Retained Surgical Items: Lessons from Australian Case Law of Items Unintentionally Left Behind in Patients after Surgery

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The retention of items within a patient after surgery is considered to be a serious issue within the health care community. Termined a “sentinel event”, a retained surgical item (RSI) is one of eight reportable adverse events deemed to have the potential to seriously undermine the health care system in the eyes of the public. Yet despite the gravity of these events, there has been little opportunity for the courts to examine the liability issues surrounding RSIs. This article reviews the limited case law in this area and analyses the key legal issues which arise in claims for redress, including civil, criminal and disciplinary liability, involving those who have suffered harm from RSIs.

Keywords: unintentional retained surgical item; unintentional retained foreign body; RSI, sentinel event; medical negligence; patient safety; perioperative practice; perioperative nursing

I. INTRODUCTION

A retained surgical item (RSI) occurs when a surgical item – such as a surgical sponge, gauze swab, or instrument – is inadvertently left behind in a patient. The retention of instruments or other material after surgery requiring reoperation or further surgical procedure is considered by the Australian Productivity Commission to be an event with “the potential to seriously undermine public confidence in the healthcare system”.1 A RSI is one of eight core reportable events, also known as “sentinel events”, that “occur because of hospital system and process deficiencies, and which result in the death of, or serious harm to, a patient”.2 Sentinel events are also known as “never events” as they should be preventable if standard procedures are followed.3 About 360 sentinel events are reported per year as part of routine data, with about 100 sentinel events being reported via specific reporting systems annually.4

RSIs are a comparatively uncommon type of sentinel event. Between 2005/2006 and 2015/2016, 322 incidents of RSIs requiring reoperation were reported.5 However, this form of adverse event is still sufficiently prevalent to raise concerns, especially when it is considered that retained items may remain in the patient for many years before discovery, resulting in significant harm, pain and suffering. Yet, despite the potentially grave consequences of RSI, there appears to be limited consideration of RSI

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3 S Duckett et al, Safer Care Saves Money: How to Improve Patient Care and Save Public Money at the Same Time (Grattan Institute, 2018) 14.
4 Duckett et al, n 3, 15.
events in the case law. This study involved a review of civil cases, medical disciplinary cases, coroners’ cases, and criminal cases across all Australian jurisdictions from 1981 to 2018. The study date range was chosen to commence in 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. The authors were able to locate only 10 Australian cases since 1981 which concerned a RSI.

It is speculated that the large disparity between the reported number of RSI cases and the number of RSI legal cases may be due to the private settlement of cases. Indeed, according to the Australian Institute of Health and Welfare, of the 5,309 private and public sector medical indemnity claims closed between 1 July 2012 and 30 June 2013, 21% were finalised through negotiation, 75% were discontinued, and only 4% were finalised through a court decision. This finding is consistent with the phenomenon of the vanishing trial, notably highlighted by Professor Marc Galanter in 2003, who found that the proportion of matters resolved through trial in the United States had fallen to 1.5% in 2002, down from 11.8% in 1962. The resolution of matters by way of trial is also on the decline in Australia, with a study of the civil filings in the Sydney Registry of the New South Wales District Court finding that the incidence of filings in 2004 was less than one-third of the number of filings in 1990. This study also found an increase in the number of cases that settled once listed for trial which corresponded with a decline in cases disposed of by trial. While it is unclear why this is the case, it has been speculated that the availability of dispute resolution and adjudicatory processes, as well as judges taking on a more proactive role as case managers, may be in part responsible for such settlements.

A majority of the 10 cases reviewed in this study were unreported, with only two involving a final consideration of liability and damages. One matter was a Tasmanian Coroners Court decision while the remaining seven cases were procedural actions in which the plaintiff sought leave to amend their statement of claim, appeal against the dismissal of a matter, or appeal to commence proceedings outside of the civil limitation period. The procedural nature of these latter cases is indicative of a striking feature of RSI, namely, the possibility of a lengthy delay between the item being retained and its discovery. Despite the scarcity of case law in this area, the available cases provide useful guidance as to the courts’ treatment of liability issues in these circumstances. Additionally, given the “vanishing” nature of civil litigation in Australia, the question remains as to how to promote patient-reported experiences effectively within the hospital system in this context.

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6 The cut off date for searches was 1 November 2018.
11 Spencer, n 10, 23.
12 Hayne, n 9, 4.
14 Magistrates Court of Tasmania – Coroners Court, Record of Investigation into Death (without Inquest) of James Stirling McKinlay, 2013 TASCD 142.
16 Gaynor v Milton (Unreported, Supreme Court of New South Wales Court of Appeal, Hope, Glass and Mahoney JJA, 5 November 1981).
17 Ives v Australian Capital Territory (Unreported, Supreme Court of the Australian Capital Territory, Higgins J, 20 October 1995, 8 December 1995); Australian Capital Territory v Ives (Unreported, Federal Court of Australia, Gallop, Wilcox and Finn JJ, 16 April 1996, 26 July 1996); Miller v Broadbent (Unreported, Supreme Court of Queensland, Muir J, 6 August 1999, 12 August 1999); Smith v Marcus (Unreported, Supreme Court of New South Wales, Studdert J, 6 March 1989); O’Hagan v Sakker (2011) 12 DCLR (NSW) 329; [2011] NSWDC 60.
This article identifies and critically evaluates key themes which emerged from our analyses of the case law. Part II considers issues relating to attributing liability and establishing causation in the context of the changing role of the surgeon; Part III discusses issues relating to record-keeping and the implications for defending RSI cases; and Part IV critically evaluates the implications of alternative dispute resolution and RSI cases.

II. ATTRIBUTING LIABILITY AND ESTABLISHING CAUSATION IN RSI CASES: THE CHANGING ROLE OF THE SURGEON

The duty of care owed by a medical practitioner to their patient was articulated by the Australian High Court in *Rogers v Whitaker*. It is a comprehensive duty to exercise reasonable care and skill in the provision of professional advice and treatment.

The limited number of cases concerning RSIs identified in our study revealed the presence of disputes regarding attribution and apportionment of liability between various potential defendants. In particular, disputes generally arose about whether a surgeon ought to be held wholly liable for an event which may have also involved other members of operating room staff. In fact, it is asserted that this dispute ( attribution and apportionment of liability) is the main factor which prevents such matters from settling and results in the matter proceeding to a judicial determination by the courts.

In *Langley & Warren v Glandore Pty Ltd & Thomson*, a sponge was retained in a patient’s abdomen after a total abdominal hysterectomy in 1990. The surgery was carried out by two surgeons who were not employees of the private Mount Isa Hospital in which the surgery took place. At trial the principal surgeon was considered to be “in charge” of the surgery and was supported by the assistant surgeon and the operating room staff employed by the hospital, including two nurses, one in the role of “scrub” or instrument nurse and one in the role of “scout” or circulating nurse. These nurses were found to have made an incorrect tally, in which the number of sponges opened for use in the surgery was incorrectly balanced against the number of sponges retrieved at the end of the procedure. The patient made allegations of negligence against both the surgeons and the nurses, which led to the hospital (as the nurses’ employer) being joined.

The surgeons based their case both at trial and on appeal on the claim that:

> [U]nder the procedures in place and relied upon by all concerned in the operation, the primary duty for establishing that a correct count had been made of all items, instruments, sponges, packs and the like to establish that they had all been retrieved from the plaintiff’s body at the conclusion of the operation, lay upon the nurses.

At trial the jury found that the principal surgeon was liable in negligence, but determined that the nurses were not liable. However, in 1997 the jury’s verdict was set aside on appeal. The Queensland Court of Appeal held that it was unsound for the jury to find that the surgeon was guilty of negligence in failing to retrieve a sponge, yet find that the nurses, who had primary responsibility for accounting for all of the sponges used during the surgery, were not guilty of negligence. The Court of Appeal set aside the trial decision and ordered Glandore Pty Ltd, the company operating the private hospital, to pay the patient $527,000 with interest and costs, which was the amount awarded at trial relating to consequences of the surgical pack being left in the plaintiff’s abdomen. Any contribution proceedings between the hospital as employer of the nurses and the doctors were remitted to the trial judge.

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In *Elliott v Bickerstaff*, a sponge was retained in the patient’s abdominal cavity after she underwent a hysterectomy and colposuspension. The surgery was performed by a specialist surgeon at a private hospital, with assistance from the operating room staff employed by the hospital. At trial, it was inferred that the nurses miscounted the number of sponges used, which resulted in the surgeon being mistakenly informed that all of the sponges used had been retrieved. The surgeon, but not the hospital, was sued by the patient for damages in negligence. At trial, the surgeon was found liable, despite a lack of personal negligence, due to a finding that his duty of care to the patient was non-delegable. Damages were assessed at $167,108.15. This finding was later rejected by the Court of Appeal in 1999, which held that the surgeon did not owe a non-delegable duty of care to his patient and was therefore not liable for the operating room staff’s failure to keep proper count of the sponges used during the surgery. Rather, it held that a surgeon’s duty of care required the taking of reasonable care and skill in searching for any sponges that might be remaining in the surgical wound and checking whether the sponge count tallied. The Court of Appeal found that the surgeon should not have been found liable for the harm to the patient and upheld his appeal.

By bringing her claim solely against the surgeon in this instance, the patient was unable to fall back upon the liability of the hospital as the employer of nurses.

The decisions in the two cases described above deal with the surgeon’s role in the operating room as the leader of a team of skilled staff each of whom is responsible for his or her own independent tasks. The Court in *Langley & Warren v Glandore Pty Ltd & Thomson* specifically stated that it was not a “helpful analogy” to liken a head surgeon to the “captain of the ship”, a doctrine first raised in the United States case of *McConnell v Williams* which has been repudiated or refused by a number of States in the United States.

In contrast, the Court in *Elliott v Bickerstaff* referred with approval to the 1936 decision of *Ingram v Fitzgerald* which regarded the operating room nurses as “skilled collaborators with independent duties”. Giles JA held in that case that although a surgeon could be regarded as the “master of ceremonies”, he or she was entitled to rely on the other members of the team to discharge their responsibilities, such as ensuring a proper count. This formulation of the surgeon’s role was cited with approval by the New South Wales Court of Appeal in 2018.

The characterisation of a principal surgeon as a “master of ceremonies” rather than a “captain of the ship” reflects the role of surgeons in modern operating rooms increasingly defined by complex technology, specialisation, and the division of responsibility among operating room staff. It also corresponds with the current Standards for Perioperative Nursing in Australia, published by the Australian College of Perioperative Nurses, which state 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”. The finding that surgeons are not generally liable for the negligence of hospital staff also recognises that modern hospitals have evolved into large organisations which can

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30 *McConnell v Williams* 65 A2d 243 (Pa, 1949).

31 EK Murphy, “‘Captain of the Ship’ Doctrine Continues to Take on Water” (2001) 74(4) AORN Journal 525, 525.


35 Murphy, n 31, 526.

insure themselves against patient claims for compensation in cases where they may be found vicariously liable for employee negligence.37

The reviewed cases’ characterisation of the surgeon’s role also reflects the waning power of the common law doctrine of res ipsa loquitur in Australian medical jurisprudence. Res ipsa loquitur, literally translated as “the thing speaks for itself”, is a principle which “permits, but does not require, an inference of negligence to be drawn from the mere fact that an accident occurred and an injury was sustained”.38 In Elliott v Bickerstaff, the defendant submitted that res ipsa loquitur could be relied upon to establish the surgeon’s liability, stating that “if ever there was a res ipsa situation … this is one”.39 However, the Court found that while the retention of a surgical sponge in a patient’s abdominal cavity may be evidence of negligence, it did not necessarily indicate negligence on behalf of the surgeon in a circumstance where he was incorrectly assured by nursing staff that the sponge count tallied correctly. In doing so, the Court drew upon the findings in the South African case of Van Wyk v Lewis40 and the New Zealand case of Ingram v Fitzgerald41 which cast doubt on the use of the res ipsa maxim when surgery is carried out by a team of surgical staff operating under a system of divided yet shared responsibility.42

The Australian Capital Territory Supreme Court in Kenjar v Australian Capital Territory43 agreed with the reasoning of the New South Wales Court of Appeal in Elliott v Bickerstaff with respect to the application of res ipsa loquitur in cases of RSIs. In this case, a K-wire fragment was left in the hand of the plaintiff during surgery. A K-wire (or Kirschner wire) is a type of stabilisation wire or pin used for temporary fracture fixation during orthopaedic surgery. The plaintiff returned to the hospital complaining of pain and swelling in his hand. After undergoing a second operation to remove the fragment, he contracted a Staphylococcus aureus (golden staph) infection and claimed to have suffered permanent injury to his right hand. The plaintiff sought leave to amend his further amended statement of claim to include particulars pertaining to a failure to detect and remove the K-wire fragment during the course of the initial operation, or during subsequent operations. However, the Court found that the expert evidence led by the plaintiff did not demonstrate an arguable case of negligence to a sufficient degree to make it appropriate to grant the amendment, stating that: “Leaving broken bits of fixation devices inside the body of a patient and apparently failing to see them when they are clearly shown on the image intensifier films are clearly matters which give rise to concern. However, as the decision in Elliott v Bickerstaff illustrates, the fact that an item is incorrectly left inside a patient does not necessarily prove negligence on the part of the surgeon”.

III. RECORD-KEEPING: IMPLICATIONS FOR DEFENDING RSI CASES

Many of the RSI cases reviewed illustrate the importance of maintaining complete and accurate medical records. The Tasmanian Coroners Court inquiry into the death of James Stirling McKinlay44 found that a surgical pack was left in the abdomen of the deceased due to his being transferred to the Royal Hobart Hospital with an incomplete medical record which failed to communicate the number of packs intentionally left in situ at the time of the handover. While Coroner Pearce found that the retained pack did not contribute to the patient’s death, he made the following recommendations with respect to limiting the risk of RSIs:

To the extent that counting packs is to be used as a means of controlling risk then particular care should be taken to ensure accuracy of recording, consistency of recording between nursing and medical staff and

37 Lewis v Physicians Insurance Co et al, 627 NW2d 484 (Wis, 2001).
38 LexisNexis, Encyclopaedic Australian Legal Dictionary (at 20 August 2018): “res ipsa loquitur”.
40 Van Wyk v Lewis (1924) App D (S Af) 438.
41 Ingram v Fitzgerald [1936] NZLR 905.
44 Magistrates Court of Tasmania – Coroners Court, Record of Investigation into Death (without Inquest) of James Stirling McKinlay, 2013 TASCD 142.
clear and easily accessible communication of information between practitioners and hospitals, particularly on transfer between hospitals. 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.45

While leaving packs in intentionally, with plans to remove them in a subsequent procedure, is sometimes employed as a temporary option to control bleeding or to allow wound healing by secondary intention, such as in the case of an infected wound, this case highlights the imperative of accurate documentation and communication of intentionally retained items, particularly where the clinical setting or the team charged with removing the item may differ from the context in which the original operation took place. As well as potentially contributing to an adverse event as demonstrated by the above case, deficient record-keeping has been found to be detrimental to medical practitioners’ ability to defend claims. A central issue surrounding RSI is the possibility of a lengthy delay between the harm caused and its discovery. As a result, applications for leave to commence proceedings outside of the civil limitation period constitute a large proportion of the reviewed cases.46 New South Wales, the Australian Capital Territory, and Victoria have legislated to require that medical records should be kept for a minimum of seven years from the date of last entry for an adult and until the age of 25 for a child.47 While some of the foreign objects left in the patients were discovered soon after their retention, some were only discovered after a lengthy period. In O’Hagan v Sakker, a retained surgical pack was located 15 years after the relevant operation. By this time, the foreign body was described to be about the size of a grapefruit and the claimant had suffered through multiple operations and years of pain and illness.48 The passage of time, coupled with a lack of records and an absence of recollection on the part of the surgeon, meant that the surgeon’s evidence regarding the surgery was limited. The defendant surgeon gave evidence about usual hospital practice and procedures as at the operation date in 1992 and claimed that it was “his unerring practice not to close a patient unless and until he was satisfied that the initial count of surgical items matched the final count”.49 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, as the District Court Judge declared:

[M]ost 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.50

The Court held that the plaintiff had identified a triable case and allowed an extension of time to file proceedings.

The absence of complete medical records was also an issue in Ives v Australian Capital Territory,51 and its subsequent appeal on a procedural point.52 This matter involved the retention of a straight needle53

45 Magistrates Court of Tasmania – Coroners Court, Record of Investigation into Death (without Inquest) of James Stirling McKinlay, 2013 TASCD 142, [15].
46 Ives v Australian Capital Territory (Unreported, Supreme Court of the Australian Capital Territory, Higgins J, 20 October 1995, 8 December 1995); Australian Capital Territory v Ives (Unreported, Federal Court of Australia, Gallop, Wilcox and Finn JJ, 16 April 1996, 26 July 1996); Miller v Broadbent (Unreported, Supreme Court of Queensland, Muir J, 6 August 1999, 12 August 1999); Smith v Marcus (Unreported, Supreme Court of New South Wales, Studdert J, 6 March 1989); O’Hagan v Sakker (2011) 12 DCLR (NSW) 329; [2011] NSWDC 60.
47 Health Practitioner Regulation (New South Wales) Regulation 2016 (NSW) r 10; Health Records and Information Privacy Act 2002 (NSW) s 25; Health Records (Privacy and Access) Act 1997 (ACT) Sch 1, Principle 4.1, s 3(b); Health Records Act 2001 (Vic) Sch 1, Principle 4, 4.2.
51 Ives v Australian Capital Territory (Unreported, Supreme Court of the Australian Capital Territory, Higgins J, 20 October 1995, 8 December 1995).
52 Australian Capital Territory v Ives (Unreported, Federal Court of Australia, Gallop, Wilcox and Finn JJ, 16 April 1996, 26 July 1996).
53 Straight needles are about two inches long, a fact which has the potential to make the retention of straight needles all the more distressing.
after a hysterectomy in 1974. This needle had allegedly moved over time from the patient’s abdomen to a chamber in her heart. The defendant surgeon led evidence that:

It was standard practice for all needles to be counted at the conclusion of the operation and to check them off against the record of those used. This was done on a whiteboard by a 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.54

The surgeon’s evidence as to his standard practice was confirmed by a nurse who often assisted him. However, no record of the count was available as evidence as it was not usual practice to keep permanent records of counts at the time. In this matter, leave to extend was refused against the defendant surgeon on separate prejudice grounds. However, leave to extend was granted in respect to the hospital, despite the argument that the operating room record and clinical notes relating to Mrs Ives’ procedures were unavailable. The Court held that the prejudice experienced by the hospital due to the elapse of time and loss of relevant evidence was “inevitable in some degree” and not sufficient to preclude an extension of time.55 As such, these cases underscore the need for consistency and accuracy in documentation of patient care, including relevant factors related to context and process. Furthermore, they highlight the risk management benefits for hospitals of retaining documentation, particularly in the form of patient medical records (but perhaps also in the form of supplementary records such as incident reports or count sheets), longer than the standard period in order to provide evidence in respect of RSI which possibly may only be discovered many years after the fact.

IV. THE IMPLICATIONS OF VANISHING RSI CASES

Case law in the area of RSIs is scarce. It is speculated that the gap between the reported number of RSI cases identified through mandatory reporting mechanisms and the number of RSI cases litigated is due to claims being settled privately between the parties. While such negotiations and early settlement of claims may limit the parties’ legal costs and reduce pressure on the judicial system, they often involve confidentiality agreements which prevent disclosure and may assume states of affairs which have not been tested by the courts.56 A reduction in matters brought to trial limits the development of and access to principles that litigators can draw upon to negotiate a just and reasonable settlement.57 In contrast, court determinations ensure that the legal analysis of factual situations is placed on the public record, creating precedents which can provide guidance to potential litigants, judicial officers, and policymakers.58 Litigation demonstrates the common risk factors for RSIs and provide examples of the harms caused, causing RSI to be better understood by the medical community and public.59

Additionally, civil trials serve as avenues for public accountability and healing, as plaintiffs bear witness to the harms that they have suffered and seek redress. In the case of Smith v Marcus, a drainage tube was discovered in the plaintiff’s abdomen some 10 years after it was retained. The plaintiff suffered from persistent pain during the retention period but she was told by her doctors that “everything was fine”, that she should “eat bran” and avoid “fatty foods”.60 As a “relatively unsophisticated lady”, the plaintiff “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”.61 By applying

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54 Ives v Australian Capital Territory (Unreported, Supreme Court of the Australian Capital Territory, Higgins J, 20 October 1995, 8 December 1995) [3].
55 Australian Capital Territory v Ives (Unreported, Federal Court of Australia, Gallop, Wilcox and Finn JJ, 16 April 1996, 26 July 1996) [13].
57 Landsman, n 56, 978.
58 Landsman, n 56, 977.
59 Landsman, n 56, 977.
60 Smith v Marcus (Unreported, Supreme Court of New South Wales, Studdert J, 6 March 1989) [2].
61 Smith v Marcus (Unreported, Supreme Court of New South Wales, Studdert J, 6 March 1989) [10].
to the Court to extend the limitation period on her pleading, the plaintiff was given the opportunity to speak up and be heard after years of being undermined and ignored by medical practitioners.

Despite the public and private benefits of medical negligence trials, it is likely that they will continue to disappear from legal system. It is therefore imperative that rigorous reporting mechanisms are implemented and utilised to ensure that medical issues remain in the public consciousness. Currently, much reporting about incidents of harm to patients and “near misses” is voluntary and lacking in comprehensiveness and representativeness. Incident reporting is conducted by hospitals and medical practitioners, with details de-identified in order to safeguard patient privacy. However, this system of reporting inadvertently serves to de-humanise the individuals who are the subjects of these reports.

Patient-reported experience measures (PREMs) and patient-reported outcome measures (PROMs) are emerging reporting categories of hospital outcomes data which may provide patients with greater agency with respect to their care. PREMs record patients’ experience of their hospital stay while PROMs may report symptom severity, pain, function, or quality of life. Collecting and sharing these measures may assist hospitals to engage with patients about the quality of their experience and promote patient-centred care. By doing so, it is to be hoped that incidents of RSI will be forestalled or recognised rapidly, limiting harms to patients and the need for further litigation in this area. Ultimately, public development and sharing of information, whether in the form of litigation or reporting, is fundamental for progress in this area.

V. CONCLUSION

RSIs are regarded by the Australian medical community as “never events” and undermine public confidence in the health care system. Despite the significant harms which may arise from RSIs, there is a large disparity between reported RSI events and the number of RSI cases that are litigated in the courts. This review located only 10 Australian cases since 1981 which dealt with the issue of medical practitioner liability for a RSI, seven of which were procedural. Despite the paucity of judicial decision-making in this area, the cases that are available serve to illuminate two important aspects of surgical practice. First, is the contemporary nature of operating room practice in which surgeons and operating room staff work as a team with shared responsibility and shared accountability for patient safety. Second, is the importance of keeping complete and accurate records, which may need to be drawn upon beyond the standard time-keeping period. The cases also indicate that the current forms of risk management, including counting and documenting items used during surgery, are not always effective in preventing retention and as such, additional measures should be explored. In an environment of diminishing numbers of civil trials and increasing health care reporting, this review also considers that PREMs and PROMs may be a powerful means of promoting patient agency in Australian health care.


63 Duckett, Jorm and Danks, n 62, 16–18.