Detecting Patient Safety Indicators: How Valid Is "Foreign Body Left During Procedure" in the Veterans Health Administration?

Qi Chen, MPH, Amy K Rosen, PhD, Marisa Cevasco, MD, MPH, Marlena Shin, JD, MPH, Kamal MF Itani, MD, FACS, Ann M Borzecki, MD, MPH

BACKGROUND: The Agency for Healthcare Research and Quality (AHRQ) developed patient safety indicator (PSI) 5, "Foreign body left during procedure," to flag accidental foreign bodies in surgical and medical procedures. This study examined how well this indicator identifies true foreign body events in the Veterans Health Administration (VA).

STUDY DESIGN: This was a retrospective study within 28 selected VA hospitals from fiscal year 2003 to 2007. Trained abstractors reviewed medical charts flagged by PSI 5 and determined true foreign body cases. We calculated the positive predictive value (PPV) of this indicator and performed descriptive analyses of true positive and false positive cases.

RESULTS: Of the 652,093 eligible cases, 93 were flagged by PSI 5 (0.14 per 1,000). Forty-two were true positives, yielding a PPV of 45% (95% CI 35% to 56%). False positives were due to a foreign body that was present on admission (57%) or coding errors (43%). True foreign bodies were associated with surgical (n = 23) and medical (n = 19) procedures. The most common type of surgical foreign body was a sponge (52%). Overall, approximately 40% of foreign bodies were related to a device failure or malfunction (30% surgical vs 53% medical foreign bodies). Postoperative complications included pain (24%), infection (12%), adhesions (5%), and bowel obstruction (5%).

CONCLUSIONS: The reported rate of foreign body events as detected by PSI 5 is low in the VA, but occurs in both surgical and medical procedures. Despite widespread implementation of surgical counts, quality improvement efforts should focus on novel ways to eliminate this "never event" from operations. Future studies are needed to better understand the preventability of medical procedure-associated foreign bodies and particularly, device failure-related foreign bodies. (J Am Coll Surg 2011;212:977–983. © 2011 by the American College of Surgeons)

According to the National Quality Forum (NQF), a "foreign body" unintentionally left in a patient during a procedure is one of the serious reportable events (ie, NQF "never events").[1] It is a rare event, with an estimated incidence rate of 1 in 5,000 operations,[2,3] but has a reported mortality rate as high as 11% to 35%.[4] Risk factors associated with this event include incorrect counts, surgical team transitions, multiple procedures,[5] unplanned changes in the operation, the emergent nature of procedure, and high body mass index.[6] Theoretically, foreign body events can be eliminated by instituting standardized processes of care such as surgical counts of sponges and instruments before and at the end of each operation. However, despite widespread adoption of standardized processes, foreign body events still occur.

Given its potential preventability, the Agency for Healthcare Quality and Research (AHRQ) developed patient safety indicator (PSI) 5, "Foreign body left during procedure," to detect foreign body events using adminis-

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From the Center for Organization, Leadership, and Management Research (COLMR) (Chen, Rosen, Shin) and the Department of Surgery, VA Boston Healthcare System (Cevasco, Itani); the Department of Health Policy and Management, Boston University School of Public Health (Chen, Rosen, Borzecki); the Department of Surgery, Brigham and Women's Hospital (Cevasco); Boston University School of Medicine (Rosen, Itani, Borzecki); and Department of Surgery, Harvard Medical School (Itani), Boston, MA; and the Center for Health Quality, Outcomes and Economic Research (CHQOER), Bedford VAMC, Bedford, MA (Borzecki).

Correspondence address: Amy K Rosen, PhD, Center for Organization, Leadership and Management Research (COLMR), 150 S Huntington Ave, Boston MA 02130. email: akrosen@bu.edu or amy.rosen2@va.gov

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Abbreviations and Acronyms

AHRQ = Agency for Healthcare Research and Quality
CMS = Centers for Medicare and Medicaid Services
EMR = electronic medical record
IRR = inter-rater reliability
NQF = National Quality Forum
POA = present on admission
PPV = positive predictive value
PSI = patient safety indicator
VA = Veterans Health Administration

trative data. This indicator is defined as discharges with ICD-9-CM codes for foreign body left in during a procedure in any secondary diagnosis field of surgical and medical discharges. ICD-9-CM codes for foreign body used in this PSI include 998.4 (foreign body accidentally left during a procedure not elsewhere classified), 998.7 (acute reaction to foreign substance accidentally left during a procedure not elsewhere classified), and external cause of injury codes (E-codes) E871.x (foreign object left in body during procedure).[7] Similarly, the Centers for Medicare and Medicaid Services (CMS) is currently using an administrative data-based measure (hospital acquired conditions, also known as CMS "never events") to track rates of foreign bodies associated with surgical procedures.[8] However, PSI 5 is the only indicator that flags both surgical and medical foreign bodies.

The accuracy of PSI 5 in identifying true events is unknown. Such information is necessary if this measure is to be used to improve the quality of care. The purpose of this study was to evaluate the positive predictive value (PPV) of this indicator in the Veterans Health Administration (VA) (ie, to evaluate the degree to which the PSI flagged case represents a true foreign body based on data obtained from the medical record). To our knowledge, this is the first study to validate this indicator. We also aimed to examine clinical circumstances and outcomes associated with these true foreign body events.

METHODS

Study design

This was a retrospective observational study using VA inpatient administrative data and electronic medical record (EMR) data from VA fiscal years 2003 to 2007 (from October 1, 2002 to September 30, 2007).[9,10] The required Institutional Review Board approvals from the Bedford VA Medical Center and the VA Boston Healthcare System were obtained for this study.

Study population

We applied the PSI software, version 3.1a, to the VA inpatient dataset to obtain counts of individual PSIs and composite rates. We then selected 28 of 158 VA acute-care hospitals using a stratified sampling method to obtain a diverse sample of VA hospitals. Full details of sampling are provided elsewhere.[9]

PSI 5 technical specifications (v. 3.1)

The denominator of this indicator includes all medical and surgical discharges of patients age 18 or older except for patients with ICD-9-CM codes for foreign body left in during procedure (998.4, 998.7, or E871.x) in the principal diagnosis field or secondary diagnosis present on admission. The numerator includes any discharges with ICD-9-CM codes for foreign body in any secondary diagnosis field among cases meeting the inclusion and exclusion rules for the denominator.[7]

Medical record abstraction

Two trained nurses used standardized abstraction instruments modified from AHRQ-developed instruments to review selected EMRs for the occurrence of a foreign body event and to obtain patient demographics.[9,10] If a foreign body event occurred (ie, a true positive), records were further abstracted for risk factors, clinical circumstances surrounding the procedure associated with the foreign body, and patient outcomes. If no foreign body event occurred (ie, a false positive), abstraction stopped once the reason for exclusion was determined. To assess inter-rater reliability (IRR), both nurses reviewed the same records in groups of 5 until they achieved an average observed agreement of at least 90% across all questions (n = 41) in all records, after which abstraction proceeded independently. IRR was also assessed on 5 charts toward the end of the abstraction process to make sure abstractor reliability did not drift. Further details of the abstraction process are available elsewhere.[9]

Specific to this PSI, we performed 2 early rounds of IRR assessment in order to have enough records to adequately evaluate all questions. Average observed agreement for these 2 rounds combined was 96%. Agreement on late IRR testing was 98%.

Analysis

We calculated PPV as the rate of true positives divided by the total number of flagged cases and derived 95% confidence intervals. We also examined the PPVs of ICD-9-CM codes 998.4, 998.7, and the group of E-codes separately, due to concerns regarding the validity of E-codes in previous.[11,12] We reviewed demographics (age, sex, race and eth-

Table 1. Positive Predictive Values (PPVs) Based on Different Foreign Body ICD-9-CM Codes

ICD-9-CM code(s)	True positives flagged by this code(s), n	False positives flagged by this code(s), n	Positive predictive value, %	95% CI
Overall	42	51	45	35–56
Overall without E871.x	36	37	49	37–61
998.4 only	22	20	52	36–68
998.7 only	1	5	17	0–64
E871.x only	6	14	30	12–54

nicity) in the total sample of 93 patients. Specific to false positives, we examined the type of foreign bodies and the reasons why they were incorrectly flagged by the PSI algorithms. For true positives, we performed descriptive analyses of continuous and categorical variables, including characteristics of foreign bodies, nature of the procedures, risk factors, and patient outcomes, based on whether the foreign body was associated with a surgical or a medical procedure. All statistical analyses were performed using SAS version 9.1 (SAS Institute, Inc).

RESULTS

Across all VA hospitals, a total of 290 foreign body cases out of 2,342,690 eligible discharges were flagged by PSI 5 (0.12 per 1,000); within the 28 selected hospitals, 93 of 652,093 eligible discharges were flagged (0.14 per 1,000). Of the 93 flagged cases, 42 were true positives, yielding a PPV of 45% (95% CI 35% to 56%). ICD-9-CM code 998.4 had a higher PPV (52%) than both ICD-9-CM code 998.7 (17%) and the E-codes (30%), although the confidence intervals overlapped. The overall PPV increased to 49% when we excluded E-codes (Table 1).

Demographics

Flagged patients had an average age of 67 years (SD 11 years) and a median length of stay of 7 days (range 1 to 91 days). Ninety-two patients were male and 73% were white. Demographic characteristics were similar in true positives and false positives (Table 2).

Reasons for false positives

Of the 51 false positives, 29 (57%) were foreign bodies that were present on admission (POA) and 22 (43%) had no documentation of an accidental foreign body event in the EMR during the index hospitalization. Of these 22 cases, 5 false positives represented intentional foreign bodies; 2 (4%) of these had laparotomy pads intentionally left in and 3 had "feeding tubes" (ie, percutaneous endoscopic gastrostomy tubes) inserted. We did not find any evidence of foreign bodies in the other 17 cases. Foreign bodies that were POA included sponges, pads, and fragments of guidewires, drains, and leads— similar to the foreign body types in true positives.

To better understand the accuracy of each individual ICD-9-CM code (998.4, 998.8, and E871.x), we further analyzed the false positive cases flagged by 998.7 or E871.x separately. Of the 5 false positives flagged only by ICD-9-CM code 998.7 ("acute reaction to foreign substance accidentally left during a procedure not elsewhere classified"; Table 1), 2 were POA, and the other 3 were "feeding tubes" that did not cause any postoperative complications. Fourteen false positives were flagged only by external cause-of-injury code E871.x, "foreign object left in body during procedure." (Note that "accidentally or unintentionally" is not incorporated into this definition.) Of these 14 false positives, 10 patients had no evidence of an accidental foreign body, and 1 patient had 3 laparotomy pads intentionally left in an open abdomen to ensure hemostasis during surgery. (Note that the other patient who had laparotomy

Table 2. Patient Demographics (n = 93)

Variable	All flagged cases (n = 93)	True positives (n = 42, 45%)	False positives (n = 51, 55%)
Age, mean (SD), y	67 (11)	67 (12)	67 (11)
Length of stay, median (range), d	7 (1–91)	7 (1–80)	8 (1–91)
Male sex, n (%)	92 (99)	41 (98)	51 (100)
Race, n (%)			
White	68 (73)	31 (74)	37 (73)
Black	13 (14)	5 (12)	8 (16)
Hispanic	4 (4)	2 (5)	2 (4)
Other/missing	8 (9)	4 (9)	4 (8)

pads intentionally left in was flagged by ICD-9-CM code 998.4.)

True positive analyses

Of the 42 true positives, 23 foreign bodies (55%) were related to a surgical procedure; 15 (61%) of these were related to an abdominopelvic procedure. Twenty-one surgical foreign bodies were associated with the original operation, and the other 2 foreign bodies (drain fragments) occurred during postoperative drain removal. Sponges were the most common type of foreign body left behind during surgical procedures (n = 12, 52%); the remainder were instrument or device fragments (Foley tips, drill tips, a steel fragment from a resectoscope, and drain fragments). All surgical procedures had documentation of correct surgical counts (sponge, instrument, and sharp counts) except 4, which documented a disagreement in counts (1 in the final sponge count and 3 in the final instrument count). Intraoperative radiologic survey was performed in these 4 discrepant count cases, and in 3 other cases based on surgeon's concern. Overall, 9 foreign bodies (39%) were discovered at the time of procedure (7 by intraoperative radiologic survey, 1 by surgeon's manual exploration of surgical site, and 1 drain fragment that was discovered immediately after drain removal). Of the 8 foreign bodies that were detected during the original operation, 4 were discovered before skin closure and 4 afterwards. However, only 2 foreign bodies were removed before the patient left the operating room; the rest (n = 6) were left in the patient and scheduled for removal in subsequent procedures based on the surgeon's decision (eg, the patient was hemodynamically unstable and required additional stabilization before object retrieval). Among the other 14 true positives (61%) who had foreign bodies discovered postoperatively, 7 were discovered during investigation of symptoms, 6 were discovered during routine postoperative screening in patients with no symptoms, and 1 was discovered incidentally during a subsequent operation. Seven of the surgical foreign bodies (30%) were related to device failure or malfunction (an instrument broke during the procedure or a device fragment was accidentally left in patient) (Table 3).

The remaining true positives (n = 19) were related to a medical procedure, including cardiac catheterization (n = 12), central line placement (n = 3), and pacemaker placement (n = 2). The most common types of foreign bodies were guidewires or guidewire fragments (n = 13, 68%). Ten of these (53%) were related to device failure or malfunction. Eleven foreign bodies (58%) were discovered at the time of procedure (the physician found part of the instrument was missing when he or she pulled it out) (Table 4).

Patient symptoms related to retained foreign bodies included pain (n = 10), infection (n = 5), adhesions (n = 2), and bowel obstruction (n = 2) (Table 5). Two patients died during the index hospitalization, but neither death was due to the retained foreign body.

Table 3. Characteristics of Foreign Body and Procedure in Surgical Procedure Related True Positives (n = 23)

Variable	n	%
Type of surgical foreign body		
Sponge or gauze	12	52
Instrument or device fragments (Foley tips, drill tips, and a steel fragment from a resectoscope)	7	30
Drain fragments	2	9
Other*	2	9
How foreign body was discovered		
At the time of the original procedure	9	39
Routine postprocedure screen or test without presenting symptoms	7	30
Clinical detection with presenting symptoms	6	26
During subsequent surgery related to signs/symptoms/complications	2	9
During subsequent drain removal procedure	2	9
Incidental discovery during subsequent surgery	1	4
Surgical site		
Abdomen and pelvis	14	61
Spine and extremity (1 vascular and 5 orthopaedic)	6	26
Chest	3	13
Intraoperative radiographic study performed†	7	30
Operative site reopened to look for foreign body or remove foreign material:		
Before leaving operating room and after skin closed	2	9
After leaving operating room	12	52
Unable to determine	1	4
Obesity (body mass index ≥30 kg/m^2)	8	35
Multiple surgical teams involved in procedure	3	13
Procedure performed on emergent or urgent basis	2	9
Unplanned change in procedure‡	3	13
Procedure performed on weekend or weekday night	4	17
Foreign body related device failure or malfunction	7	30

*1) The basket used to retrieve kidney stone; 2) A piece of tape from camera drape during esophagectomy.
†Three radiology studies were performed before skin closure, 4 were after.
‡1) Video-assisted thoracic surgery converted to thoracotomy; 2) unplanned splenectomy; 3) laparoscopic converted to open cholecystectomy.

DISCUSSION

"Unintentionally retained foreign body" was a rare event in the VA. The reported rate of this safety event by PSI 5 was 0.14 per 1,000 cases in the 28 sample hospitals and 0.12 per 1,000 cases across all VA hospitals. As the first study to examine the accuracy of the AHRQ PSI 5, "foreign body left during procedure," we found that the PPV (45%) of this indicator was relatively low compared with other examined PSIs.[9,10]

Table 4. Characteristics of Foreign Body and Procedure in Medical Procedure Related True Positives (n = 19)

Variable	n	%
Type of medical foreign body		
Guidewire or guidewire fragment	13	68
Other instrument fragments	5	26
Stent	1	5
Procedure type		
Cardiac catheterization	12	63
Pacemaker placement or removal	3	16
Central line placement	2	11
Other (eg, replace gastrostomy tube)	2	11
Rank of person performing this procedure*		
Attending physician	2	11
Physician-in-training	2	11
Physician, unknown ranking	5	26
Not documented	10	53
How foreign body was discovered		
At the time of procedure	11	58
Routine postoperative physical examination or radiology without presenting symptoms	6	32
Clinical detection with symptoms	2	11
Procedure performed on emergent or urgent basis	3	16
Procedure was performed on weekend or weekday night	3	16
Foreign body related to device failure or malfunction	10	53

*We collected only the ranking of physicians in medical procedures.

The reasons for false positives were due to conditions being POA (57%) and coding errors (43%). Such a high rate of POA conditions highlights the need to implement POA codes in the VA; the frequency of coding errors underscores existing concerns about coding accuracy, particularly the validity of E-codes.[11,12] Presumably because of such concerns, only codes 998.4 and 998.7 are used for the CMS hospital-acquired condition measure, "foreign object obtained after surgery." This measure also assumes that POA coding is in place and being implemented correctly.[8] Assuming appropriate POA coding and using only the 998.x codes, the PPV of PSI 5 in our study would have increased to 80%, a more moderate PPV.

Our detailed review of false positive cases raised some additional concerns about coding. First, it is unclear whether VA coders are familiar with how to use these foreign body codes. For example, we found that 1 patient had 3 laparotomy pads intentionally left in the open abdomen to ensure hemostasis, but it was coded as an accidental foreign body event. It might be difficult for a coder to determine whether a foreign body was intentionally or unintentionally left in a patient if he or she did not have a strong clinical and/or surgical background or the medical record did not provide explicit details about the scenario. Second, implementation of POA codes in the VA would undoubtedly improve the validity of PSI 5 for detecting true in-hospital events. However, one might argue that from the perspective of measuring performance, it is also important to capture foreign bodies that are POA, because they might reflect true complications of care that occurred during a previous admission or in the outpatient setting. For example, in our false positive review, we found a patient who underwent low anterior resection of the rectosigmoid at Hospital A. After discharge he developed low-grade fevers and left upper quadrant abdominal pain. On return to the hospital 1 month later for a follow-up examination, an abdominopelvic CT showed a retained sponge in his left upper quadrant. He was admitted and brought to the operating room to remove this foreign body. After implementing POA codes in the VA, this case would not be flagged as a foreign body event. However, it is a true safety event that occurred in Hospital A, and should be counted when we evaluate the performance of this facility.

In the true positive review, despite seemingly universal compliance with manual counting protocols for sponges in VA, we still found 12 cases of sponges left in a patient during an operating room procedure when pre- and post-sponge counts supposedly "agreed." This highlights the issue of "false correct counts" (final counts erroneously thought to be correct), suggesting human error in surgical counts. Previous studies have also found other types of human errors in surgical counts.[5,6,13,14] For example, Greenberg and colleagues[14] found that 1 in 8 operations involved at least 1 counting discrepancy (defined as "any instance in which a subsequent count does not agree with a previous one") while they were observing procedures in the operating room, and 41% of these discrepancies were due to miscounting (disagreements between pre- and post-counts that are due to an error in counting). Study authors

Table 5. Patient Outcomes in Surgical and Medical Foreign Bodies (n = 42)

	Surgical foreign bodies (n = 23)		Medical foreign bodies (n = 19)	
Patient outcomes	n	%	n	%
Additional pain or discomfort	5	22	5	26
Sepsis or infection, inflammatory process or other acute reaction	4	17	1	5
Adhesions	2	9	0	0
Bowel obstruction	2	9	0	0
Other*	2	9	0	0
No discomfort	15	65	13	68
Additional procedure or surgery to remove foreign body	22	96	19	100

*1) Mental status changes; 2) Pressure ulcer.

suggested that technological solutions may be needed to reduce such surgical count errors. They subsequently conducted a clinical trial with cost-effectiveness analysis, showing that bar-coding of sponges can improve the detection of miscounted and misplaced sponges in operations at an acceptable cost.[15,16] Although more research needs to be done, technological solutions may be one way to reduce foreign body events, at least in surgical settings.

Although surgical foreign bodies, such as sponges left behind, may be eliminated either by standardized counting or introduction of some of the available technologies to track sponges, we found that almost 40% of all foreign bodies (both surgical and medical foreign bodies) were related to a device failure or malfunction. For example, one patient had a Foley catheter placed before arthroscopic shoulder surgery. The Foley balloon broke and a missing portion (about 0.25 × 0.25 inch) was accidentally left in the patient. Device-related foreign body events occurred more often in medical (n = 10) than surgical (n = 7) procedures. Although previous studies have shown the general public health burden of adverse events associated with medical devices,[17-19] none of these have focused on foreign body events. This study was the first to examine device-associated foreign bodies; our results underscore a concern about the preventability of this type of foreign body event. Although operator inexperience may be one of the reasons for device failure or malfunction, it is hard to determine if a sheared-off guidewire occurred due to physician error or other factors. It will be difficult to prevent such device-associated foreign body events if we cannot clearly identify the reason for device failures.

This was also the first study to examine foreign body events related to medical procedures. Although quality improvement efforts should focus on both medical and surgical procedures, further research is necessary to determine the degree to which these medical foreign body events (and as noted, those associated with device failure) are preventable. Until such information is available, any public reporting of foreign body events, as CMS is doing, should be limited to events associated with surgical procedures.[8]

Notably, the timing of the foreign body event is one of the key components in defining a true event. In this study, 2 foreign bodies discovered after surgical site closure but before leaving the operating room were deemed to be true positives based on the AHRQ definition. Surgical studies usually do not recognize this type of scenario as a true event, because the patient was still in the operating room and therefore the procedure was not officially completed.[6,13,14,20] These 2 cases highlight the discrepancy between the surgical and AHRQ definitions of foreign body. Further discussion and clarification may be needed to ensure that the definition of a foreign body event is consistent across coders, surgeons, and health service researchers, especially in comparing provider performance.

As with any study, there are some inherent limitations. We do not report the sensitivity, specificity, or negative predictive value of this PSI because we did not examine patients who were not flagged by PSI 5. Furthermore, all the data used in this study were abstracted from the EMR, where providers may not completely document all relevant clinical details related to the hospitalization. However, as discussed earlier, the strengths of this study are that it is the first to examine the PPV of this PSI, examine foreign body events occurring outside the operating room, and report on foreign body events associated with device failures. There are study design strengths as well: we selected a nationwide representative sample of VA hospitals; we performed explicit review of the EMR to collect data; high abstractor agreement was obtained in IRR tests; false positives were reviewed to identify ways to improve the validity of this PSI; and we examined true positives in detail to try to determine the preventability of this safety event.

CONCLUSIONS

Based on the reported rate of PSI 5, a foreign body unintentionally left in a patient is a rare event in the VA. However, it occurs in both surgical and medical procedures. Because both NQF and CMS have defined a surgical foreign body as a "never event," quality improvement efforts should focus on novel ways of eliminating unintentionally retained foreign bodies. Although medical procedure-associated foreign bodies are also considered as "never events" by NQF, future studies are needed to better understand the preventability of medical foreign bodies, and particularly device failure-related foreign bodies.

Author Contributions

Study conception and design: Chen, Rosen, Cevasco, Shin, Itani, Borzecki

Acquisition of data: Chen, Borzecki

Analysis and interpretation of data: Chen, Cevasco, Itani, Borzecki

Drafting of manuscript: Chen, Borzecki

Critical revision: Chen, Rosen, Cevasco, Shin, Itani, Borzecki

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