among staff).[15]

Prevention strategies are consistent around the world and supported by national professional organisation standards for practice, or local policies and procedures. Strategies range from manual counting of accountable items to reconcile baseline counts (undertaken before incision) with final counts (undertaken before wound closure); methodical wound exploration prior to wound closure; clear processes to be undertaken in the event of an incorrect surgical count, such as searching in the patient, in and around the aseptic field, and in the operating room environment for the missing item; use of radiographs of the operative site to locate the missing item; and effective communication among the surgical team.[16] Surgical teams routinely rely on discrepancies – for example, an incorrect count – in the manual surgical count procedure as a prevention strategy to identify situations of potential or actual RSIs. However, evidence suggests that sole reliance on manual counting procedures and radiographs (x-rays) are inadequate prevention strategies. Large seminal trials estimate that manual counting procedures are only 77 per cent effective in picking up an RSI[17] and intra-operative x-rays are only 67 per cent effective in picking up RSIs.[18] Furthermore, in 62 to 88 per cent of RSI cases, the count at the end of the procedure was actually reported as correct.[10,18,19] In the past decade, several adjunctive technologies have been incorporated into prevention strategies, such as radio frequency identification (RFID), bar coding of surgical items or other automated counting technologies[20–22]; however, none of these newer technologies are used consistently across jurisdictions or facilities.

Global incidence and prevalence of retained surgical items

Quantifying the incidence and prevalence of RSIs is problematic. The most frequently quoted estimates to date of the incidence of RSIs from the published literature range from 1 in 5500 to 1 in 18760 in-patient operations.[10,17,18] Around the world, the true incidence is difficult to accurately quantify due to inconsistencies in reporting criteria and reporting requirements. The Organisation for Economic Co-operation and Development (OECD), an intergovernmental economic organisation of 37 member countries, reports annually on key indicators for population health and health system performance. In 2017, the OECD reported that an average rate in 2015 for a foreign body left in during a procedure was 5.4 per

100 000 surgical discharges, ranging from 0.2 per 100 000 (Poland) to 12.3 per 100 000 (Switzerland).[23] In the 2019 data, the average rate had decreased slightly to 5.2 per 100 000 surgical discharges.[24]

Attempts to quantify incidence or prevalence of RSIs have historically been drawn mainly from studies of incident reports and, in some cases, medical insurance claims. It has long been established that adverse events are underreported and studies in the last decade continue to support this finding. A retrospective study[25] of 5375 patient records in 14 hospitals in the Netherlands compared adverse events found in the patient records against the four main mechanisms of reporting: informal patient complaints, formal patient complaints, incident reports submitted by health professionals, and medico-legal claims filed by patients. Of the 498 adverse events identified in the patient records, only 18 (3.6%) were found in one or more of the four reporting systems.[25]

Retained surgical items and the Australian context

In 2004, Australian health ministers agreed on a national core set of eight sentinel events requiring mandatory reporting by all Australian public hospitals,[26] with RSIs being one of the eight. Comparatively, the incidence of RSIs in Australia is higher than the international OECD average, with a reported rate in Australia in 2015 of 8.8 per 100 000 surgical admissions,[23] decreasing to 8.2 per 100 000 surgical admissions in 2017.[24] In the ten years between 2005–2006 and 2015–2016, 322 incidents of RSIs requiring re-operation or a further surgical procedure were reported by Australian hospitals.[27] In Australia, the true incidence and prevalence is also difficult to accurately quantify due not only to inconsistencies in national reporting requirements but also inconsistencies in the types of organisations that are required to report. For instance, mandatory reporting does not apply to private facilities in all states (see Supplementary material S1). Individual state and territory government reports detail events and circumstances, usually explored by root-cause analysis, as possible contributors to retention in specific cases. While these reports provide a useful snapshot of actual reported incidents, they contain limited detail on antecedents for retention or on the longer-term impacts on patients.

Discovery of an RSI usually occurs while the patient is still in hospital or shortly after discharge. Despite international, state and territory government reports compiled from mandatory reporting, we still know little about the antecedents to items being retained or the unintended and long-term consequences of RSIs. Other publicly available data sources, such as case law reports, could provide more and different information that may assist in accurately quantifying the true incidence and risk and allow us to fully appreciate the aftermath and long-term consequences of RSIs.

With this in mind, a review of legal cases brought before a court or tribunal has the potential to offer valuable additional insights that may contribute to the collection of prevention measures currently in place. These cases may provide supplementary insight into the factual circumstances, antecedents and impacts of retention, given that detailed information is required for determining legal responsibility and personal and economic damages. Thus, the purpose of this study was to describe a methodology for reviewing legal documents and critically examine the circumstances contributing to, and the human costs (long-term patient impact) arising from, the retention of surgical items through the lens of Australian case law.

Methods

We adopted the four-step process for conducting a systematic review of legal doctrine described by Baude et al.[28] to enable better analysis of claims made about legal doctrine and reduce actual or perceived researcher bias. The four steps for conducting the systematic review were:

1. establishing a clear and precise legal question
2. defining a sample of cases
3. explaining how cases will be weighted
4. critically analysing the cases to inform a stated conclusion.[28]

A protocol for this review has not been previously published.

Legal questions guiding the critical case review

The research questions guiding the review were:

1. What are the material factual circumstances of cases concerning RSIs in Australian hospitals brought before Australian courts and tribunals from 1981 to 2018?
2. Can a pattern of antecedents for risk of RSIs be established from analysing case law to:
   - determine a more accurate estimate of patient risk, and
   - offer insight into additional strategies for reducing risk or prevention?
3. What are the long-term impacts on patients associated with an RSI?

Sample of cases and search strategy

Cases were included in the sample if they met the following inclusion criteria: civil claims, criminal cases, medical disciplinary cases and coronial court cases from 1981 to 2018 from Australian jurisdictions concerning incidents of RSIs in Australian hospitals. The search start date was 1981 because national guidance for nurses working in the operating room for the management of accountable items used during surgery was first published in 1980 by the professional body then known as the Australian Confederation of Operating Room Nurses.[29] Cases were excluded if a surgical item was intentionally retained and later removed without incident and no harm was attributed to that item.

Using variations of the search terms surg* OR medical AND retain* OR "adverse event" AND count and related words, the following publicly available data sources were searched for the period 1981 to 2018: LexisNexis (searches for Australian case law), Australasian Legal Information Institute (AustLII) (searches of state and territory professional regulatory boards), coroners' courts for each state and territory (for summaries of coronial cases), civil and administrative tribunal decisions in all jurisdictions (for health practitioner case summaries), and the Australian Health Practitioner Regulation Agency (AHPRA) Medical Board and Nursing and Midwifery Board Panel tribunal hearings (for health practitioner case summaries).

We sought to consider all online cases relating to the research questions within the relevant period; however, the disparate nature of these online sources meant that the chronological cut-off for the online availability of legal cases varied across platforms. The full search strategy parameters, brief descriptions of the key databases searched and an example of the search string used in LexisNexis can be found in Supplementary materials S2–S4.

Weighting of included cases

As we had no preconceived expectations of how many or what type of cases would be found, cases were equally weighted. However, following the legal doctrine of precedent, which provides that similar cases should be decided in similar ways and achieve similar outcomes, it could be appropriate to give cases whose reasoning is partly rejected or disputed by the courts in subsequent cases less weight in the final analysis, and give those cases which were considered and followed in subsequent cases more weight.

Method for critical case analysis

Following a systematic search of case law, the included cases were reviewed by a university law professor (TC) with experience in civil medical litigation and case law review and cross-checked by the project law research assistant (JD). Key case characteristics were extracted, and a coding framework was settled upon by the research team (TC, JD, SRO). The cases were then coded, critically analysed and synthesised to draw out key trends. These trends were then expanded into narrative summaries of the relevant facts and law in each case and discussed by the research team. Details of the data extracted can be found in Supplementary material S5.

This approach to legal doctrine review was strengthened by using a narrative synthesis approach, which relies mainly on the use of words and text to summarise and explain the findings from the included cases. Although originally described for use with systematic reviews of intervention effectiveness or factors influencing the implementation of interventions, we adopted the general framework for narrative synthesis described by Popay et al.[30] to 'tell the story' of the findings from the included cases. The four main elements of the narrative synthesis framework were:

1. developing a theory of how, why and for whom the prevention interventions work (or in the case of RSIs, did not work)
2. developing a preliminary synthesis of findings
3. exploring relationships in the data
4. assessing the robustness of the synthesis for drawing and generalising conclusions.

The theory underpinning our narrative synthesis is James Reason's accident causation model,[31] which proposes that in complex systems multiple barriers or layers exist to prevent accidents and errors and that failure in the system can occur if the plan is adequate but associated actions are not deployed as intended or that the actions go as intended but the plan is flawed.[32]

Results

As depicted in Figure 1, from a search pool of 5728 case records (after two duplicates were removed), only 11 decisions reporting on ten cases[33–43] were found concerning incidents of RSIs and meeting the inclusion criteria, including one coronial case,[43] three civil appeal cases,[33,34,39] and six civil first instance cases,[35,38,40–42] including two decisions referring to the same legal matter.[36,37] Despite the small sample of cases available, it is possible to derive a number of observations about how RSI claims

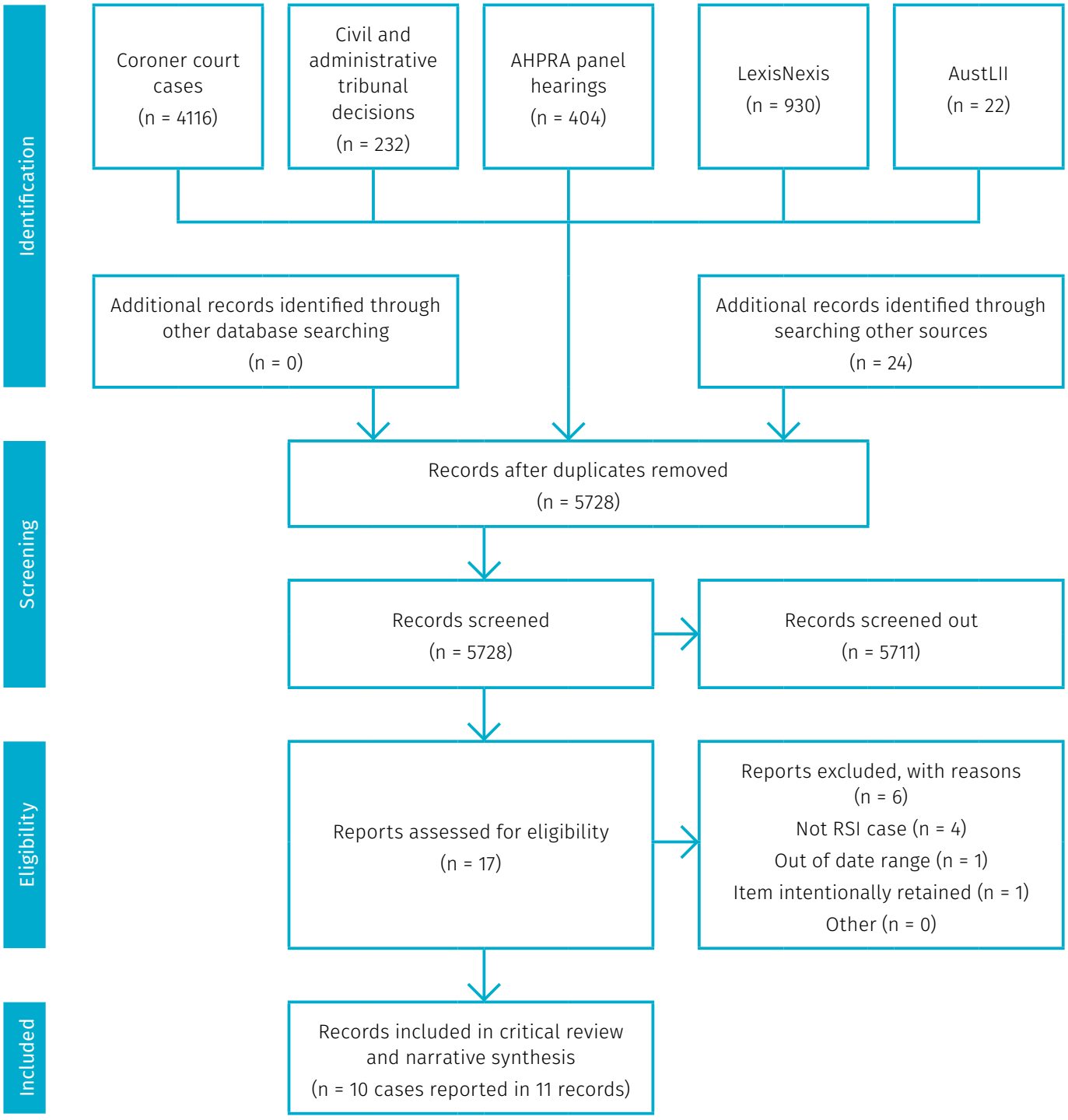

Figure 1: Australian case law flow diagram

(Diagram adapted from Moher D, Liberati A, Tetzlaff J, Altman DG. The PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: The PRISMA statement. PLoS Med. 2009;6(7):e1000097).[44])

are considered in the Australian legal system. It should be noted that the majority of the ten cases located are unreported, with only two involving a final consideration of liability and damages.[33,39]

Most cases reviewed were procedural, which means that the plaintiff (usually, this was the patient or patient's family or estate) sought the Court's permission (called 'leave' in legal terms) to bring an action, usually against the surgeon, the nurses, and/or the hospital or health service organisation, outside the limitation period (including an appeal against the dismissal of a matter),[34] or to amend their previous statement of claim based on new evidence.[35,38] Under Australian law, a statute of limitation restricts the time within which a person (the plaintiff) can commence proceedings and a medical negligence case cannot generally be brought after three years from the date on which the cause of the action was discoverable to the plaintiff.[45]

A brief summary of the findings of key characteristics from each of the 10 included cases are presented in Table 1. A more detailed summary of findings table, including the material factual circumstances of the cases, antecedents for risk, and long-term impacts, can be found in Supplementary materials S6 and S7.

Material factual circumstances of cases concerning retained surgical items

Types of surgery and items retained

The legal cases revealed little uniformity in the items retained as presented in Table 1 – silicon tubing in the abdominal cavity retained during a laparoscopy stomach banding operation[40]; Kirschner-wire (K-wire) fragment retained in the right hand after an open reduction and multiple K-wire fixation[38]; one instance of a drainage tube retained after a recurrent umbilical hernia[35] and another after a hysterectomy[42]; a straight needle, which had migrated into the heart after being retained during a hysterectomy[36,37]; a broken piece of forceps retained in the body after an appendicectomy[34]; one instance of a surgical sponge being retained in the patient's abdominal cavity at the conclusion of a colectomy,[41] two instances of a sponge being retained after the patient underwent a hysterectomy[33,39] and a final instance of a sponge being accidentally retained after being initially left in situ deliberately to stem intra-abdominal bleeding.[43] While the majority of cases involved open abdominal or pelvic surgical procedures (n = 8), one case was a minimally invasive abdominal surgical procedure, and one case was an orthopaedic upper limb procedure. The most frequently retained item was the surgical sponge, which occurred in four of the ten cases.

Means of discovery and disclosure of retained surgical items

Time from retention to discovery of RSIs ranged from 12 days to 20 years with significant disparity in the manner of discovery of the retained item across the cases (see Table 1). In most cases, the discovery came after the patient presented with physical symptoms. In one case,[36,37] a retained straight surgical needle was discovered incidentally after a chest x-ray for an unrelated condition; and in another, a retained surgical sponge was discovered after presentation to the emergency room following a fall.[41] In two other cases, the RSIs were device fragments that were known to be retained at the time of the surgery – a broken forceps tip in *Gaynor v. Milton*[34] and a broken piece of a K-wire in *Kenjar v. Australian Capital Territory.*[38]

A notable feature in three of the reviewed cases was a failure to identify a retained item that was visible on post-operative x-ray scans taken at the time of the suspected missing item. In *Kenjar v. Australian Capital Territory*,[38] the patient underwent day surgery for an open reduction and multiple K-wire fixation to his right hand on 26 August 2008, and a later surgery on 16 September 2008 to remove the K-wires. Images taken during the earlier surgery revealed a fragment of K-wire retained in his right hand, but no action was taken to remedy this until the patient returned to hospital, with pain and swelling in his right hand, necrotic skin and an abscess, on 30 September 2008, 14 days later. In *O'Hagan v. Sakker*,[41] the patient, who suffered from longstanding abdominal and pelvic problems, underwent a partial removal of her colon on 10 August 1992 and consequently experienced fevers, abdominal cramps and loss of bowel control. She had an abdominal x-ray on 7 June 2003 in anticipation of a planned colonoscopy procedure. This x-ray film showed the retained surgical pack in the patient's abdominal cavity; however, the Court accepted that she was not informed of this x-ray finding in 2003, when it was initially examined. The patient underwent an abdominoplasty in February 2005 and a further colonoscopy in February 2007; however, there was no evidence that x-rays were taken or viewed for these surgeries. The foreign body, which by the time of its removal was 'about the size of a grapefruit', was only discovered in late September 2007 when the patient was admitted to hospital suffering from abdominal

Table 1: Summary of key findings table (abbreviated)

Case, citation [date, state]	Type of hospital	Date of retention (i.e. date of surgery)	Type of surgery	Item(s) retained	Means of discovery	Date of discovery [Disclosure]	Time from retention to discovery/ removal
Elliott v. Bickerstaff [1999, ACT][33]	Private	13 Jun 1991	Total hysterectomy and colpo-suspension	sponge	Patient complained of 'physical problems'	'about six weeks later'	'about six weeks'
Gaynor v. Milton; Ulladulla Hospital [1981, NSW][34]	Public	10 Jun 1975	Appendicectomy	piece of forceps	Item known to be retained, confirmed with x-ray	*[Authors' note: Date of discovery unclear]*	*[Authors' note: Details missing from record]*
Hughes v. Minister for Health East Pilbara Health Service [1999, WA][35]	Public	20 Dec 1994	Insertion drainage tubes	drainage tube	Patient complained of physical symptoms (severe central abdominal pain, nausea, vomiting, constipation, fatigue); item found by x-ray and ultrasound scan	21/22 Dec 1994 (item missing) 19 Jan 1995 (retention of item in adbominal wall discovered)	28 days
Ives v. Australian Capital Territory and Anor [1995, ACT][36] *The Australian Capital Territory v. Ives* [1996, ACT][37]	Public	'on or around 12 Mar 1974'	Securing/removing drainage tube in connection with hysterectomy	straight needle	Patient had chest and spinal x-rays for unrelated condition, item revealed	11 Oct 1994	20 years, 7 months *[Authors' note: item not removed due to greater perceived risk]*
Kenjar v. Australian Capital Territory [2014, ACT][38]	Public	26 Aug 2008	Open reduction, multiple K-wire fixation of right hand	piece of K-wire	Patient had pain, swelling, necrotic tissue, abscess in right hand; x-ray taken days after debridement surgery revealed item	2 Oct 2008 *[Authors' note: Patient not informed of retention after initial surgery]*	16 days
Langley & Warren v. Glandore Pty Ltd & Thomson [1997, QLD][39]	Private	22 Feb 1990	Total abdominal hysterectomy	sponge	Patient had 'painful symptoms' following surgery, subsequent surgery revealed item	'some ten months later'	'some ten months later'
Miller v. Broadbent [1999, QLD][40]	Private	Oct 1992	Laparoscopy stomach banding	silicon tubing	Patient had ongoing abdominal pain, item revealed during exploratory surgery to identify cause of pain	5 Jun 1996	3 years, 8 months
O'Hagan v. Sakker [2011, NSW][41]	Private	10 Aug 1992	Hemi-colectomy / sigmoid colectomy	sponge	Patient admitted following fall, complained of abdominal pain, x-ray taken, item revealed	2 Oct 2007 *[Authors' note: Patient only became aware of RSI after removal]*	15 years, 1 month
Smith v. Marcus [1989, NSW][42]	Public	24 Nov 1977	Hysterectomy and insertion of drainage tube	drainage tube	Patient had persistent pain and discomfort in the stomach and pelvic area exacerbated by walking. Eventually had IVP examination, item present on film but not in report; IVP film later re-examined by GP, item confirmed by ultrasound and CT scan.	24 Nov 1987 *[Authors' note: Patient not aware of RSI previously]*	10 years
Investigation into Death of James Stirling McKinlay [2013, TAS][43]	Public	2 Jun 2012	Follow-up surgery for internal bleeding post pancreaticoduo-denectomy	sponge	Multiple surgeries: item intentionally retained to be removed at subsequent surgery, item not found; x-ray and later CT scan taken, item visible on both films but not in either report; item revealed during subsequent surgery	14 Jun 2012	12 days

ACT = Australian Capital Territory, NSW = New South Wales, WA = Western Australia, QLD = Queensland, TAS = Tasmania

pain after falling several days earlier. In the Tasmanian Coroners Court matter of the *Investigation into Death of James Stirling McKinlay*,[43] the retained pack was visible on an x-ray taken on 6 June 2012, but the radiologist did not report it, and managing doctors did not see it. The retained pack was visible in a CT scan of the abdomen on 7 June 2012, but again it was not noted. The retained pack, which was tightly compressed and separately located from the other packs, was discovered and removed during another operation on 14 June 2012.

In *Hughes v. Minister of Health*,[35] the discovery of a retained object was hindered by post-operative care failures. The patient underwent surgery in September 1993 to repair a recurrent umbilical hernia. In a later surgery, two drainage tubes were inserted to drain fluid build-up. These drainage tubes protruded from the patient's abdomen and were connected to a fluid suction apparatus. On 20 December 1994, the drainage suction apparatus was removed, as were stitches that held the drainage tubes in place. The drainage tubes remained in place, extending approximately 20 mm from the patient's abdomen. On 22 December 1994, the left-side drainage tube was found to be missing. Despite this discovery, the plaintiff was discharged from the hospital after the removal of the right-side drainage tube. After discharge, the patient suffered from 'severe central abdominal pain, nausea, vomiting, constipation and fatigue and was incapable of working'.[35] X-rays and an ultrasound scan taken in early 1995 located the lost drainage tube within the anterior abdominal wall.

Antecedents for risk of retained surgical items

While information about antecedents for item retention is limited in some of the reviewed cases, a number of cases in the sample reflect current literature on contributing influences related to human factors, such as deviations from protocols and poor or no communication between health professionals.

Human factors – deviation from standard protocol

The review considered whether operating room staff involved in the litigated procedures had performed appropriate procedural steps and checks in relation to the management and accountability of surgical supplies and equipment. Deviation from established protocols regarding counts and record-keeping was implicated in five cases. Only five case reports discussed counts and contemporaneous record-keeping in any detail. In four cases reporting on count status, the count was deemed correct at the end of surgery (see Table 2).

In *Langley & Warren v. Glandore Pty Ltd & Thomson*,[39] a sponge was left inside the patient's abdomen after a total abdominal hysterectomy. The surgeons were given general assistance by an instrument nurse and a circulating nurse employed by the hospital. The nurses were found to have made an error in tallying the number of sponges used, incorrectly balancing the number of sponges retrieved at the end of the surgery with the number opened during the procedure. In *Elliott v. Bickerstaff*[33] it was inferred at trial that the nurses present at the surgery miscounted the number of sponges used and provided the surgeon with 'unfounded assurances' that all items were accounted for, leading to the retention of a sponge in the patient's abdominal cavity. In *Ives v. Australian Capital Territory*,[36] and its 1996 appeal on a procedural point,[37] the court examined the retention of a straight needle in the patient's ventricle, which was alleged to have migrated from her abdomen after a hysterectomy in 1974. Evidence was led about the 'standard practice' of counting all needles at the end of the surgery and recording of the count reconciliation on a whiteboard by the nurse. 'There was no record of a needle having gone missing or having broken. If there had been, it would have been regarded as a serious event.'[36]

This recital of usual practice was confirmed by a nurse who routinely assisted the defendant surgeon. There was, however, no record kept of reconciling the needle check as it was not usual practice to keep a permanent record of the count in 1974. In *O'Hagan v. Sakker*,[41] which concerned the retention of a surgical pack after a sigmoid colectomy, the defendant surgeon also led evidence about usual hospital practice and procedures as at the operation date in 1992. However, in the absence of documentation in the medical records, the evidence of the surgeon's usual practice was treated with caution by the Court because '... most drivers of motor vehicles would assert that they invariably stop at red traffic control lights, yet common knowledge indicates that the work of red light traffic cameras tells a very different story'.[41]

The fifth case concerning a retained surgical sponge, the Tasmanian Coroners Court inquiry into the death of James Stirling McKinlay[43] specifically discusses the importance of easily accessible and consistent documentation. The court found that the deceased underwent a lengthy and complicated 'Whipples procedure' on 15 May 2012 to remove

Table 2: Count status at key timepoints in the counting procedure

Case, citation [date, state]	Item(s) retained	Initial count	Wound closure count	Skin closure count	X-ray taken
Elliott v. Bickerstaff [1999, ACT][33]	sponge	Not recorded in case note	Not recorded in case note	Correct	Unable to determine if x-ray was taken
Gaynor v. Milton; Ulladulla Hospital [1981, NSW][34]	piece of forceps	Not recorded in case note	Item known to be missing	Item known to be missing	Yes, later (+)
Hughes v. Minister for Health East Pilbara Health Service [1999, WA][35]	drainage tube	Not recorded in case note	Not recorded in case note	Not recorded in case note *[Authors' note: Tube known to be missing day after stitches removed]*	Yes, later (+)
Ives v. Australian Capital Territory and Anor [1995, ACT][36] *The Australian Capital Territory v. Ives* [1996, ACT][37]	straight needle	Not recorded in case note	Not recorded in case note	Correct	Yes, much later and unrelated (+)
Kenjar v. Australian Capital Territory [2014, ACT][38]	piece of K-wire	Not recorded in case note	Not recorded in case note	Not recorded in case note	Yes, later (DOS) (+)
Langley & Warren v. Glandore Pty Ltd & Thomson [1997, QLD][39]	sponge	Not recorded in case note	Not recorded in case note	Correct	Unable to determine if x-ray was taken
Miller v. Broadbent [1999, QLD][40]	silicon tubing	Not recorded in case note	Not recorded in case note	Not recorded in case note	Yes, later (-); later exploratory surgery (+)
O'Hagan v. Sakker [2011, NSW][41]	sponge	Not recorded in case note	Not recorded in case note	Correct	Yes, 2003 x-ray (+) but reported (-); 2003 x-ray re-examined later (+)
Smith v. Marcus [1989, NSW][42]	drainage tube	Not recorded in case note	Not recorded in case note	Not recorded in case note	Yes, later, several x-rays reported (-); x-rays and IVP re-examined later (+)
Investigation into Death of James Stirling McKinlay [2013, TAS][43]	sponge	Not recorded in case note	Item intentionally retained	Incorrect – intentional retention	Yes, later, misread (-); later CT scan misread (-); later exploratory surgery (+)

Notes: (+) Retained item found on x-ray; (-) Retained item not found on x-ray

Abbreviations: DOS = day of surgery, IVP = intravenous pyelogram, ACT = Australian Capital Territory, NSW = New South Wales, WA = Western Australia, QLD = Queensland, TAS = Tasmania

a cancer of the bile duct. Between the date of surgery and 1 June 2012, he underwent multiple surgeries, which unsuccessfully sought to address internal bleeding. The operating room nurse's report for a further surgery on 2 June 2012 recorded that one large pack and six small packs were deliberately left in position to stem intra-abdominal bleeding. After surgery, the patient was transferred, with his medical records and notes, to the Royal Hobart Hospital. Surgery was undertaken on 4 June 2012 and six packs were removed, but one pack was accidentally retained. While Coroner Pearce found that the retained pack did not contribute to the patient's death, he found that the deceased was transferred to the Royal Hobart Hospital with an incomplete medical record, which failed to formally communicate the number of packs left in situ on the handover. The Coroner recommended that because the count procedure is used as a risk mitigation strategy, it requires due diligence and care to ensure that the recording of the count is accurate, consistent between nursing and medical team members, and easily accessible as a communication tool, not only between clinicians but also between facilities when patients are transferred.[43] The Coroner also made the following recommendation: 'Each hospital should also consider whether a practice of abdominal x-ray following emergency abdominal surgery to identify and reduce the risk of retained packs might be appropriate'.[43]

In all of these cases, the procedures described correspond with the 15th edition of the Australian College of Perioperative Nurses (ACORN) *Standards for Perioperative Nursing in Australia*, which states that 'All members of the operating or procedural team have a duty to collaborate to ensure that all items used during surgery and procedures are retrieved … accounted for and appropriately documented.[16 p.75]

Human factors – communication, verbal and written

Judgments in many cases linked deviations from the protocol closely to either inadequate verbal communication or written communication in the patient records. In two of the four cases concerning a retained surgical sponge, the count was communicated and documented (according to medical records) to be correct at the end of the surgery.[33,39] In one case, the correct count was implied from the trial transcripts, despite a lack of written records confirming this.[41] In either case, the presence or absence of written records impacted on the success of the plaintiff's or defendant's case. For example, in *O'Hagan v. Sakker*,[41] the judge commented on the expectation of certain documents contained in the medical record to be able to provide evidence '... whether or not the relevant items were counted at the conclusion of the operation, and whether such counting was the subject of the signing off, in conformity with the usual practice'.[41]

The cases in this sample underline the importance of clear and accessible communication, both verbal and written, as a safeguard to preventing RSIs.

Harm suffered and unintended consequences

Eight out of ten records reported harm suffered by the patient as a consequence of a retained surgical item. Physical harm was described in two cases.[39,40] In five cases, a range of both physical harms and psychosocial harms were described,[33,35,38,40,41] although in one of these the physical symptoms were masked due to multiple existing co-morbidities and were re-investigated after the patient presented to the emergency department for an unrelated fall.[41] In one case, there was no mention of physical harm prior to discovery; however, psychosocial symptoms manifested after the retained item was discovered on a chest x-ray taken for an unrelated reason.[36,37]

It is important to note the potential for psychosocial harm as a corollary of a lengthy retention as evidenced in the following cases. In *O'Hagan v. Sakker*,[41] the patient suffered from ill-health and pain most of her life and had undergone multiple operations in an attempt to improve her quality of life. Evidence was tendered that as a consequence of the discovery and removal of a retained pack in her abdomen 15 years after the relevant surgery '...the plaintiff has become preoccupied with, and focussed upon, what she considers to have been the deleterious effects upon her health as a result of the pack having been left in her abdominal cavity. She has been preoccupied with psychological problems'.[41]

Similarly, the patient in *Ives v. Australian Capital Territory* became 'depressed and anxious' after learning about the presence of an 'extremely long' and fractured needle in her heart ventricle, which had migrated from her abdomen after being retained there more than twenty years earlier.[36] In *Elliott v. Bickerstaff*,[33] the patient developed 'ongoing psychological and physical problems' as a result of the six-week retention of a sponge in her abdomen. In the case of *Smith v. Marcus*,[42] the plaintiff endured constant pain, soreness and discomfort in the pelvic and stomach region, exacerbated by walking. After ten years of persistent pain, multiple visits to a range of medical practitioners ordering a myriad of diagnostic tests, the cause was later discovered to be a retained drainage tube, determined to be in situ ten years after surgery. Apart from the apparent physical harm in this case, psychosocial harm manifested in the patient's feeling of self-doubt after years of being told that there was nothing wrong with her. The Court assessed that the patient was '...a relatively unsophisticated lady who understandably seems to have adopted the attitude that whatever the cause of her problems a variety of skilled doctors after testing could detect nothing wrong and that she should learn to live with her ongoing discomfort'.[42]

The plaintiffs (patients) in all cases suffered from harm post-surgery, regardless of the type of surgery, the item retained or the length of time from retention to discovery; with psychosocial harm manifesting more in cases where the patient complained of ongoing physical pain but whose complaints were dismissed or in those patients living with an RSI once they became aware of the presence of the item and potential worse outcomes they could have suffered.

Discussion

Supplementing existing retained surgical item data sets by analysis of Australian case law

It is well accepted in the academic and popular literature that reported incidents of RSIs are considered the 'tip of the iceberg' when looking at the true extent of the problem in hospitals around the world. This may be due to the current absence of mandatory reporting of 'near misses' and failures or delays in discovering RSIs due to patients who may be asymptomatic or suffering from non-specific symptoms[46] – that is, symptoms not initially linked to a prior surgical procedure.

Furthermore, the number of incident reports for a specific event may not be a reliable reflection of the frequency of that event nor of the true risk of the event occurring. For example, following their study of a falls prevention program, Abujudeh et al. warned that the prevalence of incident reports may be more a reflection of a particular organisational focus on reporting of particular incidents at that point in time.[47] More concerning is the Grattan Institute report on strengthening safety statistics,[48] which concluded that incident reports cannot be relied upon to benchmark performance over time or across organisations, or to help understand what types of adverse events or harm to patients are most prevalent. This may be because incident reporting is mostly voluntary; and, where mandatory, reporting criteria and definitions (such as 'end of surgery') are not always clear or consistent, resulting in inconsistency in measurement indicators. This, therefore, contributes to the possible underestimation of the actual risk of a patient leaving the operating room with an RSI.

The National Hospital Morbidity Database, published by the Australian Institute of Health and Welfare (AIHW),[27] provides a useful overview of the incidence of RSI retention, while a number of state government reports detailed circumstances that contributed to the retention of surgical items in specific cases. The range of factors at different levels of the process leading up to an RSI, from unsafe individual actions to latent hazard conditions within the organisational system, demonstrate the application of Reason's accident causation model.[31,32] Some of these incidents arose from procedural failures (e.g. operating staff's non-adherence to the use of the instrument count sheet, reliance on memory to remove a surgical gauze at the end of a procedure, performance of an organ closure despite incorrect swab count, commencement of wound closure prior to the completion of the first surgical count), and some from communication failures (e.g. a failure to report a missing swab after the initial swab tally was found to be incorrect, failure to confirm removal of a pack inserted by the anaesthetist). Retention also arose from issues with surgical instruments or equipment (e.g. use of equipment with easily removable parts, equipment failure) and use of other ancillary equipment (e.g. incorrect reading of intra-operative or post-operative x-rays or other scans).

Government reports provide a useful glimpse of RSI incidents; however, findings from government reports of mandatory reporting are typically based on root cause analysis, which is inherently subject to human biases of the investigators, such as hindsight bias or attribution error, as they attempt to determine causal factors of an adverse event.[49] The aim of our study was not to find the one cause, *per se*, of the RSI or to attribute blame. We took the stance recommended by Henriksen et al.[49 p.71] 'to be fair and yield new knowledge'. As such, our efforts were directed at the antecedent circumstances that existed for the operating room personnel before the item was retained to make sense of the previously unknown factors contributing to the retention. This study sought to examine the antecedent circumstances leading up to, and the human costs arising from, the retention of surgical items through the lens of Australian case law reports of legal proceedings relating to RSIs.

Review and synthesis of Australian case law

Our study involved a review of civil cases, medical disciplinary cases, coronial cases and criminal cases across all Australian jurisdictions. Only ten original cases concerning incidents of retained surgical items were located, a very small number when compared with the 322 incidents of retained items requiring re-operation or a further surgical procedure reported by Australian hospitals in the years between the years 2005–2006 and 2015–2016.[27]

Despite the small sample of cases available, it was possible to derive a number of observations regarding the Australian legal system's consideration of claims relating to RSIs, particularly in relation to most commonly retained items, the length of delay between retention and discovery, antecedents to retention, the human costs of retention and risk prevention strategies. We found that surgical sponges made up the highest proportion of surgical items retained (40%). This not only aligns with previous studies but also continues to be confirmed in more recent studies of root cause analysis investigation reports.[50]

In their study of reports from 2010 to 2015, Hibbert et al. found that nearly a quarter of the retained surgical items were discovered either immediately in the post-operative period or on the day of the procedure, while about one sixth were only detected after six months, with the longest period being 18 months.[50] As our study examined legal cases across a much longer time frame, we were able to uncover that the time between retention and discovery could be as long as 20 years.

From these cases, it is evident that retention of surgical items (which encompasses a diverse range of items) is a widespread phenomenon that cannot be attributed to a particular surgical practice or type of surgery. As discussed above, retention may be impacted by a number of human factors including failure to adhere to established risk mitigation processes, deficient communication and record-keeping,[50] and issues surrounding post-operative care practices including omissions in clinical handover information or misreading or misinterpretations of post-operative diagnostic x-rays, where in some cases, retained items later determined to be visible on post-operative scans were not identified at the time of the scan. The human factors implicated in the reviewed cases were referred to by the judges in their decisions and recommendations to address failures in the system that enabled human factors failures. The cases also revealed physical and psychosocial harms allegedly experienced by patients due to retention of the surgical item. Some of these harms were exacerbated by a lengthy delay before discovery, and most were certainly not known or expected at the time of transfer from the operating room or even prior to discharge from hospital.

Clark and Oakley[51,52] argued that patients should be provided with comparative information about surgeons' performance as part of the informed consent process (which is a universal pre-requisite for elective surgery) and quality assurance processes. The identified cases illustrate that operating room staff work as a team with shared responsibility and accountability for patient safety;[7] therefore, surgeon performance data alone may not necessarily be useful in the case of minimising RSIs, particularly in cases of prolonged retention. We did find, though, that current team-based risk mitigation strategies, including counting, communicating and documenting items used during surgery, are not always effective.[7]

Need for multidisciplinary guidelines for perioperative practice

Like in many countries around the world, most facilities in Australia have incorporated the World Health Organization's (WHO's) Surgical Safety Checklist into routine practice in the operating room, with varying degrees of success.[53] Although the WHO has encouraged facilities to adapt the checklist to fit local practice, the checklist includes only one item specifically targeting prevention of RSIs – that is, during the 'sign out' phase the 'nurse verbally confirms with the team … that instrument, sponge and needle counts are correct (or not applicable)'. In Australia, ACORN is the only professional body providing explicit guidance, in the form of standards for perioperative practice, related to the prevention of RSIs.[16] We have not been able to identify any published equivalent guidance produced by the Royal Australasian College of Surgeons (RACS) or the Australian and New Zealand College of Anaesthetists (ANZCA) for their members. This may be because the responsibility for the management of accountable surgical items has historically been considered the domain of the perioperative nurse, despite the multidisciplinary team environment in which surgical procedures are typically conducted. It is therefore timely to consider the development of multidisciplinary guidelines for perioperative practice that are endorsed by the professional bodies of all disciplines that make up the team.

The cases analysed in our study highlight the importance of shared responsibility, particularly for communication and documentation, and for compliance with established processes to reduce the risk of harm. The cases also highlight varying outcomes in judicial determinations of alleged negligence in the advent of an RSI. However, as such, it appears that the 'elaborate ritual'[33] of manual counting and management of accountable items prescribed by ACORN in the national standards for the profession is not sufficient to prevent all incidents of RSIs from occurring. In all included case reports that explicitly discuss the count procedure, the procedures described correspond with current *Standards for Perioperative Nursing in Australia*[16] [15th edition]. As such, the fact that these procedures were not sufficient to avoid the retention of surgical items is a relevant consideration for contemporary prevention and protective strategies. Our findings in this context align with the recent findings by Gunnar et al.[54] in their study of root cause analysis of RSI events, which found that a majority of incidents (64%) involved human factors issues (e.g. staffing changes during shifts, staff fatigue), policy/procedure failures (e.g. failure to perform methodical wound sweep) or communication errors.[54]

In addition, standard and usual processes outlined in the 15th edition of *Standards for Perioperative Nursing in Australia* for locating missing items in the event of a discrepancy in the count, including immediately notifying the surgeon, requesting a thorough re-exploration of the wound, search of environmental surroundings and intra-operative imaging, do not provide a completely effective prevention strategy. This conclusion, derived from an analysis of case law, is supported not only by

the literature but also by state government patient safety reports that point to procedural non-compliance as a key contributing factor to surgical item retention. This naturally leads us to consider the need to adopt newer, technologically advanced adjunctive strategies, particularly those with evidence of effectiveness.[20,21,54] This strategy to improve detection and supplement counts, and the need for an evidence base in this area, was also highlighted by Hibbert et al.[50] The continued persistence of RSIs across the world, including Australia, highlights the shortcomings of current prevention strategies in totally preventing this sentinel event and at the same time questions the assumption that an RSI is a never-event.

Patient engagement for early detection of retained surgical items

The occurrence of never-events, such as RSIs, undermines the trust and confidence that the public has in a health care system. Most facilities follow patients up for signs and symptoms of infection. A survey of 462 internal medicine patients across five university hospitals in Finland[55] found that when patients have positive health care service experiences, they participate more in ensuring their own safety during hospital care. This premise could naturally extend to post-hospitalisation patient safety practices. It is worth considering a longer post-operative follow-up period and investigation of all patient-reported outcome measures (PROMs), regardless of whether the symptoms reflect 'usual' post-operative complaints (like surgical pain or surgical site infection) or are non-specific. Of course, the patient may not tell us at the time that something had been left behind. However, health care professionals need to improve the information and encouragement we give to patients, so patients can be more pro-active in their own post-operative safety practices,[55] such as reporting signs and symptoms, some of which could assist in identifying RSIs earlier in the post-discharge period.

Perhaps, RSI should become a routine differential diagnosis until ruled out when patients report post-operative complaints. This recommendation may serve as a useful outward indicator to patients that the health care system values their participation in improving the safety and quality of health care, is listening to their worries, and is concerned with their safety.

Need for globally standardised ontology and taxonomy and mandatory reporting

The true incidence and prevalence of RSIs is difficult to accurately quantify due to the nature of reporting as well as the inconsistency in operational definitions and measurement indicators. For example, inconsistency in reporting near misses, that is, situations of an incorrect count where the RSI is subsequently located prior to wound closure or prior to the patient leaving the operating room. Furthermore, there is very little data on miscounts, that is, situations where the count is deemed correct at the end of the procedure, yet an RSI is identified later after the wound is closed and the patient has left the operating room, and in many cases, the hospital.

The original definition of RSI in Australia was changed from 'retained instruments or other material after surgery requiring re-operation or further surgical procedure' in 2002 to 'unintended retention of a foreign object in a patient after surgery or other invasive procedure resulting in serious harm or death' in 2018.[56] Serious harm is defined by the Australian Commission on Safety and Quality in Health Care (ACSQHC) as being permanent or long-term physical harm, permanent or long-term loss of function, shortened life expectancy, or the patient requiring life-saving surgical or medical intervention.[56] This implies that if no serious harm or death results, then the incident does not need to be reported. This would also exclude near misses where the missing item was found before the wound was closed or the patient was transferred from the operating room. However, once again, this limits the opportunity to estimate true risk.

By contrast, in the United States of America (USA), the current Joint Commission definition is that 'an unintended retained foreign object (URFO) [is] an object that is retained after skin closure has occurred following an invasive procedure'[57]; that is, the definition is not limited to cases where the retention results in serious harm or death and does not specify that the patient has left the operating room. Contrary to this, the definition from the National Quality Forum, also in the USA, states, '…the patient has been taken from the operating/procedure room' (pB-4) [sic]. In the United Kingdom, the 2009 never-event was called 'retained surgical instrument post-operation', then 'retained instrument' and, finally, in 2011 'retained foreign body post-operation'.[58] The definitional inconsistency around the world has the potential to impact on the accuracy of indicators not only of actual RSIs but also of the true risk, making benchmarking problematic and contributing to the underestimation of the extent of the problem. Standardised data collection is important for accurately

interpreting outcomes data.[59] What is needed is a globally standardised ontology and taxonomy including operational definitions and clearly demarcated measurement indicators, and mandatory reporting based on these standard indicators.

Open access to data

Once accurate data is captured, the data need to be stored and made accessible. Changes in health care and developments in information systems have seen an increase in the use of big data sets captured in large national databases, particularly in surgical research.[60] Establishing a national or international registry for the tracking and surveillance of patients identified as having an RSI and those with a differential diagnosis of RSI would provide the opportunity for accurate estimates of the problem and of the risk, and may lead to global collaborative efforts to address this never-event. Donabedian's model of quality improvement posits that structure measures have an effect on process measures, which have an effect on outcome measures.[61] Thus, registry data that includes structure, process and outcome indicators would allow a more complete evaluation of current strategies for preventing RSIs as well as how we have moved forward to any sustainable improvements in reducing incidence and prevalence which, technically, should be zero.

Limitations

We acknowledge the inherent limitations of using case law as a data source. First, in legal proceedings, the parties and their legal representatives argue their case and present the facts in a way that is likely to advance their claim and establish the necessary elements. In addition, when a judge is drafting their decision (judgment), the judge generally filters the detailed information presented at trial to only the facts that are material to the judicial reasoning process. This limits the case details that are publicly available for analysis. Second, the extent of information contained in the cases was a limitation. For example, some cases contained very detailed factual information, including antecedents and human costs of living with an RSI, whereas others simply provided a brief overview of the outcomes limited to less than a page of information. Varying degrees of information were provided about counts and contemporaneous record keeping.

The study was limited to cases that were available by searching publicly accessible databases, which resulted in our systematic review identifying only a small number of cases. In addition, most cases reviewed were procedural; as such, some of the factual circumstances, which would have been recorded in a report of the full trial decision were missing.

Further to this, more than 95 per cent of Australian medical litigation is settled (resolved) through negotiation or discontinued before a final judicial determination,[7] and the outcomes of the fact and details of the settlements are usually confidential. This limits the ability to engage in additional fine-grain analysis that would have been undertaken in this review had these cases gone to trial.

Despite this, our critical analysis of these cases expands upon many of the issues raised in the government reports in terms of antecedents and human costs of living with RSI.

Conclusion

An RSI can be discovered days, weeks, months or years after the original operation, usually following the development of patient symptoms. Unintentional retention of surgical items has been recognised as such for more than a decade by the ACSQHC as an event that causes serious harm to patients and threatens society's perception of the Australian health care system. Mandatory federal reporting of RSIs as a sentinel event allows researchers to track the frequency of these events, while state reporting provides some anecdotal evidence as to specific case studies. Despite this, there is a current dearth of online, publicly available information that provides clear insights into the nature and extent of RSIs.

Our case law analysis supplemented data from state government reports that examine the immediate physical complications impacting the patient. Our analysis highlighted patient circumstances related to the aftermath of not only living with an RSI but also psychosocial and emotional distress once a patient becomes aware of living with an RSI, information that only comes to light following the delayed discovery of the retained item.

The case law related to RSIs to date is very limited, with only nine civil cases and one coronial case dealing with this issue since the early 1980s, which is explained by the small number of claims that proceed to publicly available judicial determination. Further research could extend to reviewing trial transcripts, as well as de-identified insurance claims and settlement documents (if not subject to a confidentiality agreement). Nevertheless, our review of the decided cases indicates that current forms of risk management to minimise or eliminate the incidence of this sentinel event, including standards-based professional perioperative

practice and mandatory reporting of adverse events, are not always effective in preventing retention. Additional measures, including newer technologies for detection, should be explored, and those with clear evidence of effectiveness should be deployed where resources permit. In addition, estimates of the true risk of RSI in Australia can be improved by more standardised and consistent reporting of risk of RSIs – not just reporting of actual events but also near misses – and consistency across jurisdictions about the definition of RSIs, including whether it is limited to cases involving serious harm or death, and the timing of when an item is considered retained (for example, before or after wound closure, before or after leaving the operating room). Finally, this study has presented a starting point for a call to action for a consistent methodology, ontology and taxonomy for mining data from case law to inform better understanding of RSIs that can contribute to better estimates of the global nature and extent of the risk, as well as the problem.

Data sharing statement

The data (case reports) underpinning the results presented in this study are available from publicly available databases and repositories. Details of these databases and repositories are included in the supplementary material related to the search strategy.

Author contributions

SRO conceived the original idea and wrote the original study protocol and methodology, secured funding and resources, and provided project administration and supervision. JD contributed to the final methodology and collated and curated the case law data. JD extracted the data and material factual circumstances of the cases. TC supervised and verified data extraction from the case law data. SRO and JD prepared the original draft manuscript. All authors conducted the investigation and formal text analysis, including data validation. SRO and JD prepared tables and figures for data visualisation. All authors critically reviewed and edited the submitted manuscript. All authors approved the final submitted version of the manuscript and are accountable for their own contributions to the work.

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Disclosure

The authors have declared that no competing interests exist.

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Exploring risk, antecedents and human costs of living with a retained surgical item: A narrative synthesis of Australian case law 1981–2018

Supplementary materials

Supplementary material S1: Summary of legislative requirements for private and day hospitals to provide patient admitted data

Jurisdiction	Facilities licensed	Stated reporting requirement*	Data provided to DoHA**
New South Wales (NSW)	• private hospitals • day facilities In addition, there are 18 prescribed classes of private health facilities.	Required under legislation: • adverse events • root cause analysis • regular audit • admitted patient collection.	No
Victoria (VIC)	• private hospitals • day facilities	Required under legislation: • self-audit tool • episode level data • admitted patient collection.	No
Queensland (QLD)	• private hospitals • day facilities	Required under legislation: • sentinel events, including retained surgical items • root cause analysis • adverse outcome data on six-monthly basis • self-audit tool • admitted patient collection.	Informally
South Australia (SA)	• private hospitals, excluding day facilities	Provided voluntarily: • provision of documents for inspections.	No
Western Australia (WA)	• private hospitals • day facilities, A–D • private nursing posts • private psychiatric nursing hostels • private nursing homes	Required under legislation: • sentinel events, including retained surgical items • root cause analysis • mortality review • in-patient statistics.	Informally
Tasmania (TAS)	• private hospitals • day facilities	Provided voluntarily: • nil.	No
Northern Territory (NT)	• private hospitals, including day hospitals	• Provided voluntarily: • unknown.	No
Australian Capital Territory (ACT)	• health care facilities, including public, private and day hospitals	Provided voluntarily: • notifiable incidents • annual report.	

Table data organised by state and territory jurisdiction.[1]

DoHA = Department of Health and Aging, Australia

* Across Australian states and territories, the basis on which private hospitals provide admitted patient data is either that data provision is required by legislation or data provision is provided voluntarily.

** No jurisdiction has a formal arrangement in place with DoHA to provide DoHA with updates to licence details for private hospitals and day hospitals. Informal arrangements operate for two jurisdictions.

Supplementary material S2: Search strategy parameters

General parameters: date of publication limited to 1986–2018, searches limited to Australian case law, language restricted to English.

	Data bases	Other sources	Search terms
Part 1	1. Coroner court websites in all jurisdictions a. ACT – www.courts.act.gov.au/magistrates/courts2/coroners_court/selected-findings b. NSW – www.coroners.justice.nsw.gov.au/Pages/findings.aspx c. NT – www.justice.nt.gov.au/courts/coroners-decisions d. QLD – www.courts.qld.gov.au/courts/coroners-court/findings e. SA – www.courts.sa.gov.au/CoronersFindings/Pages/All-Findings.aspx f. TAS – www.magistratescourt.tas.gov.au/about_us/coroners/coronial_findings g. VIC – www.coronerscourt.vic.gov.au/home/coroners+written+findings h. WA – www.coronerscourt.wa.gov.au 2. Health practitioner tribunal websites in all jurisdictions a. ACT Civil and Administrative Tribunal – www.acat.act.gov.au b. NSW Civil and Administrative Tribunal – www.ncat.gov.au c. NT Civil and Administrative Tribunal – www.ntcat.nt.gov.au d. QLD Civil and Administrative Tribunal – www.qcat.qld.gov.au e. SA Health Practitioners Tribunal – www.healthpractitionerstribunal.sa.gov.au f. TAS Health Practitioners Tribunal – www.healthpractitionerstribunal.tas.gov.au g. VIC Civil and Administrative Tribunal – www.vcat.gov.au h. WA State Administrative Tribunal – www.sat.justice.wa.gov.au 3. AHPRA and national boards panel hearings – www.ahpra.gov.au	a. AIHW notifications contained in the AIHW Private and Public Sector Medical Indemnity Claims Report in Australia (initially only the last 5 reports were checked) b. NSW Clinical Excellence Commission and other state bodies c. National Health Practitioner Ombudsman and Privacy Commissioner d. Factiva for news articles on incidents e. Insurance claims and other data held by medical insurers f. Medical Incident Management Reports (IMMS in NSW, and similar reporting agencies in other Australian jurisdictions) g. Relevant policies and guidelines for anecdotal evidence (e.g. see the Australian Commission on Safety and Quality in Health Care)	Five categories of search terms are detailed below with draft terms. Terms within and across these categories were searched solely or in combination using Boolean logic; with different terms used, as appropriate, for research questions. Truncators and proximity operators were used as required. Bolded terms indicate starting point to generate initial broad sample. Doctor Surgeon **Doctor** Physician Health practitioner Nurse Nursing staff Theatre staff Hospital Medical practitioner Health care professional Health institution **Medical negligence** Medical negligence Clinical negligence Medical malpractice Negligence Duty of care Adverse event Medical error Res ipsa loquitur **Retained surgical instrument** RSI Retained instrument Surgical sponge Sponge Retained foreign object Retained foreign bod* Surgical mesh Mesh
Part 2	Databases 1. LexisNexis 2. AustLII 3. CCH IntelliConnect 4. Westlaw (AU) 5. Google Scholar		

Supplementary material S3: Brief descriptions of key databases and sources searched

AHPRA: The Australian Health Practitioner Regulation Agency (AHPRA) is the organisation responsible for the implementation of the National Registration and Accreditation Scheme for health professions across Australia. AHPRA works with 15 national health practitioner boards whose primary role is to protect the public. The boards relevant to this study include the Nursing and Midwifery Board of Australia and the Medical Board of Australia.

AustLII: The Australasian Legal Information Institute (AustLII) is a joint facility of the University of Technology Sydney (UTS) and the University of New South Wales (UNSW) faculties of law and is Australia's most popular online free-access resource for Australasian legal information, with over 700 000 hits daily.

LexisNexis: LexisNexis is a corporation providing computer-assisted legal research (CALR) that pioneered the electronic accessibility of legal and journalistic documents. The company has the world's largest electronic database for legal and public-records related information.

CCH IntelliConnect (Legal): CCH IntelliConnect offers streamlined legal and regulatory research, analysis and workflows for legal professionals, law firms, general counsel offices and corporate legal departments to assist with transparent, data-driven decision-making.

Westlaw (AU): Westlaw maintains a comprehensive library of resources in Australia to expedite searching by combining industry-leading legal expertise and the latest in smart technology.

Supplementary material S4: Sample search phrases used in LexisNexis

Search strings:

1. ("left in" OR retain OR retained OR "leave in" OR "forgot to remove") AND (inadvertent OR error OR miscount) AND (surgery OR surgeon) AND cavity
2. "failure to remove" AND surgery
3. "foreign body" and surgery
4. "foreign object" OR "foreign body" AND remove AND surgery OR operat*
5. "left in" OR retain OR retained OR "leave in" OR "forgot to remove" AND perioperative
6. "medical negligence" AND surgery AND retained
7. "res ipsa loquitur" AND surgery AND "medical negligence"
8. remove AND surgery AND error OR mistake OR accident AND "foreign body" OR "foreign object*" OR fragment OR instrument OR tool OR device OR sponge OR screw OR swab OR pin OR clip OR clamp OR tweezer OR "electrosurgical adapter" OR forceps OR scissor OR tip OR tube OR tubing OR "ultrasound tissue disruptor" OR bulb OR "laser guide" OR "guide wire" OR "guide-wire"
9. surgery OR surgical OR operat* AND retain* OR unretriev* OR forgot

Supplementary material S5: Data extraction for case law review

A standardised template (coding framework) was developed to guide data extraction of key features and findings of the cases for consideration in the analytical phase of the study and, in particular, features identified in the literature as being associated with retained surgical item events. Key features and findings extracted included:

- general case note: facts, issues and decision
- characteristics of patient (age, sex, location (rural/regional/urban), ethnicity, indigenous, non-English speaking, obesity status)
- characteristics of hospital (public/private)
- characteristics of personnel (junior/senior, nurse/surgeon)
- characteristics of operation (type, location of operation, date)
- item retained (e.g. sponge, raytex gauze swab, instrument, consumable item)
- reason given for retention of item (e.g. risk factors such as change in nursing personnel during surgery, excessive loss of blood, lack of a complete count of sponges and other surgical items, fatigue in the surgery team due to the lengthiness or lateness of the operation, urgency of the surgery, obesity of the patient, unexpected intra-operative developments, the involvement of multiple surgery teams, performance of more than one major procedure simultaneously)
- where retained item was left in patient (e.g. abdomen/pelvis, thorax, vagina, spinal cord, face, brain, extremity)
- when/how retained item was detected (e.g. number of days after the operation – range: day of surgery to >six years)
- was there disclosure of the adverse event to patient? When? By whom?
- patient outcome (e.g. death, readmission to hospital, prolonged hospital stay, sepsis/infection, fistula or small bowel obstruction, visceral perforation)
- type of hearing (e.g. civil/disciplinary/coronial)
- category of legal action (e.g. negligence, nervous shock, breach of contract, employment law)
- nature of hearing (e.g. procedural, first instance decision/trial, appeal)
- nature of defendant (nurse/doctor/hospital)
- nature of plaintiff (patient/relatives seeking compensation)
- legal outcome and decision, and rationale for decision
- amount of compensation paid and defence costs
- types of harm for which compensation was awarded (e.g. loss of income, cost of care, future medical costs, psychosocial damage)

Supplementary material S6: Summary of findings table (detailed)

Case citation [date]	Type of case	Date of retention (date of surgery)	Date of discoverability (of retained item)	Type of surgery (original)	Item(s) retained	Pathway to discovery	Antecedents	Factors and judges' ruling	Long term impacts/ consequences
Elliot v Bickerstaff [1999] NSWCA 453[2]	Civil appeal from a trial verdict	13 Jun 1991	Exact detail on date of discovery missing from record; however, noted from record 'it was necessary for the respondent to undergo further surgery for removal of the sponge about six weeks later'.	Total hysterectomy and colpo-suspension	Surgical sponge *[Author note: Final count correct – communicated and recorded.]*	All sponges and swabs accounted for [count correct] at the end of surgery on 13 June 1991. 'Physical problems afflicting the respondent led to discovery of the sponge…'	Trial judge inferred that 'there was a miscount or error by the theatre sister [i.e. operating room nurse] or a nurse subservient to her which resulted in unfounded assurances being given to the surgeon'.	The patient could not rely upon the maxim res ipsa loquitur. The appellant surgeon should not have been found liable as he did not breach his duty of care to his patient.	Item unintentionally retained for six weeks. Patient was left with a 'disfiguring scar from second operation and ongoing physical and psychiatric problems'.
Gaynor v Milton [&] Ulladulla Hospital [and two honorary staff doctors] (Unreported, Supreme Court of New South Wales Court of Appeal, Hope JA, Glass JA and Mahoney JA, 5 November 1981)[3]	Civil appeal (procedural) – Appeal against the case being taken from the jury	10 Jun 1975	Exact detail missing from record; however, record indicates operating room staff knew that missing piece of forceps was there before the operation was concluded.	Appendicectomy	Piece of forceps (about ½ inch) broken off in course of operation and left behind 'for reasons not explained'.	Operating room staff were aware the forceps had broken and decided to close the patient, check the x-ray, and remove the retained piece later [rationale not provided in record].	Exact detail missing from record. [Author note: Exact detail missing from record on date, if any, of subsequent operation to remove retained item.]	Appeal against first defendant (the hospital) dismissed. There must be a new trial against the 2nd and 3rd defendants (the surgeons); the plaintiff (patient) was entitled to have the case submitted to the jury. 'The doctrine [of res ipsa loquitur] will not be in applicable.	*[Author note: Exact detail missing from record to estimate how long item unintentionally retained.]* *[Author note: Detail missing from record on long-term impacts and consequences.]*
Hughes v Minister for Health in his capacity as Board of East Pilbara Health Service (Unreported, Supreme Court of Western Australia, Malcolm CJ, Pidgeon and Steytler JJ, 16 April 1999, 20 April 1999)[4]	Civil action (procedural) – Appeal against dismissal of application for permission to commence an action outside of limitation period	20 Dec 1994 – stitches holding drainage tubes in place were removed *[Author note: Patient re-admitted to hospital on 2 Dec 1994 and discharged on 4 Dec 1994. Patient re-admitted to hospital on 15 Dec 1994 and discharged on 22 Dec 1994.* Exact detail missing from record on actual date of surgery to insert drainage tubes]	21/22 Dec 1994 – missing left draining tube discovered. Patient discharged 22 Dec 1994. 19 Jan 1995 – missing left drainage tube confirmed retained in patient via scans. Time to confirmed discovery – 28 days. *[Author note: Actually 'missing' for about 35 days.]*	Insertion of two drainage tubes to drain fluid build-up. *[Author note: Date unclear].* Removal of stitches holding tubes in place (20 Dec 1994). Removal of right drainage tube (22 Dec 1994). Removal of retained left drainage tube 6 Feb 1995. *[Author note: removal approx. two more weeks after discovery to removal*	Left drainage tube *[Author note: When stitches removed, tubes were left protruding by 20 mm and covered with two dressings.]*	Patient suffered severe central abdominal pain, nausea, vomiting, constipation and fatigue and was unable to work and was referred. He underwent x-rays and an ultrasound scan which showed the missing drainage tube.	No additional details in record. *[Author note: Patient had four operations in Sep 1993, Jan 1994, May 1994 and Nov 1994 for repair of recurrent umbilical hernia prior to surgery to insert drainage tubes for wound seroma developed in previous surgery.]*	'…not a case for application of…res ipsa loquitor' Appeal allowed – patient granted permission (leave) to commence an action in terms of a proposed amended statement of claim. There was discussion about the contribution of the retained item to the patient's symptoms with the judge stating, '[t]he exclusion of the drain as the "prime cause for the excessive symptoms [the patient] now has" leaves the inference open that it was a cause'.	Item unintentionally retained for approx. 46 days. Continued to suffer from abdominal pain, fatigue and loss of enjoyment of life. Also claimed damages for loss of his earning capacity as a sign writer and painter and for medical and traveling expenses. *[Author note: Patient underwent subsequent surgery on 6 Feb 1995 at Bentley Hospital to have missing tube removed.]*
Ives v Australian Capital Territory and Anor BC9506456 (Unreported, Supreme Court of the Australian Capital Territory, Higgins J, 20 October 1995, 8 December 1995)[5] *The Australian Capital Territory v Ives* (Unreported, Federal Court of Australia, Gallop, Wilcox and Finn JJ, 16 April 1996, 26 July 1996)[6]	Civil action (procedural) – permission to commence action outside of limitation period	On or around 12 Mar 1974	11 Oct 1994 Time to discovery approx. 20 years, 5 months	Securing, resecuring or removing a Redivac™ draining tube in connection with a hysterectomy	Straight surgical suture needle *[Author note: Count correct implied.]*	Patient underwent a chest and spinal x-ray for an unrelated matter which revealed the presence of a metallic object in her heart.	Labelled an emergency; however, surgery was performed the day after admission so surgeon considered that it would not have been a 'rushed' operation.	Extension of time for filing claim allowed in part. *[Author note: A later application by the defendants for permission to appeal to the Full Court against this judgement approving extension to file was dismissed.]*	Medical opinion was that the needle should be left undisturbed but scanned annually. Since learning of the needle in her heart, the patient has become depressed and anxious.

Case citation [date]	Type of case	Date of retention (date of surgery)	Date of discoverability (of retained item)	Type of surgery (original)	Item(s) retained	Pathway to discovery	Antecedents	Factors and judges' ruling	Long term impacts/ consequences
Kenjar v ACT BC201402661 (Unreported, Supreme Court of the Australian Capital Territory, Master Mossop J, 17 April 2014)[7]	Civil action (procedural) – application to amend claim	26 Aug 2008 (k-wire insertion) 16 Sep 2008 (k-wire removal)	2 Oct 2008 Note: x-ray taken on date of surgery found to show k-wire fragment present.	Open reduction and multiple k-wire fixation of his right hand. *[Author note: Subsequent surgery to remove k-wires on 16 September 2008.]*	Piece of k-wire	Plaintiff was reviewed on 23 September. Presented at the hospital on 30 Sept 2008 with pain and swelling, necrotic skin and abscess in his right hand. Procedure undertaken to excise necrotic tissue and wash the abscess.	Exact detail missing from record.	Application dismissed as amendment was not supported by expert evidence.	Pain and swelling; subsequent procedure to remove necrotic skin and wash abscess that had formed. Claimed to have contracted a *Staphylococcus aureus* infection and suffered permanent injury to his right hand.
Langley v Glandore Pty Ltd (in liq) [1997] QCA 342 [8]	Civil appeal from negligence verdict against surgeons	22 Feb 1990	Exact detail missing from record; however, time to discovery described as 'some ten months later'.	Total abdominal hysterectomy	Sponge *[Author note: Correct count recorded. Nurse admitted to a counting error at trial.]*	Painful symptoms manifested themselves, leading to another operation performed some ten months later.	None of the witnesses had a recollection of anything untoward occurring in the course of the operation.	Judge indicated incorrect count performed by nurses. Appeal upheld – surgeons to recover from hospital in respect of damages owing to plaintiff.	Painful symptoms. From law text book – 'After the operation it became apparent, as a result of certain symptoms suffered by the woman, that a surgical sponge had been left inside her abdomen. The painful symptoms manifesting this fact were such that she was required to undergo a further operation some ten months after the first operation to have that sponge removed'.
Miller v Broadbent BC9905589 (Unreported, Supreme Court of Queensland, Muir J, 6 August 1999, 12 August 1999)[9]	Civil action (procedural) – permission to commence action outside of limitation period	Oct 1992	5 June 1996	Laparoscopy stomach banding operation	Silicon tubing	Exploratory surgery in abdominal cavity due to ongoing abdominal pain. 'On 5 June 1996 a piece of silicon tubing was discovered in and removed from the applicant's abdominal cavity in the course of exploratory surgery.'	Exact detail missing from record.	Judge agreed to hear submissions.	Abdominal pain; underwent various investigative procedures which failed to reveal source of pain.
O'Hagan v Sakker BC201140099 (Unreported, New South Wales District Court, Levy SC DCJ, 24 February, 15 April, 13, 27 May, 11 July 2011)[10]	Civil action (procedural) – permission to commence action outside of limitation period	10 Aug 1992	2 Oct 2007 *[Author note: X-ray in 2003 – later examination of that film (in 2010) revealed presence of pack in abdomen; patient not informed in 2003; fall in 2007 and subsequent x-ray for abdominal pain revealed intra-abdominal foreign body.]*	Hemi-colectomy / sigmoid colectomy	Surgical pack *[Author note: Correct count implied.]* *[Author note: pack removed 0 2 Oct 2007; although link to specific previous surgery not confirmed with patient until Sept 2010.]*	Patient suffered a fall and several days later was admitted to hospital suffering from abdominal pain, resulting in an abdominal x-ray which revealed the presence of the retained surgical item.	Exact detail missing from record.	Retained surgical pack had been overlooked and left behind following the procedure. Extension of time for filing claim allowed. '…case based on res ipsa loquitur … unatenable.'	Abdominal pain/cramping, fevers and loss of bowel control; psychosocial problems stemming from the retention of the pack, for which patient obtained psychiatric treatment; subsequent to pack removal patient preoccupied with deleterious effects on her health from retained pack and sought psychiatric treatment.
Smith v Marcus BC8902456 (Unreported, Supreme Court of New South Wales, Studdert J, 6 March 1989[11]	Civil action (procedural) – permission to commence action outside of limitation period	24 Nov 1977	24 Nov 1987	Hysterectomy and insertion of drainage tube	Redivac™ drainage tube 'measuring 125 mm in length' *[Author note: Detail on date of original drain removal procedure missing from record.]* 'On the 24 November, 1987, [a surgeon] explored her lower abdominal tranverse wound and removed the Redivac™ drain, measuring 125 mm in length.'	Patient suffered persistent pain and discomfort in the pelvic area. She underwent a series of tests over a number of years including a bowel x-ray, blood tests, medical examinations, an abdominal ultrasound. Retained surgical item was discovered by her doctor's further examination of IVP plates (not mentioned in the radiologists' report).	Exact detail missing from record. The plaintiff gave evidence of 'her recollection of a comment made by the first defendant [surgeon] when the tube was being removed to the effect that he "thought the tube was longer than that"'. Patient returned to surgeon for follow up; internal exam performed, patient informed that 'nothing was wrong'.	Extension of time for filing claim allowed	Pain and discomfort in the stomach and pelvic area, exacerbated by walking, over a period of ten years with multiple visits to many different health professionals. Advised to 'eat bran' and 'no fat diet'.

Case citation [date]	Type of case	Date of retention (date of surgery)	Date of discoverability (of retained item)	Type of surgery (original)	Item(s) retained	Pathway to discovery	Antecedents	Factors and judges' ruling	Long term impacts/ consequences
Record of *Investigation into Death (without inquest) of James Stirling McKinlay,* 2013 TASCD 142[12]	Coronial investigation	02 Jun 2012 'Then operating room nurse's report records that six small packs and one large pack were left in situ. It also records that 40 packs were used and the final count of packs removed is 33.' Patient transferred to Royal Hobart Hospital later that day.	14 June 2012	Follow-up surgery to address internal bleeding following a pancreatico-duodenectomy (Whipples procedure)	Surgical pack *[Author note: All intentionally retained surgical packs were not removed in subsequent surgery – one left behind.]*	Additional surgeries undertaken (4 and 11 Jun). During the surgery at Royal Hobart Hospital (RHH) on 4 June 2012, six packs were removed. A plain x-ray taken on 6 June 2012 shows the retained pack but it was not reported by the radiologist reading the film or seen by the managing doctors. A CT scan of the abdomen on 7 Jun again shows the retained pack which was not noted. Between then and 14 Jun 2012 Mr Turner became aware of the possible retention of one surgical pack in Mr McKinlay's abdomen. During another surgical procedure on 14 Jun 2012 a tightly compressed pack was discovered away from the site of the other packs and was removed.	Transferred between hospitals with an incomplete medical record and a lack of clear communication of the number of packs left in situ on the handover. 'Although the LGH nursing records of retained packs were correct, the medical record was incomplete. Mr McKinley was transferred to the RHH with a relatively brief accompanying letter. I have no doubt that there was considerable discussion through numerous phone calls but examination of the medical records reveals no clear formal communication of the number of packs left in situ on the handover. Patient 'was extremely ill and being treated in circumstances of emergency'.	'It is easy to appreciate how the retained pack might have been missed both on the handover and the X-ray in this case. He was extremely ill and being treated in circumstances of emergency.' Death occurred as a result of a fungal infection following major abdominal surgery for cancer. No other contribution to his death.	Retained pack did not contribute to death. Both hospitals were recommended to review their procedures with regards to retained packs.

Supplementary material S7: Pathway to discovery, antecedents, long term impacts

Case citation [date, state]	Pathway to discovery	Antecedents	Factors and judges' ruling	Long term impacts/consequences of living with a retained surgical item (human costs)
Elliott v Bickerstaff [1999, ACT][2]	All sponges and swabs accounted for [count correct] at the end of surgery on 13 Jun 1991. 'Physical problems afflicting the respondent led to discovery of the sponge…'	Trial judge inferred that 'there was a miscount or error by the theatre sister [i.e. operating room nurse] or a nurse subservient to her which resulted in unfounded assurances being given to the surgeon'.	The patient could not rely upon the maxim res ipsa loquitur. The appellant surgeon should not have been found liable as he did not breach his duty of care to his patient.	Item unintentionally retained for six weeks. Patient was left with a 'disfiguring scar from second operation and ongoing physical and psychiatric problems.
Gaynor v Milton [&] Ulladulla Hospital [1981, NSW][3]	Operating room staff were aware the forceps had broken and decided to close the patient, check the x-ray, and remove the retained piece later. *[Author note: Rationale not provided in record.]*	Exact detail missing from record. *[Author note: Exact detail missing from record on date, if any, of subsequent operation to remove retained item.]*	Appeal against first defendant (the hospital) dismissed. There must be a new trial against the 2nd and 3rd defendants (the surgeons); the plaintiff (patient) was entitled to have the case submitted to the jury. 'The doctrine [of res ipsa loquitur] will not be in applicable.'	Exact detail missing from record to estimate how long item unintentionally retained. Detail missing from record on long term impacts and consequences.
Hughes v Minister for Health East Pilbara Health Service [1999, WA][4]	Patient suffered severe central abdominal pain, nausea, vomiting, constipation and fatigue and was unable to work and was referred. He underwent x-rays and an ultrasound scan which showed the missing drainage tube.	No additional details in record. *[Author note: Patient had four operations in Sep 1993, Jan 1994, May 1994 and Nov 1994 for repair of recurrent umbilical hernia prior to surgery to insert drainage tubes for wound seroma developed in previous surgery.]*	'…not a case for application of…res ipsa loquitor' Appeal allowed – patient granted permission (leave) to commence an action in terms of a proposed amended statement of claim. There was discussion about the contribution of the retained item to the patient's symptoms with the judge stating, '[t]he exclusion of the drain as the "prime cause for the excessive symptoms [the patient] now has" leaves the inference open that it was a cause'.	Item unintentionally retained for approximately 46 days. Patient continued to suffer from abdominal pain, fatigue and loss of enjoyment of life. Also claimed damages for loss of his earning capacity as a sign writer and painter and for medical and traveling expenses. *[Author note: Patient underwent subsequent surgery on 6 Feb 1995 at Bentley Hospital to have missing tube removed.]*
Ives v Australian Capital Territory and Anor [1995, ACT][5] *The Australian Capital Territory v Ives* [1996, ACT][6]	Patient underwent a chest and spinal x-ray for an unrelated matter which revealed the presence of a metallic object in her heart.	Labelled an emergency; however, surgery was performed the day after admission so surgeon considered that it would not have been a 'rushed' operation.	Extension of time for filing claim allowed in part *[Author note: A later application by the defendants for permission to appeal to the Full Court against this judgement approving extension to file was dismissed.]*	Medical opinion was that the needle should be left undisturbed but scanned annually. Since learning of the needle in her heart, the patient has become depressed and anxious.
Kenjar v ACT [2014, ACT][7]	Plaintiff was reviewed on 23 Sep. Presented at the hospital on 30 Sep 2008 with pain and swelling, necrotic skin and abscess in his right hand. Procedure undertaken to excise necrotic tissue and wash the abscess.	Exact detail missing from record.	Application dismissed as amendment was not supported by expert evidence.	Pain and swelling; subsequent procedure to remove necrotic skin and wash abscess that had formed. Claimed to have contracted a Staphylococcus aureus infection and suffered permanent injury to his right hand.
Langley v Glandore Pty Ltd [1997, QLD][8]	Painful symptoms manifested themselves, leading to another operation performed some ten months later.	None of the witnesses had a recollection of anything untoward occurring in the course of the operation.	Judge indicated incorrect count performed by nurses. Appeal upheld – surgeons to recover from hospital in respect of damages owing to plaintiff.	Painful symptoms. From law textbook description of case – 'After the operation it became apparent, as a result of certain symptoms suffered by the woman, that a surgical sponge had been left inside her abdomen. The painful symptoms manifesting this fact were such that she was required to undergo a further operation some ten months after the first operation to have that sponge removed.'

Case citation [date, state]	Pathway to discovery	Antecedents	Factors and judges' ruling	Long term impacts/consequences of living with a retained surgical item (human costs)
Miller v Broadbent [1999, QLD][9]	Exploratory surgery in abdominal cavity due to ongoing abdominal pain; 'On 5 Jun 1996 a piece of silicon tubing was discovered in and removed from the applicant's abdominal cavity in the course of exploratory surgery'.	Exact detail missing from record.	Judge agreed to hear submissions	Abdominal pain; underwent various investigative procedures which failed to reveal source of pain.
O'Hagan v Sakker [2011, NSW][10]	Patient suffered a fall and several days later was admitted to hospital suffering from abdominal pain, resulting in an abdominal x-ray which revealed the presence of the retained surgical item.	Exact detail missing from record.	Retained surgical pack had been overlooked and left behind following the procedure. Extension of time for filing claim allowed. '…case based on res ipsa loquitur …unatenable.'	Abdominal pain/cramping, fevers and loss of bowel control; psychosocial problems stemming from the retention of the pack, for which patient obtained psychiatric treatment; subsequent to pack removal patient preoccupied with deleterious effects on her health from retained pack and sought psychiatric treatment.
Smith v Marcus [1989, NSW][11]	Patient suffered persistent pain and discomfort in the pelvic area. She underwent a series of tests over a number of years including a bowel x-ray, blood tests, medical examinations, an abdominal ultrasound. Retained surgical item was discovered by her doctor's further examination of IVP plates (not mentioned in the radiologists' report).	Exact detail missing from record. The plaintiff gave evidence of 'her recollection of a comment made by the first defendant [surgeon] when the tube was being removed to the effect that he "thought the tube was longer than that"'. Patient returned to surgeon for follow up; internal exam performed; patient informed that 'nothing was wrong'.	Extension of time for filing claim allowed	Pain and discomfort in the stomach and pelvic area, exacerbated by walking, over a period of ten years with multiple visits to many different health professionals. Advised to 'eat bran' and 'no fat diet'
Record of *Investigation into Death of James Stirling McKinlay* [2013, TAS][12]	Additional surgeries undertaken (4 and 11 Jun). During the surgery at Royal Hobart Hospital (RHH) on 4 June 2012, six packs were removed. A plain x-ray taken on 6 June 2012 shows the retained pack but it was not reported by the radiologist reading the film or seen by the managing doctors. A CT scan of the abdomen on 7 Jun again shows the retained pack which was not noted. Between then and 14 Jun 2012 Mr Turner became aware of the possible retention of one surgical pack in Mr McKinlay's abdomen. During another surgical procedure on 14 Jun 2012 a tightly compressed pack was discovered away from the site of the other packs and was removed.	Transferred between hospitals with an incomplete medical record and a lack of clear communication of the number of packs left in situ on the handover. 'Although the LGH nursing records of retained packs were correct, the medical record was incomplete. Mr McKinley was transferred to the RHH with a relatively brief accompanying letter. I have no doubt that there was considerable discussion through numerous phone calls but examination of the medical records reveals no clear formal communication of the number of packs left in situ on the handover. Patient 'was extremely ill and being treated in circumstances of emergency'.	'It is easy to appreciate how the retained pack might have been missed both on the handover and the X-ray in this case. He was extremely ill and being treated in circumstances of emergency.' Death occurred as a result of a fungal infection following major abdominal surgery for cancer. No other contribution to his death.	Retained pack did not contribute to death. Both hospitals were recommended to review their procedures with regards to retained packs.

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