



The High Cost of Inaction

How retained surgical sponges harm hospital finances and reputations

Executive summary

It's not something that any healthcare leader or medical professional wants to see on local TV or splashed across a newspaper's front page: A 38-year-old patient at a California hospital files a lawsuit following the grisly discovery of a large lap towel left in her abdomen two years after having had surgery at the hospital.¹ The standard sponge count done after the surgery had been falsely reported as correct. A second surgery has had to be conducted to remove the mass, which involved severe bowel adhesions. Part of her uterus, including her fallopian tubes, was incorporated into the mass. Surgeons were able to free her small bowel and sigmoid colon from the lap pad, and she was treated with intravenous antibiotics for 48 hours. The patient lost a section of her colon.

The woman's insurance company, citing a policy in its contract with the hospital, refused to pay for the second surgery to remove the mass. The state swept in to investigate the incident and fined the hospital \$100,000, providing the full documentation of its probe to the media. The case had to be reported as a sentinel event to the Joint Commission and a root cause analysis and report on corrective actions compiled. A financial settlement was reached with the patient.

In the unique nomenclature of healthcare, surgical sponges mistakenly left inside patients following surgeries are called "retained surgical items" or "retained foreign objects." Sponges make up about two-thirds of all objects left inside patients; the remainder are wires, pieces of surgical tools and sometimes full instruments.²

As the case above shows, for such benignly named events, retained sponges often have devastating results. Nobody comes out well. Patients face at best a second surgery to remove the towel or gauze; at worst they endure significant loss of function or even a painful death. Physicians face litigation and investigations by internal review boards, and must report the case to the National Practitioner Data Bank, a searchable public repository of malpractice claims. Nurses, who are responsible for sponge counts that must be reconciled after surgery, are also dragged into litigation, and must defend their actions in medical reviews and court testimony. Nurses also must deal with the emotional toll of having contributed to a serious medical error. Hospitals face paying for the costs of medical care for the surgery to remove the sponge and are often forced to pay the biggest share of a settlement as the "deep pocket." They also take a huge hit to their reputation, as local media covers the litigation and national ratings organizations account for these errors.

With health reform's focus on high-quality, safe and patient-centered care – as well as new healthcare delivery models such as accountable care organizations that put providers at risk for both cost and quality – a preventable medical error such as a retained sponge is harder to justify than ever before.

An overwhelming amount of clinical evidence shows that manual counting of sponges – even when carried out under evidence-based guidelines – often fails as a result of human error and other factors.

This paper is an update of a 2013 white paper and article in *Becker's Hospital Review*³ that garnered widespread attention in the healthcare industry as the most comprehensive look at the true cost of retained surgical sponges. It lays out the business and clinical case for positive action to prevent retained sponges, including the use of assistive technology to make the sponge count far more accurate. That includes barcoded surgical sponges, radiopaque material (visible on X-ray) and radio frequency identification (RFID) systems.

¹ California Department of Public Health, CCDPH Issues Penalties to Eight Hospitals, July 24, 2014, accessed online at <http://www.cdph.ca.gov/Pages/NR14-065.aspx>

² O'Connor A. When Surgeons Leave Objects Behind. *New York Times*, 24 Sept 2012

³ Sloane T. The High Cost of Inaction: Retained Surgical Sponges are Draining Hospital Finances and Harming Reputations. *Becker's Hospital Review*. 12 Aug 2013.

Medical malpractice insurers, payers, accreditation agencies and associations have called on providers to examine the potential of these technologies to reduce the frequency of this “never event.”

This paper shows an average malpractice case involving a retained surgical item such as a sponge costs a hospital more than half a million dollars in indemnity payouts and defense expenses. These data underscore the significant cost avoidance/risk mitigation benefits associated with an investment in assistive technology.

The anatomy of a never event

Surgical sponges range from small gauze pads to full towels, some measuring more than a square foot. The clinical term for a retained surgical sponge is *gossypiboma*, which comes from the Latin for cotton, *gossypium*, combined with the Swahili for place of concealment, *boma*. It is an accurate term, in that a retained sponge is good at hiding. Immediately after surgery, a *gossypiboma* is often mistaken for an abscess. As they are soft goods, they produce unclear images on X-rays, appearing as a mass or tumor or simply part of an organ or bowel. As the soft material shifts in the body, it produces vague, inconsistent symptoms.

A clinical account of a case involving a 28-year-old female is illustrative:

“She came in four weeks after a Caesarean section because of unusual stomach pains and was examined. The ultrasound showed nothing abnormal and she returned home. However, six months later she came back because the stomach pains were persisting. This time, the ultrasound showed an obvious mass in her stomach extending from her pelvic area to the navel. The woman then underwent surgery under the assumption that she had an ovarian tumor. Surgeons cut through her abdominal wall to see a huge mass stuck to the last three feet of her small intestine and the right colon with large associated local lymph nodes. Since the doctors thought the mass was a tumor likely to spread or even cause death, the mass was immediately removed, taking with it part of the small intestine and right colon. After surgery, the mass was cut open and was full of about 2 liters of yellow pus and fluid with a large surgical pack (sponge) in the middle of an abscess cavity wall.”⁴

That patient survived, but a retained sponge can also lead to death, as the case of Geraldine Nicholson of Lumber Bridge, N.C., demonstrates.

Prior to her death, Nicholson spent a year in a hospital with complications after surgery to remove cancerous tissue in her rectum and colon. A surgical sponge measuring more than a square foot was left inside her abdominal cavity, and it stayed there for 10 weeks. The sponge created infections and other complications that disqualified Nicholson from receiving cancer treatment that could have saved her life, testimony at the malpractice trial of Arleen Kaye Thom, MD, showed. The surgeon had failed to order a sponge count before concluding the surgery. A jury agreed that Thom acted with negligence, and a judge ordered her to pay \$5.1 million to Nicholson’s estate and \$750,000 to Nicholson’s husband.

⁴ Lata I, Kapoor D, Sahu S. Gossypiboma, a rare cause of acute abdomen: A case report and review of literature. *International Journal of Critical Illness and Injury Science*. 2011;1(2):157-160.

Other outcomes include fistulas, which are incredibly painful masses that conjoin separate organs, and perforations of the bowel. Many patients with retained sponges in their abdomen wind up wearing ostomy bags to evacuate waste for the rest of their lives.

Outcomes of 90 patients with RSIs across two retrospective case-control studies	
Outcomes	No. of cases
Death	1
Readmission to hospital	40
Reoperation	62
Intra-abdominal abscess or sepsis	26
Small bowel obstruction/intestinal fistulation	10
Visceral perforation	5

Sources: Gawande AA, Studdert DM, et al. Risk Factors for Retained Instruments and Sponges after Surgery N Engl J Med 2003;348:229-35.; Lincourt AE, Harrell A, et al. Retained Foreign Bodies after surgery. J Surg Res. 2007 Apr;138(2):170-4

Rate of occurrence

The true incidence of retained surgical items is not precisely known, ranging from one in every 1,500 abdominal surgeries to one in every 18,000 inpatient procedures.⁵ A lack of transparency in reporting is cited by many experts as causing this imprecision.

Most researchers now cite as benchmarks two large-scale studies, a four-year project at Mayo Clinic⁶ and the other at five large teaching institutions covering 41 1,526 inpatient surgeries.⁷ The Mayo study found an incidence of one in 5,500 operations. The multicenter study estimated an overall RSI incidence of one in 6,975 cases.

Another study, by Johns Hopkins patient safety researchers, looked at data from the National Practitioner Data Bank, a federal repository of medical malpractice claims, to identify malpractice judgments and out-of-court settlements related to an array of medical errors, including retained objects. They calculated that a surgeon in the United States leaves a sponge or a towel inside a patient’s body after an operation 39 times a week.⁸

Sponges are most often left in the abdomen, but almost any surgery can result in a retained sponge. In March 2016 a lawsuit was filed against an Oklahoma hospital after a surgical sponge was left inside the knee of a runner who underwent arthroscopic surgery.⁹ Gauze has been left in the sinus of patients undergoing rhinoplasty and fibers of sponges have been found in the eyes of patients being treated for cataracts.¹⁰

⁵ Cima RR, Kollengode A, et al. Using a Data-Matrix-Coded Sponge Counting System Across a Surgical Practice: Impact After 18 Months. *Jt Comm J Qual Patient Saf.* 2011 Feb;37(2):51-8.

⁶ Cima RR, Kollengode A, et al, Incidence and characteristics of potential and actual retained foreign object events in surgical patients. *J Am Coll Surg.* 2008 Jul;207(1):80-7.

⁷ Stawicki SP, Moffatt-Bruce SD, et al, Retained surgical items: a problem yet to be solved. *J Am Coll Surg.* 2013 Jan;216(1):15-22.

⁸ Mehtsun WT, Ibrahim AM, et al. Surgical never events in the United States. *Surgery.* 2013 Apr;153(4):465-72.

⁹ Falsetti J, Lawsuit alleges Mercy Hospital left medical equipment in woman’s knee, Fox25 News, 2016 Mar 17

¹⁰ Stawicki SP, Evans DC, Cipolla J, et al. Retained surgical foreign bodies: a comprehensive review of risks and preventive strategies. *Scand J Surg.* 2009;98:8-17.

“Unlike the majority of instruments, sponges are used in very high numbers during a case. They are used by many members of the operating team and, unlike instruments, frequently leave the hands of the team members for use on or in the patient,” wrote Robert R. Cima, MD, MA, vice-chair of quality and safety in the Department of Surgery at the Mayo Clinic College of Medicine, in a commentary on AHRQ PSNet, a patient safety website. “During the course of an operation, sponges can move quite easily from one place to another inside a body cavity as the result of patient position change, manipulation of the body cavity contents, or movement of organs, especially the intestines. Additionally, over the course of a surgery, the sponge color and size changes dramatically, making it more difficult to identify within a cavity. Lastly, counting sponges removed from the operating site over the course of a procedure is associated with simple counting’ errors and is further compounded by different personnel performing the counts, competing activities, distraction and poor intra-team communication.”

In many cases, retained sponges manifest themselves quickly and are resolved through a second surgery, resulting in no lasting injury. However, the Johns Hopkins team found that in more than one in five cases, the outcome of a retained sponge was permanent injury or death (Figure 1), a figure significantly higher than earlier estimates.

Figure. 1 Patient outcomes of surgical never events, 1990-2010

Outcome	All surgical never events N = 2,355 (% of total)	Retained surgical items N = 1,126 (% of total)
Death	155 (6.6)	51 (4.5)
Permanent Injury	774 (32.9)	184 (16.3)
Temporary Injury	1,395 (59.2)	879 (78.1)
Emotional Injury	31 (1.3)	7 (1.1)

Source: Mehtsun WT, Ibrahim AM, et al. Surgical never events in the United States. *Surgery*. 2013 Apr;153(4):465-72

Although there are published operating room guidelines and recommended procedures to account for surgical instruments and sponge products used during surgery, their effectiveness in preventing retained sponges is limited. In fact, count discrepancies are quite common. In an observational study, a count discrepancy occurred in one out of every eight operations.¹¹ That study identified discrepancies that were recognized at the time of the operation resulting in activation of procedures to resolve them. However, a consistent finding in nearly all the published reports of retained sponges was that the instrument and sponge counts were reported as "correct" prior to closure in a majority of cases.¹²

¹¹ Greenberg CC, Regenbogen SE, et al. The frequency and significance of discrepancies in the surgical count. *Ann Surg*. 2008;248:337-341.

¹² Gawande AA, Studdert DM, Orav EJ, Brennan TA, Zinner MJ. Risk factors for retained instruments and sponges after surgery. *N Engl J Med*. 2003;348:229-235.

The leading sentinel event

In October 2013 the Joint Commission issued a Sentinel Event Alert on retained surgical items, which for four of the five years from 2010-2015 were the most reported adverse event to the Commission. The Commission defines sentinel events as serious, life-threatening or life-ending errors. Each hospital is encouraged, but not required, to report to the commission any incident meeting the criteria for reviewable sentinel events.¹³ Increasingly, the Commission is becoming aware of sentinel events from communications by patients, family members, hospital employees and the media.

If the Commission becomes aware of a sentinel event at an accredited hospital, the hospital is expected to:

- Prepare a thorough and credible root cause analysis and action plan within 45 calendar days of the event or of becoming aware of the event. The hospital should look for systems that might be improved to prevent recurrence.
- Submit to the Commission its root cause analysis and corrective action plan under an approved protocol within 45 calendar days of the known occurrence of the event.
- The Commission then determines whether the root cause analysis and action plan are acceptable.

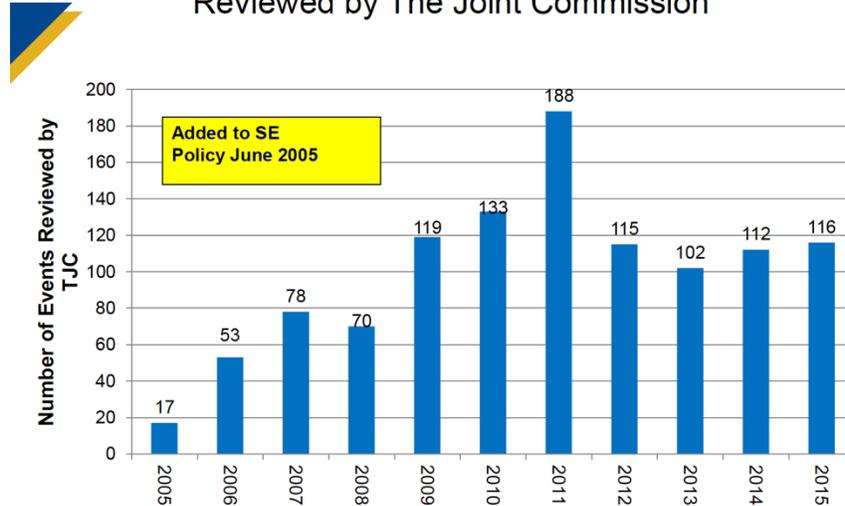
About 95% of the retained foreign object cases reported to the Commission resulted in additional care and/or an extended hospital stay.¹⁴ In hospital settings, these incidents occurred in operating rooms, labor and delivery areas, as well as ambulatory surgery centers and other areas where invasive procedures are performed.

According to the Commission, the three most common categories of root causes of retained surgical items identified from 2004 to 2015 were leadership, human factors and communication.¹⁴ And in root-cause analyses of the events involving retained objects, the Mayo Clinic team identified breakdown in communication, such as failing to communicate placement of an item within a body cavity to other team members, as the single most commonly cited contributing factor.

¹³ Joint Commission. Sentinel Event Policy and Procedures, accessible at jointcommission.org/sentinel_event_policy_and_procedures/

¹⁴ Joint Commission-Sentinel Event Data – root causes by event type, Feb 2016, accessible at jointcommission.org/sentinel_event_statistics/.

Unintended Retention of Foreign Object Events Reviewed by The Joint Commission



“We know that the actual number of (retained surgical items) is vastly underreported, likely accounting for not much more than 10% of the events that actually occur,” said Ronald M. Wyatt, MD, MHA, the Commission’s patient safety officer. “Most hospitals are just at the starting point of working on and improving the reliability of processes, and this is one of them.”

Payment at risk

Though estimates vary widely, a retained surgical item adds significantly to the average total cost of caring for the patient. Since 2008 Medicare has had a policy of not reimbursing hospitals for the added costs of treating 11 hospital-acquired conditions, including retained surgical items. According to the Centers for Medicare and Medicaid Services (CMS), “A foreign object left in the body constitutes an adverse event that should never occur.”

This policy has had rather limited effect in terms of refused claims. A 2010 CMS study found that the policy resulted in 3,416 payment reductions in 2009 from a total of 9.3 million Medicare hospital discharges, yielding \$18.8 million in savings out of \$133 billion in total hospital expenditures.

It seems likely, however, that some hospitals simply absorb the cost of the additional care rather than submit a claim to Medicare. An inflation-adjusted 2007 estimate from CMS finds the added cost of a second surgery and follow-up care for a retained surgical item is \$79,639.¹⁵

“Many Medicare claims for beneficiaries who experienced adverse events did not include diagnosis or

¹⁵ Centers for Medicare and Medicaid Services. CMS Proposes Additions to List of Hospital-Acquired Conditions for Fiscal Year 2009. 14 April 2008.

procedure codes relating to the events," the agency said in a 2010 report.¹⁶ "When Medicare claims included codes associated with the events, the codes often had no effect on costs because the claims included other costly diagnoses or procedure codes that elevated the reimbursement to equivalent or higher amounts."

Atul Gawande, a surgeon at Boston's Brigham and Women's Hospital as well as a well-known writer and public health researcher, adds: "The stay associated with the bill is for someone who has already been in the hospital, so they are there for another reason. Thus, the code for a retained sponge can disappear at the bottom of the bill. Taking somebody back to the operating room is expensive, and hospitals want to have further cost reimbursed."

State Medicaid payment is also withheld for the added care of a second surgery. More than half of all states publicize hospitals' track records on medical errors.

New Jersey passed a law in 2004 under which any hospital that discovers a retained item as a result of a surgical procedure that occurred at its facility must report the event within five days and is responsible for performing a root cause analysis. Under mandatory reporting of all preventable adverse events, retained surgical items have been the most frequently reported surgery-related event type in the state.

Hospitals in Maine won't charge patients or their insurers for 28 errors, as defined by the National Quality Forum. In other states, hospitals – encouraged by medical associations – have agreed not to charge patients for certain preventable errors.

In 12 years of public reporting of adverse health events, the Minnesota Department of Health has collected detailed information on more than 3,000 events. The state has used the information from those events to identify ways to improve patient safety. In 2015, hospitals and surgical centers reported 22 cases of retained foreign objects, continuing a downward trend.

In terms of its financial effect on hospitals, California may have the toughest law. It has been fining hospitals for adverse events since 2009. The fines rose significantly in 2014 up to a maximum of \$75,000 for the first event, as much as \$100,000 for the second, and up to \$125,000 for the third and every subsequent violation within three years. When hospitals are investigated following an incident, they are required to provide the state with a plan of correction to prevent future incidents.

A review of state records found that from January 2010 to January 2016, California hospitals paid out \$2,486,000 in administrative penalties for 39 cases of retained surgical sponges, or \$63,744 per incident. That average has risen significantly in the past two years.

The accountable care effect

New payment and organizations created by the 2010 Affordable Care Act may incentivize healthcare providers to reduce the incidence of retained surgical sponges.

¹⁶ Levinson D. Department of Health and Human Services Office of Inspector General. Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries, November 2010

The Accountable Care Organization (ACO) replaces the idea of reimbursing individual doctors and hospitals by procedure with a lump-sum payment to clinicians working as a formal ACO team. Under the terms of the Affordable Care Act, a Medicare ACO agrees to be responsible for all the care needs of a group of patients and to be paid based on those patients' health outcomes, satisfaction and costs.

It's a big shift culturally for hospitals that have always focused on volume, Gawande says. "Under ACOs, hospitals are going to be on the hook for complications and the population-based care of all their patients. Hospitals have often left money on the table that could have gone toward improving quality and saved on costs."

A similar arrangement is the federal bundled payment program, under which a hospital and physicians assume the financial risk for delivering all care for one price for one patient episode over a set period — anywhere from 30 days to a year. Private insurance companies such as UnitedHealth Group, Humana, Aetna and most Blue Cross and Blue Shield plans are also making bundled payments to groups of doctors and hospitals.

Bundled payments are effective in transforming care because they focus providers on areas where there are unwarranted variations and realizable savings. Bundled payment brings alignment with physicians, which allows hospitals to cut their variable costs and reduce post-surgical complications, pharmacy costs and length of stay. Obviously, a medical error such as a retained surgical sponge runs counter to the goals of bundled payment.

Private sector 'no-pay'

The debate over who should pay for medical mistakes shot to the forefront in 2005 when Minnesota's HealthPartners became the first insurer to declare it would not pay hospitals for anything on the National Quality Forum's list of never events, including retained surgical items. Since then, Cigna Corp., Aetna, Anthem and most Blues plans have followed suit.

Horizon Blue Cross and Blue Shield of New Jersey uses the Leapfrog Hospital Survey, a voluntary program to analyze safety practices, to recognize hospitals with an annual bonus based on achievement scores for patient safety. The average payment was close to \$150,000, with a maximum of \$250,000. Hospitals must complete the survey to be eligible for the recognition program.¹⁷

Some corporations have also taken an interest in adverse events. At General Electric, which is one of the founding members of Leapfrog, employees see information about safety and quality on their internal website.

A malpractice minefield

Without a doubt, the most significant financial fallout from a retained surgical sponge comes from malpractice litigation. When a patient becomes aware that a retained sponge is the cause of pain and suffering, a settlement or lawsuit are sure to follow.

¹⁷ Merchant M. Pay for Performance at Work: Horizon BCBSNJ's Partnership with The Leapfrog Group, March 21, 2012

In many jurisdictions, statutes of limitations allow plaintiffs to bring an action within a certain amount of time after the alleged negligence is discovered, even if the precipitating event happened years earlier. If these cases do get to court, they're usually challenging to defend. Plaintiffs often rely on *res ipsa loquitur* – “the thing speaks for itself” – a doctrine that may be applied to injuries that normally do not occur without negligence. This doctrine let judges and juries infer negligence, shifting the burden of proof to the defendant, and in some jurisdictions, the plaintiff does not need to retain an expert witness to establish the standard of care in these cases.

A decades-old Indiana court ruling illustrates this principle: “A surgeon is charged, as a matter of law, with the duty to remove sponges used in the operation, which sponges will not be of use in the abdomen after the operation. Ordinary care and caution forbids a surgeon to delegate the absolute authority and responsibility to a nurse or nurses to account for sponges and to thus escape responsibility himself.”¹⁸

Which defendants are responsible for the event – the hospital or the physician – is in question in many cases. “This blame game, which is exacerbated if the defendants are insured by differed insurers, may make it easier for plaintiffs to ‘divide and conquer,’ ” a recent article in the journal *Inside Medical Liability* stated.¹⁹

Recent guidelines from the Association of Perioperative Registered Nurses (AORN) emphasize that the responsibility for preventing retained surgical items is shared among the perioperative team, including the registered nurse circulator, scrub person, surgeon, anesthesia professionals and others assisting in the procedure. Significantly, the entire surgical team may be held legally responsible for a retained sponge.

When examining the financial fallout from a retained surgical sponge, much focus is, deservedly, on jury verdicts and settlements. Often, the initial jury award is reduced significantly, either by an appellate court or through an effort to settle the case. It is therefore best to look at closed claims.

The Johns Hopkins study of the closed claims included in the National Practitioner Data Bank found that retained surgical items ranked No. 1 on the list of medical errors associated with a malpractice judgment or out-of-court settlement, but only fifth in average payout at \$86,000.

A similar finding arose from a data request made for this paper to Physician Insurers Association of America (PIAA), the physician insurance industry trade association. For the most recent 10-year period, the retention of surgical foreign bodies was the ninth most frequent chief medical factor leading to closed claims. Of the 94,000 total closed claims reporting for analysis, 1,741 named retention of surgical objects. Of these, 29% resulted in an indemnity payment to the patient, for an average payment of \$87,243 (Figure 2).

Physician malpractice payments per surgical never event				
	No. of events	Mean	Median	Highest payout

¹⁸ Travis, J, Funk v. Bonham, 204 Ind. 170, 183 N.E. 312. 1932

¹⁹ Wergin, J, Retained Objects: Why They Keep Happening and What You Can Do About It, *Inside Medical Liability*, Third Quarter 2016;32-34.

All never events	9,744	\$133,055	\$46,172	\$7.1 million
Wrong procedure	2,447	\$232,035	\$106,777	\$4.3 million
Wrong site	2,413	\$127,159	\$43,197	\$7.1 million
Wrong patient	27	\$109,648	\$18,928	\$1.1 million
Retained object	4,857	\$86,247	\$33,953	\$4 million
<i>Source: Mehtsun WT, Ibrahim AM, et al. Surgical never events in the United States. Surgery. 2013 Apr;153(4):465-72</i>				
<i>Data are from National Practitioner Data Bank, covering 1990-2010</i>				

Figure. 2 Physician indemnity costs for retained foreign objects

Years	Closed claims	Paid claims	Avg. payout	Largest payout	Total payout
2002-2006	727	244	\$73,889	\$1.35 million	\$18 million
2007-2011	892	253	\$104,842	\$865,000	\$26.6 million

Source: PIAA Data Sharing Project

Hospitals, being the deep pockets of most litigation, not too surprisingly pay out much more. For this paper, the Risk Management Foundation of the Harvard Medical Institutions was asked to review its Comparative Benchmarking System database of medical malpractice cases from academic and community hospitals and physician practice groups across the country. It found that from 2007-2011, the average final disposition of a lawsuit against hospitals and/or physicians involving a retained surgical item was \$473,022 (Figure 3).

Figure. 3 Indemnity costs for hospitals and physicians from retained surgical items, 2007-2011

Total No. of Cases	% With Indemnity paid	Average Indemnity Paid
307	46%	\$473,022

Source: Risk Management Foundation of the Harvard Medical Institutions, Inc.

The foundation also examined the clinical injury severity of retained surgical item cases, and found that indemnity payments are distributed more equally between medium- and high-severity cases. The high-severity cases with “permanent major” injury represent the most severe financial penalties, with average settlements of \$2 million.

Clinical severity of retained surgical items, 2007-2011

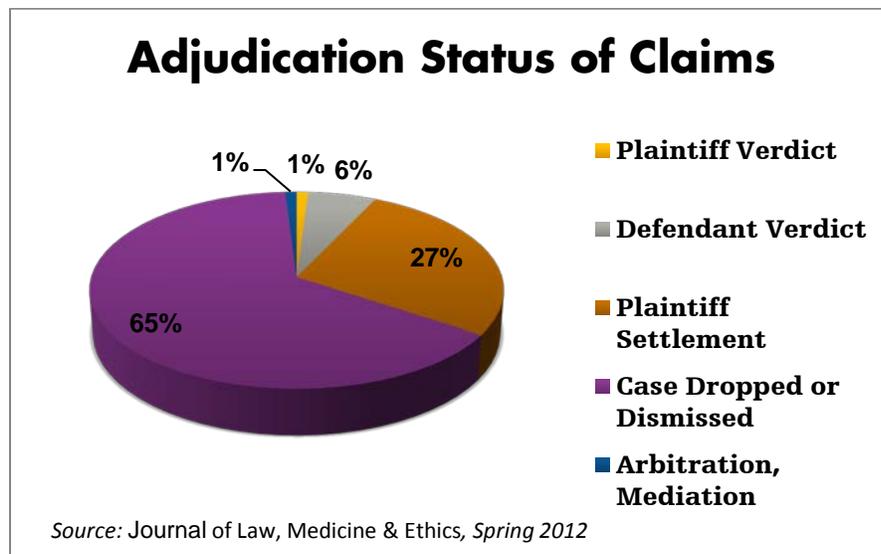
Severity	No. of Cases	Total Indemnity Paid	Share of Cases	% of Indemnity Paid
Low	3	\$0	1%	0%
Emotional only	2	\$0	1%	0%
Temporary insignificant	1	\$0	0%	0%
Medium	280	\$43,207,827	91%	65%
Permanent minor	28	\$15,056,912	9%	23%

Temporary major	223	\$27,210,915	73%	41%
Temporary minor	29	\$940,000	9%	1%
High	24	\$23,015,190	8%	35%
Death	13	\$9,571,000	4%	14%
Permanent grave	1	\$464,190	0%	1%
Permanent major	5	\$10,000,000	2%	15%
Permanent significant	5	\$2,980,000	2%	4%
Totals	307	\$66,223,017	100%	100%

Source: Risk Management Foundation of the Harvard Medical Institutions

The indemnity payment is not the end of this story, however. What is known about defense costs is limited, with many earlier estimates being partly or entirely anecdotal. According to the Insurance Information Institute, approximately 61% of medical professional liability insurers' total incurred losses was spent on defense costs and cost containment expenses in 2010, compared to 40% in 2000.²⁰

A 2012 study published in the *Journal of Law, Medicine & Ethics* found that the majority of reported claims are either dropped, withdrawn or dismissed, therefore resulting in no indemnity payout.²¹ Notably, that finding does not extend to retained surgical item; the above data show nearly half of all cases result in an indemnity payment.



The relevant finding here is that for whatever reason, defense costs are rising, regardless of whether

²⁰ Insurance Information Institute, *The Insurance Fact Book 2012*

²¹ Carroll AE, Parikh PD, Buddenbaum JL. The impact of defense expenses in medical malpractice claims. *J Law Med Ethics*. 2012 Spring;40(1):135-42.

a claim is fully adjudicated. Legal defense costs generally include attorney fees, expert witness fees, court costs and securing of medical records. In terms of total money spent on legal costs, those claims that are dropped, withdrawn or dismissed are almost as expensive as those claims that result in a plaintiff settlement – a result of the sheer volume of claims.

Since 1985, the average amount of money spent on legal costs has been steadily increasing for all claims. This holds true regardless of the adjudication status of the claim.

Defense costs rise as percentage of indemnity payouts*			
2000	\$383,104	\$38,311	30%
2001	\$388,280	\$37,014	30%
2002	\$400,389	\$35,409	29%
2003	\$386,229	\$34,292	35%
2004	\$406,107	\$36,212	36%
2005	\$374,394	\$35,287	39%
2006	\$381,368	\$38,061	40%
2007	\$376,304	\$42,324	42%
2008	\$370,089	\$46,719	45%
* in 2013 dollars <i>Source: Journal of Law, Medicine & Ethics, Spring 2012</i>			

Combining indemnity and legal costs from additional data supplied by the PIAA produces insight into what procedures result in the highest total malpractice costs – at least for physicians.

Procedures with highest average physician indemnity payments and defense costs for retained surgical items, 2002-2011			
Procedure	Average indemnity	Average Defense Cost	Average Total Cost
Gallbladder, biliary tract	\$173,139	\$24,716	\$197,855
Abdominal	\$158,500	\$32,285	\$190,785
Small and large intestine	\$137,250	\$26,613	\$163,863
Uterus	\$96,606	\$24,310	\$120,916
C-section	\$76,458	\$27,777	\$104,235
<i>Source: PIAA Data Sharing Project</i>			

Based on all of this data, an admittedly rough calculation was made of the malpractice impact per case of a retained surgical item in the U.S. annually (Figure. 4). This calculation is based on the Centers for Disease Control and Prevention’s National Hospital Discharge Survey, which showed 34.1 million inpatient procedures for which a retained sponge was possible; the incidence of RSIs found in the most-cited study, done at Mayo; the average indemnity payout from the Harvard database; and legal defense costs from the *Journal of Law* study.²¹

Figure. 4 Cost of retained surgical item per inpatient surgical procedure

34.1 million inpatient procedures ÷ 5,500 = 6,200 annual retained objects

6,200 retained items X \$519,741 = \$3.22 billion in total annual costs

\$3.22 billion ÷ 34.1 million procedures = \$94.50 legal cost of RSIs per surgery

This result far exceeds earlier estimates and is roughly nine times the per-procedure cost of assistive counting technology. And it does not include the lost revenue due to retained surgical items from payment reform.

Effect on reputation

The damage to a hospital's brand from publicity surrounding a retained sponge is harder to calculate in dollar figures, but it is surely considerable. *USA Today* in March 2013 published a lengthy investigative report on retained sponges, naming patients and hospitals. Every time California publishes a list of hospitals fined for safety lapses, local TV stations pile on, citing grim details of the cases. Lawsuits that result in jury jackpot awards to plaintiffs get major press attention.

The Leapfrog Group's Hospital Safety Score has received major attention in national and local media. The effort, which awards hospitals letter grades from A to F, is based on a methodology created by an expert panel that included nationally known health policy researchers Ashish Jha of Harvard, Arnold Milstein of Stanford, Peter Pronovost of Johns Hopkins and others. The formula uses publicly available data, drawing from the CMS' Hospital Compare database, Leapfrog Group's annual hospital survey and the American Hospital Association's annual member survey. The Hospital Safety Score contains three measures of hospital-acquired conditions: foreign object retained after surgery, air embolism, and falls/trauma.

In April 2016 Leapfrog released its latest round of safety scores. Of the 2,571 hospitals issued a Hospital Safety Score, 798 earned an A, 639 earned a B, 957 earned a C, 162 earned a D and 15 earned an F.

An analysis of the safety score led by Matt Austin, PhD, assistant professor at the Armstrong Institute for Patient Safety and Quality and the Department of Anesthesiology and Critical Care Medicine at John Hopkins University School of Medicine, found that D and F hospitals carry a nearly 50% greater risk of mortality than A hospitals, and over 33,000 lives could be saved if all hospitals performed at the level of A-graded hospitals.²²

"Our board considers the Hospital Safety Score the most important patient safety initiative we have ever done, and we are full speed ahead on this," said Leah Binder, Leapfrog's CEO. "We got hospitals' attention, but more importantly, we got consumers' attention. We have had tens of thousands of pieces written about the safety score. I don't think there is a media market that hasn't covered the Hospital Safety Score at great length."

²² Austin M, Derk J. Lives Lost, Lives Saved: A Comparative Analysis of Avoidable Deaths at Hospitals Graded by the Leapfrog Group. Armstrong Institute for Patient Safety and Quality, Johns Hopkins Medicine. April 2016

The promise of assistive technology

A growing number of organizations, including the Joint Commission, AORN, the Agency for Healthcare Research and Quality and the Leapfrog Group, have called on providers to evaluate the possible use of technology in reducing the incidence of retained sponges.

“Technology-based sponge counting and identification systems have been employed with striking success,” wrote Mayo’s Dr. Cima, in the AHRQ PSNet commentary. He noted that in the largest reported experience using barcoded sponges, the Mayo Clinic eliminated retained sponges over an 18-month period, while previously they were experiencing one such case every 76 days.⁵

In a simulation model of measures to prevent cases involving retained surgical sponges, researchers found that standard counting alone detects 82% of retained sponges, at a cost of \$1,500 for each case averted.²³ Barcoding prevents at least 97.5% of cases, costing \$95,000 for each averted case. RFID tagging prevents 97.5% to 100% of cases, but it costs \$620,000 to \$720,000 for each case averted. Universal X-ray and selective X-ray are less effective than bar coding at detecting sponges, and they cost more, ranging from \$1.1 million to \$1.4 million per case averted.

Currently, 492 hospitals use the Stryker SurgiCount barcoded sponge system.

Conclusion

Retained surgical sponges have continued to be a patient safety focus. An Association of Perioperative Registered Nurses survey in June 2013 found that retained surgical items were the No. 2 patient safety concern of members, right behind wrong site/wrong patient surgeries.²⁴ Sixty-one percent of the nurses who were surveyed identified preventing RSIs as a high priority.

Retained surgical items were ranked eighth on the ECRI Institute’s Top 10 Patient Safety Concerns for Healthcare Organizations in 2016. With unintentionally retained objects, “the problem is the enormous amount of harm that can result, such as perforation, infection, pain, damage to other body parts, and death,” says Gail Horvath, MSN, RN, ECRI’s patient safety analyst. Counting surgical items is an important preventive measure. However, “counting is a human process that’s very prone to error, especially in a busy environment where multiple things are happening simultaneously,” Horvath notes.

So why hasn’t every hospital adopted an assistive technology?

The problem with adoption, Dr. Gawande of Brigham and Women’s says, is that while the technology comes from the operating room budget, the malpractice payout comes from the chief counsel’s budget, and the issue may not rise to the level of the C-suite.

“When you look back, every hospital that has made this shift has done so either because there has been a leader at the top level who has decided that this is what he wanted to do or there has been a

²³ Regenbogen, SE, Greenberg CC, Resch SC, et al. Prevention of retained surgical sponges: a decision-analytic model predicting relative cost-effectiveness. *J Surg*, 2009 May;145(5):527-35.

²⁴ Steelman VM, Graling PR. Top 10 Patient Safety Issues: What More Can We Do? *AORN Journal*, June 2013;97(6):679-701.

high-publicity bad event, and when those events happen, it is an opportunity," he said.

"Spending money for the operating room to save money for the general counsel leaves the CMO saying, 'Why bother doing that?' Then you have a CEO who might be motivated to prevent a retained sponge, but is not sure whether a new counting technology will upset nurses, so he sends it down to them and they evaluate the three main technologies, etc., etc. So it has been easier not to do anything," he said.

"The good news is that we are starting to see that when there is publicity around an event, someone is asking, 'Why don't you have an automated system?' The *USA Today* article was an example of that," Gawande said.

Many leading academic institutions – including Mayo Clinic, Cleveland Clinic and Ochsner Health System – have adopted bar-coded sponges, as have Veterans Affairs hospitals and a number of smaller facilities. The experiences of these pioneers in getting to or close to zero retained surgical sponges and reducing malpractice exposure should point the way for more hospitals to follow suit.