# PENNSYLVANIA PATIENT SAFETY ADVISORY

Produced by ECRI Institute
and ISMP under contract
to the Pennsylvania
Patient Safety Authority

**Vol. 6, No. 2**

**June 2009**

## IN THIS ISSUE


### Reviews & Analyses

39 Beyond the Count: Preventing Retention of Foreign Objects
Surgical counts are intended to prevent the retention of a sponge, sharp, or instrument during a surgical procedure, yet despite the highly regulated nature of the process, discrepancies in the surgical count occur.

46 Medication Errors Occurring in the Radiologic Services Department
The complexity of the procedures, the use of high-alert medications, and the risk of communication failures during handoffs can contribute to medication errors in the radiologic setting.

51 Uterine Perforation Associated with Minimally Invasive Gynecologic Procedures
Uterine perforation is a known risk of minimally invasive gynecologic procedures, and the physician must thoroughly evaluate patients to identify who is at risk.

56 Safety in the MR Environment: Ferromagnetic Projectile Objects in the MRI Scanner Room
To avoid serious or fatal injury from projectiles, magnetic resonance personnel must understand the principles of the projectile effect and properly screen individuals before entering the scanner room for ferromagnetic objects.

### Other Features

37 Enhancing Patient Safety through Education and Collaboration
Megan Shetterly, RN, MS

### Focus on Infection Control

63 Successful Reduction of Ventilator-Associated Pneumonia

### Updates

69 Quarterly Update on the Preventing Wrong-Site Surgery Project

### Other Patient Safety Information

72 Patient Safety in Pennsylvania Healthcare Facilities

# About the Pennsylvania Patient Safety Advisory

## OBJECTIVE

The *Pennsylvania Patient Safety Advisory* provides timely original scientific evidence and reviews of scientific evidence that can be used by healthcare systems and providers to improve healthcare delivery systems and educate providers about safe healthcare practices. The emphasis is on problems reported to the Pennsylvania Patient Safety Authority, especially those associated with a high combination of frequency, severity, and possibility of solution; novel problems and solutions; and those in which urgent communication of information could have a significant impact on patient outcomes.

## PUBLISHING INFORMATION

The *Pennsylvania Patient Safety Advisory* (ISSN 1941-7144) is published quarterly, with periodic supplements, by the Pennsylvania Patient Safety Authority. This publication is produced by ECRI Institute and the Institute for Safe Medication Practices under contract to the Authority.

## COPYRIGHT 2009 BY THE PENNSYLVANIA PATIENT SAFETY AUTHORITY

This publication may be reprinted and distributed without restriction, provided it is printed or distributed in its entirety and without alteration. Individual articles may be reprinted in their entirety and without alteration provided the source is clearly attributed.

Current and previous issues are available online at http://www.patientsafetyauthority.org.

## SUBSCRIPTION INFORMATION

This publication is disseminated by e-mail at no cost to the subscriber. To subscribe, go to https://www.papsrs.state.pa.us/Workflow/MailingListAddition.aspx.

## INDEX INFORMATION

The *Pennsylvania Patient Safety Advisory* is indexed in the Cumulative Index to Nursing and Allied Health Literature® (CINAHL®) print index and electronic database.

The *Pennsylvania Patient Safety Advisory* is also indexed in ECRI Institute's International Health Technology Assessment Database.

## CONTINUING MEDICAL EDUCATION

The Pennsylvania Patient Safety Authority works with the Pennsylvania Medical Society to offer AMA *PRA Category 1 Credits*™ for selected portions of the *Pennsylvania Patient Safety Advisory* through the online publication *Studies in Patient Safety*. Go to http://www.pamedsoc.org to find out more about patient safety CME opportunities.

## PATIENT SAFETY AUTHORITY

### Board of Directors

Ana Pujols-McKee, MD, *Chair*
Anita Fuhrman, RN, BS
Joan M. Garzarelli, RN, MSN
William F. Goodrich, Esq.
Roosevelt Hairston, Esq.
Lorina L. Marshall-Blake
Gary A. Merica, RPh
Cliff Rieders, Esq.
Stanton Smullens, MD
Marshall Webster, MD

### Staff

Michael Doering, MBA, *Executive Director*
Laurene Baker, MA, *Director of Communications*
Franchesca J. Charney, RN, BS, MSHA, CPHRM, CPHQ, CPSO, FASHRM, *Director of Educational Programs*
Christina DeCoskey, RN, MSN, MBA, HCM, *Patient Safety Liaison*
Richard Kundravi, BS, *Patient Safety Liaison*
Megan Shetterly, RN, MS, *Patient Safety Liaison*
Judith Marpoe, *Program Manager*
Teresa Plesce, *Administrative Specialist*

### Contact Information

539 Forum Building,
Harrisburg, PA 17120
Telephone: 717-346-0469
Facsimile: 717-346-1090
Web site: http://www.patientsafetyauthority.org
E-mail: patientsafetyauthority@state.pa.us

## PENNSYLVANIA PATIENT SAFETY ADVISORY

John R. Clarke, MD, *Editor*

### Contributing Editors

Arthur J. Augustine, BS
Sharon Bradley, RN, CIC
Hedy Cohen, RN, BSN, MS
Edward Finley, BS
Michael J. Gaunt, PharmD
Matthew Grissinger, RPh
Charlotte Huber, RN, MSN
Deborah D. Kobelansky, RN, MPH
Cynthia Lacker, RN, MS, LNCC
William M. Marella, MBA
Denise Martindell, RN, JD
H.T.M. Ritter III, BA, CBET
Phenelle Segal, RN, CIC

### Advisors

Michael Cohen, RPh, MS, ScD, *President, ISMP*
Ronni Solomon, JD, *Executive Vice President and General Counsel, ECRI Institute*
Allen Vaida, PharmD, *Executive Vice President, ISMP*

### Production Staff

Jesse Munn, BA, *Managing Editor*
Miranda R. Minetti, BS
John Hall
Tara Kolb, BFA

### Contact Information

Mailing address: PO Box 706
Plymouth Meeting, PA 19462-0706
Telephone: 866-316-1070
Facsimile: 610-567-1114
E-mail: support_papsrs@state.pa.us

### Consideration of Submitted Manuscripts

Manuscripts consistent with the objectives of the *Pennsylvania Patient Safety Advisory* are welcome. For information and guidance about submission and instructions for authors, please contact the editor.

### Editorial Advisory Board

Albert Bothe Jr., MD, *Geisinger Health System*
Mark E. Bruley, BS, CCE, *ECRI Institute*
Vincent Cowell, MD, *Temple University*
Monica M. Davis, CRNP, MSN, MBA, *Children's Hospital of Philadelphia*
William R. Dubin, MD, *Temple University*
Caprice C. Greenberg, MD, MPH, *Harvard University, Brigham and Women's Hospital*
Bonnie Haluska, RN, CRRN, *Allied Services Rehabilitation Hospital*
Richard J. Hamilton, MD, *Drexel University*
Norman A. Johanson, MD, *Drexel University*
Janet Johnston, RN, MSN, JD
Harold S. Kaplan, MD, *Mount Sinai School of Medicine*
Michael L. Kay, MD, *Wills Eye Hospital, Thomas Jefferson University Hospital, Pennsylvania Hospital*
John J. Kelly, MD, FACP, *Abington Memorial Hospital*
Curtis P. Langlotz, MD, PhD, *University of Pennsylvania*
Michael Leonard, MD, *Kaiser Permanente, Institute for Healthcare Improvement*
James B. McClurken, MD, FACC, FCCP, FACS, *Temple University*
Patrick J. McDonnell, PharmD, *Temple University School of Pharmacy*
Francine Miranda, RN, BSN, FASHRM, *Lehigh Valley Hospital*
Pekka Mooar, MD, *Temple University*
David W. Orskey, MSHS, *Hershey Outpatient Surgery Center*
Steve D. Osborn, Vice President, *Saint Vincent Health Center*
Christopher M. Pezzi, MD, FACS, *Abington Memorial Hospital*
Hyagriv N. Simhan, MD, MSCR, *University of Pittsburgh*
Rachel Sorokin, MD, *Thomas Jefferson University*
Jennifer A. Taylor, PhD, MPH, *Drexel University School of Public Health*
Donald P. Underwood, DO, *Drexel University*
Nielufar Varjavand, MD, *Drexel University*
Harold C. Wiesenfeld, MD, *University of Pittsburgh*
Zane R. Wolf, PhD, RN, FAAN, *LaSalle University School of Nursing*

## ACKNOWLEDGEMENTS

The *Advisory* staff would like to thank the following individuals who graciously offered us their insight and/or reviewed selected articles for Vol. 6, No. 2:

John Castronuovo, Jr., MD, *WellSpan Surgical Assoc-WMG*
Matthew K. Clarke, BS, RT(R)(N)
Tobias Gilk, M Arch, *Mednovus, Inc.*
Jane Gould, MD, *St. Christopher's Hospital for Children*
Caprice C. Greenberg, MD, MPH, *Harvard University, Brigham and Women's Hospital*
Patricia Hennessey, RN, MSN, CIC, *St. Christopher's Hospital for Children*
Russell H. Jenkins, MD, *Institute for Safe Medication Practices*
Andrea Kiernan, MLT(ASCP), CIC, *St. Christopher's Hospital for Children*
Jason Launders, MSc, *ECRI Institute*
Francine Miranda, RN, BSN, FASHRM, *Lehigh Valley Hospital*
Larry Veltman, MD

# Enhancing Patient Safety through Education and Collaboration

Megan Shetterly, RN, MS

Megan Shetterly, RN, MS
Patient Safety Liaison, Northeast Region
Pennsylvania Patient Safety Authority

In my encounters with nearly 65 patient safety officers (PSOs) since becoming the Patient Safety Liaison (PSL) for the Northeast Region of Pennsylvania, there is one common theme: the need to collaborate and share in ongoing education about patient safety. Patient safety is influenced by many issues in healthcare, including human factors, high-tech equipment and devices, and often dangerous medications and/or procedures. Complex systems of healthcare delivery demand the use of evidence-based practices and standardization in order to achieve the best clinical outcomes. Ongoing education is necessary to support patient safety.

The Pennsylvania Patient Safety Authority recognizes that responsibilities and internal support vary for PSOs. The Authority is engaged in ongoing efforts to collaboratively identify and address PSOs' educational needs. Through the PSL program, the Authority continued its efforts with two recent educational offerings.

## 2009 Patient Safety Officer Foundation Education Program

In early 2009, PSOs in the Northeast Region were offered a patient safety foundation education course. Eleven PSOs who were either new to their role or who desired more information about patient safety attended this program. Of the participants, eight were from ambulatory surgical facilities (ASFs) and three were from hospitals.

The learning objectives of this program included PSOs being able to recall key elements of Chapter 3 of the MCARE Act of 2002; recognize their role, responsibility, and scope; identify the components and framework of a patient safety infrastructure; identify how to develop and implement a patient safety plan; and recognize patient safety challenges.

A key item of discussion was event reporting—specifically, event determination. This is not unique to this particular group, as other PSOs often struggle with categorizing events that they report to the Authority. During this particular session, the group had the opportunity to work through various scenarios and collectively decide its respective event classification. In some scenarios, there was debate and controversy over each person's interpretation of the criteria used to distinguish a Serious Event and an Incident. But, working through the scenarios aided the PSOs' interpretations. One participant said this experience helped her learn "the different ways people report events and how to determine the type of event." Another participant expressed interest in additional programs dedicated solely to event reporting.

PSOs from ASFs, who represented the majority of participants at the program, discussed appropriate patient selection for services at an ASF. No clear guidelines identify patient comorbidities or other specific criteria that would help to determine which setting is the most appropriate for outpatient surgery.[1] Patient selection is typically determined through medical screenings performed by the surgeon in consultation with the referring physician and the anesthesia practitioner. All participating PSOs agreed that comprehensive preoperative screening measures capture critical information that can help to determine whether a patient is appropriate for the ASF setting. For example, if a patient presents to an ASF with an exacerbation of an existing medical condition that predisposes him or her to harm, that case is aborted and the patient is transported to a local hospital for care and treatment.

All participating PSOs identified communication among all providers and patients as a key factor in ensuring a good patient safety program. An example discussed by the group was correct-site surgery protocols. Each person in the operating room (OR) plays a part to ensure not only the correct patient, correct procedure, and correct site, but to identify potential complications, procure necessary equipment, and monitor to ensure proper recovery management. The benefits of using forcing functions such as time-out checklists were discussed by the group. Some participants have enhanced their existing OR checklists to include the World Health Organization's (WHO) Surgical Safety Checklist. (Information on the WHO Surgical Safety Checklist and accompanying correct-site surgery information can be accessed via the Authority's Web page at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Pages/home.aspx.)

The 2009 Patient Safety Officer Foundation Education Program was well received. The Authority replicated the program for the South Central region in June and will take it to other regions in conjunction with the expansion of the PSL program. The Authority will also build on this success to address more in-depth topics of interest to PSOs.

 ©2009 Pennsylvania Patient Safety Authority 

## MRSA Education Program for Ambulatory Surgery Centers

An objective of the PSL program is to develop and conduct educational programs dedicated to the needs of specific care settings. One of the first Northeast regional sessions involved PSOs of ASFs.

The ASFs of the Northeast Region comprise approximately 50% of all medical facilities in that region. Although ASFs share some of the same patient safety challenges that hospitals and other medical facilities encounter, ASFs are unique in many ways. Most are separate and distinct from a hospital setting. ASF procedures and surgeries are performed on low-risk patients who do not require the more extensive resources available in a hospital setting. In order to obtain/maintain licensure, ASFs must comply with state standards that differ from state standards for hospitals (e.g., limit of four hours of operating time).[2] In addition, ASFs are accredited by different voluntary regulatory bodies. While hospitals are accredited by the Joint Commission, the majority of ASFs are accredited by the Accreditation Association for Ambulatory Health Care.

During my visits with PSOs of ASFs, they voiced interest about methicillin-resistant *staphylococcus aureus* (MRSA). Each PSO understands the core infection prevention elements for MRSA, but all are continually looking at best practices for surveillance. Regarding patients' infectious disease status, some PSOs commented about inconsistent cooperation from other care settings that transferred patients to ASFs for care. Others requested additional education about elements of Act 52 of 2007. As a result, the Authority conducted a MRSA education program for ASFs on April 7, 2009. The program addressed clinical features, mode of transmission, infection prevention strategies, recognition of high-risk patients, surveillance measures, infection control practices, and elements of Act 52.

PSOs from 62% of ASFs in the Northeast participated in this program. PSOs represented various types of ASFs (e.g., single procedure versus multiple procedure settings). Overall participant response was quite positive (satisfaction rating of 98%). Evaluation comments reflected that current knowledge was reinforced, and additional education was provided about items such as the availability of rapid MRSA testing and recommendations from the Centers for Disease Control and Prevention (CDC). The education prompted some PSOs to say that they will modify facility policies as a result. Another attendee from the Southeast Region, who accompanied a PSO from her sister facility in the Northeast Region, asked when the Authority would be hiring a PSL for, and have functions like this in, the Southeast Region.

Toward the conclusion of the program, the attendees had the opportunity to participate in a limited open forum about shared issues. One PSO was from a facility in which a malignant hyperthermia event had resolved successfully. The PSO offered to share this experience so that others could learn from it. Another PSO offered to share her facility's medication reconciliation process, including policy and forms. Yet another was willing to share preoperative assessment forms.

PSOs also offered topics of interest for future programs, including correct-site surgery, team building, medication reconciliation, and preoperative screening/assessment. (See the March 2009 *Pennsylvania Patient Safety Advisory* for articles on the first and last topics.) All participants were referred to the Authority's Web site (http://www.patientsafetyauthority.org) to access existing information about these topics and others and were encouraged to provide feedback about their usefulness. PSOs were likewise encouraged to comment on entries to the Authority's Time-Out in the OR Competition (entries were reprinted in the March 2009 *Advisory* and are available for comments by all at http://www.patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Pages/scripts.aspx).

## Ongoing Efforts

The Authority's PSL program will continue to communicate with all the medical facilities in the Northeast Region to both identify and respond to their patient safety needs and initiatives. These and future Authority-sponsored educational programs will offer continuing education hours for Pennsylvania professional nurses. The programs shared in this article are among many being planned for the Northeast and other regions throughout the Commonwealth. Those individuals within the Commonwealth who have an interest in learning about future programs should contact the Authority.

The Authority is in the process of broadening the reach of the PSL program beyond the Northeast Region. Two new PSLs will soon engage healthcare facilities within their respective regions of Pennsylvania (see listings under Authority staff on the *Advisory* masthead page). Within the next year, it is anticipated that the program will grow to encompass three more regions of the Commonwealth and provide medical facilities with guidance and education relative to their patient safety needs.

### Notes

1. Patient screening and assessment in ambulatory surgical facilities. Pa Patient Saf Advis [online] 2009 Mar [cited 2009 Apr 27]. Available from Internet: http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2009/mar6(1)/Pages/03.aspx.

2. The Pennsylvania Code, Chapter 551.21, § 1005.10, Licensure and general operating standards, Section I, (c), (A)., Amended October 1999, Criteria for Ambulatory Surgery [online]. [cited 2009 May 18]. Available from Internet: http://www.pacode.com/secure/data/028/chapter551/chap551toc.html.

 ©2009 Pennsylvania Patient Safety Authority 

# Beyond the Count: Preventing Retention of Foreign Objects


## ABSTRACT

*Failure to account for all sponges, sharps, and instruments postoperatively may lead to the inadvertent retention of a foreign object. The retention of a foreign object may cause serious patient harm and often requires further medical treatment. Surgeons and operating teams routinely rely on the practice of a sponge, sharp, and instrument count to reduce the risk of a retained foreign object. Surgical counts are intended to prevent the retention of a sponge, sharp, or instrument, yet despite the highly regulated nature of the process, discrepancies in the surgical count occur. In 2008, the Pennsylvania Patient Safety Authority received 2,228 reports involving an incorrect sponge, sharp, or instrument count. The Authority also received 194 reports of retained foreign objects (RFOs). Preventing RFOs requires a multipronged strategy, including reliable counting methods. However, counting alone may be insufficient. This article examines risk factors for RFOs following surgery and addresses the role of human factors analysis to uncover system vulnerabilities. Risk reduction strategies include improved perioperative processes, perioperative team communication, and the use of assistive technology. (Pa Patient Saf Advis 2009 Jun;6[2]:39-45.)*


## Introduction

Foreign objects can be left behind following a surgical procedure in any part of the body—most frequently in the abdominal cavity and thorax—although no body cavity is invulnerable.[1] Authority reports and a case-control study of retained foreign objects (RFOs) in surgical patients show that sponges are the items most frequently reported as retained, followed by instruments.[2] RFOs may lead to serious complications, such as sepsis, fistula or small bowel obstruction, or visceral perforation.[2] The retention of a foreign object is considered a serious preventable event by the National Quality Forum.[3] The Centers for Medicare & Medicaid Services (CMS) includes the retention of a foreign object in its list of hospital-acquired conditions for which reimbursement will not be provided.[4] The Joint Commission categorizes the unintended retention of a foreign object as a sentinel event.[5]

Estimates of the incidence of RFOs vary.[2,6,7] It may be difficult to arrive at a true estimate of the incidence of RFOs since an RFO can remain undetected for years.[7] A 2003 study involving claims and incident reports related to RFOs over a 10-year period estimated that RFOs are rare, occurring at a rate of 1 in 8,801 to 1 in 18,760 inpatient operations.[2] Two later studies estimated that RFOs occur more frequently. In an analysis of administrative and event reporting data, the authors determined that of 153,263 operations, the rate of RFOs was 1 in 7,000 surgeries.[6] A study involving 191,168 surgical procedures in an institution that performed routine postoperative radiographs reported that the incidence of RFOs was 1 in 5,500.[7]

The costs related to an RFO can be significant. According to CMS, the cost of an RFO after surgery is $62,631 per hospital stay.[8] In addition to hospital costs, RFOs can generate significant litigation costs. Kaiser et al.'s review of 9,729 closed malpractice claims demonstrated 40 retained surgical sponge cases over a 7-year period from 1988 through 1994 with an average expenditure of $66,110 for legal defense costs and indemnity payments,[9] or approximately $103,504 adjusted to current dollars. Thus, the total cost for an RFO, including legal defense, indemnity payments, and surgical costs unreimbursed by CMS, would be approximately $166,135. At the previously quoted incidence of 1 in 5,500 operations,[7] the cost of an RFO amortizes to about $30 per operation.

Counting objects before, during, and after surgery is a common method for screening for and preventing RFOs. When count discrepancies occur, reconciliation of the count may involve additional time and cost. The effect of count discrepancies on the cost of treatment has been estimated. A study reviewed all coronary artery bypass graft (CABG) procedures conducted at a major academic health center between 2000 and 2004.[6] The total cost of CABG procedures and the additional cost related to count discrepancies, including extended operating room (OR) time and the additional cost of imaging, were calculated. In 153,263 surgical procedures, 1,062 discrepancies were reported. The incremental OR cost for CABG because of a count discrepancy was $932. On the basis of the national volume of CABG operations per year (347,570 in 2004), the estimated national cost of count discrepancies for CABG procedures is $24 million. Moreover, the rate of RFOs was 1 in 70 discrepancy cases;[6] therefore, the cost of detecting an RFO from a count discrepancy can be calculated to be $65,240, demonstrating the importance of reliable counting and reconciling count discrepancies in RFO prevention.

## Risk Factors Related to Retention of a Foreign Object

RFOs may cause serious injury.[2] Knowledge of the factors that increase the chance that an RFO may occur can improve preventive practices. The infrequency of RFOs has been described as limiting observational and single-institution studies of risk factors and patterns of causation.[2] Nonetheless, retrospective studies of closed claims and medical records have cited several risk factors, including emergent surgery, unexpected changes in the operative procedure, high

 ©2009 Pennsylvania Patient Safety Authority 

patient body mass index (BMI), and breakdowns in communication.[2]

A case-control analysis of medical malpractice claims identified several risk factors for RFOs.[2] Occurrence of an RFO was nine times as likely when an operation was performed on an emergency basis and four times as likely when the surgical procedure changed unexpectedly. A higher mean BMI was also identified as a risk factor. Another case-control analysis of hospital billing records and reimbursement data over a 10-year period identified 30 RFO cases.[1] In this study, BMI, emergency surgery, and unexpected changes in operative procedures were not found to be independent predictors of RFO. Surgeries resulting in RFO involved more serious procedures as part of the same operation and were more likely to have an incorrect sponge and instrument count.

A retrospective review of the records of 191,168 operations at the Mayo Clinic, Rochester, Minnesota, from 2003 to 2006, identified 34 cases of RFOs discovered after the patient left the OR, representing a rate of approximately 1 RFO per 5,500 operations.[7] An additional 34 events were classified as near misses, in which an RFO was suspected but could not be confirmed with high-resolution postoperative imaging. Thirty-one near misses involved an incorrect count. Previously identified predictors of RFOs, including BMI, emergency surgery, or unexpected changes in operative procedures, were not demonstrated. However, root-cause analysis of the actual RFO events showed that the most common contributing factor was breakdown in communication, most frequently the failure of team members to communicate when an item was placed in a body cavity.[7]

## Authority Reports

In 2008, the Pennsylvania Patient Safety Authority received 2,228 reports involving an incorrect sponge, sharp, or instrument count. Of the reports, 1,040 (47%) involved incorrect needle counts, 731 (33%) involved incorrect equipment counts, and 454 (20%) involved incorrect sponge counts. Of the reports involving an incorrect sponge, sharp, or instrument count, 1,564 reports indicate that a radiograph was performed. In 1,123 of these reports, the radiograph was negative for an RFO. Twenty-four reports indicate that the radiograph was positive for an RFO in the presence of an incorrect count. Four hundred and seventeen reports did not indicate whether a radiograph was performed to detect the presence of an RFO. The rate of RFOs related to these reported incorrect counts is unknown; however, each event represents a potential risk for an RFO. An additional 233 reports involved an incomplete count or the failure to perform a count.

During the same 1-year period, the Authority received 194 reports of RFOs reported as a separate event category. Of these reports, 160 (84%) indicate that a radiograph was done. In 43 (22%) reports, the RFO was discovered after the patient left the OR. The following are examples of reports related to RFOs:

*The patient had a procedure for an abscess. The patient had continued pain, and the wound was not healing. The patient had a repeat procedure for nonhealing of the wound. During the procedure, it was identified that the patient had retained packing (from previous procedure); approximately 20 inches of packing [was] found.*

*During postoperative follow-up for a possible surgical site infection, the incision was opened to allow drainage, and a retained surgical sponge was discovered. Review of perioperative documentation shows three counts were performed, and the final count was correct. The patient was prescribed antibiotics.*

*The patient required multiple incision and drainage procedures of an abdominal wound. Scheduled surgery revealed a blue towel left from a VAC [vacuum-assisted wound closure] dressing change.*

*The patient presented with an abscess. The patient had a history of trauma with multiple OR procedures and prior hospitalizations to wash out a large wound. When the abscess was drained in the OR, a drain was found retained in the wound.*

## Counting as a Risk Reduction Strategy

Counting procedures to prevent RFOs are in place in most hospitals. However, regulations do not prescribe how counts should be performed, who should perform them, and when they should be performed. Guidelines have been provided by the American College of Surgeons (ACS), the Association of peri-Operative Registered Nurses (AORN), and the Joint Commission. The guidelines recommend counting of all sponges, sharps, and instruments at the following times:[10,11,12]

- Before the procedure, to establish a baseline
- Before the closure of a cavity within a cavity
- Before wound closure begins
- At skin closure
- At the time of permanent relief of either the scrub person or circulating nurse

Adding to the count sheet any sponge, sharp, or instrument subsequently introduced to the operative field and performing counts to coincide with personnel handoffs is also recommended.[11] AORN, with the support of ACS, published the best practices for preventing the retention of a foreign object. Best practices related to the surgical count are as follows:[11]

- Consistently perform surgical counts according to national standards and facility policy.
- Conduct a methodical wound exploration before wound closure and whenever a count discrepancy is noted.

 ©2009 Pennsylvania Patient Safety Authority 

- Document the outcomes of the surgical count, items intentionally used for packing, and actions taken to rectify a count discrepancy.
- Develop and review count policies and procedures through a collaborative process to promote consistency in practice across disciplines.
- Make count policies and procedures readily available in the practice setting.

## Reliability of Surgical Counts

Surgical teams routinely rely on discrepancies in the surgical count procedure to screen for the presence of a potential RFO. However, several studies suggest that reliance on the surgical count for this purpose may not be sufficient. One of the earliest studies that evaluated the likelihood of an RFO in the presence of a count discrepancy demonstrated that 88% of RFOs were associated with a count that was erroneously thought to be correct.[2] Cima et al. also demonstrated that counting procedures may have limitations. In an analysis of RFO events and near misses, 62% of the true RFO events involved a correct sponge, sharp, and instrument count.[7] Egorova et al. determined that of 1,062 count discrepancies among 153,263 surgical procedures, 17 were true positives in which the foreign object was inside the patient.[6] For that reason, AORN and ACS recommend methodical wound exploration in addition to a surgical count.[11]

A recent study evaluated whether surgical counts successfully detect potential RFOs.[13] Researchers observed 148 elective general-surgery procedures. A count discrepancy, defined as a count that does not agree with a previous count, occurred once in eight observed cases. In 51% of these discrepancies, a misplaced item, one that was lost on the floor, in the trash, or in the drapes, was detected and represented the possibility of an RFO. Sponges were the items most frequently retained. Forty-one percent of discrepancies were attributed to human errors, such as addition, incorrect documentation, or miscounting. The author concludes that despite recognized limitations in manual counts, any count discrepancy should prompt a thorough search and reconciliation and never be ignored.

The Egorova et al. study evaluated count discrepancy data from a four-year period derived from the event reporting system and administrative data at a major academic healthcare institution to estimate the rate of RFOs and the ability of counting to detect RFOs.[6] The authors report the rate of RFOs was 1 of 70 discrepancy cases. The study demonstrated that accuracy of the count was affected by the following:

1. The complexity of the surgery (number of nursing teams and duration)
2. The emergent or urgent nature of the surgery
3. The surgical team's fatigue and workload (duration and late-day procedures)

The authors suggest that the reduced reliability of counting in certain circumstances argues for adoption of additional safety measures and technological support.[6] Counting is not reliable enough to be used without concurrent manual visual checks.[6,14]

## Human Factors in the Counting Process

Daily activities in the OR environment can increase the risk of errors during the counting process. Communication failures, distractions from multiple competing interests, pressure for increased productivity, and lack of sufficient personnel are all factors that may contribute to errors in the surgical count.[11,13,14] The counting procedure is dependent to a great degree on human performance, and it has been estimated that in the event of a count and subsequent recount, the chance that the counts will not match is substantial, representing inherent potential for human error in the process.[14]

Communication in the OR can be effected by cultural factors. The OR team consists of individuals with specific roles, requiring specific expertise and skills, performing interdependent tasks. Teams are prone to conflicts, such as a dispute, disagreement, or difference of opinion related to patient management, requiring some decision or action.[15] In addition, the culture of the OR often is hierarchical, contributing to communication failures.[16] Hierarchical relationships between individuals or groups include the following:[16]

- Cross-cultural: nurse to surgeon
- Gender-related: male to female
- Captain to crew: surgeon to OR team
- Structural: medical staff to hospital staff

Environmental factors can influence human performance during the counting process. Interruptions, equipment noise, conversations, and OR traffic can all distract participants in the count procedure. Transfer of responsibility between staff members during change of shift or breaks can also create distractions, interfering with the transfer of information between OR team members. In addition, the length of surgery can contribute to fatigue.[11,13,14]

ElBardissi et al. studied the transferability to the OR of a human factors model originally developed in the aviation industry.[17] Potential areas of error causation indentified by OR team members that may affect the counting process are summarized as follows:[17]

- Routine violation and bending of rules
- High staff turnover, necessitating recruitment of inexperienced team members
- Performance of too many jobs by OR staff
- Consistent underestimation by OR management of the time-consuming nature of scrub technician and registered nurse duties
- Effect of extended operative time on OR members

Communication and handoff issues were also demonstrated in a prospective study involving observation and systems analysis of 10 complex surgical cases. Handoffs of patient care across physical locations and

 ©2009 Pennsylvania Patient Safety Authority 

providers were observed to be particularly vulnerable to loss of information leading to delays, overuse of staff and resources, and uncertainty in clinical decision making. High workload and multiple competing tasks were also identified as areas compromising patient safety.[18]

## Additional Risk Reduction Strategies

As the literature regarding the reliability of counting suggests, counting alone may not prevent postoperative retention of a foreign object. The integration of multiple methods of prevention has been recommended.[9] Consideration of human factors that may affect the count as well as adherence to a standardized counting procedure are important ways to reduce the risk of RFOs. Additional strategies to consider include radiographic screening, multidisciplinary approaches, and the use of assistive technology.

### Radiographic Screening

Some institutions conduct surveillance using routine postoperative screening radiographs. Instruments made of stainless steel are likely to be detected successfully on screening radiographs; however, radiographs are less sensitive in detecting sponges and needles.[13,14] Sponges may be difficult to detect because they may become twisted or folded, distorting visualization of the marker, or a sponge without a radiopaque marker may have been used.[13,14] Needles may be difficult to visualize due to their size.[13,14]

A limited number of studies have been undertaken to evaluate the effectiveness of intraoperative and postoperative radiographs. Cima et al. demonstrated that in 34 cases of an actual RFO in which the count was correct, 20 (60%) of the RFOs were detected on a postoperative high-resolution radiograph survey film.[7] In 68 events of near misses and actual RFOs, 46 (67%) had intraoperative radiographs performed. In 18 incidents in which an RFO was eventually detected, intraoperative radiographs identified 12 of those objects. The authors conclude that given the unreliability of portable intraoperative radiographs, postoperative survey radiographs should be performed with dedicated high-resolution radiograph equipment in a dedicated imaging area.[7] Kaiser et al. demonstrated that in 3 of 29 (10%) cases in which intraoperative radiographs were taken to detect radiopaque sponges, the radiograph was falsely negative. Poor-quality radiographs, multiple foreign objects in the field, and failure to communicate the purpose of the radiograph to the interpreting radiologist were cited as factors involved.[9] In an abstract, Devgan et al. concluded that the net cost of a routine intraoperative screening was $450. The calculated cost of a routine intraoperative radiographic screening of all surgical patients to detect an RFO would be approximately $11.5 million.[19] Detection of needles on radiograph screening depends on the needle size. A recent study evaluated the accuracy of plain abdominal films in the detection of retained surgical needles of varying sizes in the peritoneal cavity. Radiologists identified 195 needles in 360 abdominal segments. Abdominal radiographs had high sensitivity in the detection of retained surgical needles that were more than 10 mm in length.[20] Earlier studies are inconsistent; one study reported detection of needles as small as 6 mm, while another reported that needles smaller that 13 mm could not be detected.[21-23]

Gawande et al. have recommended radiographic screening at the end of cases involving an emergent procedure, unexpected change in procedure, or high patient BMI.[2] Conversely, citing the low quality of portable radiographs and the "large logistical and financial commitment" that would accompany a mandatory radiograph policy, Gibbs et al. have recommended obtaining an radiograph if the count is incorrect and before wound closure.[14] In addition, intraoperative radiographs should be reviewed by a radiologist.[14] ACS recommends the use of radiographs "as indicated."[10] A 2006 Department of Veterans Affairs multistakeholder directive on the prevention of RFOs suggests that when a radiograph is requested to locate a missing item, the type of foreign object that is missing and the OR suite number and telephone number must be specified in the radiology request.[24]

### Multidisciplinary Approaches and the Counting Process

A multidisciplinary, multiphase approach to RFO prevention has been implemented at the Mayo Clinic. Its three-phase quality improvement program began with policy review and analysis of true and near-miss RFOs to identify patterns of failures. The second phase involved multidisciplinary educational programs. The third phase included monitoring and the response of rapid leadership response teams to any event. The program has resulted in an increase in the interval between RFO events from every 16 days to every 69 days sustained over a 2-year period. Highlights of the program related to the surgical count are summarized as follows:[25]

- Implementation of a "Conscientious Count Campaign"—an educational program that includes the in-house production of a video documenting the correct counting process, team training in a simulation center, and in-room audits
- Daily reminders of appropriate counting techniques in staff morning reports
- Use of a counting whiteboard with standardized documentation criteria
- Introduction of "red rules" that are prominently displayed in all ORs
  - Any team member can invoke a red rule to stop the procedure, including the rule that all counts must be performed by two team members. During the closing pause, the surgeon and residents are required to stop all activity other than appropriate wound exploration to avoid any interruption of the count process.

 ©2009 Pennsylvania Patient Safety Authority 

- Deployment of a rapid response leadership team to any near-miss or real RFO event to analyze the event (A memo describing the event and findings must be shared with all OR personnel within 24 to 48 hours of the event.)
- Use of posters to track the number of days since the last RFO event

A multidisciplinary approach to RFO prevention is also suggested in a national RFO prevention initiative, "No Thing Left Behind," a surgical patient safety project aimed at encouraging all members of the OR team to reduce the incidence of RFOs. A summary of the highlights related to the surgical count are as follows:[26]

- Use a standardized counting process.
  - Develop a standardized method that must be used by all OR personnel for all ORs in the facility.
  - Allow sufficient time for the count.
  - Perform the count using audible and visual confirmation between two team members.
  - Use a standardized counting process using hanging sponge holders.
  - Document the count for all personnel to see.
  - Develop a standard nomenclature for all sponges used in the OR.
  - Develop a standard, visual means to record and display the surgical count, such as a dry-erase board.
  - Unless absolutely necessary, avoid disturbing the nursing staff while they are counting.
  - Take recommended steps to explore the wound during procedures in the abdomen and pelvis and mediastinum or thorax.
  - Inform the the scrub team about all additional items added to the count.
- Verify that sponges are accounted for through the following actions:
  - Actively ask whether appropriate counting procedures have been performed at the end of the procedure.
  - Verify the final count before the patient leaves the OR.
- If there is an incorrect count, take the following actions:
  - Stop closing the wound.
  - Remove enough sutures to allow a visual and tactile exploration.
  - Obtain a radiograph of the complete operative field, and provide a description of the missing item to the radiologist to aid in detection.
  - Enlist the assistance of additional personnel.
  - Locate the missing item before the patient leaves the OR.
  - The surgeon should consider dictating what actions were taken in response to the incorrect count and the results of the search.

## Assistive Technology

Technological aids to assist the OR team in the detection and prevention of the retention of sponges, gauze towels, and laparotomy pads include radio-frequency (RF) detectable sponge systems, radio-frequency identification (RFID)-detectable sponge systems, and bar-coded sponge systems.[27] These aids are intended to augment the manual count, not replace it. RF sponge detection systems operate as "detect only" and involve a surgical sponge with an embedded RF tag, along with an antenna or a wand RF reader to detect the RF tag. During and/or after the surgery, the user passes the wand over and around the surgical site to detect the presence of a retained surgical sponge.[27,28] RFID-tagged sponge systems count and detect. The sponges are scanned before surgery, and a running count of sponges is kept during the procedure. The wand can be used to detect a missing sponge; however, scanning of the patient has been recommended regardless of the outcome of the sponge count.[27] Potential benefits of RF/RFID technology include early identification of a sponge and prevention of the need for additional surgery and the reduction or elimination of the need to take radiographs to detect the presence of a sponge.[27] The cost of RF systems using a wand scanned over the patient to detect RF tags embedded in sponge, gauze, and towels is estimated to be $50 to $55 per open procedure.[29] The cost associated with RFID sponge systems is estimated to be $35 to $50 per case on average.[29] However, the costs may decrease as newer RF and RFID technologies becomes available.

Bar-code scanning is another technology available to reduce the likelihood of a retained sponge. Bar-code technology for this application became available in early 2006.[30] The process involves labeled sponges or towels that are passed under a bar-code reader, providing a count of each sponge. A recent randomized controlled study compared a bar-code-assisted surgical count with a manual count in 300 general-surgery procedures.[30] The bar-code system detected significantly more counting discrepancies involving sponges than the traditional counting method. The benefit of a bar-code system is that using the system decreases the risk of an incorrect count.[27] However, bar-code sponge systems have limitations when compared with RF-detectable sponge technology. Bar-code technology will not detect misplaced or retained sponges, and scanning a bar-coded label covered in blood may be difficult.[27] The cost of bar-code systems has been estimated to be $12 to $14 per procedure.[30]

 ©2009 Pennsylvania Patient Safety Authority 

### Accompanying Patient Safety Tool

Visit the Pennsylvania Patient Safety Authority Web site (http://www.patientsafetyauthority.org/EducationalTools/PatientSafetyTools/rfo/Pages/home.aspx) for a sample auditing tool to help staff assess events involving retained foreign objects.

## Conclusion

As reports to the Authority demonstrate, incorrect counts occur frequently. Incorrect counts may lead to the inadvertent retention of a foreign object after surgery, which may result in serious harm to a patient. The counting process is highly dependent on human performance in an increasingly complex environment. However, the risk of RFOs can be reduced by a multifaceted and multidisciplinary approach, including strict adherence to a standardized counting process, consistent and methodical wound exploration before closing, attention to human factors contributing to error, and use of assistive technology.

### Notes


1. Lincourt AE, Harrell A, Cristiano J, et al. Retained foreign bodies after surgery. *J Surg Res* 2007 Apr; 138(2):170-4.
2. Gawande AA, Studdert DM, Orav EJ, et al. Risk factors for retained foreign bodies after surgery. *N Eng J Med* 2003 Jan 16;348(3):229-35.
3. Centers for Medicare & Medicaid Services. Hospital-acquired condition (present on admission indicator) [online]. 2009 Feb 19 [cited 2009 Mar 11]. Available from Internet: http://www.cms.hhs.gov/HospitalAcqCond/06_Hospital-Acquired_Conditions.asp.
4. National Quality Forum. *Serious reportable events in healthcare 2006 update: a consensus report*. Washington (DC): National Quality Forum;2007.
5. Joint Commission. Joint Commission fact sheet. Facts about the sentinel event policy [online]. 2008 Mar 20 [cited 2009 Mar 11]. Available from Internet: http://www.jointcommission.org/AboutUs/Fact_Sheets/sep_facts.htm.
6. Egorova NN, Moskowitz A, Gelijns A, et al. Managing the prevention of retained surgical instruments. What is the value of counting? *Ann Surg* 2008 Jan;247(1):13-8.
7. Cima RR, Kollengode A, Garnatz J, et al. Incidence and characteristics of potential and actual retained foreign object events in surgical patients. *J Am Coll Surg* 2008 July;207(1):80-7.
8. Centers for Medicare & Medicaid Services. CMS fact sheets. CMS proposes additions to list of hospital-acquired conditions for fiscal year 2009 [online]. 2008 Apr 14 [cited 2009 Apr 7]. Available from Internet: http://www.cms.hhs.gov/apps/media/press/factsheet.asp?Counter=3042.
9. Kaiser CW, Friedman S, Spurling KP. The retained surgical sponge. *Ann Surg* 1996 July;224(1):79-84.
10. American College of Surgeons. Statement on the prevention of retained foreign bodies after surgery. *Bull Am Coll Surg* 2005 Oct;90(10):15-6.
11. Best practices for preventing a retained foreign body. *AORN J* 2006 July;84(Suppl 1):S30-6.
12. Joint Commission. Resources for managing hospital-acquired conditions. Foreign objects retained after surgery [online]. 2009 Jan [cited 2009 Mar 13]. Available from Internet: http://www.jcrinc.com/Foreign-Objects-Retained-After-Surgery.
13. Greenberg CC, Regenbogen SE, Lipsitz SR, et al. The frequency and significance of discrepancies in the surgical count. *Ann Surg* 2008 Aug;248(2):337-41.
14. Gibbs V, Coakley FD, Reines HD. Preventable errors in the operating room: retained foreign bodies after surgery—Part 1. *Curr Probl Surg* 2007 May;44(5):281-337.
15. Booij LH. Conflicts in the operating theatre. *Cur Opin Anaesthesiol* 2007 Apr;20(2):152-6.
16. Gibbs VC, McGrath MH, Russell TR. The prevention of retained foreign bodies after surgery. *Bull Am Coll Surg* Oct 2005;90(10):12-4,56.
17. ElBardissi AW, Wiegmann DA, Dearani JA, et al. Application of the human factors analysis and classification system methodology to the cardiovascular surgery operating room. *Ann Thorac Surg* 2007 Apr;83(4):1412-8.
18. Christian CK, Gustafson MI, Roth EM, et al. A prospective study of patient safety in the operating room. *Surgery* 2006 Feb;139(2):159-73.
19. Devgan L, Waters H, Pronovost PJ, et al. A cost analysis of intra-operative x-ray screening for retained surgical foreign bodies. *J Surg Res* 2007 Feb;137(2):186.
20. Ponrartana S, Coakley FV, Yeh BM, et al. Accuracy of plain abdominal radiographs in the detection of retained surgical needles in the peritoneal cavity. *Ann Surg* 2008 Jan;247(1):8-12.
21. Use of x-rays for incorrect needle counts. PA PSRS Patient Saf Advis [online] 2004 Jun [cited 2009 May 18]. Available from Internet: http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2004/jun1(2)/Documents/05.pdf.
22. Barrow CJ. Use of x-ray in the presence of an incorrect needle count. *AORN J* 2001 Jul;74(1):80-1.
23. Macilquham MD, Riley RG, Grossberg P. Identifying lost surgical needles using radiographic techniques *AORN J* 2003 Jul;78(1):73-8.
24. Veterans Health Administration (VHA). U.S. Department of Veterans Affairs. Corrected copy. Prevention of retained surgical items. VHA directive 2006-030 [online]. 2006 May 17 [cited 2009 Apr 20] Available from Internet: http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1425.
25. Cima RR, Kollengarde A, Storsveen AS, et al. A multidisciplinary team approach to retained foreign objects. *Jt Comm J Qual Saf* 2009 Mar;35(3):123-31.
26. Gibbs VC. Patient safety in the operating room; correct-site surgery and no thing left behind. *Surg Clin North Am* 2005 Dec;85(6);1307-19, xiii. Review.


 ©2009 Pennsylvania Patient Safety Authority 

27. ECRI Institute. Radio-frequency surgical sponge detection: a new way to lower the odds of leaving a sponges (and similar items) in patients [evaluation]. *Health Devices* 2008 Jul;37(7):193-202.
28. Regenbogen SE, Greenberg CC, Resch SC, et al. Prevention of retained surgical sponges: a decision-analytic model predicting relative cost-effetiveness. *Surgery* 2009 May;145(5):527-35.
29. Getting the whole team on board to prevent retained foreign bodies. *OR Manager* 2008 Sep;24(9):1,15-8.
30. Greenberg CC, Diaz-Flores R, Lipsitz SR, et al. Barcoding surgical sponges to improve safety: a randomized controlled trial. *Ann Surg* 2008 Apr;247(4):612-6.


## Self-Assessment Questions

The following questions about this article may be useful for internal education and assessment. You may use the following examples or come up with your own.

1. Which of the following factors has NOT been associated with an increased risk of retention of a foreign object following surgery?
   a. Emergency surgery
   b. Size of the sponge
   c. Multiple major surgical procedures
   d. High body mass index
2. All of the following statements about factors that can affect the accuracy of the surgical count are true EXCEPT:
   a. High music volume, excessive conversation, and equipment noise can interfere with the transfer of information between operating room (OR) team members.
   b. The transfer of responsibility between staff members during change of shift or breaks can create distraction.
   c. In the event of a miscount and subsequent recount, there is a substantial chance that the counts will be reconciled.
   d. Routine violation and bending of rules are potential areas of error causation indentified by OR team members that may affect the counting process.
3. Which of the following are NOT risk reduction strategies that will reduce the risk of a retained foreign object (RFO)?
   a. Develop a standard, visual means to record and display the surgical count, such as a dry-erase board.
   b. When a radiograph is requested to identify or rule out a suspected RFO, the type of suspected foreign object should be specified on the request.
   c. Verify the count before the patient leaves the OR only if there has been a discrepancy between the baseline and final count.
   d. Actively ask whether appropriate counting procedures have been done at the end of the procedure.
4. A patient has undergone an open abdominal procedure. During closure of the abdomen, the scrub nurse reports an incorrect needle count; a 13 mm needle is missing.

   Select the evidence-based response to this incorrect count.
   a. Stop closing the wound, cover the wound, and obtain a radiograph of the abdomen.
   b. Conduct a visual inspection. If the needle is not seen in the abdominal cavity, continue to close the wound because the needle is too small to be detected on a radiograph.
   c. Stop closing the wound, remove enough sutures to allow a visual and tactile exploration, and request and obtain a radiograph of the complete operative field, communicating to the radiologist that the team is searching for a needle.
   d. Continue closing the wound, send the patient for an abdominal radiograph, indicating to the radiologist that a needle is missing, and return the patient to the OR immediately.
5. All of the following are potential advantages of the use of radio-frequency (RF) surgical sponge detection systems EXCEPT:
   a. RF surgical sponge detection can replace manual counting.
   b. RF surgical sponge detection has the potential to reduce or eliminate the need for radiographs to detect the presence of a retained sponge.
   c. Studies have shown that RF systems detected significantly more counting discrepancies involving sponges than the traditional counting method.
   d. It has been demonstrated that RF wands have a very high success rate in detecting RF tagged sponges.

 ©2009 Pennsylvania Patient Safety Authority 

# Medication Errors Occurring in the Radiologic Services Department


## ABSTRACT

*An estimated 300 million radiologic procedures are conducted per year in the United States. In cardiac catheterization laboratories, radiology, and other diagnostic departments, medications such as contrast media are administered, rates are adjusted for intravenous (IV) fluids, and IV access lines are flushed. In addition to specific medications that are used in radiology, high-alert medications such as IV sedatives, vasopressors, and blood coagulation modifiers are given in this setting. Nearly 1,000 event reports submitted to the Pennsylvania Patient Safety Authority specifically mentioned medication errors that occurred in care areas providing radiologic services. The administration of wrong drugs and unauthorized drugs was the most commonly reported medication error, followed by wrong-dose errors. While contrast agents and radiopharmaceutical products were cited in almost a quarter of all medication error reports, a majority of the drugs listed are used across the spectrum of patient care settings, not just in radiology. Many of these drugs are high-alert medications. Further qualitative analysis of events classified as wrong-rate medication errors in these areas shows no radiologic medications. Over half of these wrong-rate events involved high-alert medications. Strategies to address these problems include conducting organizational examinations of the medication-use processes in radiology areas to uncover risks that could lead to harmful errors, proactively addressing the plan for the management of the patient's infusion therapy while they are undergoing a radiologic procedure, and including radiology staff when evaluating and validating the level of training and competency to perform medication administration or related tasks. (Pa Patient Saf Advis 2009 Jun;6[2]:46-50.)*


Radiologic services are provided in a variety of inpatient and outpatient settings but most commonly involve cardiac catheterization, radiology, and nuclear medicine services. These services use medical imaging, such as radiography, computed tomography (CT), magnetic resonance imaging (MRI), nuclear medicine, positron emission tomography, and ultrasound. Radiologic procedures are fairly common, accounting for 300 million procedures per year in the United States, and 20% of these involve one or more medications.[1] The complexity of radiologic procedures; the use of high-alert medications such as intravenous (IV) contrast agents, sedatives, vasopressors, and blood coagulation modifiers; and the risk of communication failures during handoffs can contribute to errors in this setting.[2] In cardiac catheterization laboratories, radiology, and other diagnostic departments, healthcare practitioners working in the radiology department may administer medications such as contrast media, adjust rates of IV fluids, and flush IV access lines, potentially increasing the risk for errors.

A 2005 U.S. Pharmacopeia (USP) report on medication errors in radiology[1]—that pooled error reports to MEDMARX® from 2000 to 2004—revealed that, while medication errors in radiologic services are not more prevalent when compared to other settings, they do have more potential to cause harm. Twelve percent of the medication errors reported by USP in radiologic services resulted in patient harm ("harm" defined as National Coordinating Council for Medication Error Reporting and Prevention [NCC MERP] harm category E or higher) compared to 1.7% of all medication errors. This report suggested that medication errors in radiology are seven times more likely to harm patients, compared to errors in other settings.

The USP report identifies three ways in which radiologic service areas uniquely may lead to harmful errors compared to other settings:

1. The amount of time a patient spends undergoing a radiologic procedure is very brief compared to the time he or she will spend in the primary inpatient care area.
2. As a patient is being transferred to and from a radiologic care setting, the opportunity for miscommunication and lack of access to patient information sets the stage for errors to occur. Because the care provided to the patient is very much focused on a particular procedure, drugs that were administered pre-examination, or those to be continued postexamination, may not be given sufficient attention.
3. Certification and training requirements for radiologic staff can vary by setting, state regulations, and institutional policies. Frequently, staff directly dispense and administer medications; however, there is no true standard on how much or what kind of medication-use training they receive. In cardiac catheterization laboratories, radiology, and other diagnostic departments, staff administer medications such as contrast media, adjust rates of IV fluids, and flush IV access lines. Errors with any of these tasks carry the potential to cause harm to patients.[1]

A paper published in the *American Journal of Health-System Pharmacists* in 2002 further discusses reasons why radiologic services may be more prone to harmful errors.[3] The paper comments on how imaging drugs are supposed to be administered by a radiologic staff member under the supervision of a radiologist or other physician. In reality, these medications are sometimes administered without a radiologist ever actually

 ©2009 Pennsylvania Patient Safety Authority 

seeing the patient or the patient's medical record. Additionally, there is sometimes no written prescription and no written documentation on a patient's medication administration record when these drugs are administered. Because of this, there is very little opportunity for a pharmacist's involvement in reviewing the orders and screening the patient for allergies, drug-drug interactions, or drug-disease state warnings before the medication is administered.

## A Look at the Numbers

Little information in the literature specifically mentions medication errors that occur in the radiologic setting. According to the previously mentioned USP MEDMARX® report, the most common type of medication error in radiologic services was improper dose or quantity, followed by unauthorized (defined as medications that were not authorized by a legitimate prescriber and administered) or wrong-drug use, and drug or dose omission.[1] Analysis of data submitted to the Pennsylvania Patient Safety Authority (see Table 1) from June 2004 through the end of January 2009 reveals that the most common types of reported events include wrong drug, dose omissions, and "other." However, when event types are combined to match those that appear in MEDMARX®, the combination of wrong drug and unauthorized drug (n = 200; 20.3%) comes first, followed by wrong dose (overdosage and underdosage) (n = 144; 14.6%) and drug omissions (n = 133; 13.5%).

A breakdown by harm scores shows that most events (97%) were reported as Incidents (NCC MERP harm scores of A to D), but 88% (n = 866) of the reports show that the event reached the patient (harm scores of C to I) and 2.9% (n = 29) were reported as Serious Events.

**Table 1. Most Common Event Types Assigned to "Imaging Services" and "Cardiac Invasive" (n = 985)**

| EVENT TYPE | TOTAL | % OF TOTAL REPORTS (N=985) |
|---|---|---|
| Wrong drug | 141 | 14.3% |
| Dose omission | 133 | 13.5% |
| Wrong dose/ overdosage | 105 | 10.7% |
| Wrong rate (intravenous) | 61 | 6.2% |
| Unauthorized drug | 59 | 6.0% |
| Extra dose | 54 | 5.5% |
| Documented allergy | 50 | 5.1% |
| Wrong dose/ underdosage | 39 | 4.0% |
| Prescription/ refill delayed | 34 | 3.5% |
| Other | 125 | 12.7% |

Medication errors in radiologic services may involve misuse of a number of different drugs. In fact, data submitted to the Authority suggests that these errors are more likely to occur with the types of drugs that are *not* for use exclusively in the radiology setting (e.g., heparin, insulin). Table 2 identifies the top 15 most common drugs mentioned in reports associated with the radiologic unit. While the general category of "contrast agents," which represents both IV and oral contrast, as well as radiopharmaceutical products (i.e., technetium products) represents 24.7% of all reports, a majority of the drugs listed are used across the spectrum of patient care settings, not just in radiology. Furthermore, many of these drugs are high-alert medications. When combining the medications listed into their respective class of medications, 28.3% of all medications mentioned are considered high-alert medications, excluding IV contrast agents (which are also high-alert medications). (See Table 3.)

## In-Depth Look at Medication Errors in Radiology

Among reports submitted to the Authority, the most common type of medication error was wrong drug (n = 141; 14.3%) (see Table 1). Forty (28.4%) of the wrong-drug errors involved mix-ups of the various

**Table 2. Top 15 Medications Involved in Medication Errors in the Radiologic Care Area (n = 567)**

| MEDICATION | TOTAL | % OF TOTAL REPORTS (N = 985) |
|---|---|---|
| Contrast*,† | 168 | 17.1% |
| Radiopharmaceuticals | 75 | 7.6% |
| Heparin infusion†,‡ | 45 | 4.6% |
| Eptifibatide (Integrilin®)† | 41 | 4.2% |
| Insulin† | 40 | 4.1% |
| Hydration§ | 25 | 2.5% |
| Sodium bicarbonate | 23 | 2.3% |
| Bivalirudin (Angiomax®)† | 23 | 2.3% |
| Nitroglycerin | 22 | 2.2% |
| Heparin bolus†,‡ | 21 | 2.1% |
| Cefazolin | 18 | 1.8% |
| Morphine† | 17 | 1.7% |
| Heparin flush‡ | 17 | 1.7% |
| Alteplase (Activase®)‡ | 14 | 1.4% |
| Unknown | 18 | 1.8% |

* Includes both intravenous (IV) and oral contrast

† High-alert medications

‡ Reports mentioning heparin were subdivided into these respective types of therapy (i.e., IV infusions, bolus doses, flushes)

§ Includes IV solutions such as dextrose 5%, sodium chloride 0.9%, and other solutions used to replenish fluids

 ©2009 Pennsylvania Patient Safety Authority 

formulations of technetium, a radiopharmaceutical widely used as a diagnostic aid. Its applications include imaging procedures of the brain, myocardium, lungs, thyroid, and bone. Technetium has numerous uses in nuclear medicine, and it is available in more than 60 different products. Some examples of trade names include Cardiolite®, Myoview®, and Technoscan®. These products can be easily confused, especially if they appear on preprinted order forms and/or pharmacy labels due to the similarity of their generic names.

There were 23 wrong-drug reports involving contrast agents (16.3%). This means that 44.7% (n = 63) of wrong-drug reports involved medications specific to that setting. In most cases, the result of this mix-up does not lead to patient harm; however, it may lead to the rescheduling of the intended test and result in increased cost and loss of productivity.

The second most commonly reported type of medication error was drug omission (n = 133; 13.5%). Unlike reports of wrong-drugs, omissions did not primarily involve radiologic medications. In fact, the most common medications listed included insulin and heparin infusions, such as in the following example:

> *The patient has been in radiology since early this morning. Apparently, the insulin pump was disconnected before the patient's arrival in the radiology department. No report was given by sending nurse. After several hours passed, the radiology technicians made the nurse from the unit aware that the patient would be in the radiology department a while longer. The patient's companion alerted me in the early afternoon to the fact the patient had an insulin pump and it has been disconnected since this morning, so a blood sugar was obtained. The blood sugar registered over 250. The floor nurse was notified of the patient's status and that the radiology department does not carry insulin.*

**Table 3. High-Alert Medication Classes, Other than Intravenous Contrast, Listed in Medication Error Reports (n = 279)**

| HIGH-ALERT CLASS | TOTAL | % OF TOTAL REPORTS (N = 985) |
|---|---|---|
| Anticoagulants, etc* | 146 | 14.8% |
| Opiates† | 48 | 4.9% |
| Insulin | 40 | 4.1% |
| Ionotropics‡ | 19 | 1.9% |
| Antiarrhythmics§ | 10 | 1.0% |
| Moderate sedation** | 8 | 0.8% |
| Adrenergic agonists†† | 8 | 0.8% |
| **Totals** | **279** | **28.3%** |

* Anticoagulants (e.g., therapeutic unfractionated heparin, enoxaparin, eptifibatide), direct thrombin inhibitors (e.g., argatroban, lepirudin, bivalirudin), thrombolytics (e.g., alteplase, reteplase), and glycoprotein IIb/ IIIa inhibitors (e.g., eptifibatide)

† Narcotics/opiates, intravenous (IV), transdermal, and oral (including liquid concentrates, immediate, and sustained-release formulations)

‡ Inotropic medications, IV (e.g., dopamine, dobutamine, milrinone)

§ Antiarrhythmics, IV (e.g., lidocaine, amiodarone)

** Includes both moderate sedation agents, IV (e.g., midazolam) and oral agents for children (e.g., chloral hydrate)

†† Adrenergic agonists, IV (e.g., epinephrine, phenylephrine, norepinephrine)

This example reported to the Authority demonstrates a bigger problem, which is the effect any procedure may have on a patient's current drug therapy. This is especially true when patients are on medications that require the use of an infusion pump, including high-alert medications such as heparin, eptifibatide, alteplase, or insulin, and the therapy has to be temporarily stopped for the procedure (e.g., MRI, CT scan). Errors may occur when the infusion pump is restarted by radiology staff or if the pump is off for a prolonged period of time. Also, any breakdowns in communication or retrieval of important patient information (e.g., allergies, laboratory values, conditions) to radiology staff may impact the intended radiologic procedure or lead to administration of an inappropriate drug to the patient.

## Infusion Pumps in Radiology

A qualitative review of the medication errors revealed unanticipated results. It would be expected that medication errors that occur in this area would primarily involve problems with medications specifically given for radiologic procedures. However, as indicated in Tables 2 and 3, a majority of the medications involved in errors in radiologic settings were not radiologic medications, such as contrast or radiopharmaceuticals. A review of all the Serious Events (harm scores E to I) classified as wrong-dose/overdose revealed errors involving medications used for moderate sedation as well as heparin, epinephrine, or fentanyl infusions. The following are two examples submitted to the Authority:

> *Patient was consented for MRI with conscious sedation. A registered nurse (RN) administered Versed® (midazolam) and fentanyl IV push prior to MRI. Thirty minutes later, the patient began moving and the RN repeated the dose. Approximately five minutes later, the $O_2$ saturation was low. The patient was removed from the MRI and an ambubag was used to ventilate patient. Reversal agents were administered without response. CPR was initiated and a code was called; however patient was subsequently diagnosed with anoxic encephalopathy and died.*

> *A pediatric patient in the MRI suite was given 2 mL of 50 mcg/mL [emphasis added] fentanyl solution intravenously instead of 2 mL of 1 mcg/mL [emphasis added] fentanyl solution. Patient developed respiratory distress and cyanosis for which an airway emergency was called. The patient stabilized and was taken to recovery room and subsequently was transferred to pediatric intermediate care for observation.*

 ©2009 Pennsylvania Patient Safety Authority 

In addition, analysis of events classified as wrong-rate medication errors in these areas shows not one radiologic medication, and over half of these events involved high-alert medications. (See Table 4.)

Analysis of the reports to determine which events involved the use of medications given with infusion pumps revealed that 109 of 985 total reports (11%) showed breakdowns that included problems with the use of infusion pumps and the handling of IV lines. These problems include misprogrammed infusion pumps, infusions that were stopped for the radiologic test but not restarted, tubing misconnections, and wrong-patient errors. The following reports illustrate these problems:

*The patient arrived to the intensive care unit (ICU) from the cardiac catheterization lab. The report given to the ICU nurse was for dopamine to run at 5 mcg/kg/min. On arrival to the ICU, the dopamine bag was almost empty, with the IV pump set and infusing at 5 mg/min (188 mL/hr).*

*A patient was sent to ultrasound with an insulin infusion running at 5 units/hour. When the patient returned from ultrasound, the infusion was found to be no longer running and clamped.*

*Patient arrived at the MRI suite for an abdominal study. A subclavian catheter and tracheostomy were present and all of the ports had similar injection valves. The anesthesiologist connected the injector tubing to the patient's IV site. Contrast and saline were injected, but the scan showed no contrast. Patient was then pulled out of the MRI and discovered that contrast had been injected into tracheostomy cuff with a rupture of the balloon. The patient's $SPO_2$ decreased slightly with no other changes in vital signs.*

*An emergency department (ED) patient went to radiology for an x-ray. The patient returned from x-ray with a heparin IV infusing at 12 mL/hour. This patient was not ordered a heparin IV. Following a preliminary investigation, it was determined that an inpatient was in x-ray around the same time the ED patient was in the ED, and for unknown reasons the inpatient's IV was connected to the ED patient. The ED patient was admitted for observation and lab work.*

## Errors with Patient Information

As mentioned in previous *Pennsylvania Patient Safety Advisory* articles, patient information helps guide the appropriate selection of medications, dosing, and routes of administration.[4] Having complete and accurate patient information, such as past allergic reactions to contrast media, patient weights that would affect the amount of medication (e.g., heparin) to administer, concurrent medications that are contraindicated with contrast, and laboratory values that would affect the type of study to be done (i.e., creatinine clearance) is critical when ordering and performing a radiologic procedure. The probability of renal impairment after a low-osmolality contrast media is administered intravascularly in creases markedly in the patient with chronic renal insufficiency.[5-7] In addition, other nephrotoxic medication should be used cautiously after administration of low-osmolality contrast media.[8] Wrong patient errors can also be averted when key pieces of patient information are available and accessed. A review of the data submitted to the Authority reveals 126 reports (13%) where breakdowns in obtaining and using patient information occurred, including the following case examples:

*Patient presented to the ED with abdominal pain and vomiting. A CT scan of the abdomen/pelvis with contrast was ordered. A blood urea nitrogen (BUN) and creatinine (Cr) was ordered prior to the CT scan. The CT scan was performed prior to review of lab result. The patient's creatinine came back at a critical level and contrast should not have been given.*

**Table 4. Medications Involved in "Wrong Rate" Medication Errors in the Radiologic Setting (n = 61)**

| PRESCRIBED MEDICATION | TOTAL |
|---|---|
| Heparin infusion* | 9 |
| Eptifibatide (Integrilin®)* | 9 |
| Hydration | 7 |
| Sodium bicarbonate | 6 |
| Nitroglycerin | 4 |
| Alteplase (Activase®)* | 3 |
| Abciximab (ReoPro®)* | 3 |
| Adenosine | 3 |
| Vancomycin | 2 |
| Diltiazem* | 1 |
| Dopamine* | 1 |
| Fentanyl* | 1 |
| Bivalirudin (Angiomax®)* | 1 |
| Dobutamine* | 1 |
| Insulin* | 1 |
| Milrinone (Primacor®)* | 1 |
| Nesiritide (Natrecor®) | 1 |
| Amiodarone* | 1 |
| Potassium chloride | 1 |
| Pantoprazole (Protonix®) | 1 |
| Ceftriaxone | 1 |
| Saline | 1 |
| Albumin human | 1 |
| Tirofiban (Aggrastat®)* | 1 |
| **Total** | **61** |

* High-alert medications

 ©2009 Pennsylvania Patient Safety Authority 

*A nurse gave a verbal order for a heparin dose to be given IV push and the physician assisting with the heart catheterization did not know that the heparin was already administered. The heparin was administered again. The patient developed a hematoma at the catheter site and required blood products.*

*A patient received a dosage of IV contrast for a CT scan administered by CT technicians without checking the lab values of the patient's BUN and Cr before administering the contrast. The physician was notified and stated [the intent to] hydrate the patient.*

*A four-year-old patient underwent a Cardiolite® (technetium Tc99m sestamibi) cardiac imaging scan. A routine audit of the records discovered that the dose was based on 50 kg and not the patient's weight of 50 lbs. Upon internal review, it was discovered that the weight was obtained verbally by the technician and then forwarded to the pharmacy for nuclear medicine. The patient received a one time dose of Cardiolite for the scan based on the 50 kg weight.*

## Risk Reduction Strategies

Healthcare facilities should identify the error risks currently present in cardiac catheterization laboratories, radiology, and other diagnostic departments and take steps to implement risk reduction strategies. Based on analysis of reports submitted to the Authority and the literature, as well as observations at the Institute for Safe Medication Practices, risk reduction strategies for preventing the types of medication errors observed in radiology include the following:

- Examine the medication-use processes in radiology areas as well as those medications for patients on continuous IV infusions to uncover risks that could lead to harmful errors.[2]
- Patient care units that are transferring patients to the radiology department can proactively address the plan for the management of the patient's infusion therapy, recognizing the potential need to interrupt the infusion during the procedure and how the therapy would be affected by the length of the procedure.
- Some organizations employ nurses specifically dedicated to radiologic services or send a nurse to accompany patients to radiology if they have a high-alert drug infusing.[9] A verbal handoff between the accompanying nurse and the radiology staff, including verification of infusing IV therapy, must occur.
- Adequate supervision by a physician or nurse must be provided where technicians are administering contrast media and other medications. Ultimately, the responsibility for patient safety falls to the licensed medical professional supervising the technician.
- Include radiology staff when evaluating and validating the level of training and competency to perform medication administration or related tasks. Keep technicians in the information loop regarding safe medication administration practices by providing in-service education.[11]
- Organizations need to carefully consider current and recent patient information before ordering, dispensing, and administering any medication in this setting that may affect the procedure. Pharmacists can help in the assessment of patients about to undergo radiologic procedures by providing a continually updated list of drugs that should be withheld before a procedure and the corresponding time intervals.[10] This information should be obtained as part of the preprocedure assessment and communicated to the ordering physician as well as the radiology departmental staff.

### Notes


1. Santell JP, Hicks RW, Cousins DD. *MEDMARX® data report: a chartbook of 2000-2004 findings from intensive care units and radiologic services*. Rockville (MD): USP Center for the Advancement of Patient Safety; 2006.
2. Institute for Safe Medication Practices. USP focuses on radiological procedures in 6th annual MedMarx report. *ISMP Med Saf Alert* 2006 Jun 26;11(2):2.
3. Barrs TJ. Establishing safeguards for the use of imaging-related drugs. *Am J Health-Syst Pharm* 2002 Aug 1;59(15):1449-53.
4. Medication errors associated with documented allergies. Pa Patient Saf Advis [online] 2008 Sep [cited 2009 Mar 25]. Available from Internet: http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2008/Sep5(3)/Pages/75.aspx.
5. Rudnick MR, Goldfarb S, Wexler L, et al. Nephrotoxicity of ionic and nonionic contrast media in 1196 patients: a randomized trial. *Kidney Int* 1995 Jan;47(1):254-61.
6. Parfrey PS, Griffiths SM, Barrett BJ, et al. Contrast material-induced renal failure in patients with diabetes mellitus, renal insufficiency, or both. *N Engl J Med* 1989 Jan; 320(3):143-9.
7. Rich MW, Crecelius CA. Incidence, risk factors, and clinical course of acute renal insufficiency after cardiac catheterization in patients 70 years of age or older. A prospective study. *Arch Intern Med* 1990 Jun;150(6):1237-42.
8. Cronin RE, Henrich WL. Pathogenesis of renal disease. In: Brenner BM, Levine SA, eds. The kidney. Vol. 2. 6th ed. Philadelphia: Saunders; 2000:1564-7.
9. Institute for Safe Medication Practices. Safety Brief. *ISMP Med Saf Alert* 2006 Apr 6;11(7):1-2.
10. Institute for Safe Medication Practices. ADR Prevent-ERR™: Preventing renal failure from contrast media. *ISMP Med Saf Alert* 2006 Apr 6;11(7):3.
11. Institute for Safe Medication Practices. The Persantine® stress test. *ISMP Med Saf Alert* 1997 Aug 27;2(27):2.


 ©2009 Pennsylvania Patient Safety Authority 

# Uterine Perforation Associated with Minimally Invasive Gynecologic Procedures


## ABSTRACT

*Dilation and curettage, dilation and evacuation, and hysteroscopy are three minimally invasive gynecologic procedures that are performed to diagnose and treat various female pelvic health conditions. Studies show that these procedures have relatively low complication rates and can be performed safely in multiple clinical settings. The most frequent complication noted is puncture of the cervix or uterus related to cervical dilation or uterine entry techniques. The Pennsylvania Patient Safety Authority has received 376 reports related to complications associated with these gynecologic procedures. The predominant complication reported is perforation of an organ (77%), most frequently the uterus (96%). Risk reduction strategies employed to decrease the incidence of uterine perforation involve conducting a thorough preprocedure evaluation to identify any predisposing factors, preparing the cervix for the procedure, and using careful cervical/uterine entry techniques. (Pa Patient Saf Advis 2009 Jun;6[2]:51-5.)*


In their lifetime, many women will experience some type of pelvic health condition, such as abnormal uterine bleeding, that requires further evaluation. Minimally invasive procedures such as dilation and curettage (D&C), dilation and evacuation (D&E), and hysteroscopy are commonly performed to diagnose or treat female pathology. All three procedures require that an instrument be inserted through the cervical os into the uterus. A review by Lohr showed that these procedures have a low overall risk of complications and can be performed in both the inpatient and outpatient setting.[1] Uterine perforation, a risk known to be associated with all three procedures, occurs in about 1% of all hysteroscopic procedures as well as during cervical dilation or uterine entry. When uterine perforation occurs, the patient may require more invasive procedures (e.g., laparoscopy, laparotomy) to determine the extent of injury and for repair as needed.[1,2]

From June 2004 to December 2008, the Pennsylvania Patient Safety Authority received 376 reports related to complications associated with the following minimally invasive procedures: D&C, D&E, and hysteroscopy. The predominant complication reported was uterine perforation. This article will illustrate the Authority's data, discuss whether patients at risk for this complication can be identified before the procedure, and discuss risk reduction strategies that may be implemented to eliminate adverse outcomes.

## Patient Safety Authority Data

Reports identified in the Authority's event report database were reviewed for D&C, D&E, and hysteroscopy procedures for which a complication was reported. Facility types submitting reports included hospitals, ambulatory surgical facilities, and abortion facilities in Pennsylvania. Analysis of the data revealed that perforation was the most frequently reported complication of these procedures (see Figure 1) and, of the reported perforation complications, 96% reported that the uterus was the most affected organ (see Figure 2). Usually, more than one procedure, such as D&C and hysteroscopy, was performed during a surgical session. Figure 3 shows the overlap and combination of procedures that resulted in uterine perforation. The most commonly reported procedures that resulted in a perforated uterus were hysteroscopy and D&C combined with hysteroscopy. The procedures associated with the fewest number of uterine perforations were D&E and D&E combined with D&C. Endometrial biopsy is another minimally invasive procedure, but since the Authority database contained only five reports in which biopsy was performed in conjunction with a D&C or hysteroscopy, endometrial biopsy was not included in the scope of this article.

## Minimally Invasive Procedures

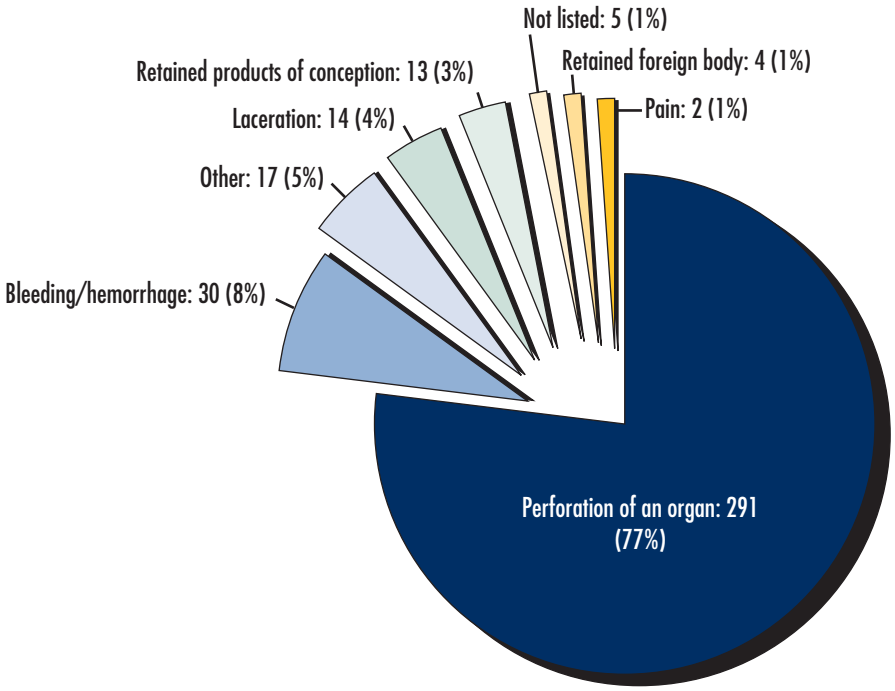
### Dilation and Curettage

D&C is a procedure in which the cervical os is dilated and the uterine lining is removed using a spoon-shaped instrument or curette. This procedure is performed to diagnose or treat pathology such as abnormal bleeding from the uterus. For this purpose, a D&C is used to provide a sample of uterine tissue in order to assess the cause of abnormal bleeding. This sample is examined microscopically to determine the presence of abnormal cells. As with a D&E, D&C also may be performed when a woman has experienced a miscarriage; the purpose of D&C is to remove remaining products of conception from the uterus. This is important because the tissue left in place may cause infection or heavy bleeding. In cases in which the cervical os/canal is narrow, caution must be taken to carefully dilate the cervical canal to avoid uterine perforation.[3] The following Authority report narratives exemplify this point.

> *Patient had D&C early today. The patient [then experienced] heavy bleeding and abdominal pain. The patient was returned to [operating room (OR)] for D&C, diagnostic laparoscopy, and abdominal hysterectomy. After diagnostic scope, [it] was determined that a hysterectomy was needed because of uterine perforation and broad ligament hematoma. The*

 ©2009 Pennsylvania Patient Safety Authority 

**Figure 1. Complications Reported for D&C, D&E, and Hysteroscopy (n=376), June 2004 to December 2008**




*patient was transferred to postanesthesia care unit in stable condition.*

*During a D&C procedure, the patient sustained an iatrogenic uterine perforation. The procedure was aborted when what appeared to be a loop of bowel was seen through the hysteroscope. An unplanned diagnostic laparoscopy confirmed perforation at the fundus of the uterus. A catheter was placed in the bladder to assess possible bladder injury. The urine was clear. Upon diagnostic laparoscopy, no active bleeding was noted and no further surgery was deemed necessary. The patient was observed overnight. The patient remained afrebrile and her [hematocrit and hemoglobin was] stable.*

## Dilation and Evacuation

D&E is most frequently performed for abortions occurring between 13 and 21 weeks gestation or to remove the products of conception after a miscarriage, medically defined as a missed abortion.[1] Patients can undergo this second trimester procedure on an outpatient basis or in a nonhospital setting. Bleeding is the most common complication of D&E, and the risk of hemorrhage increases with advancing gestational age. Underestimation of gestational age is associated with uterine perforation; therefore, care in accurately determining gestational age is critical.[1] Uterine perforation is a potentially serious complication of second trimester D&E and may be associated with bowel injury.[1] The following Authority reports depict complications reported with D&Es.

*The doctor dilated the cervix with no resistance, began suctioning, and noticed omentum protruding through the uterus. The doctor immediately stopped the procedure (D&E). The patient was transferred by ambulance to the hospital in stable condition.*

*[The physician] perforated the uterus during the evacuation of the uterus. The physician performed a laparoscopy with fulguration of a small tear in the uterus.*

## Hysteroscopy

Hysteroscopy allows direct visualization of the uterus via insertion of a thin endoscopic device that is passed through the cervical os into the endometrial cavity. Hysteroscopy can be performed for diagnostic purposes, such as evaluation of abnormal uterine bleeding. It can also be used operatively to treat a range of uterine pathologies such as myomas, endometrial polyps, and adhesions.[4]

Hysteroscopic surgery performed by well-trained surgeons is a safe procedure with an overall complication rate of 3% and uterine perforation rate of 1%.[5] The American Association of Gynecologic Laparoscopists surveyed its members in 1993 regarding their use of and experiences with performing hysteroscopic procedures. This survey recounted that the most frequently reported complication was uterine perforation not requiring transfusion.[2,6] Propst et al. reported that, with hysteroscopic procedures, uterine perforation was directly related to the type of procedure being performed and that diagnostic hysteroscopy had a lower complication rate than operative hysteroscopy.[7] In a 1997 study by Jansen et al., 82 hospitals in the Netherlands recorded findings on complications related to hysteroscopies. Thirty-eight complications

 ©2009 Pennsylvania Patient Safety Authority 

were reported out of 13,600 hysteroscopic procedures. In addition, Jansen et al. reported that 55% of uterine perforations were entry-related and 45% were related to technique of the surgeon.[8] In a study by Agostini et al., the risk of uterine perforation rate was 1.61%. Risk was evaluated according to hysteroscopic procedure, with adhesiolysis associated with the highest risk. It was suggested that adhesions might mask uterine cavity delineation.[9]

Women who experience uterine perforation during surgical hysteroscopic procedures and then go on to become pregnant are at an increased risk for uterine rupture.[10] Uterine perforation, as well as resection of endometrium, myomas, or endometrial ablations, may allow access for excessive absorption of distending media, which can lead to complications such as hyponatremia, fluid overload, and pulmonary/cerebral edema.[11] In addition, uterine perforations created by the use of electrical or laser energy pose the risk of burns to the bowel and must be evaluated appropriately.[9,12] The following Authority reports depict complications reported with hysteroscopy.

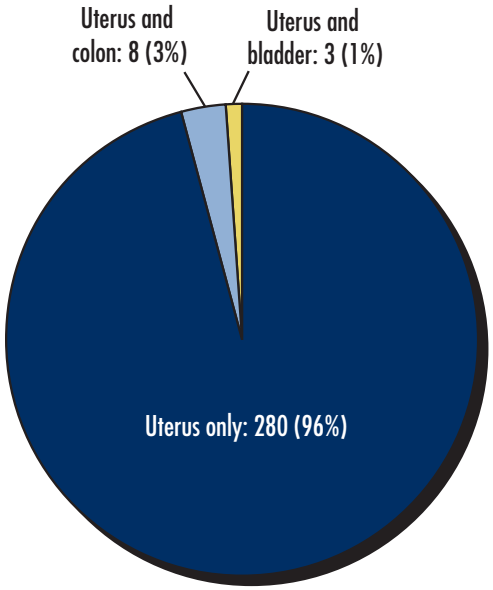
> *In the course of cervical dilation in preparation for the hysteroscopy, the left fundal myometrium was perforated. The perforation was suspected by the surgeon based on the sudden absence of resistance on the dilator during cervical dilation. The perforation was subsequently confirmed with hysteroscopy. The perforation did not extend the time required to complete the surgery or prevent completion of the operative hysteroscopic portion of the surgery, which included resection of intrauterine adhesions and endometrial polypectomies. With release of the fluid pressure during the hysteroscopy, there was minimal bleeding from the perforation site, and there was no blood emanating from the cervix following the procedure. No interventions were required to treat the complication. Uterine perforation during cervical dilation is a known complication of this procedure that is of infrequent occurrence. In this case, the presence of intrauterine adhesions may have contributed to this event.*

> *The patient had a hysteroscopy done [at the beginning of the week] in the surgical center. The patient returned to the emergency room [the following day] and was sent to the OR that evening. Investigation showed she had a perforated uterus and small bowel perforation from the [hysteroscopy] to remove fibroids.*

## Reducing the Risk of Uterine Perforation

The first step in preventing uterine perforation is identifying the patients who may be at risk. Several factors have been reported to increase the chance of a patient experiencing a uterine perforation during one of the aforementioned procedures. Cooper states that in respect to hysteroscopic surgery, uterine perforation occurs commonly during dilation of the cervix and that the presence of cervical stenosis, severe uterine anteflexion or retroflexion, synechiae, and Asherman's syndrome (intrauterine adhesions) may increase the incidence of uterine perforation.[13] Bradley cited additional patient-specific factors that included nulliparity, menopause, gonadotropin-releasing hormone (GnRH) agonist use, previous cone biopsy, and markedly retroverted uterus.[14] The physician should address this information during the informed consent discussion with the patient, including what steps he or she will take to reduce the risk of uterine perforation.

**Figure 2. Perforations Associated with D&C, D&E, and Hysteroscopy (n=291), June 2004 to December 2008**



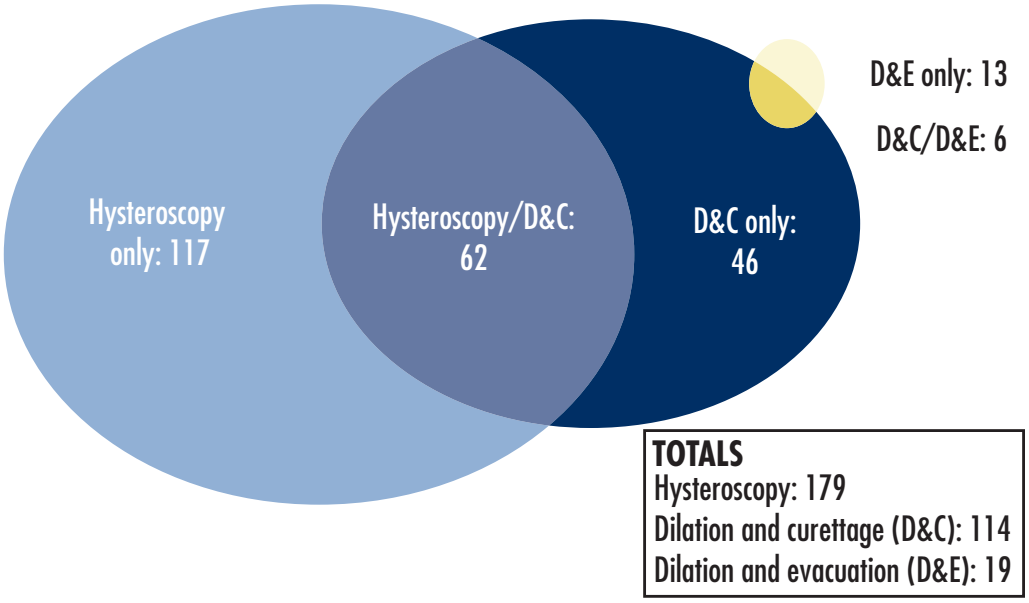

In addition to performing an appropriate preprocedure evaluation, care must be taken while preparing the cervix and entering the uterine cavity. Use of laminara to prepare the cervix is associated with a lower risk of uterine perforation than mechanical dilation.[13,14] The use of misoprostol intravaginally several hours before surgery is also associated with a lower risk of perforation.[14]

Use of intraoperative ultrasound guidance during D&E has been associated with a decreased rate of perforation.[1,4] Since blind dilation of the cervical canal is more frequently associated with uterine perforation, use of a visualized approach, via diagnostic hysteroscopic sheath, to dilate the cervical canal may result in a reduced incidence of uterine perforation during hysteroscopic procedures.[15] Use of a uterine sound to measure the depth of the uterus may give the physician a more accurate assessment of uterine length and direction. Recognizing a uterine perforation when the procedure is not performed under direct visualization is more difficult because there is no sensation of encountering the uterine wall. The only way to make the diagnosis may be when the uterine sound or other passed instrument goes beyond the measured depth of the uterus.

Operative inexperience may also increase the risk of uterine perforation. Cooper reported that 33% of

 ©2009 Pennsylvania Patient Safety Authority 

**Figure 3. Procedures Resulting in Uterine Perforation, June 2004 to December 2008**




uterine perforations occurred during a surgeon's first procedure and 52% during the first five procedures.[13] Use of undue force when dilating the cervix or entering the uterus may also lead to perforation.[14]

## Management of Uterine Perforation

If the physician suspects that uterine perforation has occurred, the procedure must be stopped immediately.[7,9,13,14] Uterine perforation associated with use of a sound or dilator may be managed with observation if bleeding is not present. If bleeding is present, a diagnostic hysteroscopy or other diagnostic measures should be considered to determine the severity of the bleeding or whether other visceral injuries are present.[13] The physician must be prepared to perform a laparoscopy or laparotomy depending on the patient's condition.[9,13,14]

When a distending medium is used in conjunction with a hysteroscopic procedure, meticulous measurement of intake and output is recommended. A fluid deficit of greater than one liter may be an indication of uterine perforation.[7,9,11,13,14] Pelvic ultrasound may be used to estimate the level of intraperitoneal fluid.[9,14] As uterine perforation may result in excess absorption of the distending medium, the patient's cardiovascular and neurological status will need to be monitored for any symptoms of electrolyte imbalance and/or fluid overload.[11,13,14]

Finally, if the outpatient setting does not have the resources noted above, then a plan must be in place to transfer the patient to an appropriate facility for further treatment and/or observation. Discharge teaching and written discharge instructions should include all pertinent signs and symptoms the patient should report regarding complications, including increased/lingering pain, bleeding, and fever.[14] These symptoms will require a prompt evaluation by the physician.

## Conclusion

D&C, D&E, and hysteroscopy are minimally invasive gynecologic procedures that are frequently used for both diagnostic and therapeutic purposes. They have been shown to be associated with an overall low risk of complications. Uterine perforation is a known risk of all three procedures, and the physician must thoroughly evaluate the patient to determine what risks are foreseeable. Care must be taken in preparing the patient for cervical dilation and uterine entry so that the risk of uterine perforation can be reduced. If uterine perforation does occur, the physician and facility must be prepared to further evaluate and treat the patient.

### Notes

1. Lohr PA. Surgical abortion in the second trimester. *Reprod Health Matters* 2008 May;16(31 Suppl):151-61.
2. Paschopoulos M, Polyzos NP, Lavasidis LG, et al. Safety issues of hysteroscopic surgery. *Ann N Y Acad Sci* 2006 Dec;1092:229-34.
3. Dabirashrafi H, Moghadami-Tabrizi N, Mohammad K, et al. New technique for reducing the risk of perforation of the uterus at the beginning of dilatation and curettage. *J Am Assoc Gynecol Laparosc* 1996 Aug; 3(4 Supplement):S7-8.
4. Panoskaltsis TA. Mid-trimester termination of pregnancy by dilatation and evacuation. *J Obstet Gynaecol* 2001;21(3):280-4.
5. Shveiky D, Rojansky N, Revel A, et al. Complications of hysteroscopic surgery: "beyond the learning curve" [see comment]. *J Minim Invasive Gynecol* 2007

 ©2009 Pennsylvania Patient Safety Authority 

Jul-Aug;14(4):530-1; author reply: 531. Source: *J Minim Invasive Gynecol* 2007 Mar-Apr;14(2):218-22.

6. Hulka JF, Peterson HB, Phillips JM, et al. Operative hysteroscopy. American Association of Gynecologic Laparoscopists 1993 membership survey. *J Am Assoc Gynecol Laparosc* 1995 Feb;2(2):131-2. Abstract
7. Propst AM, Liberman RF, Harlow BL, et al. Complications of hysteroscopic surgery: predicting patients at risk. *Obstet Gynecol* 2000 Oct; 96(4):517-20.
8. Jansen FW, Vredevoogd CB, van Ulzen K, et al. Complications of hysteroscopy: a prospective, multicenter study. *Obstet Gynecol* 2000 Aug;96(2):266-70.
9. Agostini A, Cravello L, Bretelle F, et al. Risk of uterine perforation during hysteroscopic surgery. *J Am Assoc Gynecol Laparosc* 2002 Aug;9(3):264-7.
10. Cooper JM, Brady RM. Late complications of operative hysteroscopy. *Obstet Gynecol Clin North Am* 2000 Jun;27(2):367-74.
11. Estes CM, Maye JP. Severe intraoperative hyponatremia in a patient scheduled for elective hysteroscopy: a case report. *AANA J* 2003 Jun;71(3):203-5.
12. Vilos GA, Brown S, Graham G, et al. Genital tract electrical burns during hysteroscopic endometrial ablation:report of 13 cases in the United States and Canada. *J Am Assoc Gynecol Laparosc* 2000 Feb;7(1):141-7.
13. Cooper JM, Brady RM. Intraoperative and early postoperative complications of operative hysteroscopy. *Obstetrics Gynecol Clin North Am* 2000 Jun;27(2):347-66.
14. Bradley LD. Complications in hysteroscopy: prevention, treatment and legal risk. *Curr Opin Obstet Gynecol* 2002 Aug;14(4):409-15.
15. Hysteroscopy complications rare, preventable by understanding meds and instruments. *Laparosc Surg Update* 2001 Mar;9(3):29-32.

### Reviewer Commentary

*A technique I utilize to prevent uterine perforation is to hold the dilating instrument between the thumb and the forefinger, while using the heel of the same hand as a stop against the vulva. This allows the physician to pass the instrument into the uterine cavity but no deeper.*

*Larry Veltman, MD*
*Risk Management and Perinatal Safety Consultant*
*Portland, Oregon*

## Self-Assessment Questions

The following questions about this article may be useful for internal education and assessment. You may use the following examples or come up with your own.

1. Which of the following steps may NOT assist the physician in reducing the risk of uterine perforation during a minimally invasive gynecologic procedure?
   a. Performing a thorough preprocedure evaluation to identify patients at risk for uterine perforation
   b. Preparation of the cervix by use of laminara or medication
   c. Use of blind visualization to dilate the cervix
   d. Use of intraoperative ultrasound guidance
2. All of the following factors may increase the risk of a patient experiencing a uterine perforation EXCEPT:
   a. Nulliparity
   b. Menopause
   c. History of breast feeding
   d. Cervical stenosis
3. During a D & C, what appeared to be a loop of bowel was seen through the hysteroscope. An unplanned diagnostic laparoscopy confirmed perforation of the fundus of the uterus. Upon diagnostic laparoscopy, no active bleeding was noted.

   Which of the following statements is inaccurate about management of a uterine perforation?
   a. If perforation is suspected, the procedure should be stopped.
   b. Other diagnostic procedures, such as laparoscopy, may be performed to evaluate potential visceral injuries.
   c. If no active bleeding is present at the uterine perforation site and no peritoneal signs are present on abdominal examination, the patient may be a candidate for observation.
   d. Blood should be administered immediately.

**Thomas Jefferson University Offers Masters in Healthcare Quality and Safety**

Thomas Jefferson University, Philadelphia, has established the Jefferson School of Population Health (JSPH). David B. Nash, MD, MBA, is the school's founding dean.

JSPH provides graduate academic programming, continuing education courses and conferences, and research and consulting in areas of health policy, healthcare quality and safety, and chronic care management. Jefferson's Master of Science in Healthcare Quality and Safety (MS-HQS) is the first such program in Pennsylvania and one of the first in the nation. The program prepares healthcare professionals—providers, payers, purchasers, and policymakers—to be leaders and advocates in the design, implementation, and dissemination of programs and policies that measurably improve healthcare quality and patient safety.

JSPH is currently enrolling students for classes beginning in September 2009. For more information, contact (215) 503-5305 or visit http://www.Jefferson.edu/population_health.

 ©2009 Pennsylvania Patient Safety Authority 

# Safety in the MR Environment: Ferromagnetic Projectile Objects in the MRI Scanner Room


## ABSTRACT

*The static magnetic field of a magnetic resonance imaging (MRI) scanner exerts forces on ferromagnetic and other magnetic materials near the field. These forces can draw unrestrained objects, making them airborne, into the scanner's magnet bore. This phenomenon is known as the projectile effect and can result in catastrophic consequences for individuals near the scanner and significant damage to equipment. To avoid serious or fatal injury from projectiles, magnetic resonance (MR) personnel must understand the principles of the projectile effect and properly screen individuals before entering the scanner room for ferromagnetic objects. In some cases, medical equipment needed in the scanner room for patient assessment or treatment (e.g., physiologic monitor, infusion pump) could also pose projectile risks. Additionally, the static magnetic field may cause medical equipment to malfunction, which may result in serious or fatal patient injury. MR personnel must know what equipment is safe to allow into the scanner room and what equipment is unsafe and should be left out of the room. Between June 2004 and December 2008, the Pennsylvania Patient Safety Authority received 27 reports of objects becoming projectiles in the MR environment, 16 ferromagnetic items that were brought into the MRI scanner room without becoming projectiles, and 5 ferromagnetic items almost allowed into the MRI scanner room. Proper MR screening practices for ferromagnetic items and establishing protocols for identifying and labeling equipment that can and cannot be brought into the scanner room will help reduce the risk of objects becoming projectiles within the MR environment. (Pa Patient Saf Advis 2009 Jun;6[2]:56-62.)*


*Editor's Note*

*A March 2009* Pennsylvania Patient Safety Advisory *article discussed magnetic resonance (MR) safety screening practices. This article continues the discussion of MR safety, focusing on the safety concerns of ferromagnetic objects and ferromagnetic medical equipment entering the magnetic resonance imaging scanner room.*

Ferromagnetic materials can be influenced by translational (linear) and torque (rotational) forces exerted by the static magnetic field of the magnetic resonance imaging (MRI) scanner. These forces, primarily translational forces, can draw unrestrained objects, making them airborne, into the magnet's bore. This hazardous phenomenon is known as the projectile, or missile, effect, which can potentially result in serious or fatal injuries to individuals in the scanner room. Any object, regardless of size, can become a dangerous projectile. For example, paper clips and hairpins have been shown to travel at speeds up to 40 mph into a 1.5 T magnet.[1]

Some incidents of the projectile effect have been reported in the mainstream news media. For example, one fatal event involved a six-year-old child undergoing an MRI scan. During the scan, while the child was lying on the MRI table, an oxygen canister consisting of ferromagnetic materials was brought into the room. The force of the magnet pulled the oxygen canister into the magnetic bore, causing the canister to strike the child's head. The child eventually died from the injuries.[2]

In another well-known event, an off-duty police officer was scheduled to undergo a MRI examination. A misunderstanding occurred between the officer and the magnetic resonance (MR) technologist when the technologist asked the officer to proceed to the MRI patient waiting area. The officer mentioned his holstered handgun to the technologist before entering the MRI dressing room. The technologist informed the officer to proceed to the patient waiting area with the gun; the technologist planned to secure the weapon in that room. However, the officer misunderstood and brought the gun into the MRI scanner room. While the technologist was entering the officer's patient information into a computer, the officer entered the scanner room and attempted to place the gun on top of a cabinet, which was approximately 3 feet away from magnet bore. The force of the magnet pulled the gun from the officer's hand and drew the gun to the magnet bore. When the gun struck the magnet, it spontaneously discharged a bullet (despite that fact that the firearm's safety mechanism was engaged), which struck a wall in the scanner room. There were no injuries as a result of this incident.[3]

Between June 2004 and December 2008, the Pennsylvania Patient Safety Authority received 44 reports describing 27 ferromagnetic items that became projectiles, 16 ferromagnetic items that were brought into the MRI scanner room without becoming projectiles, and 5 ferromagnetic items that were almost brought into the MRI scanner room. (Forty-eight items were cited in 44 reports: in 2 projectile reports, an oxygen tank and a ventilator were reported; and in 2 other reports, an oxygen tank and a stretcher were reported.) Of the 44 reports, only 3 minor injuries were reported. See Tables 1 through 3 for information about the ferromagnetic items cited in the reports.

For illustration, the following are examples of the narratives of Serious Events and Incidents involving projectiles reported to the Authority.

*After completion of the MRI study, the technician proceeded to place the patient's wheelchair at the door threshold of the MRI room. When she leaned*

 ©2009 Pennsylvania Patient Safety Authority 

**Table 1. Projectile Ferromagnetic Items in MRI Scanner Rooms Reported to the Pennsylvania Patient Safety Authority, June 2004 through December 2008**

| FERROMAGNETIC ITEMS | QUANTITY OF ITEMS |
|---|---|
| Cardiac monitor | 1 |
| Clipboard | 1 |
| Hearing aid battery | 1 |
| Infusion pump | 1 |
| Intravenous (IV) basket | 1 |
| IV pole | 1 |
| Knife | 2 |
| Laryngoscope | 1 |
| Monitor (type unknown) | 1 |
| Nail clippers | 1 |
| Oxygen tank | 2* |
| Ring (jewelry) | 1 |
| Sandbag | 2 |
| Scissors | 2 |
| Step stool | 2 |
| Stethoscope | 1 |
| Stretcher | 1 |
| Telemetry transceiver | 1 |
| Ventilator | 1* |
| Wheelchair | 2 |
| Wooden chair with metal strip in seat cushion | 1 |
| **Total** | **27** |

* One oxygen tank and one ventilator were recorded on the same report submitted to the Authority.

**Table 2. Nonprojectile Ferromagnetic Items in MRI Scanner Rooms Reported to the Pennsylvania Patient Safety Authority, June 2004 through December 2008**

| FERROMAGNETIC ITEMS | QUANTITY OF ITEMS |
|---|---|
| Cardiac monitor | 3 |
| Cardiac monitor/recorder (long-term) | 1 |
| Cell phone | 1 |
| Face mask with metal nose strip | 1 |
| Hairpin | 5 |
| Infusion pump | 2 |
| Insulin pump | 2 |
| Telemetry transceiver | 1 |
| **Total** | **16** |

*over the wheelchair to lock the wheels, the wheelchair was attracted to the MRI and rolled into the equipment. There was no injury to the patient or staff. The MRI equipment suffered slight damage to the cover.*

*A patient was brought to the MRI room. [The patient's] IV [intravenous line] became kinked. A technician entered the room to fix the IV tubing. The technician forgot to take scissors out of pocket. The scissors became attached to the machine. There was no apparent injury.*

*A post cardiac catheterization patient with a sandbag placed on right groin went to radiology for MRI. Patient was placed on the table. When the technician began advancing the table, the magnet pulled the sandbag from the patient's groin onto the outer housing of the MRI unit.**

*The critical care patient was taken to MRI with a nurse and respiratory technician. . . . The patient was hooked up to the MRI monitoring system and the respiratory technician acknowledged to the two MRI technicians that the oxygen tank could not go into the MRI room. The respiratory technician asked for the MRI-compatible ventilator stand for the ventilator (the patient was bagged at the time). The respiratory technician took the ventilator that had two oxygen tanks into the MRI room. [The technician] realized that the oxygen tanks were on the ventilator and went to the leave the room when the magnet took the tanks and the ventilator into the MRI. The patient was outside the MRI while this occurred.*

*A [brand omitted] [syringe] pump used in the nursery accompanied a patient to MRI. A label on the pump stated that it was MR-compatible and upon initial review it appeared to be safe. The pump was taken into the MRI suite with the patient, and the patient was positioned on the table. The pump was placed at the end of the table. As the table advanced in the bore of the magnet, the pump flew to the front of the magnet, sticking itself to the magnet cover. The baby was not injured and the pump was removed from the magnet cover. The pump was placed at a safe distance and the examination was performed as ordered.*

*The patient was placed on the MRI table and the [MR] safe monitor was connected to the patient. While positioning the patient, the monitor became attracted to the magnet, grazing the patient's head.*

*The patient came to the [MRI] department and required anesthesia. The patient was [positioned] in the [MR] scanner when the anesthesiologist decided to use the laryngoscope. [The laryngoscope] was MR compatible without batteries. The handle went into the magnet and was retrieved without trauma to the patient or staff.*

The reports above illustrate the dangers of ferromagnetic items making their way into the MRI scanner room. The risk of an object becoming a projectile increases the closer the object gets to the magnet bore. Individuals entering the MRI scanner room must

* For more information about sandbags in the magnetic resonance environment, refer to the article "Sandbags May Not Be What You Think" in the September 2006 issue of the *Pennsylvania Patient Safety Advisory*.

 ©2009 Pennsylvania Patient Safety Authority 

understand that, for the vast majority of MRI systems, the magnet is always on and that the magnetic field is always present even when no scan is being performed. Precautions are necessary when bringing any item into the MRI scanner room.

Additionally, visual inspection alone may be inadequate to distinguish ferromagnetic projectile threats. Many objects that appear to be nonferromagnetic (e.g., wooden furniture) have been brought into MRI scanner rooms only to be discovered to have concealed ferromagnetic components. For this reason, effective screening of items, equipment, or belongings that have not been specifically tested and labeled for use in the MRI scanner room should be conducted. Many objects can be effectively tested with high-strength permanent magnets or, as discussed later in this article, ferromagnetic-only detection systems.

## MRI Magnetic Field Strength Relative to Distance from Magnet

The magnetic field extends as a 3-D volume outside the scanner and is known as the fringe field. For convenience, the magnetic field is often mapped using gauss lines, which are lines of equal magnetic field strength; gauss is abbreviated "G." For the translational (attractive) force, the field strength increases, usually very rapidly, approaching the entrance of the magnet bore. The gradient of the gauss lines are roughly analogous to the steepness of a mountain slope. If the grade (gradient) is gentle, the slope is reasonably safe, regardless of how high on the mountain you are. If it is very steep, such as at a cliff, the risk of falling becomes more immediate and dangerous, again regardless of how high you are on the mountain. It should be noted that the MR gradient is higher when the field strength lines are closer together.

The distance of these gauss lines from the magnet bore largely depends on the magnetic shielding used. When shielding is used, the magnetic field drops off very steeply, which means that an object needs only to move a small distance (e.g., about 1 inch) from experiencing no force effect to becoming uncontrollable. Modern systems use active shielding, which helps confine the fringe field close to the magnet's bore. Each MRI system will have a fringe field that is unique to the specific supplier's model of MRI system and the scanner room in which it is located. For illustration purposes only (these dimensions are not associated with specific suppliers of MRI systems), for an unshielded 1 tesla (T) (1 T = 10,000 G) MRI system, the 5 G line might be approximately 15 feet from the magnet bore; the 100 G line, stronger magnetic field, might be approximately 8 feet from the magnet bore; and the 10,000 G, the strongest field for a 1 T magnet, will be at the entrance to the bore. The gauss line distances are available from the specific MR system suppliers. The 5 G line is cited as the boundary at which the magnetic field strength has diminished sufficiently to pose no physical threat to the general public or, more specifically, to individuals with implanted cardiac devices. Ferromagnetic objects placed within the 5 G line could be drawn into the magnet, and many devices may fail to operate properly.[1] Some medical devices are designed for use in the MR environment; however, these devices have conditional uses relative to specific MR environments (i.e., medical devices designed for use in one MR environment cannot be used in all MR environments).

**Table 3. Ferromagnetic Items That Were Almost Brought into MRI Scanner Rooms Reported to the Pennsylvania Patient Safety Authority, June 2004 through December 2008**

| FERROMAGNETIC ITEMS | QUANTITY OF ITEMS |
|---|---|
| Oxygen tank | 2* |
| Stretcher | 2* |
| Wheelchair | 1 |
| **Total** | **5** |

* One oxygen tank and one stretcher were recorded on the same report submitted to the Authority.

## Terminology for MRI-Specific Medical Devices

### Old Terminology

In 1997, in a draft guidance document,* the Center for Devices and Radiological Health (CDRH) of the U.S. Food and Drug Administration (FDA) adopted terminology from the American Society of Testing and Materials (ASTM) International—*MR Safe* and *MR Compatible*—to help characterize the safety of medical devices in the MR environment. The guidance called for devices designed for use in a MR environment to be marked with these terms to distinguish them from devices contraindicated for use in MR environments. The terms in the 1997 guidance document are defined as follows:[4]

***MR Safe:*** "The device, when used in the MR environment, has been demonstrated to present no additional risk to the patient, but may affect the quality of the diagnostic information."

***MR Compatible:*** The device, when used in the MR environment, is MR Safe and has been demonstrated to neither significantly affect the quality of the diagnostic information nor have its operation affected by the MR device."

The guidance document also states that the use of these terms "without specification of the MR environment to which the device was tested should be avoided since interpretation of these claims may vary and are difficult to substantiate rigorously."[4] This statement refers to the fact that any device designed for use in a MR environment has not been tested and validated for use in *all* MR environments. For

* "A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems"[4]

 ©2009 Pennsylvania Patient Safety Authority 

example, a device designed and tested for use with MRI systems with magnetic fields up to 1.5 T may be contraindicated for use with systems above 1.5 T (e.g., 3 T MRI systems). Additionally, devices designed for use in MR environments typically have restrictions on the placement distance from the magnet bore. For example, an infusion pump designed for use in a 1 T MRI system may be restricted to no closer to the magnet than the 150 G line. In this example, the pump brought closer to the magnet than the 150 G line could be pulled to the magnet bore, potentially resulting in serious or fatal injuries to individuals near the magnet.

While, in theory, this terminology was developed to help users better understand the MR safety characteristics of medical devices, in practice, it has also created confusion. Distinguishing between the two terms may often be misunderstood if users are not aware that devices have been validated for use under specific MR conditions such as a maximum magnetic field strength. The terms are also often mistakenly used interchangeably, adding to the confusion. Both terms indicate no additional risks to individuals in specific MR environments. However, a device designated as *MR Safe* may affect the diagnostic information of the scan, while a device designated as *MR Compatible* will not affect the diagnostic information, which means that not all *MR Safe* devices are also *MR Compatible*. Because of this, users may not be sure when it is, or is not, appropriate to use equipment as *MR Safe* or *MR Compatible*.[6]

## New Terminology

In 2005, in an effort to reduce or eliminate the confusion with the old terminology, ASTM International introduced a new standard* for marking medical devices for safety in the MR environment. The ASTM standard defines three terms to be used for permanently marking medical devices that may be brought into the MR environment. Unlike the old terminology, the new terminology does not include image quality considerations because, as stated in the standard, image artifact is not considered a safety issue for the purposes of the standard. The three new ASTM terms are MR SAFE, MR CONDITIONAL, and MR UNSAFE. (For the purposes of this article, to distinguish between the old terminology and the new terminology, italicized font represents the old terminology, and the new terminology is capitalized). The new terminology is defined as follows:[5]

**MR SAFE:** "An item that poses no known hazards in all MR environments."

A note within the definition states "MR SAFE items include nonconducting, nonmagnetic items such as a plastic Petri dish. An item may be determined to be MR SAFE by providing a scientifically based rationale rather than test data." [Emphasis added.]

**MR CONDITIONAL:** "An item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions for use. Field conditions that define the specified MR environment include field strength, spatial gradient, *dB/dt* (time rate of change of the magnetic field), radio-frequency (RF) field, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item, may be required."

**MR UNSAFE:** "An item that is known to pose hazards in all MR environments."

A note within the definition states that "MR UNSAFE items include magnetic items such as a pair of ferromagnetic scissors." [Emphasis added.]

Although the term "safe" is used in both nomenclature systems, the main difference between the old *MR Safe* term and the new MR SAFE term is that devices labeled safe under the old terminology are understood to be safe under specific MR conditions (e.g., magnetic field strength), whereas devices labeled safe under the new terminology are understood to be safe for all MR conditions without exception. The new MR SAFE term has no limitations or restrictions, unlike the old *MR Safe* term. Therefore, the new term should reduce confusion regarding devices brought into the MRI scanner room. The icon representing MR SAFE consists of two versions of the letters "MR" surrounded by a green square as shown in Figure 1.

The new MR CONDITIONAL term should also reduce confusion regarding devices brought into the MRI scanner room, since the word "conditional" will specifically alert clinicians that the device has

**Figure 1. ASTM Recommended Icon Associated with the MR SAFE ASTM Term**

*Reprinted with permission from ASTM F2503-08 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment, ©ASTM International.*

* "Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment"[5]

 ©2009 Pennsylvania Patient Safety Authority 

limitations or restrictions when brought into the MRI scanner room. The icon for MR CONDITIONAL consists of the letters "MR" within a yellow equilateral triangle with a black band around the edge of the symbol, as shown in Figure 2. The new MR UNSAFE term should greatly reduce, if not eliminate, projectile risks due to the explicitness of the term (i.e., if a device is marked MR UNSAFE, it *does not* belong in the MRI scanner room). The MR UNSAFE icon consists of the letters "MR" surrounded by a red circle with a diagonal red line across the diameter of the circle over top of the letters, as shown in Figure 3.

The new MR safety marking standard will only be effective if it is well understood and properly implemented by device manufacturers and MR departments. Confusion may still exist, and there still may be an adjustment period as manufacturers and users migrate from the old nomenclature to the new nomenclature. Users may still see a mix of devices with the old MR safety markings and the new safety markings. During this period, users must know how to interpret the various device markings and how to ascertain which devices can and cannot be used in a particular MR environment.[6] One way for facilities to reduce confusion between the old and new terminologies is to consult with equipment suppliers to obtain the information needed to relabel equipment with the new markings as soon as possible.

**Figure 2. ASTM Recommended Icon Associated with the MR CONDITIONAL ASTM Term**

*Reprinted with permission from ASTM F2503-08 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment, ©ASTM International.*

**Figure 3. ASTM Recommended Icon Associated with the MR UNSAFE ASTM Term**

*Reprinted with permission from ASTM F2503-08 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment, ©ASTM International.*

## MR Safety Screening for Potential Projectiles

The March 2009 *Pennsylvania Patient Safety Advisory* article on MR safety screening processes focused on clinical screening of patients for exposure to metal that could compromise the safety of the patient or the quality of the image diagnostic information of the scan. However, MR safety screening also encompasses screening for ferromagnetic objects, external to the patient, which if allowed into the MRI scanner room, could potentially become dangerous projectiles. In addition to MR personnel checking to ensure that ferromagnetic objects do not make their way into the MRI scanner room, any facility personnel with access to the scanner room must be aware of which objects are permitted and restricted from entering the scanner room. This includes knowing and understanding the ASTM MR safety device markings and, as applicable, the safety conditions of each piece of equipment.

## The Use of Ferromagnetic Detection Systems

A method that may help in screening for ferromagnetic objects that are external to the patient is the use of ferromagnetic-only detectors. The March 2009 *Advisory* article discussed the use of ferromagnetic-only detectors as an adjunct to the MR safety screening process that may significantly reduce the likelihood of objects becoming projectiles in the MR environment. Ferromagnetic-only detectors are designed to distinguish between ferromagnetic and nonferromagnetic materials. The detectors warn MR personnel of the presence of ferromagnetic items external to the body (the detectors are not currently approved for use in detecting ferromagnetic implants) before the item is brought into the MRI scanner room. The use of these detectors may significantly reduce the likelihood of objects becoming projectiles in the MR environment. A University of Pittsburgh Medical Center study demonstrated that ferromagnetic detectors were successful in detecting ferromagnetic items, even items as small as a safety pin, on patients before MRI scans.[6] The University of Pittsburgh study also found that 44% of patients who indicated that they had complied with the MR screening instructions to remove all loose metallic objects before the MRI scan set off the ferromagnetic detector. This may suggest that patient compliance with MR screening instructions for metallic objects may not be comprehensive. Ferromagnetic-only detectors may not only be prudent for detecting larger ferromagnetic objects before entering the MRI scanner room, but may also prove useful as an adjunct practice in the MR patient screening process.

The use of ferromagnetic-only detectors has been recommended by the American College of Radiology (ACR) in its 2007 "ACR Guidance Document for Safe MR Practices" and the U.S. Department of Veterans Affairs (VA) in its 2008 "VA Magnetic Resonance Imaging Design Guide." Use of ferromagnetic-only detectors has been cited as an approved means of screening verification in the Joint Commission's

 ©2009 Pennsylvania Patient Safety Authority 

Sentinel Event Alert Issue No. 38 "Preventing Accidents and Injuries in the MRI Suite."[7-9]

## Medical Device Malfunction in the MR Environment

In addition to the projectile effect, another safety concern is malfunction of medical devices in the MR environment. The proper operation of medical devices can be affected by the static, RF, and gradient magnetic fields of MRI systems. (For a discussion of the static, RF, and gradient magnetic fields, see the sidebar "Basic Operating Principles of Magnetic Resonance Imaging.")

The static magnetic field can affect devices that incorporate components such as analog gauges or electric motors, which contain magnets and coils (e.g., ventilators, infusion pumps), or electronic components such as transformer or relays. The effects can cause devices to malfunction or completely stop operating, potentially resulting in serious patient harm. ECRI Institute cites one example of a patient-controlled analgesic infusion pump that malfunctioned in the presence of a static magnetic field.[1] The field caused the pump's motor to reverse direction without indication to the user. Because of the reversed motor action, the pump could have drawn blood from the patient into the IV line. However, the IV tubing incorporated a one-way valve that prevented backflow of blood.[1]

Devices that rely on magnetization to attach to a patient (e.g., otologic implants) can become demagnetized in the static magnetic field of the scanner.[1] Implanted devices that are magnetically, electrically, or mechanically activated, which may be affected by the static magnetic field, are typically contraindicated for MRI scans. Other devices, such as those that measure physiologic electric signals (e.g., electrocardiogram [ECG] monitors) may be affected by high field strength MRI systems (greater than or equal to 1 T).[1] For example, high field strengths can distort the ECG of patients within the field.[1] The distortion may appear as an increase in the amplitude of the T wave or ST segment of the signal, causing clinicians to believe the patient's physiologic condition changed.[1]

The RF magnetic field can affect devices, such as physiologic monitors, that incorporate lead wires (e.g., ECG monitors, pulse oximeters). The lead wires act as antennas in the presence of the RF energy. The RF energy of the MRI system can be electrically coupled to the lead wires if they are in close proximity to the MRI scanner. The coupling can result in temporary loss of the measured parameter or damage to the devices.[1] The gradient magnetic field can mimic physiologic signals (e.g., ECG signals), and interfere with the ECG signal, which could cause misinterpretation of the ECG signal.[1] However, through design of physiologic monitors, this interference can be eliminated using filtering and digital signal-processing techniques.[1]

## The Price of Projectiles

Even in the absence of patient harm, the financial consequences of interrupted patient throughput or equipment damage, including emergency shutdown of the MRI scanner, resulting from ferromagnetic projectiles can be significant. The VA National Center for Patient Safety recently published information on the average cost of a ferromagnetic projectile event in a VA facility to be $43,172 (excluding lost revenue and legal expenses).[10] The VA also indicated that the cost of an emergency shutdown of the MRI scanner, known as "quenching the magnet," can range from $20,000 to $500,000.[10]

## Conclusion

Ferromagnetic objects in the MRI scanner room can pose a serious, even catastrophic, projectile risk to individuals in the room. Additionally, the magnetic field can affect the operation of devices brought into the field. A good understanding of equipment and objects that can and cannot be brought safely into the MR environment will help reduce or eliminate the likelihood of projectiles or device malfunctions, thereby reducing the potential for serious harm to individuals within the MR environment.

As part of a risk reduction strategies to reduce or eliminate the possibility that objects will become projectiles or that medical devices will malfunction, consider the following:

- Identify the four MR safety boundaries as defined by ACR in its "ACR Guidance Document for Safe MR Practices." Mark the boundaries with

### Basic Operating Principles of Magnetic Resonance Imaging

Magnetic resonance imaging (MRI) creates cross-sectional images of anatomic structures placed in the magnet bore using (nonionizing radiation) electromagnetic fields. The static magnetic field of the MRI scanner causes the protons in the body tissue to align in the direction of the static magnetic field. Electromagnetic pulses from a radio-frequency (RF) transmitter create an RF magnetic field that alters the static magnetic field. When this occurs, the direction of the magnetized protons in the static magnetic field changes alignment with that static field. When the pulses stop, the magnetized protons revert to their original position. While reverting to their original position, the protons emit RF energy that is detected by RF receivers of the MRI system. Computer analysis then converts the signals into images of the scanned anatomy. The gradient magnetic field is produced by coils inside the MRI system. The coils are rapidly pulsed on and off during the time the RF magnetic field is pulsed. The gradient magnetic field determines the location of the scanned anatomic section, the thickness, and the field of view of the section.

**Source:** ECRI Institute. The safe use of equipment in the magnetic resonance environment [guidance article]. *Health Devices* 2001 Dec;30(12):42-44.

 ©2009 Pennsylvania Patient Safety Authority 

appropriate signage. Zone 4, the area containing the MRI scanner that is associated with the strongest magnetic field, should be clearly marked. Access should be restricted to this area without supervision by appropriate MR personnel.[1] (For more information on the MR safety boundaries, see the article "Safety in the MR Environment: MR Safety Screening Practices" in the March 2009 issue of the *Advisory*.)

- Provide training on MR safety considerations to all MR staff and other personnel who may need access to the MRI scanner room. Include education on the new MR device terminology, the old MR device terminology, and the difference between the two nomenclatures.[1]
- Prohibit equipment and devices within Zone 4 without first verifying that (1) they have been tested by the device manufacturer or properly trained expert and (2) they have been labeled according to the ASTM device terminology—MR SAFE or MR CONDITIONAL—for the specific MR environment.[1]
- Maintain a list of MR SAFE, MR CONDITIONAL (including conditions for safe use), and MR UNSAFE equipment in every MR department or facility. When possible, identify the safety conditions directly on an object or device. If MRI systems are upgraded or newly purchased, the MR safety officer determines whether the equipment is still MR SAFE, MR CONDITIONAL, or MR UNSAFE with the upgraded or new system.[1]
- Do not alter MR SAFE or MR CONDITIONAL equipment. Altering equipment may negate the MR safety characteristics of the equipment.[1]
- Care should be taken when equipment containing ferromagnetic components is brought into the MR environment. For example, devices may be validated for use in some areas of the MR environment (e.g., field strengths not exceeding 150 G), but not other areas.[1]
  - All equipment brought into the MR environment should be properly labeled (e.g., MR SAFE, MR CONDITIONAL) and should be physically secured at a safe distance (defined by the equipment supplier) from the MRI system using nonmagnetic means (e.g., nonmagnetic bolts), as appropriate. The method of restraint should be adequately tested before implementation, and care should be taken to protect the integrity of the RF shielding for any attempt at providing anchorage within the MRI scanner room.
- Consider the use of ferromagnetic-only detection systems as an adjunct to your facility's MR safety practices (based on the findings of the University of Pittsburgh Medical Center study,[1] and recommendations from ACR[7], VA[8], and the Joint Commission[9]).

## Notes


1. ECRI Institute. The safe use of equipment in the magnetic resonance environment [guidance article]. *Health Devices* 2001 Dec;30(12):421-44.
2. Chen DW. Boy, 6, dies of skull injury during MRI. NY Times [online]. 2001 Jul 31 [cited 2009 Mar 23]. Available from Internet: http://www.nytimes.com/2001/07/31/nyregion/boy-6-dies-of-skull-injury-during-mri.html?n=Top/Reference/Times%20Topics/Subjects/C/Children's%20Health.
3. Beitia A, Meyers S, Kanal E, et al. Case report: spontaneous discharge of a firearm in an MR imaging environment. *AJR Am J Roentgenol* 2002 May;178(5):1092-4.
4. Center for Devices and Radiologic Health (CDRH) Magnetic Resonance Working Group. A primer on medical device interactions with magnetic resonance imaging systems [draft online]. 1997 Feb [cited 2009 Mar 23]. Available from Internet: http://www.fda.gov/cdrh/ode/primerf6.html.
5. American Society of Testing and Materials (ASTM). Standard practice for marking medical devices and other items for safety in the magnetic resonance environment. ASTM F2503-05. 2005 Aug:1486-92.
6. ECRI Institute. What's new in MR safety; the latest on the safe use of equipment in the magnetic resonance environment [guidance article]. *Health Devices* 2005 Oct;34(10):333-49.
7. Kanal E, Barkovich A, Bell C, et al. ACR guidance document for safe MR practices: 2007. *AJR Am J Roentgenol* 2007 Jun;188(6):1447-74.
8. U.S. Department of Veterans Affairs (VA). VA MRI design guide [online]. 2008 Apr [cited 2009 May 20]. Available from Internet: http://www.cfm.va.gov/til/dGuide/dgmri02.pdf.
9. Joint Commission. Preventing accidents and injuries in the MRI suite. Sentinel Event Alert Issue No. 38 [online]. 2008 Feb 14 [cited 2009 May 20]. Available from Internet: http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_38.htm.
10. U.S. Department of Veterans Affairs (VA) National Center for Patient Safety. MR hazard summary [online]. 2008 Sept 29 [cited 2009 May 21]. Available from Internet: http://www.va.gov/ncps/SafetyTopics/mrihazardsummary.html.


 ©2009 Pennsylvania Patient Safety Authority 

# Successful Reduction of Ventilator-Associated Pneumonia

## Introduction

Intensive care unit (ICU) patients, due to their critical illnesses and compromised immunity, are at high risk for healthcare-associated infections (HAIs). The overall infection rate in critically ill patients approaches 40%, as reported by Girou et al., and may be as high as 50% or 60% in patients who remain in the ICU for more than 5 days, as discussed in a study conducted by Bueno-Cavanillas et al.[1,2] The incidence of ICU-acquired pneumonia ranges from 10% to 65%.[3] Ventilator-associated pneumonia (VAP) is defined as healthcare-associated pneumonia in a patient who is on mechanical ventilatory support (by endotracheal tube or tracheostomy) for more than 48 hours.[4] Patients at high risk for VAP include those who have chronic obstructive pulmonary disease, burns, neurosurgical conditions, acute respiratory distress syndrome, and witnessed aspiration; those who are reintubated; and those who receive paralytic agents or enteral nutrition.[5]

A prospective study conducted by Ibrahim et al. for 22 months in a 500-bed community nonteaching hospital showed that 15% of mechanically ventilated patients developed VAP. Approximately 34% of patients who received mechanical ventilation died during hospitalization. The study further revealed that the following factors were independently associated with patients who developed VAP: tracheostomy, multiple central venous line insertions, reintubation, and the use of antacids, which neutralize the ability to kill bacteria in the stomach. The hospital mortality of patients with VAP was significantly greater than the mortality of patients without VAP (45.5% versus 32.2%, respectively).[6] In a retrospective matched cohort study using data from a large U.S. inpatient database, Rello et al. found that patients with VAP remained in the ICU approximately 6 days longer than patients who did not have VAP (11.7 ± 11 days versus 5.6 ± 6.1 days) and had significantly longer durations of mechanical ventilation (14.3 ± 15.5 days versus 4.7 ± 7 days) than those patients who did not have VAP.[7]

## Targeting Zero Infections

In 2005, the Institute for Healthcare Improvement (IHI) launched the 100,000 Lives Campaign, which evolved into the 5 Million Lives Campaign, with the goal of protecting patients from 5 million incidents of medical harm between December 2006 and December 2008. The campaign involved a nationwide effort to reduce mortality and morbidity associated with hospital care by recruiting healthcare institutions to implement process measures. This included measures to prevent VAP through implementation of evidence-based practices, including the ventilator bundle. The ventilator bundle is a series of evidence-based interventions related to ventilator care that, when implemented together with ongoing compliance, will achieve significantly better outcomes than when implemented individually.[8]

Components of the ventilator bundle include the following:

- Elevation of the head of the bed (HOB) between 30 and 45 degrees
- Daily "sedation vacation" (i.e., lightening or weaning of sedation for the purpose of allowing patients to assist themselves to breathe and hence be ready for extubation as soon as possible)
- Daily assessment for readiness to extubate
- Peptic ulcer disease (PUD) prophylaxis
- Deep vein thrombosis (DVT) prophylaxis

For more information, see the sidebar "Components of the Ventilator Bundle."

The Association for Professionals in Infection Control and Epidemiology (APIC) has been instrumental in providing education and guidance to prevent the most common HAIs as part of its "Targeting Zero" initiative through Webinars, conferences, and tools in the form of elimination guides for certain HAIs. These elimination guides have been developed using Centers for Disease Control and Prevention (CDC) recommendations for infection prevention for healthcare workers. The infection control community is awaiting publication of a new VAP elimination guide, due for release in 2009.

In an effort to reach "zero," many hospitals in Pennsylvania have employed ventilator bundles during the past few years. Of note are two hospitals that have been successful in reducing their VAP rates and maintaining very low or zero rates by consistent application of risk reduction strategies. This article addresses implementation of the ventilator bundle and the subsequent significant positive results at these two hospitals. Hospital personnel, including the infection preventionists, were contacted and interviewed directly. They provided written reports and documentation of their programs, results, and successes.

## Roxborough Memorial Hospital

Roxborough Memorial Hospital (RMH) is a 137-bed community teaching hospital in Philadelphia. RMH includes a nursing school as well as a residency program for the Philadelphia College of Osteopathic Medicine.

### Problem

During 2003, the 10-bed combined medical-surgical ICU identified 10 cases of VAP, and in 2004, the number rose to 12. At that time, the hospital was not reporting total ventilator-days, and benchmarking against the National Healthcare Safety Network (NHSN) was not possible. However, internal rate

 ©2009 Pennsylvania Patient Safety Authority 

## Components of the Ventilator Bundle

### Elevation of the Head of the Bed

Elevation of the head of the bed is an integral part of the ventilator bundle and has been correlated with reduction in the rate of ventilator-associated pneumonia (VAP). The recommended elevation is 30 to 45 degrees.

### Daily "Sedation Vacations" and Assessment of Readiness to Extubate

It appears that lightening sedation decreases the amount of time spent on mechanical ventilation and therefore the risk of VAP. In addition, weaning patients from ventilators becomes easier when patients are able to assist themselves during extubation with coughing and control of secretions. However, sedation vacations are not without risks. Patients who are not sedated as deeply will have an increased potential for self-extubation. Therefore, extubation must be conducted carefully.

### Peptic Ulcer Disease Prophylaxis

Applying peptic ulcer disease prophylaxis is an appropriate intervention in all patients who are sedentary; however, the higher incidence of stress ulceration in critical illness justifies greater vigilance. In addition, decreasing the pH of gastric contents may protect against a greater pulmonary inflammatory response to aspiration of gastrointestinal contents. Critically ill intubated patients lack the ability to defend their airway. While it is unclear whether there is any association with decreasing rates of VAP, experience has shown that when applied as a package of interventions for ventilator care, the rate of pneumonia decreases precipitously. The intervention remains excellent practice in the general care of ventilated patients.

### Deep Vein Thrombosis Prophylaxis

Applying deep vein thrombosis (DVT) prophylaxis is an appropriate intervention in all patients who are sedentary; however, the higher incidence of DVT in critical illness justifies greater vigilance. The risk of venous thromboembolism is reduced if prophylaxis is consistently applied.

**Source:** Institute for Healthcare Improvement. Implement the ventilator bundle [online]. [cited 2009 Apr 9]. Available from Internet: http://www.ihi.org/IHI/Topics/CriticalCare/IntensiveCare/Changes/ImplementtheVentilatorBundle.htm.

*Reprinted from http://www.ihi.org with permission of the Institute for Healthcare Improvement (IHI), ©2009.*

calculation and collection strongly suggested a problem with the rising number of VAP infections. In 2005, the first year for which device-days were collected, there were 4 cases, for a rate of 2.6 cases per 1,000 device-days. While the absolute numbers were small, a single VAP has the potential to significantly affect patient morbidity and cost of care. Baseline assessment of nursing practices in the ICU indicated compliance with many risk reduction strategies, but opportunities for improvement with a number of additional evidence-based measures were identified (see Table).

## Intervention

In January 2005, the ventilator bundle was introduced to the ICU staff, and collection of device-day denominator data began. This process was initiated in conjunction with the hospital's overall commitment to the IHI 100,000 Lives Campaign, including the use of a ventilator bundle, through the multidisciplinary ICU committee. The committee comprised pulmonary/critical care physicians, the hospital's medical director, the ICU nurse manager, and the hospital's infection control practitioner. Other disciplines, such as quality improvement, respiratory therapy, and pharmacy, provided key input during various stages of the process. The plans for protocol implementation were shared with senior members of the administrative team, and data was presented to the medical staff and governing board on a regular basis. Flow sheet documentation of the six basic elements of the bundle, along with other evidence-based practices, began in April 2005. Specific protocols for sedation vacation and extubation assessment, standing orders for DVT and PUD prophylaxis, and an oral care program were developed by the pulmonary/critical care physicians in 2006. Standing orders for all elements of the bundle were instituted. Flow sheet documentation and VAP rates were tracked by the ICU nurse manager and hospital infection control practitioner. Regular updates were provided to the ICU committee, infection control committee, medical executive committee, and governing board.

## Results

In 2006, 2 VAP cases were documented, for a rate of 1.9 per 1,000 device-days (see Figure 1). From November 2006 through June 2008, there were zero cases of VAP. In July 2008, an intubated patient who was on a sedation vacation extubated himself and caused an aspiration pneumonia. This incident resulted in one case of VAP for 2008. Nursing compliance with all aspects of the ventilator bundle has been documented with marked improvement. These results demonstrate the value of the ventilator bundle strategy as well as the dramatic effect of a collaborative, multidisciplinary performance improvement process on patient care.

## Commentary

Evidence-based approaches to the management of ventilated patients in the ICU are available from the literature. The CDC publication "Guidelines for Preventing Health-Care-Associated Pneumonia, 2003"

**Table. Baseline Assessment of ICU Nursing Measures at Roxborough Memorial Hospital, October through December 2004**

| ELEMENTS | COMPLIANCE |
|---|---|
| Perform oral care every four hours | Not always |
| Suction oral cavity and back of mouth as needed | Yes |
| Perform oral suctioning before deflating the endotracheal cuff | Yes |
| Aspirate for gastric residual, if on enteral feeding | Yes |
| Turn patient every two hours | Not always |
| Move patient out of bed every eight hours if stable | Not always |
| Evaluate and describe secretions at least every four hours | Yes |
| Drain and dispose of condensation from the ventilator | Yes |
| Notify physician of changes in secretions and any suspected/witnessed aspiration | Yes |
| Clean, sterilize, and disinfect reusable equipment | Yes |
| Engage in handwashing before ventilator contact | Not always |
| Change ventilator circuits and inline suction catheters only when visibly soiled or malfunctioning | Yes |
| Maintain adequate ventilation and cuff pressure | Yes |
| Drain condensate from the ventilator circuit using appropriate technique to avoid contamination of the circuit | Yes |
| Change humidifier every 24 hours | Yes |
| Ensure that ventilator circuits are not unnecessarily broken | Not always |
| Elevate head of bed 30 to 45 degrees at all times | Not always |
| Practice daily sedation vacation | No |
| Conduct daily assessment of readiness to extubate | Not daily |
| Institute peptic ulcer disease prophylaxis protocol | No |
| Institute deep vein thrombosis prophylaxis protocol | Not always |
| Track ventilator-associated pneumonia (VAP) cases and device-days | Yes |
| Provide staff education relative to VAP prevention | Yes |
| Identify high-risk patients | Yes |
| Place high-risk patients on an intensive VAP prevention protocol | No |

contains a compilation of recognized practices. IHI's incorporation of several key measures in the ventilator bundle that accompanies its campaigns has further established best practices with regard to preventing VAP. These tools are readily available to all healthcare organizations that provide care for patients at risk for VAP.

At RMH, the multidisciplinary input of the ICU committee was key to the successful development and implementation of the VAP protocol. Support from physician leaders, particularly those practicing in the ICU, was essential. The ICU nurse manager and the hospital's infection control practitioner provided the necessary hands-on dedication to the task. The process of changing nursing routine in a busy ICU was daunting, but the combination of high-quality background data, rigorous monitoring, and ongoing education contributed to the success of the project. Finally, an evolving sense of pride at all levels of hospital management about the staff's accomplishments reinforced the efforts and provided the necessary leadership support to maintain success.

## St. Christopher's Hospital for Children

St. Christopher's Hospital for Children is a 189-bed pediatric teaching hospital located in Philadelphia. St. Christopher's has a Level I trauma center, a burn center, and a level III neonatal intensive care unit (NICU).

### Problem

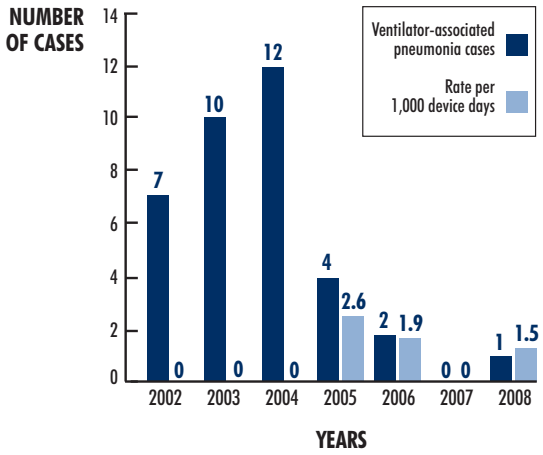
During 2006, St. Christopher's identified that the VAP rate in its NICU was high in comparison to the NHSN NICU pooled mean rates. Its baseline VAP rate was 3.9 per 1,000 ventilator-days in 2006. The NHSN neonatal pooled mean ranges from 0.8 to 3.3, depending on birth weight.

Further evaluation revealed inconsistent clinician knowledge and practice related to VAP prevention. At the time that this increased rate was discovered, ventilator bundling was beginning to gain popularity in the adult population, but scientific evidence was lacking regarding its use in neonates. St. Christopher's assembled a multidisciplinary team to undertake the following:

- Analyze current practice.
- Identify opportunities for improvement.
- Identify new evidence, including best practices.
- Develop a process for ongoing evaluation of VAP prevention elements.

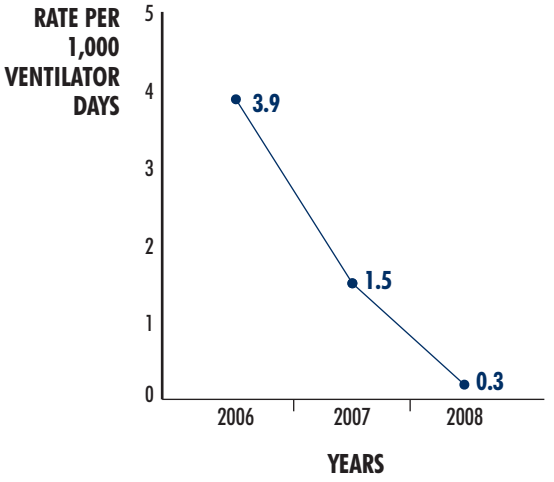
 ©2009 Pennsylvania Patient Safety Authority 

**Figure 1. Roxborough Memorial Hospital: Ventilator-Associated Pneumonia Trends, 2002 through 2008**




*Adapted with permission from Roxborough Memorial Hospital, Philadelphia, Pennsylvania.*

**Figure 2. St. Christopher's Hospital for Children: Neonatal Intensive Care Unit Ventilator-Associated Pneumonia Rates, 2006 through 2008**




*Reprinted with permission from St. Christopher's Hospital for Children, Philadelphia, Pennsylvania.*

The team modified its previous ventilator bundle to include the neonatal population.

Characteristics of 27 NICU VAP patients from 2005 through 2007 revealed that the typical VAP patient in the NICU was less than 35 weeks' corrected gestational age, was intubated for more than 3 weeks on conventional ventilation before VAP occurred, had a length of stay less than 1 month before VAP diagnosis, and was infected with organisms known to cause HAIs. Predominant VAP organisms included *Pseudomonas aeruginosa* (38%, n=8), *Klebsiella pneumoniae* (33%, n=7) and *Staphylococcus aureus* (29%, n=6); of the last, 50% of the cases were methicillin–resistant.

## Outcomes

Following a literature review and networking with other pediatric hospitals, the multidisciplinary team implemented a series of revisions to an existing pediatric ventilator bundle to better serve the neonate population. The resulting elements are called PREVENT (see the sidebar "Elements of the Revised Ventilator-Associated Pneumonia Bundle [PREVENT]—St. Christopher's Hospital for Children").

Some of the changes included the following:

- Elevating HOB 15 to 30 degrees for NICU patients
- Using neonatal oral hygiene care kits for patients of more than 25 weeks' gestational age
- Implementing neonatal oral hygiene with sterile water for patients of less than 25 weeks' gestational age
- Securing endotracheal tubes using standard procedures
- Discarding all tubing and circuits from standby ventilators
- Altering the frequency of ventilator circuit, tubing, and disposable oxygen equipment changes
- Adopting a standard for depth of suctioning and suction pressures
- Implementing a patient flow sheet to document completion of bundle elements

Following implementation of the bundle, the VAP rate decreased by 60% to 1.5 per 1,000 ventilator-days in 2007 and 0.3 in 2008. The following further summarizes the results of implementation:

- The NICU VAP infection rate (number of VAP cases/1,000 ventilator-days) decreased to 0.3 (1/3,396) in 2008 as compared with 1.5 (4/2,641) in 2007 and 3.9 (10/2,523) in 2006. (See Figure 2.)
- Following implementation of the bundle, the NICU had zero cases of VAP between June 2007 and December 2008 (see Figure 3).
- NICU hand hygiene compliance, a bundle component, continued to increase after implementation of the revised ventilator bundle (see Figure 4). NICU staffing ratios increased from 13.5 hours per patient-day in 2006 to 15 in 2007 and remained at 15 hours in 2008.

## Commentary

Development and implementation of the modified neonatal ventilator bundle (PREVENT) resulted in improvement in practices and a significant and sustained decrease in NICU VAP. The initiative required the skill, knowledge, and dedication of nurses, physicians, infection preventionists, and respiratory therapists. As seen with a number of HAI reduction and prevention programs, a multidisciplinary team approach was key to the success of this initiative.

*(continued on page 68)*

 ©2009 Pennsylvania Patient Safety Authority 

## Elements of the Revised Ventilator-Associated Pneumonia Bundle (PREVENT)—St. Christopher's Hospital for Children

### Practice Meticulous Hand Hygiene

Perform hand hygiene by washing with soap and water and using friction for at least 15 full seconds, or use an alcohol-based hand sanitizer (unless hands are visibly soiled or the patient has *Clostridium difficile*).

### Remember Barrier Precautions

Barrier precautions include the following:

- Wear *gloves* when
  - performing intubation or manipulation of the airway,
  - opening the ventilator circuit (i.e., to manually ventilate, to drain fluid from the circuit, to open or replace the in-line suction system),
  - performing respiratory procedures, or
  - handling respiratory secretions or objects potentially contaminated with respiratory secretions.
- Wear a *surgical mask* and *eye protection* when performing high-risk respiratory procedures or when within three feet of a coughing or sneezing patient.
- Wear a *gown* when soiling with respiratory secretions is anticipated. Change gown before providing care to another patient.

### Elevate the Head of Bed

This element includes the following:

- Elevate the head of bed (HOB) 15 to 30 degrees for neonates (less than 28 days old) and 30 to 45 degrees for older patients, unless contraindicated.
- Reposition patient every two to four hours, unless contraindicated.
- Document HOB elevation and times of repositioning on flow sheet.

### Vigilant Oral Hygiene

The registered nurse initiates the patient assessment by evaluating the endotracheal tube and completing oral care.

Oral hygiene includes the following:

- Brushing of teeth every 12 hours (as applicable)
- Cleansing and suctioning the oral cavity every four hours (between brushing) and as needed
- Hypopharyngeal suctioning

### Effective but Minimal Sedation/Extubation Readiness

- Avoid constant heavy sedation.
  - Use minimal but effective sedation.
  - Avoid neuromuscular blockade.
  - Assess/document level of sedation every four hours.
- Assess readiness for extubation (by a physician or designee) at least daily.

### Need for Friendly Reminders

Prevention of infection is the responsibility of all healthcare workers.

- Offer a friendly reminder if someone is not following precautions/procedures of the ventilator bundle.
- Accept reminders as courteously as they are given.

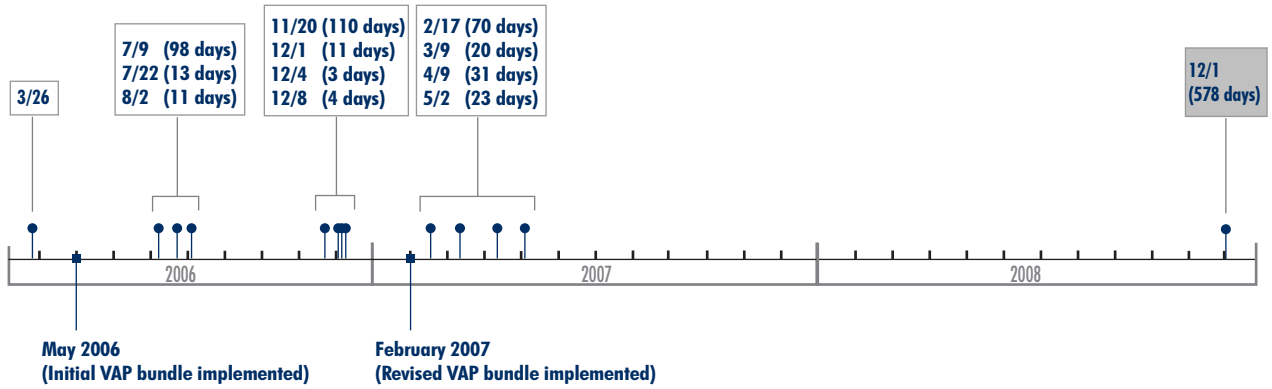
### Techniques for Proper Suctioning and Ventilator/Supply Management

Various techniques for suctioning and maintenance of ventilators/supplies have been instituted in conjunction with policies and procedures specific to the neonatal intensive care unit. These procedures are summarized below:

- Perform endotracheal tube suctioning as needed (i.e., not routinely performed at regular intervals).
  - Use nonsterile gloves for a suction catheter within a closed sheath (i.e., closed in-line suctioning) or for tracheostomy care.
  - Use sterile technique, including sterile gloves, if a closed suction system or the ventilator circuit requires opening.
  - Place a "safe suctioning" card at patient bedside at the time of intubation to indicate proper depth of endotracheal tube suctioning in a closed system.
  - Maintain closed suction setups and in-line suctioning as much as possible. If opening is required, the tip of suction catheter and tubing end should be kept sterile at all times when disconnected.
  - Open normal saline ampules with an alcohol pad and clean gloves if suctioning with saline is ordered.
  - Provide appropriate suction pressures according to intensive care unit protocol.
  - Maintain ventilator circuit lower than the patient to prevent water lavage to patient.
- Key factors in ventilator and supply management include the following:
  - Perform hand hygiene.
  - Maintain sterile technique when opening a closed suction system.
  - Keep supplies that enter or connect to suction or ventilator circuit sterile.
  - Maintain nonsterile supplies in the cleanest way possible.

 ©2009 Pennsylvania Patient Safety Authority 

**Figure 3. St. Christopher's Hospital for Children: Days Between Reported Neonatal Intensive Care Unit Events of Ventilator-Associated Pneumonia (VAP)***




*Days are the number of days between events.

*Adapted with permission from St. Christopher's Hospital for Children, Philadelphia, Pennsylvania.*

*(continued from page 66)*

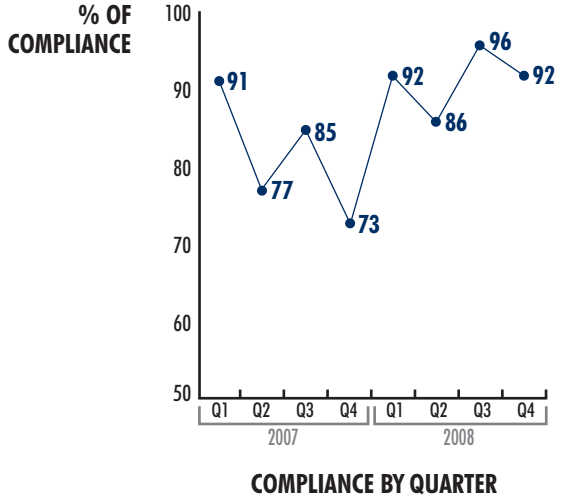
Ongoing evaluation and celebration of successes are imperative to sustaining changes in practice and culture.

A representative sample review of utilization of oral care kits demonstrated a 31% increase of kit usage and a 74% increase in documentation of oral hygiene after implementation of the revised ventilator bundle; St Christopher's attributes this to infection control feedback to the nursing units and the persistence of the NICU team with implementing the change.

## Conclusion

The key to sustained success for reduction of VAP as demonstrated by Pennsylvania's Roxborough Memorial Hospital and St. Christopher's Hospital for Children includes a multidisciplinary approach to implementing evidence-based risk reduction strategies. In addition, using various resources such as the CDC guidelines, IHI ventilator bundles, and APIC guides for prevention of infection, in combination with ongoing monitoring, education, and feedback, resulted in reduction of these infections. It has been clearly demonstrated that pride and ownership by staff members are additional key contributing factors to ongoing success when "targeting zero."

**Figure 4. St. Christopher's Hospital for Children: Neonatal Intensive Care Unit Compliance with Hand Hygiene, 2007 through 2008**




*Reprinted with permission from St. Christopher's Hospital for Children, Philadelphia, Pennsylvania.*

## Notes


1. Girou E, Stephan F, Novara A, et al. Risk factors and outcome of nosocomial infections: results of a matched case-control study of ICU patients. *Am J Respir Crit Care Med* 1998 Apr;157(4 Pt 1):1151-8.
2. Bueno-Cavanillas A, Delgado-Rodriguez M, Lopez-Luque A, et al. Influence of nosocomial infection on mortality rate in an intensive care unit. *Crit Care Med* 1994 Jan;22(1):55-60.
3. Fagon JY, Chastre J, Vuagnat A, et al. Nosocomial pneumonia and mortality among patients in intensive care units. *JAMA* 1996 Mar 20;275(11):866-9.
4. Institute for Healthcare Improvement. Implement the ventilator bundle [online]. [cited 2009 Apr 9]. Available from Internet: http://www.ihi.org/IHI/Topics/CriticalCare/IntensiveCare/Changes/ImplementtheVentilatorBundle.htm.
5. Cook DJ, Kollef MH. Risk factors for ICU-acquired pneumonia. *JAMA* 1998 May 27;279(20):1605-6.
6. Ibrahim EH, Tracy L, Hill C, et al. The occurrence of ventilator-associated pneumonia in a community hospital. *Chest* 2001 Aug;120(2):555-61.
7. Rello J, Ollendorf D, Oster G, et al. Epidemiology and outcomes of ventilator-associated pneumonia in a large US database. *Chest* 2002 Dec;122(6):2115-21.
8. Institute for Healthcare Improvement. Ventilator bundle compliance [online]. [cited 2009 Apr 9]. Available from Internet: http://www.ihi.org/IHI/Topics/CriticalCare/IntensiveCare/Measures/VentilatorBundleCompliance.htm.

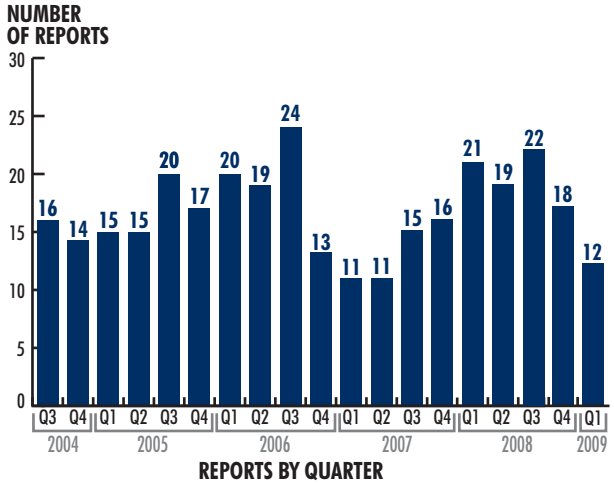

 ©2009 Pennsylvania Patient Safety Authority 

# Quarterly Update on the Preventing Wrong-Site Surgery Project

The latest update from the Pennsylvania Patient Safety Authority's reporting system database shows 12 wrong-site surgeries reported during the first quarter of 2009 (see Figure). Encouraging trends remain. The Southeastern Pennsylvania regional collaborative to prevent wrong-site surgery that began in March 2008 had one wrong-site anesthetic procedure reported among 30 facilities in February 2009 after a three-month hiatus from wrong-site procedures and an eight-month hiatus from wrong-site anesthetic blocks. The three-month hiatus is better than the 90th percentile for the time between reports for this group of hospitals. The Authority will continue to monitor the progress and continues to plan to replicate the initiative in another region.

Of the 12 facilities that reported a wrong-site surgery event to the Authority this quarter, eight had reported wrong-site surgery previously—a total of 23 previous reports, for an average of almost three previous reports per repeat reporter. The cumulative 31 wrong-site surgery reports from these eight facilities represent almost exactly 10% of all wrong-site surgery reports in the Authority's database.

**Figure. Pennsylvania Patient Safety Authority Wrong-Site Surgery Reports by Quarter**




## Authority Reports

Because of the lower-than-average number of reports of wrong-site surgery statewide this quarter, all the reports, edited for contextual deidentification, are described below. Analytical commentary follows the reports to emphasize principles that have been mentioned in previous *Pennsylvania Patient Safety Advisory* articles describing the results from the Authority's Preventing Wrong-Site Surgery Project.*

### Report 1

*The surgeon and the surgery team met with patient preoperatively. Discussion ensued between the patient and the surgeon about the skin lesion to be removed. The result of the discussion indicated that a particular lesion was to be removed. The lesion in question was circled and marked in front of the patient, family, and nurses in the preoperative area. The consent forms were not verified. The location on the consent indicated another location. The patient proceeded to the operating room (OR). The "time-out" procedure was performed. Verbiage during the time-out was miscommunicated. All the pre-, intra- and postoperative documentation was filled out according the consent form. Upon entering the recovery room, the family questioned the location of the dressing. The nurses were alerted, and corrective action began.*

**Commentary.** On analysis, this event had two prime causes:

1. The surgeon based the site marking on personal memory of the patient and the patient's input, which the surgeon misinterpreted. The surgeon did not refer to the documents when marking the site. The family did not comment because they did not appreciate that the mark was a mark to indicate the site of the incision. The site mark should always be reconciled with all the pertinent documents. The results from the Preventing Wrong-Site Surgery Project have shown that this reconciliation needs to include the consent, the history and physical examination, and the schedule at a minimum.
2. The consent was not referenced during the time-out. All information used in the time-out should be verified using the written records.

### Report 2

*The patient was in the OR for excision of a subcutaneous lesion. The area had been marked preoperatively. The lesion was removed uneventfully. Postoperatively, the patient stated that the mass the patient expected to be removed had not been removed. The physician examined the area and found a second subcutaneous lesion superior to the suture line that had not been previously identified. This mass could only be appreciated with the patient in certain positions, and when the site was marked it was not seen.*

**Commentary.** According to follow-up information captured through the Authority's Wrong-Site/-Side Surgery Error Analysis Form, the surgeon did not involve the patient in any of the site verification

* The Pennsylvania Patient Safety Authority has a Web page devoted to educational tools for preventing wrong-site surgery (available at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Pages/home.aspx). Its resources include all the Authority's publications on the subject, including self-assessment tools, sample forms and checklists, educational posters and videos, illustrative figures and tables, patient-education brochures, and online information available from other Web sites.


©2009 Pennsylvania Patient Safety Authority

process before marking the site. (A public version of this analysis form is available from the Authority at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Pages/wss_error_analysis.aspx.) The results from the project have shown the importance of verifying the site with all the pertinent documents *and* with the patient.

## Report 3

*The patient's site marking was placed where it was not easily seen after the patient was positioned for a biopsy. The other side was imaged; an incidental finding of a suspicious area was biopsied. The surgeon proceeded with scheduled biopsy on the correct side after it was noted that the wrong side had been done initially.*

**Commentary.** Results from the project make it clear that the marks should be visible when the patient is prepped and draped and the physician is poised to start the procedure. This was the fourth wrong-site surgery report from this facility.

## Report 4

*A patient [was scheduled] for right epidural injection. The time-out was performed after the patient was positioned and before the procedure was started, stating right-sided procedure was to be performed. The surgeon marked the lumbar region, but not the side. The surgeon injected local anesthetic into left-sided subcutaneous tissues, stopped, and switched to the right side. The procedure was NOT performed on wrong side; local anesthetic only was initiated on wrong side.*

**Commentary.** According to the National Quality Forum definition of serious reportable events, this *was* a wrong-side procedure, because the skin was punctured on the wrong side.

As described in the follow-up information from the Authority's error analysis form, the time-out was done correctly. The subsequent error about side was noted by the patient, who was awake during the procedure.

## Report 5

*The patient was admitted to the surgery area prior to having a procedure on the left leg and was to have a femoral nerve block. The surgeon marked the left leg as the operative site. In the preoperative area, the anesthesiologist verified the side of the block with the patient and performed a right femoral nerve block. The patient asked when [the anesthesiologist] was going to do the side [the patient] was to have surgery on, and [the anesthesiologist] realized the wrong leg had been blocked. [The anesthesiologist] proceeded to perform the block on the left leg, and the patient went to surgery.*

**Commentary.** Wrong-site surgery includes localized anesthetic blocks. The results of the Authority's wrong-site surgery project show the need to follow the Joint Commission's Universal Protocol for each separate procedure, including a time-out before an anesthetic block. According to follow-up information from the Authority's error analysis form, the anesthesiologist did not follow the Universal Protocol for this case. This was the third wrong-side anesthetic block reported by this facility.

## Report 6

*The patient [was identified], and the history and physical examination information and consent were obtained from parent. The (R) leg was marked for the procedure. The (L) leg was cleaned and prepped with the parent present. The parent then left the holding area, and the patient was sedated for the procedure. The (L) popliteal nerve block was successfully completed without incident. Upon completion of this block, it was noted that the operation was to be on the (R) leg. The attending surgeon was notified. The parent was notified by the physicians. It was decided to block the (R) leg and proceed with the surgery. The (R) popliteal . . . nerves were blocked without incident.*

**Commentary.** In the follow-up with the error analysis form, the facility attributed this wrong-side error to the patient lifting up the wrong leg just before the anesthesiologist began the procedure. The anesthesiologist did not check for the site mark. The results from the project have shown the importance of referring to the site marking just before starting the procedure. This was the sixth wrong-site surgery report—and the second report of a wrong-side anesthetic block—from this facility.

## Report 7

*Wrong side paravertebral block. Initially had left-sided placement of the catheter and then had a right-sided placement as well.*

**Commentary.** According to follow-up with the error analysis form, the anesthesiologist was disoriented as a result of being distracted while doing the procedure. The anesthesiologist had marked the site, but the mark was not visible during the procedure. It is the presence of a verified mark as a reference point, not the effect of marking on memory, that is important. Another member of the team questioned the side, but not until after the procedure had been done. This was the fourth wrong-site operative procedure reported by this facility. Two of three prior reports involved surgeons injecting local anesthetics into wrong sites before the time-outs.

## Reports 8 and 9

*A patient was scheduled for a procedure on the right eye. The patient was given all preprocedure drops in the right eye. The surgeon arrived, identified the patient, and marked the right eye. The surgeon did the procedure and, at conclusion, realized that the incorrect eye had been treated. The patient has the same pathology in both eyes. Both eyes need treatment, but the right eye was scheduled for that day.*

*Nursing discovered when comparing documentation to physical verification that the left knee was injected instead of the right knee. The physician was notified*

 ©2009 Pennsylvania Patient Safety Authority 

*and verified the incorrect knee was injected. The error was disclosed. . . . both knees were arthritic. . . .*

**Commentary.** Comparisons of wrong-site surgery reports and near-miss reports for the Preventing Wrong-Site Surgery Project have proven that bilateral pathology is a patient risk factor that increases the possibility of wrong-site surgery, as illustrated in the two reports above. With bilateral pathology, the need to verify the site with the documents is essential.

### Report 10

*A case was scheduled as a left-sided spinal procedure. The patient was marked on the left side. The consent, schedule, and the patient all agreed it was the left side. The left side was mentioned in the time-out. After the incision was closed, but before the patient had woken up, the surgeon realized that the procedure had been done on the right side. The instruments were still sterile, so the patient was reprepped, redraped, and the incision was opened. The surgeon then did the procedure on the left side, as scheduled.*

**Commentary.** The correct location of spinal surgery within a spinal segment is difficult because it can only be confirmed radiographically (for the correct level) or by intraoperative observation of the internal anatomy (for the correct side). A formal intraoperative confirmation of the side by the assistant or scrub tech would be helpful to prevent events like this one.

According to follow-up information from the error analysis form, a clue in this case was where the surgeon was standing, which was the right side of the table. The scrub technician noticed that the surgeon was on the wrong side of the table, but did not speak up. Analyses done for the wrong-site surgery project have shown that wrong-site errors are more likely to be prevented when the surgeon explicitly empowers team members to speak up if they are concerned.

This was the sixth wrong-site surgery report from this facility.

### Report 11

*The patient was to undergo a diskectomy. Under fluoroscopy, the surgeon removed another disk as well. The surgeon had difficulty visualizing the disk spaces. . . . entered and removed one disk thinking it was the other.*

**Commentary.** Based on analysis of prior reports for the project, the radiographic localization of the correct disk space should be verified by both the operating surgeon and a radiologist to ensure that the location is correct. This was the fourth wrong-site surgery report from this facility.

### Report 12

*The patient was seen at the office for pain of the right elbow, requiring surgical intervention. On the day of surgery, the patient presented complaining of pain greater on the lateral side. The surgeon chose to change the surgery and performed a right lateral elbow procedure. The consent, however, was signed for a right medial elbow procedure and was not changed. The pathology report supports pathology on the lateral side. Upon review of the chart and discussion of the case with the surgeon and the medical director, it is determined that this Serious Event should have been reported as a wrong-site surgery.*

**Commentary.** Decisions are sometimes made preoperatively to change the procedure that was originally scheduled. However, these changes should be carefully documented in the pertinent documents. The facility's decision to call this event wrong-site surgery because the actual procedure was not the originally intended procedure, despite being acceptable medical care, is commendable. Its position prevents the possibility of postoperative rationalization, such as occurred with a previous report from an earlier quarter:

*Patient with lesions of the hip underwent wide excision with myocutaneous flap of the left hip lesion. The consent form identified the right side. The surgical site verification was completed in [the special procedure unit] with the right side identified and marked by the physician and the patient; the right side identified in the holding area and during the final time-out. The patient was confused regarding which side was to be done during the final time-out. Otherwise the right [side] was confirmed by all. The patient was turned over for the procedure and the surgeon operated on the left side. When brought to his attention, the surgeon stated he discussed doing smaller lesion first with patient in his office and that it is the left side. When questioned about why all verifications and documentations stated right, the surgeon indicated he meant the left and operated on correct side.*

The Authority has received reports of decisions made intraoperatively to change the procedure based on the observed internal pathology. For instance, a computed tomography scan or ultrasound report might indicate a large cyst originating from the right ovary, but on exploration, the cyst proves to be originating from the left ovary. These events would not be considered wrong-site procedures.

## Survey on Surgical Site Marking Pens and Techniques

The Authority analysts are disseminating a survey, to be communicated through the Patient Safety Officers of Pennsylvania hospitals and ambulatory surgical facilities, in which OR managers can share their good and bad experiences using various marking pens and techniques for marking surgical sites. Others will be encouraged to also contribute by downloading the survey from the Authority's Web site and submitting their experiences to the editor at jclarke@ecri.org.

## The Time-Out Script Competition

The Authority has received five entries for the Time-Out in the OR Script Competition. The scripts are posted on the Authority's Web site at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Pages/scripts.aspx.

For the first round, the *Advisory* editors will accept open-ended review and comment from all who

 ©2009 Pennsylvania Patient Safety Authority 

wish to do so. The editors may publish some of the critiques in the second round, but will not identify any reviewers. The reviews may make a general comment on any script or comment on any parts of any scripts, positively or negatively, but should specifically consider at least three issues: (1) compliance with the time-out elements of the Universal Protocol intended to prevent wrong-site surgery, (2) active participation of all the important members of the operating team, and (3) efficiency. Efficiency will be defined as the length of time involved in performing the script. As mentioned in the March 2009 issue of the *Advisory*, the time should ideally be less than 90 seconds. Please note that the Time-Out in the OR Script Competition includes only the parts of a time-out script that identify the patient, procedure, and side or site of the procedure. Implants availability, antibiotic administration, allergies, and other additions to the Universal Protocol not related to preventing wrong-site surgery have been eliminated from the time-out scripts. Elements of the time-out that involve confirmation or documentation not based on conversation have also been eliminated. Please send your reviews and comments on any or all components of any or all scripts electronically to the editor at jclarke@ecri.org. Please make sure you link comments to specific scripts by their numbers. This is your chance to help shape robust scripts for time-outs.

### Conclusion

The Authority remains committed to preventing wrong-site surgery and welcomes any comments, suggestions, and specific inquiries from facilities with specific problems or questions concerning wrong-site surgery. Communications should be directed to John Clarke, MD, FACS, clinical director of the Pennsylvania Patient Safety Authority, by telephone at (610) 825-6000 or by e-mail at jclarke@ecri.org.

## Patient Safety in Pennsylvania Healthcare Facilities

Since inception of the Pennsylvania Patient Safety Authority's reporting system in 2004, the most challenging question asked of the Authority has been whether healthcare in Pennsylvania is becoming safer. To complement its efforts toward this goal, in January 2009, the Authority invited patient safety officers (PSOs) from all reporting facilities in Pennsylvania to participate in a survey initiative to measure the level of adoption of selected safety practices. PSOs from 200 of 525 invited facilities completed the survey, including 118 hospitals (59%), 80 ambulatory surgical facilities (40%), 1 birthing center (0.5%), and 1 abortion facility (0.5%).

The 37 safety practices were organized into the domains of leadership (4 practices), medication (11 practices), safe surgery (7 practices), infection control (3 practices), device safety (6 practices), patient identification (2 practices), transition of care (1 practice), environment (1 practice), care management (1 practice), and falls prevention (1 practice). Practices were defined according to the Centers for Medicare & Medicaid Services, the Joint Commission, and the National Quality Forum and associated with the specific *Pennsylvania Patient Safety Advisory* articles that advocated them.

Examples of the aggregate results of adopted safety practices under different domains include the following (certain practices may not apply to all facility types):

**Leadership.** Written instructions for staff about error reporting that include that "just culture" principles are fully implemented throughout the organization (60.5% of participating facilities).

**Medication.** The organization has established explicit mandatory elements of a telephone or verbal order that includes the use of read-back (83% of participating facilities).

**Safe surgery.** The organization requires *both* that the patient (or representative) is involved in confirming the surgical site *and* that the surgical site mark is made before the patient is sedated (79.5% of participating facilities).

**Infection control.** An infection control plan that specifies the inspection frequency of patient care areas for handwashing capabilities and availability of supplies is fully implemented throughout the organization (79% of all participating facilities).

**Device safety.** Prohibition of defibrillator use for routine physiologic monitoring is fully implemented throughout the organization (69% of participating facilities).

Limitations of the survey include that results represent about 38% of reporting facilities in Pennsylvania and may not reflect statewide adoption of practices or may disproportionately represent facilities. Varying interpretation of questions among the participating PSOs may have occurred. Finally, generalizing results from birthing centers and abortion facilities is not possible because of the low response from these facility types.

In May 2009, PSOs and chief executive officers of participating facilities received a detailed report of survey results comparing the level of adoption of the practices at their facilities with that of similar facilities statewide. The aggregate results of the survey were discussed in the Authority's 2008 annual report, available online at http://www.patientsafetyauthority.org/PatientSafetyAuthority/Documents/annual_report_2008.pdf. The detailed aggregate results, a sample action agenda to assess organizational assessment and schedule required actions, and links to associated *Advisory* articles, are also available from the Authority at http://www.patientsafetyauthority.org/EducationalTools/PatientSafetyTools/safety_practices/Pages/home.aspx.

 ©2009 Pennsylvania Patient Safety Authority

# Online Resources Associated with Patient Safety Advisories

**Patient Safety Officers have expressed their interest in distributing educational resources within their healthcare facilities. The Pennsylvania Patient Safety Authority provides a growing collection of resources related to *Pennsylvania Patient Safety Advisory* articles to help increase situational awareness and patient safety within healthcare facilities. Examples include sample policies, educational videos and posters, brochures, interactive learning graphics, and reference materials.**

This collection of resources is available online at http://www.patientsafetyauthority.org. Topics addressed include the following:

- Preventing wrong-site surgery
- Verbal orders
- Contrast-induced nephropathy
- Expressed breast milk
- Hospital bed safety
- Skin tears
- Color-coded wristbands
- Common hazards in the behavioral health patient room

*More improvement comes from improving a system than improving the performance of individuals within an existing system.*

PATIENT SAFETY AUTHORITY

An independent agency of the Commonwealth of Pennsylvania

Whether you would like to learn more about the topics described above, or you need tools to help you meet other challenges, these educational resources can help.

If you would like additional information, please contact us at (866) 316-1070, or e-mail support_papsrs@state.pa.us.

# PENNSYLVANIA PATIENT SAFETY ADVISORY

## THE PENNSYLVANIA PATIENT SAFETY AUTHORITY AND ITS CONTRACTORS

The Pennsylvania Patient Safety Authority is an independent state agency created by Act 13 of 2002, the Medical Care Availability and Reduction of Error ("Mcare") Act. Consistent with Act 13, ECRI Institute, as contractor for the Authority, is issuing this publication to advise medical facilities of immediate changes that can be instituted to reduce Serious Events and Incidents. For more information about the Pennsylvania Patient Safety Authority, see the Authority's Web site at http://www.patientsafetyauthority.org.

ECRI Institute, a nonprofit organization, dedicates itself to bringing the discipline of applied scientific research in healthcare to uncover the best approaches to improving patient care. As pioneers in this science for nearly 40 years, ECRI Institute marries experience and independence with the objectivity of evidence-based research. More than 5,000 healthcare organizations worldwide rely on ECRI Institute's expertise in patient safety improvement, risk and quality management, and healthcare processes, devices, procedures and drug technology.

The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit organization dedicated solely to medication error prevention and safe medication use. ISMP provides recommendations for the safe use of medications to the healthcare community including healthcare professionals, government agencies, accrediting organizations, and consumers. ISMP's efforts are built on a nonpunitive approach and systems-based solutions.