

Patient Safety Alert: Harvard Surgical Chiefs Endorse Automated Detection Technology for Retained Foreign Objects

Issue 12 | July 2013

Introduction

The Academic Medical Center Patient Safety Organization (AMC PSO) recently performed an analysis of patient safety events in the surgical setting. As part of this analysis, the AMC PSO convened key opinion leaders in surgery to elicit their expertise and opinions specific to the issue of retained surgical items (sponges, instruments, needles, and tools) collectively known as Retained Foreign Objects (RFOs). The goal of this convening session was to develop best practice recommendations to mitigate the risk of RFOs in the surgical setting. Subject matter experts discussed emerging technologies and new strategies that are now available to complement existing patient safety protocols aimed at reducing the incidence of RFOs. These include:

- monitoring surgical items with bar coding or radiofrequency
- educating operating room staff regarding the risk factors for RFO
- educating staff about the limitations of manual surgical counts
- instituting post-surgical survey x-rays for high risk patients

The following article offers further details on many of these issues and techniques and carries an endorsement from the Harvard Surgical Chiefs on the use of automated detection technology: radiofrequency identification or bar coding sponges and instruments, to complement existing surgical count procedures.

Retained Foreign Objects

RFOs in surgical patients are sentinel events that represent a fairly uncommon, yet potentially dangerous, medical error (Lincourt, Harrell et al.

2007; Steelman and Cullen 2011). Complications and adverse events (AEs) in RFO cases have been documented to include prolonged hospital stay, re-operation or re-admission, organ perforation, sepsis or infection, fistulas or bowel obstruction, and death (Gawande, Studdert et al. 2003; Steelman and Cullen 2011). While it has been difficult to estimate how frequently RFOs occur, published reports have estimated that retained surgical items occur in 1 in 1,000 to 1,500 intra-abdominal surgeries (Gawande, Studdert et al. 2003) and range from 1 in 5,500 to 19,000 in surgeries overall (Greenberg and Gawande, 2008; Steelman and Cullen 2011). A review of CRICO's Comparative Benchmark Service reveals that between the calendar years 2007-2011, a total of 320 malpractice cases were closed nationally involving RFOs events (CRICO, 2013). Of these 320 cases, 137 (45%) closed with payment. The average indemnity payment was \$120,000.00. A similar study of 47 RFO malpractice suits found the verdicts resulted in an average of more than \$50,000 in costs for compensation and defense expenses (Gawande, Studdert et al. 2003). Partly in response to law suits such as these, the Centers for Medicaid and Medicare Services now considers RFOs a "reasonable preventable" condition and has begun denying reimbursement for any costs associated with RFOs or their complications (Sack K., 2008).

Data Analysis: Contributing Factors and Strategies

The AMC PSO performed an in-depth review of previous RFOs incidents in the surgical setting and identified several human and environmental contributing factors.

- When the general atmosphere of the OR itself is distracting with increased noise and multiple teams arriving and leaving during the closing,

changeover and final count, the probability of an RFO tends to increase.

- Focus can also be diverted through surgical staff members multi-tasking with such activities as teaching.
- Non-adherence to hospital strict surgical count policies.
- No standardized guidelines given to OR staff for wound exploration and closing.

The AMC PSO members' review of RFO cases also determined a number of steps that hospitals have specifically engaged in to decrease the probability of RFOs. These steps include:

- Having OR team members complete educational materials regarding the risk factors for RFOs
- Allowing multidisciplinary teams to review RFO case studies and devise key lessons for staff members
- Revising surgical checklists to identify RFOs, particularly for exploration and closing procedures
- Verifying concurrent closing visualization for surgical item counts
- Using sponge count bags
- Encouraging staff to speak up if they think the count may be incorrect
- Instituting the use of technological aids such as radio-frequency (RFID) or bar-code systems for surgical sponges and tools

Retained Foreign Objects

RFOs, like many of the most critical medical errors, are difficult to study because they happen very infrequently and the underlying causes are often complex and heterogeneous (Gawande, Studdert et al. 2003). Moreover, RFOs present as highly variable and the onset of symptoms can occur long after surgical recovery (Rappaport W 1990; Cima, Kollengode et al. 2008).

However, patient record studies have reported that (Lincourt, Harrell et al. 2007) approximately 52% of RFOs are sponges and 43% are instruments. The abdominal cavity was involved 46% of the time and the thoracic cavity 23% of the time, though the investigators found that *no* body cavity remained uninvolved. Similar studies have reported

comparable results (Cima, Kollengode et al. 2008; Gawande, Studdert et al. 2003).

Patient Risk Factors

Together, these investigations concluded that the most significant patient risk factors for an RFO were in individuals who (Lincourt, Harrell et al. 2007; Gawande, Studdert et al. 2003):

- Received concurrent surgical procedures
- Were treated by more than one surgical team
- Had an incorrect instrument/sponge count recorded
- Experienced emergency surgery
- Were subjected to an unplanned change in operation
- Possessed a higher mass body index
- Had a procedure with no count conducted
- Underwent a procedure of long duration

Efficiency of Surgical Counts

RFOs are considered a "serious reportable event" by the National Quality Forum, which classifies them as a preventable medical error (National Quality Forum, 2007). The standard and most common OR strategy for the prevention of RFOs relies on a regimented, highly disciplined, and controlled counting protocol developed by the Association of Perioperative Nurses (AORN).

Surgical Count Risk Factors

While the manual counting protocol plays a crucial role in preventing RFOs, the surgical count can also be an insufficient control in preventing RFOs, and in some cases disabling (Christian, Gustafson et al., 2006; Egorova, Moskowitz et al., 2008; Greenberg and Gawande, 2008; Riley et al, 2006).

Specifically, the following factors have been found to impact the surgical count:

- Surgery duration
- Late time procedures
- Number of nursing teams
- Competing priorities
- Lack of tools necessary to produce an accurate count
- Power relationships among OR staff
- Exhaustion
- Chaotic environment

Other published reports indicate that auxiliary tasks, such as the counting protocol, can impact patient-centered care through increasing workload and placing competing demands on provider attention. One study found that an average of 35 minutes per operation (ranging from 16-73 minutes) was spent counting, representing 14.5% of incision time (Christian, Gustafson et al., 2006). The authors concluded that competing demands for nursing staff attention can, in some instances, increase the risk of patient safety-compromising events and/or adverse events (AEs) (Christian, Gustafson et al., 2006).

The efficacy of final count discrepancies has even been questioned. A review of surgical patient AEs revealed that final count discrepancies correctly identified patients with retained items only in 77.2% of cases and prevented RFOs only in 54% of cases (Egorova, Moskowitz et al., 2008). In fact, many RFOs were found in patients with correct counts (Cima, Kollengode et al., 2008) with one study reporting that 88% of RFO cases involved a final count that was erroneously believed to be correct (Gawande, Studdert et al. 2003).

Strategies for Improving the Manual Surgical Count

- Surgical staff should be made acutely aware that the surgical count can be unreliable, and under what conditions this is most likely to happen (Brisson P., 2008; Cima, Kollengode et al., 2008).
- Hospitals should actively monitor compliance with their existing surgical count policy, standards, and practices in surgery and obstetrics (Greenberg and Gawande, 2008).
- Each independent organization should perform a prospective analysis of the counting protocol to accurately determine discrepancy rates and factors (Greenberg and Gawande, 2008).
- OR personnel should also be mindful that counting protocols can become disabling or distracting under certain circumstances.

“If you’re under pressure, the count is secondary to getting sutures tied, stopping bleeding, suction, visibility; the count is quite secondary ... how can

you stay accountable to your count when it’s not your priority?”

Scrub nurse quoted in Riley et al., 2006

Additional Solutions for Preventing RFOs

As previously mentioned, even improvements in surgical count performance and policy are not enough in developing specific approaches to decreasing and preventing RFOs. Additional safety measures and strategies need to be adopted.

- Ideally, an RFO survey x-ray should be performed in a dedicated imaging area next to the surgical suite with high-resolution equipment (Cima, Kollengode et al., 2008; Greenberg and Gawande, 2008).
- Radiographic screening of selected patients at high-risk for RFOs should be considered at the end of operations even when counts are documented as correct. (Greenberg and Gawande, 2008).
- Discrepant surgical counts increase the odds of a RFO approximately 100 times. All discrepant counts should prompt an x-ray unless the discrepant item is too small for x-ray (Greenberg and Gawande, 2008).
- Emerging technologies such as monitoring surgical items with bar coding or radiofrequency identification (RFID) should be considered, investigated, and adopted when viable (Egorova, Moskowitz et al., 2008; Cima, Kollengode et al., 2008; Greenberg and Gawande, 2008).
- A cost-benefit analysis should be conducted when determining when to use radiography or bar coding/radiofrequency identification to prevent RFOs. This should include the costs of potential liability and potential damage to an institution’s or surgical team’s reputation (Egorova, Moskowitz et al., 2008; Greenberg and Gawande, 2008).
- Hospital staff should be educated that RFOs, while rare, are considered preventable and a “never event” by the Centers for Medicare and Medicaid and are most likely to occur during emergency cases, changes in the planned procedure, when patients receiving multiple procedures, in obese-patient procedures, in surgeries with more than one surgical team, and when there is a discrepant surgical item count.

The Surgical Chiefs from CRICO member hospitals *unanimously* voted to endorse the use of automated detection technology for surgical sponges at their respective institutions as a tool to decrease the risk of RFOs. This show of confidence for this technology was based upon both members' direct experience and from a published clinical trial showing a 100% detection rate of RFID sponges (Macario, Morris et al., 2006). While the results are promising, this investigation did state that additional studies are required and automated detection technology does not eliminate the need for a manual count but should be used to augment it.

References

- Brisson P. (2008) Prevention of retained foreign objects. *Bull Amer Coll Surg.* 94(11):28-31.
- Christian, C. K., Gustafson, M.L. et al. (2006). "A prospective study of patient safety in the operating room." *Surgery.* 139(2): 159-173.
- Cima, R. R., Kollengode, A. et al. (2008). "Incidence and Characteristics of Potential and Actual Retained Foreign Object Events in Surgical Patients." *Journal of the American College of Surgeons* 207(1): 80-87.
- CRICO, data on file, 2013.
- Egorova, N.N., Moskowitz A, Gelijns A, et al. (2008) Managing the prevention of retained surgical instruments: what is the value of counting? *Ann Surg.* 247(1):13-18.
- Gawande, A. A., Studdert, D.M. et al. (2003). Risk Factors for Retained Instruments and Sponges after Surgery. *NEJM.* 348(3): 229-235.
- Greenberg CC, Gawande A.A. (2008) Beyond counting: Current evidence on the problem of retaining foreign bodies in surgery. *Ann Surg.* 247:19-20.
- Lincourt, A. E., Harrell, A. et al. (2007). Retained Foreign Bodies After Surgery. *J Surg Res.* 138(2): 170-174.
- Macario A, Morris D, Morris S. Initial Clinical Evaluation of a Handheld Device for Detecting Retained Surgical Gauze Sponges Using Radiofrequency Identification Technology. *Arch Surg.* 2006;141(7):659-662.
- National Quality Forum (2007) Serious Reportable Events in Healthcare, 2006 Update. Washington, DC:. Available at: www.qualityforum.org/Publications/2007/03/Serious_Reportable_Events_in_Healthcare-2006_Update.aspx. Accessed April 29, 2013.
- Rappaport W, H. K. (1990). The retained surgical sponge following intra-abdominal surgery: A continuing problem. *Arch Surg.* 125(3): 405-407.
- Riley, R., Manias, E. and Polglase, A. (2006) Governing the surgical count through communication interactions: implications for patient safety. *Qual Saf Health Care.* 15(5):369-374.
- Sack K. Medicare won't pay for medical errors. *The New York Times*, October 1, 2008
- Steelman, V. M. and Cullen, J.J. (2011). Designing a Safer Process to Prevent Retained Surgical Sponges: A Healthcare Failure Mode and Effect Analysis. *AORN journal.* 94(2): 132-141.

© 2013 Risk Management Foundation of the Harvard Medical Institutions. All rights reserved. This material may not be reproduced, displayed, modified or distributed without the express prior written permission of the copyright holder.

For permissions and secure methods of communication to the AMC PSO, please contact:

amcpso@rmf.harvard.edu