PENNSYLVANIA PATIENT SAFETY ADVISORY

PATIENT SAFETY AUTHORITY
An Independent Agency of the Commonwealth of Pennsylvania

PA PSRS
Pennsylvania Patient Safety Reporting System

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

Vol. 5, No. 3

September 2008

IN THIS ISSUE

Reviews & Analyses

75 Medication Errors Associated with Documented Allergies
A review of data from PA-PSRS reveals more than 3,800 reports in which medications were erroneously prescribed for and given to patients who had documented allergies to them.

81 Anticoagulation Management Service: Safer Care, Maximizing Outcomes
Healthcare organizations have increasingly recognized the benefits of anticoagulation services in the inpatient and outpatient settings.

85 Triage of the Obstetrics Patient in the Emergency Department: Is There Only One Patient?
Optimal management of two patients requires a systematic approach and open communication between the emergency department and obstetrics department.

90 Malignant Hyperthermia: Is Your Facility Prepared to Treat This Rare Condition?
While occurrence of malignant hyperthermia is rare, the need for rapid response requires the need to be prepared.

96 Hazardous Spills: The Safe Handling of Hazardous Drugs
Safe handling of hazardous drug spills is uniquely different from other healthcare spills. Exposure extends beyond patients and healthcare practitioners because nonclinical staff are often involved with containment and disposal.

Other Features

73 Leadership Series: UPMC's Experience with Disclosure of Medical Errors
Richard P. Kidwell, JD; Robert G. Voinchet, JD

74 Editorial: WHO Surgical Safety Checklist

Focus on Infection Control

100 Hand Hygiene Practices and the Use of Alcohol-Based Sanitizers

From the Database

89 Rapid Response in the Operating Room

Other Patient Safety Information

108 Forcing Functions of Antibiotic Prophylaxis

Updates

103 Quarterly Update on the Preventing Wrong-Site Surgery Project

106 Still Not Seeing Clearly—A Second Look at Intraocular Lens Implant Events

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 Reporting System (PA-PSRS), 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 as part of the Pennsylvania Patient Safety Reporting System (PA-PSRS).

COPYRIGHT 2008 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.psa.state.pa.us.

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.

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*
Sharon Hutton, *Administrative Assistant*
Judith Marpoe, *Program Manager*
Megan Shetterly, RN, MS, *Patient Safety Liaison*

Contact Information

Office Location: 539 Forum Building, Harrisburg, PA 17120
Mailing Address: P.O. Box 8410
Harrisburg, PA 17105-8410
Telephone: 717-346-0469
Facsimile: 717-346-1090
Web site: http://www.psa.state.pa.us
E-mail: patientsafetyauthority@state.pa.us

PENNSYLVANIA PATIENT SAFETY ADVISORY

John R. Clarke, MD, *Editor*

Contributing Editors

Arthur J. Augustine, BS
Mary Blanco, RN, MSN
Hedy Cohen, RN, BSN, MS
Edward Finley, BS
Michael J. Gaunt, PharmD
Matthew Grissinger, RPh
Charlotte Huber, RN, MSN
Deborah D. Kobelansky, RN, MPH
William M. Marella, MBA
Denise Martindell, RN, JD
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: P.O. 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*
Franchesca J. Charney, RN, BS, MSHA, CPHRM, CPSO, *Holy Spirit Health System*
William R. Dubin, MD, *Temple University*
Vincent Cowell, MD, *Temple University*
Monica M. Davis, CRNP, MSN, MBA, *Children's Hospital of Philadelphia*
Caprice C. Greenberg, MD, MPH, *Harvard University, Brigham and Women's Hospital*
Bonnie Haluska, RN, *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, *Columbia University*
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, BS, *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. 5, No. 3:

Dorothy Borton, RN, BSN, CIC, *Albert Einstein Healthcare Network*
Monica M. Davis, CRNP, MSN, MBA, *Children's Hospital of Philadelphia*
Adina S. Gutstein, MSN, CRNP, *Achieving Better Control, Inc.*
Michael L. Kay, MD, *Wills Eye Hospital, Thomas Jefferson University Hospital, Pennsylvania Hospital*
Sharon L. Jacobs, RN, MS, CIC, *St. Clair Memorial Hospital*
Emily McCracken, MPH, *Hamot Health System*
Luke Petosa, MSc, HEM, HEM-CC, *ECRI Institute*
Martha Polovich, RN, MN, AOCN, *Duke Oncology Network*
Niraja Rajan, MD, FAAP, *Hershey Outpatient Surgery Center*
Edward A. Ramoska, MD, MPH, FACEP, *Drexel University*
Henry Rosenberg, MD, *Saint Barnabas Medical Center*
Carolyn R. Smith, RN, CEN, *Waynesboro Hospital*
Beverly M. Vaughn, MD, *Lankenau Hospital*
Christopher S. Walsh, PharmD, RPh, FISMP, *Saint Joseph Medical Center*

Leadership Series: UPMC's Experience with Disclosure of Medical Errors

Richard Kidwell, JD

Robert Voinchet, JD

Richard P. Kidwell, JD, Associate Counsel and Director, Department of Patient Safety/Risk Management
Robert G. Voinchet, JD, President and Counsel, Captive Insurance Program
University of Pittsburgh Medical Center

Patients who are harmed as a result of a medical error look to their physicians for three things: an apology, an explanation of what happened, and an assurance that something will be done to prevent the mistake from recurring. At the University of Pittsburgh Medical Center (UPMC), physicians fulfill their patients' expectations and remain available and accessible to their patients after such Serious Events. UPMC sees this commitment as a continuation of the dialogue between patient and physician that begins at the initial encounter. The accepted practice in the past was to avoid discussion of the topic of errors altogether. UPMC's philosophy, though, is to keep the lines of communication open, especially after a patient has been injured, because that is when a patient needs a caring physician and the information he or she provides more than ever.

UPMC has a disclosure policy that exceeds the dictates of the Joint Commission and the Pennsylvania Medical Care Availability and Reduction of Error Act of 2002 (Mcare). UPMC's doctors do not disclose errors just because of regulatory requirements; it is the right thing to do for both the patient and the physician.

We spearhead the efforts to inculcate UPMC's physicians with an appreciation for the virtues of disclosure. The captive insurance companies, which cover all UPMC facilities and about 4,500 physicians, fully support the concept of transparency with patients. Patients are steered to insurance and risk management representatives when questions of compensation arise. The authors speak at departmental and hospital medical staff meetings about the reasons for and the methods to accomplish medical disclosure. If a mistake is made during the treatment of a patient, the worst reaction is to make a second mistake by ignoring the error or covering it up.

One of the tools to educate UPMC's physicians is a video tutorial titled, "Removing Insult from Injury: Disclosing Adverse Events." This video, in which one of the authors participated, was produced by Johns Hopkins Bloomberg School of Public Health and succinctly explains why and how disclosure should take place. (For more information, see http://www.jhsph.edu/dept/HPM/Research/Wu_video.html.) UPMC is fortunate, too, to have several physician champions espousing the benefits of disclosure to their colleagues.

Unlike the majority of states, Pennsylvania does not have an apology law that protects disclosure discussions. Thus, there was some initial resistance from UPMC doctors who were concerned that an apology would be used against them in subsequent litigation. While an apology law would be beneficial (a bill is pending before the legislature), there are several reasons why disclosure should take place even in the absence of statutory protection. As previously stated, it is the moral and ethical thing to do. Second, a physician who is upset with seeing his or her patient injured can start his or her own healing process by discussing matters with the patient. (UPMC also provides a counseling service for its physicians involved in Serious Events.) Third, an honest discussion with a patient may be the key to avoid a claim, and UPMC has anecdotal evidence of such outcomes. Fourth, if a mistake has caused harm, UPMC's insurance and risk personnel move swiftly to resolve any claim that may arise and forestall the event ending up in a jury trial where the apology is admitted in evidence. If, however, the claim cannot be resolved except by means of a jury trial, it is to a defendant doctor's advantage for the jury to hear that the doctor apologized to the patient, offered an explanation of what occurred, and focused on the patient's future care needs. Last, fear that disclosures will lead to increased claims and litigation has not been proven. While actively encouraging disclosure for the past several years, UPMC's claim count has decreased and claim payments have been stable.

Part of the acceptance by physicians in UPMC's disclosure program is trust in their colleagues in other departments. UPMC's patient safety/risk management personnel work hand-in-hand with UPMC physicians when a patient is harmed as a result of a medical error. As spelled out in UPMC's policy, early notification of an event to risk management personnel is important, so the facts can be analyzed and a plan put together on how best to communicate with the patient. Risk management personnel's experience helps guide their medical colleagues through these delicate situations. Risk management personnel can also ensure compliance with regulatory requirements like Mcare's Serious Event letters. As in all aspects of healthcare, teamwork is essential.

UPMC's experience with advocating candid and forthright disclosure discussions with patients has been overwhelmingly positive. Physicians have embraced the policy as a result of the commitment of their leadership and after seeing the policy put into practice both through their efforts and the efforts of UPMC's support staff.

 ©2008 Pennsylvania Patient Safety Authority

Editorial

WHO Surgical Safety Checklist

On June 25, 2008, the World Health Organization (WHO) launched the Second Global Patient Safety Challenge: Safe Surgery Saves Lives initiative and introduced the "WHO Surgical Safety Checklist." The checklist is designed to catch omissions in the actions supporting an operation before the patient suffers harm. The "WHO Surgical Safety Checklist" was developed by the World Alliance for Patient Safety under the direction of Atul Gawande, MD, FACS, of Harvard University. It was piloted in eight hospitals on four continents, including the University of Washington. It has been endorsed by more than 200 organizations, including the American College of Surgeons, American Society of Anesthesiologists, Association of periOperative Registered Nurses, American Academy of Orthopaedic Surgeons, American College of Obstetricians and Gynecologists, American Academy of Otolaryngology—Head and Neck Surgery, North American Spine Society, and Council on Surgical and Perioperative Safety. It will be a standard of care in the United Kingdom, Ireland, and Jordan by 2009. Dr. Gawande pointed out that the endorsements covered nations providing surgical care to 75% of the world population.

The checklist has three parts: (1) Sign In, (2) Time Out, and (3) Sign Out. Each part has five to seven items for the operative team to review.

Dr. Gawande pointed out that 234 million operations are done in the world each year—1 for every 25 people. About 7 million of these operations result in complications. About half of the complications are preventable.[1] The surgical safety checklist is designed to reduce these preventable complications.

Dr. Gawande stated that before using a checklist, the eight pilot hospitals had a complication rate of 11%, with 64% of patients failing to get one or more of six safe surgical practices. After using the surgical safety checklist for the first 1,000 patients, the percentage of patients not getting one or more of six safe surgical practices dropped in half to 32%.

The Sign In consists of

- verification of the operative documents with the patient,
- checking that the site has been marked if indicated,
- completion of an anesthesia safety check,
- confirmation of pulse oximetry monitoring,
- documentation of allergies,
- assessment of airway, and
- confirmation of the adequacy of intravenous access.

The Time Out consists of

- introduction of the team members;
- confirmation of the site;
- review of critical steps by the surgeon, anesthesia professional, and nurse;
- confirmation of antibiotic use; and
- confirmation of images.

The Sign Out consists of

- confirmation of the procedure,
- confirmation of the counts,
- confirmation of the specimen label,
- mention of equipment problems, and
- plan for patient recovery.

Each of the eight pilot hospitals recounted its experience. Many of the hospitals described an initial resistance, followed by a realization that the checklist not only identified missing elements, but also reinforced teamwork. Many said that each of the three parts of the checklist took less than one minute to complete. Almost every site modified the checklist slightly, while maintaining the prescribed elements. For instance, the Canadian site added prophylaxis for deep venous thrombosis to the checklist. Within months, the members of the operating teams felt the checklist was essential.

Dr. Gawande hoped that every surgeon and surgical team would try using the checklist just once. He was confident that they would want to use it again.

As director of the Pennsylvania Patient Safety Reporting System reviewing approximately 5,000 medical error reports each week and as a surgeon, I encourage all operating room committees in Pennsylvania to incorporate the "WHO Surgical Safety Checklist" into their workflow and track the impact. For more information about the "WHO Surgical Safety Checklist," please go to the WHO Web site (http://www.who.int/patientsafety/safesurgery/en/) or contact me. For those who are interested, WHO has copies of the checklist and an implementation manual available at http://www.who.int/patientsafety/safesurgery/tools_resources/technical/en/index.html.

John R. Clarke, MD
Editor, Pennsylvania Patient Safety Advisory
Clinical Director, PA-PSRS
Professor of Surgery, Drexel University

Note

1. Weiser TG, Regenbogen SE, Thompson KD, et al. An estimation of the global volume of surgery: a modelling strategy based on available data. *Lancet* 2008 Jul 12;372(9633):139-44.

MRI Events—Your Experience Can Help

Reports have been submitted through PA-PSRS about magnetic resonance imaging- (MRI-) compatible infusion pumps being brought too close to the magnet. If your facility has developed a good solution that keeps this from happening, please contact the *Advisory* editorial staff (866-316-1070 or e-mail support_papsrs@state.pa.us) so that the solution can be included in an upcoming article on the topic.

 ©2008 Pennsylvania Patient Safety Authority

Medication Errors Associated with Documented Allergies

ABSTRACT

The selection of appropriate medications and dosages is dependent upon the availability and review of critical patient information. Without patient-specific clinical information, such as age, weight, allergies, diagnosis, and laboratory values, healthcare practitioners cannot develop safe and effective treatment plans. As many as 18% of serious, preventable adverse drug events stem from practitioners having insufficient information about the patient before prescribing, dispensing, and administering medications. Review of data from PA-PSRS reveals more than 3,800 reports of cases in which patients received medications to which they had documented allergies. Narcotics and antibiotics were the most common medications listed in reports. Types of breakdowns in the communication of allergy information include documentation of patients' allergies on paper but not entered into the organization's computerized order-entry systems, allergy information not consistently documented in expected locations, organizations' attempts to list every drug allergen on the wristband, and allergies arising during episodes of care but not documented in the medical record or communicated to appropriate staff. Strategies to address problems with patients' documented allergies include adding clear and visible prompts in consistent and prominent locations; listing patient allergies, as well as a description of the reaction to the allergen, on all admission order forms; eliminating the practice of writing drug allergens on allergy arm bracelets; and making the allergy reaction selection a mandatory entry in the organization's order-entry systems. (Pa Patient Saf Advis 2008 Sep;5[3]:75-80.)

Patient information helps guide the appropriate selection of medications, dosing, and routes of administration. This information includes patient-specific clinical information such as age, weight, allergies, diagnoses, comorbid conditions, and pregnancy status, as well as patient monitoring information such as laboratory values, vital signs, and other parameters that gauge the effects of medications and the patients' underlying disease processes. This information is critical because as many as 18% of serious, preventable adverse drug events (ADEs) stem from practitioners having insufficient information about the patient before prescribing, dispensing, and administering medications.[1] Lesar et al., in a systematic evaluation of every third prescribing error detected and averted by pharmacists in a 631-bed tertiary care teaching hospital, showed that more than 25% of prescribing errors alone were directly associated with inadequate patient information, most notably renal and hepatic function, allergies, and pregnancy status.[2] In this study, the most common specific factors associated with prescribing errors were a decline in renal or hepatic function requiring alteration of drug therapy (13.9%) and patient history of allergy to the same medication class (12.1%). The two drug categories most frequently involved in errors related to insufficient patient information were narcotics and antimicrobials; the most serious injuries were due to prescribing these drugs for patients with documented allergies to them.

A review of data from PA-PSRS reveals more than 3,800 reports in which medications were erroneously prescribed for and given to patients who had documented allergies to them. These results are based on the review of the PA-PSRS event type "A. Medication Errors, 6. Monitoring Errors, c. Documented Allergies," as well as other medication error reports identified by PA-PSRS clinical analysts as having involved patient allergies. Of the 3,813 reports, 61 (1.6%) resulted in a Serious Event, meaning the patient was harmed. Table 1 lists the care areas most cited as the location where the error occurred. Although the most frequently cited care area was the pharmacy, clearly these problems originate when orders are written by prescribers in patient care areas. Similar to findings of the study conducted by Lesar et al.,[2] narcotics and antibiotics dominate the top 15 medications listed in reports submitted through PA-PSRS (see Table 2).

An analysis of the reports show that these events fall into two broad categories: breakdowns in patient information and breakdowns in drug information.

Table 1. Care Areas Most Cited in Documented Allergy Events

CARE AREA	NUMBER OF ADVERSE EVENT REPORTS (TOTAL N = 3,813)
Medical/surgical unit	490 (12.9%)
Emergency department	442 (11.6%)
Ambulatory surgery—preoperative and discharge	224 (5.9%)
Telemetry	195 (5.1%)
Operating room	124 (3.3%)
Medical/surgical intensive care unit	78 (2%)
Postanesthesia care unit	77 (2%)
Medical/surgical/oncology unit	71 (1.9%)
Medical/surgical/cardiac intermediate unit	63 (1.7%)
Pharmacy	1,042 (27.3%)
Remaining care areas	1,007 (26.4%)

 ©2008 Pennsylvania Patient Safety Authority

Breakdowns in Patient Information

Errors associated with breakdowns in patient information, including allergies, diagnosis, comorbid conditions, current medication lists, and labs, involve breakdowns at each level of the medication-use process. These errors can occur when practitioners

- obtain information from patients, caregivers, or other healthcare facilities during the reconciliation process;
- document the information into paper-based and electronic records;
- write orders for medications or enter orders into computerized prescriber order-entry (CPOE) systems;
- enter orders into the pharmacy order-entry systems and dispense medications; and
- obtain and administer medications.

When critical patient information, which may or may not be available to the prescriber, is not available in a clear way to pharmacists or nurses at the time of dispensing or administering, opportunities for critical double-checks are bypassed. Thus, errors in prescribing may not be detected.[3]

Obtaining accurate information from patients can be difficult. One case reported through PA-PSRS exemplifies this issue.

> *A patient interviewed during [the preoperative period] stated that she had no allergies, but the nursing admission assessment, the anesthesia record, the history and physical, the emergency room record, and the medication [record] indicated that the patient had an allergy to penicillin. The patient had an Ancef® irrigation of her operative site done. Following this procedure, the nurse noted the penicillin allergy documented by anesthesia.*

Table 2. Top 15 Medications Involved in Documented Allergy Events

MEDICATION	NUMBER OF ADVERSE EVENT REPORTS
morphine	303
cefazolin (Ancef®, Kefzol®)	213
oxycodone and acetaminophen	186
hydromorphone	177
aspirin	176
furosemide	106
levofloxacin	98
ceftriaxone	81
ampicillin and sulbactam (Unasyn®)	78
ampicillin	73
ketorolac (Toradol®)	70
acetaminophen	66
hydrocodone	63
tazobactam and piperacillin (Zosyn®)	53
promethazine	48

However, a review of admission notes over a three-month period that evaluated the completeness and accuracy of drug allergy documentation by medical residents, medical students, and primary care nurses showed that approximately 20% of the healthcare professionals failed to document drug allergies in their admission notes. The authors noted that although the majority of patients could recall the dosage form of the offending drug, the time that had elapsed between administration of the drug and appearance of symptoms, and how long ago the reaction had occurred, none of this information was recorded by the practitioners. Therefore, they concluded that incomplete documentation of the drug allergy status of patients did not appear to be related to patients' inability to provide accurate information.[4] The majority of events submitted through PA-PSRS predominately describe situations in which patient allergies have been obtained and documented, yet the patients still received a medication to which they were allergic.

Documenting allergies, but not including the specific reaction the patient experienced to the medication, does not provide all the information necessary to making therapeutic decisions. Most organizations obtain a list of medication allergies from patients upon admission. Yet the most important information, the actual reaction that occurred from the medication that prompted the documented allergy, is rarely included. Knowledge of a patient's reaction to penicillin, ranging from an "upset stomach" to an anaphylactic reaction, would have a profound effect on practitioners if this information was available.

A second breakdown in the communication of allergy information occurs when a patient's allergies are documented on paper but are not entered into the organization's CPOE and pharmacy order-entry systems. Prescribers and pharmacists rely on the availability of important patient information, including allergies, when entering and screening orders for appropriateness and safety. If this information is unavailable in the organization's computer order-entry systems, a critical checking mechanism is bypassed, which increases the risk that medications will be dispensed to the patient who is allergic to them. In a report submitted through PA-PSRS, this type of breakdown occurred twice with the same patient.

> *Patient admitted through the [emergency department (ED)] with allergies listed on ED sheet as "VANCO, AVELOX, KEFLEX." The order was written for "Levaquin 500 mg IV q24H." The patient's allergies were not put into computer by anyone. The ED administered the drug although Levaquin® has allergy considerations, considering the patient's allergy to Avelox®. Later, the patient was ordered "vancomycin 1 gm IV Q24h." The order was processed despite allergy to vancomycin, and the patient developed a*

 ©2008 Pennsylvania Patient Safety Authority

rash as a result. [During the reconciliation process] it is not known [if one] medication caused the rash, or both.

When allergy information is not consistently documented in the expected locations, confusion and problems can arise. It is critical for healthcare practitioners to be able to find important information about a patient at the time of prescribing, dispensing, and administering medications. However, allergy documentation may be inconsistent and/or appear in nonstandard locations in the patients' chart and other documentation.

Patient was prescribed and received Bactrim® following shoulder surgery and subsequently had an allergic reaction, which required intubation and transfer to critical care. The ED record from the previous day identified an allergy to penicillin and sulfa drugs. The inpatient record and pharmacy records had only penicillin. The patient's mother reported only penicillin at the time admission data was collected.

On nursing assessment, an allergy to penicillin was noted. An allergy sticker was not placed on chart per procedure. Ancef® was ordered and administered. The patient developed an itchy, red rash on arms.

As was noted in the December 2005 supplementary *Patient Safety Advisory*, nearly four out of five (78%) survey respondents' facilities use patient wristbands to communicate clinical information, including allergies.[5] However, a number of errors have been associated with the methods used to identify allergies with wristbands. One problem is that admission staff and/or healthcare practitioners forget to apply the wristband. Another contributing factor is an organization's policy to list *every* drug allergen on the wristband, which is a risky procedure because not every drug to which a patient is allergic can always be listed, as illustrated in PA-PSRS reports.

A dressing change was performed on the patient's peripherally inserted central catheter line. Nurse performing dressing change utilized Betadine to clean site. The patient's chart states that the patient is allergic to Betadine, but the patient's allergy bracelet did not include Betadine as known allergy. The patient [experienced] warmth and flushing of the face and right arm, which required treatment with Benadryl® 50 mg.

Patient was status post hip surgery. Morphine was administered as ordered for complaints of pain. The patient questioned what pain medication was being administered. The patient then stated that she gets "chest pain" from morphine. Allergy band in place did not list morphine; however, anesthesiology did list morphine as an allergy.

New allergic reactions that develop during the current hospitalization are as important to capture and document as the patient's preexisting allergies. However, reports submitted through PA-PSRS illustrate that new allergies are not always documented in the medical record or communicated to appropriate staff. As the following case describes, breakdowns in the communication or documentation of new allergies can lead to additional allergic reactions during the patient's stay.

Preoperatively, the patient had documented no known drug allergies. Intraoperatively, the patient was administered Unasyn® (ampicillin/sulbactam) 1.5 gm IV and developed hives on her abdomen and chest. Benadryl (diphenhydramine) 50 mg IV and Decadron® (dexamethasone) 10 mg IV were administered. The patient was admitted to [intensive care unit (ICU)] and remained intubated. [Later], the patient was administered Unasyn 1.5 gm IV. Halfway through the infusion, the patient developed stridor and wheezing.

There are other breakdowns in the medication use system that can lead to errors. The Institute for Safe Medication Practices (ISMP) identified another error scenario involving inadequate communication of a patient's allergies.[6] A pharmacist could not read the list of patient allergies that a nurse had faxed on a new admission, so he accessed the patient's profile from a recent, previous admission and entered the allergies as they appeared on the prior profile. However, the allergies listed there were incomplete. Since her prior hospital admission, the patient developed an allergy to cefazolin. A consulting physician, also unaware of the patient's recent allergic response, telephoned an order for cefazolin. The pharmacy processed the order without detecting the allergy. The cefazolin allergy also was not listed on the medication administration record (MAR) since it was generated from the pharmacy computer system. Thus, the nurse administering the drug did not detect the allergy. The patient became hypotensive and unresponsive. The patient's nurse noticed the adverse reaction, and the patient was treated with a dose of diphenhydramine, recovered, and was discharged the next day. Because patients may develop new allergies at any time, medical records from previous admissions can be used as a reference for allergy history but should be verified with a current list.

As noted in an article about verbal orders from the June 2006 issue of the *Advisory*, verbal medication orders can result in errors, especially when prescribers do not ask about or are not asked to communicate the patient's allergies and the corresponding reaction.[7]

Automated dispensing cabinets (ADC) offer the ability for patient profiling. Pharmacists can enter and screen drug orders against allergies listed in the patient's profile before the medication is removed from an ADC and administered. Furthermore, allergy alerts can be programmed to display when a medication to which a patient has a documented allergy is selected for retrieval. However, many organizations still use nonprofiled ADCs. In facilities with nonprofiled ADCs, nurses must manually check the medical record or MAR for allergies when retrieving medications from

 ©2008 Pennsylvania Patient Safety Authority

a nonprofiled ADC or unit stock. Based on reports submitted through PA-PSRS, this manual check of the medical record does not always occur.

> *Physician ordered Neurontin® for a patient with a listed drug allergy on patient chart and [MAR]. After pharmacy hours, the nurse transcribed/verified order and pulled med from night cabinet without any pharmacist check of order. Nurse admits to not checking for drug allergy and not clarifying with physician. Neurontin dose was given without any ill effects to patient.*

Unsafe practices with the use of electronic systems (e.g., computer order-entry systems, ADCs, point-of-care bar-coding systems) include the use of overrides and workarounds. The use of overrides results in circumventing potentially critical alerts in order to enter and process orders more quickly or to obtain and administer medications before delivery by the pharmacy. For example, a Pennsylvania facility reported the following:

> *Patient had a listed allergy to oxycodone. Order for Percocet® was prescribed "as needed" for the patient. The nurse used the override feature of the medication dispensing system to obtain the medication, therefore disabling the safety feature to alert for allergies. The patient developed a rash, which resolved without further injury to patient.*

Administering medications to patients without asking the patient for possible past reactions to medications is another breakdown reported through PA-PSRS.

> *[Before noon] the patient's left knee was noted to be oozing. A dime-sized [application of] Betadine® was applied to the uppermost part of wound. The patient stated, "I am allergic to Betadine." The area was promptly washed with soap and water.*

Breakdowns in Drug Information

Breakdowns with critical drug information, lack of available information on prescribing medications, lack of knowledge of possible drug-drug contraindications as well as the lack of effective screening for drug-allergy interactions by order-entry systems have led to patient harm. One example reported through PA-PSRS discusses a patient who had a documented penicillin allergy, and a prescriber wrote an order for a medication that had a possible cross allergy to the medication listed in the patient's chart. Cross allergies most commonly reported through PA-PSRS include ketorolac with aspirin or nonsteroidal anti-inflammatory medications (e.g., ibuprofen), as well as penicillin-derivative antibiotics with Zosyn®, Unasyn, or cephalosporins (e.g., cefazolin, ceftriaxone).

A second example of errors associated with drug information concerns combination products that contain two or more active ingredients. When medications are prescribed using their brand or trade name (e.g., Zosyn, Unasyn), that name does not communicate the multiple, active ingredients contained in that product (e.g., piperacillin/tazobactam, ampicillin/sulbactam). Therefore practitioners as well as electronic systems may not identify a product that contains a potential allergen. When this occurs, a patient may experience an allergic reaction that requires initial treatment or higher levels of medical care, as illustrated in the report below from PA-PSRS.

> *The patient had a known allergy to penicillin and was prescribed Augmentin® (amoxicillin/clavulanic acid). The patient presented to the ED due to swelling of her lip and tongue. She was intubated and admitted to the ICU with the diagnosis of angioedema.*

Once patient information is correctly entered into electronic databases, it is possible to screen for any drug-allergy interactions. But the electronic screening process may not detect potentially significant interactions, as discussed in a May 2007 supplementary *Advisory* article.[8] One study, in which chart reviews were performed on a stratified random subset of all allergy alerts, showed that overrides of drug-allergy alerts were common and about 1 in 20 result in ADEs, but all of the overrides resulting in ADEs that were included in the study appeared clinically justifiable. The authors stated that the high rate of alert overrides was attributable to frequent nonexact match alerts (in which the drug and allergy had structural similarities or were in the same family but were not identical) and infrequent updating of allergy lists in their organization.[9]

Risk Reduction Strategies

Healthcare facilities should take steps to ensure that current and complete allergy information is accurately and clearly collected and readily available to all practitioners at the point of care when they are prescribing, dispensing, and administering medications. Based on the review of reports in PA-PSRS as well as observations at ISMP, some suggestions include the following:

- Review all paper and online data collection forms to determine the current location in which practitioners will document and retrieve complete allergy information, *including* descriptions of the reaction(s) (e.g., front of medical record, on the top of order forms, designated MAR locations, computer screens, resident assessment forms). This location should be standardized and should be used by all locations in your organization, including the ED, operating room, imaging services, and general medical/surgical care areas. Alert staff to always refer to these areas for reliable information. Develop a process to make sure updates occur in *all* these areas if the patient's allergies change.
- Consider adding prompts in consistent locations to document allergy information and include clearly visible and prominently placed allergy prompts on the *top* of every page of *all* prescriber order forms (including blank, preprinted, and verbal order forms).

 ©2008 Pennsylvania Patient Safety Authority

- Upon admission to a facility, list patient allergies, *as well as a description of the reaction to the allergen*, and, if possible, the date that the reaction took place, on all admission order forms. Have appropriate staff consistently transfer this information obtained on admission to subsequent order forms and place the completed forms into the charts so that they are readily accessible. This process can help visually remind physicians and nurses about the patient's allergies when prescribing medications and/or transcribing a verbal order for a medication.
- If the organization obtains archived allergy information, establish processes to verify and update this information upon each readmission or patient encounter. Errors have occurred when archived listings are assumed to be complete and correct (i.e., new allergy information has become available since the prior data was entered into the computer system).
- Establish a forcing function error reduction strategy to make the allergy "reaction" selection a mandatory entry in the organization's order-entry systems for prescribers and pharmacists.
- Eliminate the practice of writing drug allergens on allergy wristbands. Errors may occur with this practice if drug names are missed or when small wristbands are used. Confusion may also occur when drug names are abbreviated, misspelled, or smeared, leading to further risk. In addition, if a patient has many allergies, multiple bracelets may be used, increasing the chance that a practitioner may only view one bracelet and not realize there are more bracelets to check. Instead, have the single red allergy bracelet act as an "alert" to the practitioner, identifying at the point of care that the patient *has an allergy*, requiring further investigation of the patient, medical record, and MAR.
- When communicating verbal or telephone medication orders, prescribers should always ask for the patient's allergies and reactions. The receiver of the order should always present this information during this process.
- Provide prescribers, nurses, and pharmacists with education on medication allergies. Educational efforts need to focus on screening patients for the potential of a reaction, recognition of an allergic reaction, and the treatment of serious allergic reactions.[10] These efforts should include organization-specific procedures such as the locations to document/find patient allergy information, as well as to access important drug information that includes common allergies, cross allergies, and combination drug products that may have implications with common drug allergies.
- Use information reported through PA-PSRS to identify problem areas, processes, or medications to determine the types of events that occur within an individual organization. In addition, measure the use of trigger drugs used to treat allergic reactions (e.g., diphenhydramine, methylprednisolone, epinephrine) to increase detection of possible *preventable* ADEs and determine whether there are other instances of patients erroneously receiving medications with documented allergies. Collection of trigger data could be incorporated into the order-screening processes, captured by clinical pharmacists during rounds, or accomplished by those who routinely review patient records, such as quality managers or case managers.

Notes

1. Leape LL, Bates DW, Cullen DJ, et al. Systems analysis of adverse drug events. *JAMA* 1995 Jul 5;274(1):35-43.
2. Lesar TS, Briceland L, Stein DS. Factors related to errors in medication prescribing. *JAMA* 1997 Jan 22-29;277(4):312-7.
3. Institute for Safe Medication Practices. Frequent problems with medication systems noted during ISMP hospital evaluations. *ISMP Med Saf Alert* 1998 Jun 3; 3(11):2.
4. Pau AK, Morgan JE, Terlingo A. Drug allergy documentation by physicians, nurses, and medical students. *Am J Hosp Pharm* 1989 Mar;46(3):570-3.
5. Pennsylvania Patient Safety Reporting System. Use of color-coded patient wristbands creates unnecessary risk. *PA PSRS Patient Saf Advis* [online]. 2005 Dec 14 [cited 2008 Jul 2]. Available from Internet: http://www.psa.state.pa.us/psa/lib/psa/advisories/v2_s2_sup__advisory_dec_14_2005.pdf.
6. Institute for Safe Medication Practices. Safety brief. *ISMP Med Saf Alert* 1999 Mar 24;4(6):2.
7. Pennsylvania Patient Safety Reporting System. Improving the safety of telephone or verbal orders. *PA PSRS Patient Saf Advis* [online]. 2006 Jun [cited 2008 Jul 2]. Available from Internet: http://www.psa.state.pa.us/psa/lib/psa/advisories/v3n2june2006/junevol_3_no_2_article_b_safety_of_telphone_orders.pdf.
8. Pennsylvania Patient Safety Reporting System. Results of the PA-PSRS workgroup on pharmacy computer system safety. *PA PSRS Patient Saf Advis* [online]. 2007 May 31 [cited 2008 Jul 2]. Available from Internet: http://www.psa.state.pa.us/psa/lib/psa/advisories/vol._4,_sup._2_may_31,_2007/v4_s2_suppl_advisory_may_31_2007.pdf.
9. Hsieh TC, Kuperman GJ, Jaggi T. Characteristics and consequences of drug allergy alert overrides in a computerized physician order entry system. *J Am Med Inform Assoc* 2004 Nov-Dec;11(6):482-91.
10. Institute for Safe Medication Practices. Topical medications and allergic reactions. *ISMP Med Saf Alert* 1996 Jun 5;1(11):2.

 ©2008 Pennsylvania Patient Safety Authority

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. Based on reports submitted to PA-PSRS, during which phase of the medication-use process do errors involving breakdowns in communication of patient allergy information originate?
   a. Dispensing
   b. Prescribing
   c. Administering
   d. Transcribing
2. Events in which patients were prescribed and given medications to which they had documented allergies fall primarily into two categories. One occurs with breakdowns in drug information. The other is
   a. breakdowns in staff education.
   b. breakdowns in quality control.
   c. breakdowns in patient information.
   d. breakdowns in drug labeling.
3. Errors associated with breakdowns in patient allergy information may occur during each of the following activities EXCEPT?
   a. Documenting patient allergy information into paper-based and electronic records
   b. Obtaining information from patients, caregivers, or other healthcare facilities
   c. Entering orders into the computerized prescriber order-entry systems and pharmacy order-entry systems
   d. Selecting a medication to add to the organization's formulary
4. All of the following represent breakdowns or at-risk behaviors in the communication of patient allergy information EXCEPT?
   a. Failing to document the specific reaction the patient experienced to the medication
   b. Obtaining a medication by means of an override function from an automated dispensing cabinet before pharmacy review of the order
   c. Verifying patient allergies and reactions when communicating verbal and/or telephone orders
   d. Prescribing medications with insufficient critical patient information (e.g., age, weight, allergies, diagnoses, laboratory values)
   e. All of the above
5. Which of the following risk reduction strategies could reduce the occurrence of adverse drug events related to allergy information?
   a. Communicating allergy information by documenting drug allergens on patient allergy wristbands
   b. Removing prompts in prescriber order forms that would document allergy information
   c. Establishing processes to verify and update archived patient allergy information upon each readmission or patient encounter
   d. Programming forcing functions into the organization's computer order-entry systems that would not allow for the documentation of "reactions" to allergies

 ©2008 Pennsylvania Patient Safety Authority

Anticoagulation Management Service: Safer Care, Maximizing Outcomes

ABSTRACT

PA-PSRS has received hundreds of Serious Event reports between June 2004 and January 2008 associated with anticoagulation therapy with outcomes having hematologic effects from thrombocytopenia to hemorrhage. The indications, dosages, strengths, and pharmacokinetics for anticoagulants are quite variable, requiring extra attention to prescribing, dispensing, administering, and monitoring the effects of these medications. The complexity of anticoagulants has resulted in patient safety compromise. Healthcare organizations have increasingly recognized the benefits of anticoagulation management services (AMS) in the inpatient and outpatient settings. The benefits of an AMS program include a reduction in mortality rates and bleeding complications, decreased adverse drug events, including medication errors and shortened hospital stays, thereby producing safer patient care. The key components in AMS program development include defining the rationale for AMS development, outlining issues associated with anticoagulants, defining AMS scope of service and infrastructure, and outlining AMS program metrics. (Pa Patient Saf Advis 2008 Sep;5[3]:81-4.)

PA-PSRS has received hundreds of Serious Event reports between June 2004 and January 2008 associated with the prescribing, dispensing, administering, and/or monitoring of anticoagulation therapy (see Table). Patient outcomes included hematologic effects from thrombocytopenia to hemorrhage; many patients required transfusions; some patients died.

Anticoagulation medications require comprehensive dosing and monitoring strategies to minimize the risks associated with their use to produce optimal patient outcomes.[1] Healthcare organizations and physicians have increasingly recognized the benefits of an anticoagulation management service (AMS) in the inpatient and outpatient settings. Consider the following reports submitted to PA-PSRS surrounding issues with anticoagulation therapy:

> *Critically ill patient diagnosed with spontaneous retroperitoneal hematoma. Physician discontinued heparin, administered vitamin K and ordered [hematocrit and hemoglobin] every six hours. [Twice], blood specimens were not collected by the nurse. The patient arrested and died. Hemoglobin per [arterial blood gases] at time of arrest was 5.*

> *Patient was admitted after a fall at home; found to have an acute [myocardial infarction] while in the [emergency department (ED)]. Heparin bolus and drip ordered. The required heparin order form was not used. The order was apparently not weight based. No calculations or double checks were done. The patient was transferred to the [intensive care unit (ICU)] when drip was hung, heparin was set to run at to-keep-open rate. Patient received [heparin] 25,000 units in a three hour [span].*

> *Patient was noted on [admission] to have low probability of [heparin induced thrombocytopenia (HIT)] but blood work showed antibodies to heparin. Heparin 5,000 units [subcutaneously, two times per day] was ordered for the patient [for 7 days] when the patient was transferred to the [patient care unit]. [Two days later], the patient collapsed and was transferred to the ICU with diagnosis of pulmonary emboli. The heparin allergy was not placed in the electronic record until [the transfer to ICU].*

The Institute of Medicine stresses the importance of adopting an interdisciplinary approach to patient care by encouraging healthcare professionals to establish teamwork, communication, and cooperation.[2] The Joint Commission's 2008 National Patient Safety Goal 3E to improve the safe use of medications includes the new requirement to reduce the likelihood of patient harm associated with anticoagulation therapy medications such as heparin (unfractionated), low-molecular-weight heparin, warfarin, and other anticoagulant drugs.[3] These medications require comprehensive dosing and monitoring strategies to minimize the risks associated with their use and to maximize patient outcomes.

U.S. Pharmacopeia lists anticoagulants heparin, warfarin, and enoxaparin as high-risk medications and among the top 12 drugs associated with medication errors.[4] High-risk medications have greater probability of causing significant harm than other medications, when used incorrectly. Standardizing anticoagulation therapy can help to reduce bleeding complications and decrease the number of adverse drug events, including medication errors. Optimally, this will produce safer care, which contributes to the reduction in mortality and shortened length of hospital stays.

Literature Supports Anticoagulation Management Services

A randomized controlled study by Wilson et al. [5] compared outcomes when anticoagulation therapy was managed by anticoagulation clinics versus primary care physicians. The rates of thromboembolic, major hemorrhagic events, and patient satisfaction were measured between the two groups. Eighty-six percent of the time, patients in the anticoagulation clinics were within the international normalized ratio (INR) expanded therapeutic range while patients in the family physician group were within expanded therapeutic range 77% of the time. The most significant difference between the two groups was that patients

 ©2008 Pennsylvania Patient Safety Authority

Table. Serious Events Reported to PA-PSRS related to Anticoagulation Therapy Since 2004

STAGES IN ANTICOAGULATION THERAPY*	NUMBER OF SERIOUS EVENTS	PERCENTAGE (%)
Prescribing	35	6
Dispensing	44	7
Administering	94	16
Monitoring	202	34
Other (e.g., bleeding, falls with hematoma, pressure ulcers)	327*	55
Total Number of Reports	591†	

* May not be included in any stage of anticoagulation therapy

† Serious events may include multiple overlapping stages throughout anticoagulation therapy

managed by anticoagulation clinics resulted in fewer high-risk INR values of less than 1.5 or greater than 5. Differences in major bleeding events, thromboembolic events, and mortality rates between the two groups were not significant. Patient satisfaction was much also higher with the anticoagulation clinics than with routine care. The results indicated that anticoagulation clinics provided slightly better oral anticoagulation management than family physician groups.[5]

A retrospective, observational cohort study by Witt et al.[6] measured the effects of a centralized clinical pharmacy anticoagulation service (CPAS) on the outcomes of anticoagulation therapy. The intervention group's anticoagulation therapy was managed by a centralized, telephonic CPAS, while the control group was managed by primary care physicians. Thirty-nine percent fewer patients in the CPAS group experienced anticoagulation therapy complications than patients in the control group.[6] Sixty-three percent of the CPAS group had INR levels within target range compared to 55.2% of those patients receiving care from personal physicians.[6] The CPAS were managed by pharmacists and included the use of a computerized patient monitoring system that identified when patients failed to return for subsequent INR testing. This study also supported the idea that a coordinated and systematic approach to an AMS may be more important than the method of management (i.e., telephonic, in person).

A retrospective cohort study by Chamberlain et al.[7] linked record review (including outpatient, inpatient, and ED records) between two groups of patients: those treated in a traditional clinic and those treated in an AMS. The AMS group had better anticoagulation control than the traditional care group.[7] There was also less variation with INR target range with the AMS than with the traditional clinic. INR testing was conducted more frequently with the AMS, as was follow-up care, which included patient education. These findings emphasize the effects of a shared AMS to include clear clinical guidelines and patient information exchange.[7,8]

In a retrospective analysis of more than 700,000 Medicare patients, institutions with inpatient anticoagulation services had shortened lengths of stay, lower Medicare charges, and decreased rates of bleeding and transfusion complications compared to institutions without such services.[9] This was the first large-scale study that evaluated the impact of pharmacist-managed anticoagulation services on healthcare outcomes.[9]

Given the results of these studies, leaders should consider implementing AMS in their organizations. Ideally, creating an AMS that extends along the continuum of care by incorporating inpatient and outpatient services will provide patients with optimal care from the first day of anticoagulation to the completion of therapy.[10]

Several U.S. hospitals have implemented integrated AMS programs over the past decade.[1,10-12] Other hospitals have implemented AMS only for patients outside the tertiary care settings.[3,13] All program types have the same ultimate goal—to provide safer care and optimize patient outcomes.

The following PA-PSRS reports that illustrate Serious Events that occurred in the ordering, dispensing, administrating, and monitoring of anticoagulation medications.

> *[A clinic patient presented] with nontherapeutic [prothrombin (PT)/INR]. Results called to physician office, but the Coumadin® dose was not adjusted. The patient required hospitalization at another facility for PT/INR regulation.*

> *The medication [order] expired, and the physician did not renew medication. Medication dropped off computer screen due to nonrenewal. Patient was transferred to ICU. Staff did not realize patient had been getting Lovenox®. Patient developed a [pulmonary embolism two weeks later] due to not being on anticoagulants.*

> *An initial bolus of heparin and heparin nomogram protocol were calculated on an incorrect patient weight. The heparin was calculated in the ED on an estimated patient weight of 130 kilograms. The patient was transferred to the [patient care area] where the [actual] weight was measured as 103 kilograms. The physician was notified immediately and the [partial thromboplastin (PTT)] was greater than 150. Heparin was stopped. The patient developed [petechiae]. Protamine was administered in addition to additional laboratory testing.*

 ©2008 Pennsylvania Patient Safety Authority

Patient admitted and medication orders included Coumadin® 2.5 mg orally daily-hold for INR greater or equal to 3.5, and Lovenox 40 mg subcutaneously daily. No PT/INR ordered during stay until [three days later] when the patient was noted to have complications of bleeding. The physician was notified of elevated PTT and bleeding and then ordered PT/INR.

Nurse recorded wrong PTT result and adjusted heparin rate/protocol. Adjustment scanned to pharmacy and pharmacist did not confirm correct PTT result. Nurse did not obtain co-signature of second nurse [which was] required [per] policy for heparin rate adjustments.

Accompanying Patient Safety Tools

Visit the Pennsylvania Patient Safety Authority Web site to view or download a brief informational video based on this article that can be used for educational purposes. In addition, links to companion online information are provided, including a self-assessment tool for antithrombotic therapy from the Institute for Safe Medication Practices.

To view the tools, click on "Advisories and Related Resources" in the left-hand column of the Authority's home page. Then, click on "Resources Associated with Patient Safety Articles."

Key Components to Consider When Developing an Anticoagulation Management System

Patient safety committees should consider assessing anticoagulation safety to help define their organization's needs before an AMS development. This self-assessment allows facilities to outline the positive impact that an AMS program will have to provide safer care and maximize patient outcomes. An individualized AMS is based on the organization's specific needs, resources, and experiences and includes the following:

Define Rationale for AMS Development

- Develop a multidisciplinary AMS program committee comprising physicians, pharmacists, nurses, clinical laboratory, and information technology staff.[1,3,10,11]
- Evaluate current anticoagulation processes to clearly define the future AMS program development, targeting those patients with the greatest need.[1,10,12] Review prior Incidents (near misses) and Serious Events related to anticoagulation medications. This data will provide additional justification for AMS development.

Outline Issues Associated with Anticoagulation Medications

- Review literature relating to the use of anticoagulation agents. Using medical record audit, review your organization's trends in timeliness to achieve therapeutic anticoagulation levels, laboratory results monitoring capabilities, the use of overlap anticoagulants (including anticoagulation management when patients require an invasive procedure), and adequacy of anticoagulation therapy at discharge. These measurable outcomes demonstrate the difficulty in effectively managing anticoagulation therapy.[12,14]
- Standardize the use of anticoagulants.[10,15] This may include but is not limited to standardization of anticoagulation medications concentrations; formulary limits; use of only commercially or pharmacy filled heparin flushes and intravenous solutions; use of a pharmacy profiled, reconciled computerized prescriber order entry with alerts for duplicate therapy, drug contraindication, and drug and food interactions. Other considerations may be the use of automated dispensing cabinets that interface with pharmacy information systems with limited or no override capabilities, use of infusion pumps with drug libraries, and standard labeling techniques.[15] Use the electronic medication administration record to standardize the documentation of coagulation laboratory results before anticoagulation medication administration.

Define AMS Scope of Service and Infrastructure

- Determine team composition of AMS program. Some inpatient AMS programs are pharmacy-driven teams providing service for heparin therapy, while other AMS programs provide total management for all anticoagulant therapies through a consultative process.[12] Provide adequate staffing depending on program composition.[10,11]
- Create communication and documentation systems that extend along the continuum of care and incorporate both the inpatient and outpatient AMS.[3,8-11]
- Develop policies, guidelines, written protocols, heparin dosing algorithms, and safe scope of evidence-based practice, including supervision for physicians and pharmacists.[1,3,9-11,14,16]
- Develop formal anticoagulation competencies for physicians, pharmacists, and nurses to assess baseline and ongoing knowledge about anticoagulation therapy, thromboembolism, HIT, and allergies including a competency demonstration process to assess ability to apply safe practice concepts.[9,11-13] Identify key interdisciplinary champions.[10]
- Use an electronic tracking system to integrate and bridge medical records of outpatient- or community-based programs, inpatient medical records, laboratory studies, and medication records.[3,8-11]
- Develop a well-designed anticoagulation patient and family educational program to help increase compliance and contribute to improved patient outcomes.[14]

AMS Program Metrics

- Define AMS program outcomes for future measurement. Consider measurement of target INR levels, INR levels associated with hemorrhagic

 ©2008 Pennsylvania Patient Safety Authority

complications and thromboembolism rates, deaths, minor and major bleeding episodes, use of ED visits and hospital admissions associated with anticoagulation problems, hospital length of stay, patient satisfaction, and reimbursement.[12,14]

- Develop a quality program that monitors and generates annual reports (more often as deemed necessary) to document metrics, to improve performance including error reduction rates, and to manage any unanticipated risks.[9-12,14]

Notes

1. Phillips KW, Wittkowsky AK. Survey of pharmacist-managed inpatient anticoagulation services. *Am J Health-Syst Pharm* 2007 Nov 1;64(21):2275-8.
2. Kohn LT, Corrigan JM, Donaldson MS, eds. *To err is human: building a safer health system.* Washington (DC): National Academy Press, 2000.
3. The Joint Commission. Reducing anticoagulation-related adverse drug events: closely monitoring and managing risks for patients on warfarin. *Jt Comm Perspect Patient Saf* 2006 Jul;6(7):3-4.
4. U.S. Pharmacopeia. Top 50 drug products* associated with medication errors [online]. [cited 2008 June 18]. Available from Internet: http://www.usp.org/hqi/patientSafety/resources/top50DrugErrors.html.
5. Wilson SJ-A, Wells PS, Kovacs MJ, et al. Comparing the quality of oral anticoagulant management by anticoagulation clinics and by family physicians: a randomized controlled trial. *CMAJ* 2003 Aug;169(4):293-8.
6. Witt DM, Sadler MA, Shanahan RL, et al. Effect of a centralized clinical pharmacy anticoagulation service on the outcomes of anticoagulation therapy. *Chest* 2005 May;127:1515-22.
7. Chamberlain MA, Sageser NA, Rutz D. Comparison of anticoagulation clinic patient outcomes from traditional care in a family medicine clinic. *JABFP* 2001 Jan-Feb; 14(1):16-21.
8. Holm T, Lassen JF, Husted SE, et al. A randomized controlled trial of shared care versus routine care for patients receiving oral anticoagulant therapy. *J Int Med* 2002 Oct;252(4):322-31.
9. Bond CA, Raehl CL. Pharmacist-provided anticoagulation management in United States hospitals: death rates, length of stay, medicare charges, bleeding complications, and transfusions. *Pharmacotherapy* 2004 Aug;24(8):953-63.
10. Dager WE, Gulseth MP. Implementing anticoagulation management by pharmacists in the inpatient setting. *Am J Health-Syst Pharm* 2007 May 15;64:1071-9.
11. Schneider BL, Gulseth MP, Cusick MA, et al. Computer program to assist pharmacy management of an inpatient warfarin dosing service. *Am J Health-Syst Pharm* 2005 Nov 15;62:2393-6.
12. Viercinski J, Thomson L, Wilson J, et al. Establishing an inpatient anticoagulation service: a step by step review. *J Thromb Thrombolysis* 2008 Feb;25(1):67-71.
13. Bungard TJ, Archer SL, Hamilton P, et al. Bringing the benefits of anticoagulation management services to the community. *Can Pharm J* 2006 Mar-Apr;139(2):58-64.
14. Ansell JE, Buttaro ML, Thomas OV, et al. Consensus guidelines for coordinated outpatient oral anticoagulation therapy management. *Ann Pharmacother* 1997 May;31(5):604-15.
15. Institute for Safe Medication Practices (ISMP). ISMP's medication safety self assessment® for antithrombotic therapy in hospitals [online]. 2005 [cited 2008 Jul 18]. Available from Internet: http://www.ismp.org/selfassessments/asa2006/ASAISMPAssessment.pdf.
16. Weitz JI, Hirsh J, Samama MM. New anticoagulant drugs: the seventh ACCP conference on antithrombotic and thrombolytic therapy. *Chest* 2004 Sep;126(3):265S-86S.

 ©2008 Pennsylvania Patient Safety Authority

Triage of the Obstetrics Patient in the Emergency Department: Is There Only One Patient?

ABSTRACT

PA-PSRS has received a number of reports related to the management of pregnant patients in the emergency department. In many instances, reports submitted through PA-PSRS reflect a lack of effective communication between emergency and obstetrics department staff. When a pregnant patient arrives at the emergency department, there are really two patients. Optimal care of both patients can only be achieved through a systematic approach to care that involves open communication between emergency and obstetric services. Risk reduction strategies include having policy and procedures in place that ensure a systematic approach to the triage and initial assessment of the pregnant patient with consideration of the presenting complaint, gestational age, availability of testing and consultants, and fetal monitoring requirements. (Pa Patient Saf Advis 2008 Sep;5[3]:85-9.)

PA-PSRS has received a number of reports related to the management of obstetric patients in the emergency department (ED). Fifty percent of the reports reflect ineffective communication between the ED and obstetrics (OB) department staff. In one event, an obstetric patient in her third trimester presented to the ED after a motor vehicle accident. Despite the patient's stable condition, fetal monitoring was not initiated until more than one hour after her transfer to the OB triage area. An ultrasound image revealed a fetal demise. Whether timely fetal monitoring would have prevented this Serious Event is unknown, yet this case emphasizes the need for consistent and coordinated communication between the ED and OB departments. When an obstetric patient arrives at the ED, there are two patients that require care. Optimal management of both patients can only be achieved through a systematic approach and open communication between ED and OB services.

PA-PSRS Reports

Since June 2004, 20 reports have been submitted through PA-PSRS indicating ineffective interactions between the ED and the OB departments during the management of obstetric patients. Thirty percent of the reports involved delays in instituting fetal monitoring for OB patients evaluated in the ED. Forty-five percent of the reports indicated that obstetric patients with complaints not clearly OB-related were sent to the OB department without ED assessments; 20% of all of the reports involved pregnant trauma patients and 10% involved pregnant assault victims. Two events involved fetal demise, which may have been related to delays in fetal monitoring and OB care. In both events, the reports indicated that the facilities' plans to revise their policies to improve communication and clarify the roles of OB and ED staff in caring for these patients.

The following are some Incidents and Serious Events involving obstetric patients reported through PA-PSRS:

> *A pregnant woman at 32 weeks' gestation presented to the ED as a trauma patient. An initial ultrasound and fetal heart tones indicated a viable fetus. The patient underwent a series of imaging studies and treatment of superficial injuries, after which she was transferred to [the labor and delivery (L&D) department] where fetal heart tones were not detected. A nonviable fetus was delivered. Continuous fetal monitoring had not been initiated in the ED.*

> *A pregnant patient arrived in the ED with complaints of chest pain and shortness of breath. . . . The ED staff instructed her to ambulate to the OB department. She was transferred back to the ED via wheelchair for evaluation, resulting in a delay in treatment.*

> *A pregnant [trauma] patient was transported to L&D from the ED for continuous fetal monitoring. The patient's cervical spine x-rays had not been done and her cervical collar had been removed. In L&D, an ED nurse replaced the cervical collar, and portable cervical spine x-rays were performed.*

Physiology of Pregnancy

Obstetric patients may present to the ED with complaints that may be unrelated to pregnancy, and the assessment of these complaints may be complicated by physiologic changes associated with pregnancy that affect almost every organ system. Understanding these changes is essential in the evaluation and management of the obstetric patient in the ED. One such obvious change in pregnancy is the enlargement of the uterus. The uterus becomes an abdominal organ at approximately 12 weeks' gestation, rising over the pelvic rim. At 20 weeks, the fundus of the uterus can be palpated at the umbilicus, and by 36 weeks, the uterus reaches the costal margins. During the last few weeks of pregnancy, the uterine fundal height decreases as the fetal head drops into the pelvis.[1] Other physiologic changes relevant to the assessment of obstetric patients in the ED are summarized in this section.

Hematologic

By the 28th week of pregnancy, plasma volume increases by approximately 45% above nonpregnancy levels, and red blood cell mass increases by 20% to 30%.[2] The rise in blood volume greater than the increase in red blood cell mass may result in a physiologic anemia.[2] This relative hypervolemic state and hemodilution allow a pregnant patient to tolerate a significant amount of blood loss before tachycardia and hypotension occur.[2] White blood cell counts

 ©2008 Pennsylvania Patient Safety Authority

typically increase and may erroneously suggest a diagnosis of infection. Changes in an obstetric patient's coagulation system result in a relative state of hypercoagulability. As a result, they are more susceptible to deep vein thromboembolism and pulmonary embolus, which is an important consideration during ED evaluations.[2]

Cardiovascular

Cardiac output increases 30% to 50% above prepregnancy baseline. It peaks by the end of the second trimester, reaching a plateau until delivery. The cardiac output change is influenced by an increased preload due to a rise in blood volume, a decreased afterload due to a fall in systemic vascular resistance, and an increased maternal heart rate by 10 to 15 beats per minute. Blood pressure typically falls to approximately 10 mm Hg below baseline by the second trimester.[3] An obstetric patient is susceptible to hypotension when in the supine position due to vena cava compression by the gravid uterus.[4] The cardiac silhouette typically appears enlarged on a chest radiograph.[2] Characteristic electrocardiogram changes are commonly observed and include a shift in the QRS axis to the left and positional Q waves in lead II and AVF.[2]

Respiratory

Oxygen consumption and resting ventilation increase during pregnancy as a result of an increase in tidal volume (i.e., the amount of air inhaled and exhaled during a normal respiration), without an increase in respiratory rate. By the second trimester, hypocapnia (i.e., a low partial pressure of carbon dioxide in the blood) is common.[1] These changes often result in complaints of shortness of breath or "air hunger," a phenomenon commonly known as the "dyspnea of pregnancy."[2]

Gastrointestinal

Gastrointestinal function may be altered during pregnancy as increased levels of progesterone and estrogen inhibit gastrointestinal motility, leading to increased frequency of nausea and vomiting.[2,4] Constipation is more common due to decreased intestinal transit time. Decreased competency of the gastroesophageal sphincter increases the frequency of gastroesophageal reflux and the potential aspiration risk during anesthesia.[2] As the uterus enlarges, it displaces the intestines upward and laterally, stretching the peritoneum and making the physical examination of the abdomen unreliable. Physical findings, such as abdominal rigidity, guarding, and rebound tenderness are often difficult to assess.[2,4]

Renal

To accommodate maternal and fetal metabolic and circulatory changes, the renal blood flow increases by 25% to 40%.[4] Increased levels of progesterone facilitate smooth muscle relaxation, resulting in bladder expansion and decreased peristalsis in the ureters. These factors contribute to an increase in urinary tract infections during pregnancy.[2,4]

Risk Reduction Strategies

A systematic approach to the ED triage and initial assessment of the obstetric patient is essential. In particular, it is fundamental to ascertain whether: (1) the emergency problem is due to the pregnancy, (2) the problem is unrelated to but affected by the pregnancy, or (3) the problem affects the pregnancy. If any one of these is true, coordination between the ED and OB department is appropriate. The physical examination of the obstetric patient in the ED is challenging because of the physiological changes associated with pregnancy. In obstetric trauma patients, the primary treatment goal in the ED is to stabilize the patient's condition and provide treatment according to trauma guidelines, with several caveats. These caveats include the use of rapid-sequence induction with cricoid pressure and gastric decompression when oral intubation is required, the use of closed-tube thoracotomy at a higher intercostal space when treating for pneumothorax, and placement of the patient who is greater than 20 weeks' gestation in the left lateral position to maximize venous return.[5] According to American College of Obstetrics and Gynecology (ACOG) guidelines, the approach must be systematic and ensure that the patient is medically stable before evaluation of the fetus.[6]

An Agency for Healthcare Research and Quality case study described an event involving a 38 weeks' obstetric patient who presented to the ED with the complaint of left leg pain. Hospital policy required that patients greater than 20 weeks' gestation be directed to the L&D department, unless the complaint was unrelated to the pregnancy. In ED triage, the patient's pain was identified as nonobstetric in nature. Accordingly, the patient was evaluated in the ED, diagnosed with musculoskeletal pain, and discharged after a brief period of fetal monitoring in the L&D department. The next morning, the patient was found dead at home by a family member. An autopsy revealed a ruptured aortic aneurysm. This case illustrates the difficulty of recognizing nonobstetric emergencies that may threaten the life of a mother and fetus. Additionally, in case commentary, the authors note that problems occurred in the ED triage and early management of this patient. The authors suggest five general principles, which are summarized below, to be addressed when developing a systematic approach to ED triage, assessment, and management of urgent and nonurgent obstetric patients.[7] Applicable guidelines from professional organizations are also presented.

Presenting Complaint

Even though physiologic and anatomic changes in pregnancy often complicate ED assessments, a number of guiding principles have been proposed. Pearlman and Desmond suggest that pregnant patients who present to the ED with complaints that are OB-related, such as episodic abdominal pain consistent with labor, should be triaged from the ED directly to the L&D department. Obstetric patients

 ©2008 Pennsylvania Patient Safety Authority

presenting to the ED with complaints that are not clearly pregnancy-related should be triaged according to the institutions' resources, OB consultant availability, and diagnostic testing accessibility.[7] ACOG guidelines recommend coordination between the ED and the OB departments, including an agreement regarding the conditions that are best treated in the L&D unit, prioritization of the evaluation site based on patient needs, and the departments' abilities to provide for those needs.[8] Both the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) and the Emergency Nurses Association (ENA) recommend that the obstetric patient presenting to the ED in active labor should be transferred to and delivered in the L&D department. However, the care of the obstetric patient is to take place in the area best prepared to handle the needs of the patient.[9]

Consultant Availability

The availability of consultants is a consideration in the development of a triage system for obstetric patients. For obstetric complaints, the L&D department is likely the best source for clinical expertise.[7] In nonobstetric ED presentations, the expertise of ED physicians and the availability of consultants may make the ED the most appropriate setting for evaluation.[7] ACOG and American Academy of Pediatrics guidelines recommend that obstetric patients with medical or surgical conditions that could reasonably be expected to have obstetric consequences should be evaluated by qualified obstetric providers.[8] ENA and AWHONN endorse the referral of urgent and nonurgent patients with fetal gestation of 16 to 18 weeks or later with suspected labor or obstetric complications to the obstetrician or L&D department for evaluation.[9]

Timeliness of Testing

Access to advanced images and testing is another important policy consideration.[2] Depending on the resources of the facility, diagnostic testing such as CT may be more rapidly accessible in the ED.[7] (Radiation exposure is a common concern during pregnancy and has been addressed in the March 2008 issue of the *Pennsylvania Patient Safety Advisory*.[10] According to ACOG guidelines, concern about possible effects of high-dose radiation exposure should not prevent medically indicated diagnostic radiograph procedures from being performed on the mother.[6])

Gestational Age at Presentation

Some diagnoses are limited to certain time frames during pregnancy and can be considered in policies addressing the initial assessment of the obstetric patient in the ED. For example, ectopic pregnancy is the most common cause of maternal death in the first trimester of pregnancy.[11] Appendicitis, cholecystitis, pancreatitis, and bowel obstruction are the most common nonobstetric surgical conditions during pregnancy.[11,12] When a patient presents near the time of fetal viability, approximately 23 to 24 weeks, fetal monitoring and immediate consultation with the OB team are an important intervention in the event that a decision about delivery needs to be considered. A comprehensive ED triage policy can address rapid triage and transfer of obstetric patients from the ED to the L&D department under these circumstances.[2]

Need for Fetal Monitoring

In most circumstances, fetal monitoring is more readily available in the L&D department than in the ED. However, the obstetric patient's condition may require ED evaluation and initiation of fetal monitoring in the ED. The normal range for the fetal heart rate (FHR) is 120 to 160 beats/min and can be assessed by auscultation or Doppler probe.[4] Electronic fetal monitoring is the most widely used modality for FHR evaluation.[4] Frequent monitoring and documentation of FHR is important to allow early recognition of fetal distress.[4] Policies can address the availability of appropriate equipment and ongoing staff competency to perform continuous fetal monitoring in the ED. This can be accomplished through the assignment of an L&D nurse to perform fetal monitoring in the ED. In the alternative, fetal monitoring may be initiated in the ED by ED staff and interpreted and monitored remotely in L&D, if the facility has this capability.[7] ENA and AWHONN endorse the use of a fetal monitor in the ED by a monitoring nurse who meets the institutional standards for fetal monitoring.[9]

Obstetric Triage

During the last decade, obstetric triage has been one of the latest obstetric services to emerge. Hospitals have incorporated triage principles into the practice of OB by either establishing stand-alone OB triage units or creating triage areas adjacent to the L&D department.[13] Qualified nursing personnel, including nurse-midwives, nurse practitioners, and clinical nurse specialists often staff these units. Typically, laboring patients who present to obstetric triage are assessed and transferred to the L&D department. Nonlaboring patients are evaluated and managed by experienced obstetric personnel. This approach has been shown to reduce length of stay, increase patient satisfaction, and reduce unnecessary admissions.[14] Potential errors in obstetric triage have been identified as incorrect assessment of maternal condition, fetal well-being, or OB-related complications; failure to diagnose active labor; inappropriate discharge from the triage unit; incomplete or poorly documented records; and failure to comply with the standard of care.[14] Clear communication between physicians and obstetric triage personnel is recommended to rely on well-defined clinical criteria and to decrease the likelihood of these errors.[14] Consistent communication between ED and OB personnel is essential when transferring obstetric patients from the ED to the OB triage unit, as these patients may initially present to the ED.

Conclusion

Well-defined criteria exist for the assessment of obstetric patients in the OB department and the ED. Stabilization of the obstetric patient with any emergency condition, whether or not the condition

 ©2008 Pennsylvania Patient Safety Authority

is OB-related, is of the utmost importance; otherwise the effect on the fetus may be detrimental. However, as PA-PSRS reports indicate, inadequate communication between these departments can expose both the obstetric patient and fetus to risk. Policies and procedures for the care of an obstetric patient presenting to the ED can address a number of factors, including the nature of the complaint, the availability of consultants and testing, the gestational age of the fetus, the need for fetal evaluation, and transfer of the patient between ED and OB departments. In addition, open lines of communication between providers are necessary in order to provide optimum care for both patients when an obstetric patient presents to the ED.

Notes

1. Tsuei BJ. Assessment of the pregnant trauma patient. *Injury* 2006 May;37(5):367-73.
2. Challoner K, Incerpi M. Nontraumatic abdominal surgical emergencies in the pregnant patient. *Emerg Med Clin N Am* 2003 Nov;21(4):971-85.
3. Hill CC, Pickinpaugh J. Trauma and surgical emergencies in the obstetric patient. *Surg Clin N Am* 2008 Apr;88(2):421-40.
4. Desjardins G. Management of the injured pregnant patient [online]. [cited 2008 Feb 7]. Available from Internet: http://www.trauma.org/archive/resus/pregnancytrauma.html.
5. Coleman MT, Triafno VA, Rund DA. Nonobstetric emergencies in pregnancy: trauma and surgical conditions. *Am J Obstet Gynecol* 1997 Sep;177(3):497-502.
6. American College of Obstetrics and Gynecology. Trauma during pregnancy. ACOG Technical Bulletin No. 251. 1998 Sep.
7. Pearlman MD, Desmond JS. Pregnant with danger. Web M&M [online]. 2005 May [cited 2008 Jun 4]. Available from Internet: http://www.webmm.ahrq.gov/printview.aspx?caseID=97.
8. American Academy of Pediatrics. American College of Obstetricians and Gynecologists. *Guidelines for perinatal care*. 5th ed. Elk Grove Village (IL): American Academy of Pediatrics, and Washington (DC): American College of Obstetricians and Gynecologists; 2002.
9. Emergency Nurses Association. Association of Women's Health, Obstetric and Neonatal Nurses. The obstetrical patient in the ED [online]. 2000 Sep [cited 2008 Jun 4]. Available from Internet: http://www.ena.org/about/position/PDFs/ObstetricalPatient-inED.PDF.
10. Pennsylvania Patient Safety Reporting System. Diagnostic ionizing radiation and pregnancy: is there a concern? Pa Patient Saf Advis [online]. 2008 Mar [cited 2008 Jun 4]. Available from Internet: http://www.psa.state.pa.us/psa/lib/psa/advisories/v5n1march_2008/mar_2008_v5_n1_article_radiation_and__pregnancy.pdf.
11. ACEP Clinical Policies Committee and Clinical Policies Subcommittee on Early Pregnancy. American College of Emergency Physicians. Clinical policy: critical issues in the initial evaluation and management of patients presenting to the emergency department in early pregnancy. *Ann Emerg Med* 2003 Jun;41(1):123-33.
12. Angelini DJ. Obstetric triage revisited: update on nonobstetric surgical conditions in pregnancy. *J Midwifery Womens Health* 2003 Mar-Apr;48(2):111-8.
13. Angelini DJ. Obstetric triage: state of the practice. *J Perinat Neonatal Nurs* 2006 Jan-Mar;20(1):74-5.
14. Ventolini G, Neiger R. Avoiding the pitfalls of obstetric triage. *OBG Manage* 2003 Jul;15(7):49-57.

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. All of the following are factors to consider during the development of a systematic approach to emergency department (ED) triage, assessment, and management of urgent and nonurgent obstetric patients EXCEPT?
   a. Consultant availability
   b. Access to advanced images and testing
   c. The need for fetal monitoring
   d. Criteria for performing a medical screening exam
2. All of the following are typical cardiovascular changes relevant to the assessment of obstetric patients in the ED EXCEPT?
   a. Cardiac output increases 30% to 50% above baseline
   b. Blood pressure falls 10 mmHG below baseline by the second trimester
   c. There are no characteristic changes on an electrocardiogram
   d. An obstetric patient is susceptible to hypotension when in the supine position
3. Which of the following is not a physiological change of pregnancy that may impact the assessment of the pregnant patient in the ED?
   a. Displacement of the intestines upward and laterally by the enlarged uterus
   b. Inhibition of gastrointestinal mobility due to increased progesterone levels
   c. An increase in resting ventilation and oxygen consumption
   d. A decreased white blood cell count

(continued)

 ©2008 Pennsylvania Patient Safety Authority

4. In obstetric trauma patients, the primary treatment goal in the ED is to stabilize the patient's condition and provide treatment according to trauma guidelines and ensure that the patient is medically stable before evaluation of the fetus.
   a. True
   b. False

5. The use of obstetrics triage units has been shown to reduce unnecessary admissions.
   a. True
   b. False

Rapid Response in the Operating Room

Rapid response teams have proven effective for hospitalized patients in distress outside of critical care areas. The operating room (OR) functions as a critical care area, as no people are better equipped to resuscitate unstable patients in ORs than the anesthesiologists and attending surgeons. PA-PSRS staff wondered about the nature of inter-specialty consultations in the OR.

PA-PSRS staff examined 14 consecutive reports over a 4-month period that included mention of intra-operative consultations. Only 2 of the 14 consults were time-sensitive emergencies. One involved an emergency right ventricular repair for a patient receiving laparoscopic-guided radio-frequency ablation of the liver by a cardiothoracic surgeon. The second involved repair of a laceration of a major artery by a vascular surgeon as follows:

> *Female with diagnosis of endometrial cancer admitted for lap. Tear in the external iliac artery when dissecting the pelvic lymph node. Vessel was clamped with vascular bulldog clamps for hemostasis. Charge nurse was informed. Vascular surgeon notified. Vascular surgeon promptly repaired external iliac artery.*

PA-PSRS staff suspect that the latter is not an unusual scenario.

To identify similar situations, OR managers and/or committees could review their intraoperative, time-sensitive emergencies requiring consultation from another surgical service. Probably, the most important will be vascular surgery assistance. If they have not done so already, managers and/or committees might consider setting up systems for rapid response to ORs by vascular surgeons on call to cover these unique emergencies.

The other 12 consultations that were not time-sensitive emergencies were as follows:

- An ear, nose, and throat surgeon to do an esophagoscopy to confirm an esophageal laceration
- A general surgeon to evaluate infection in a leg with arterial insufficiency
- A general surgeon to consult during a hysterectomy
- A general surgeon to evaluate a Meckel's diverticulum during an abdominal hysterectomy
- A general surgeon to evaluate an unsuspected inguinal hernia during an excision of a hydrocele
- A urologist to evaluate the bladder by cystoscopy after a laparoscopic-assisted vaginal hysterectomy
- A urologist to evaluate the ureters after a laparoscopic-assisted vaginal hysterectomy
- A urologist to repair the bladder after a vaginal hysterectomy
- A urologist to repair a ureter after a sigmoid colon resection
- A hand surgeon to repair a partial laceration of the median nerve at the wrist
- A vascular surgeon to evaluate an old femoral-femoral artery bypass graft during an inguinal hernia repair
- A vascular surgeon to evaluate a ligated renal vein

 ©2008 Pennsylvania Patient Safety Authority

Malignant Hyperthermia: Is Your Facility Prepared to Treat This Rare Condition?

ABSTRACT

Malignant hyperthermia (MH) is an inherited hypermetabolic disorder of skeletal muscle, triggered by potent inhalational anesthetic agents. It is estimated to occur between 1:10,000 and 1:150,000 adult patients receiving a general anesthetic. While its occurrence is rare, development of MH may be sudden and dramatic with rapid progression of symptoms resulting in death. Manifestations of this disorder can occur without a family history or previous problem with anesthesia. Since June 2004, PA-PSRS has received 15 reports related to MH, including one case that resulted in patient death. Prompt identification and treatment are essential to minimize the possibility of harm or a fatal outcome. Awareness of the broad spectrum of clinical manifestations that present early and/or late during administration of anesthesia is vital for healthcare providers to promptly initiate treatment of malignant hyperthermia. Clinical signs and symptoms may include tachycardia, increased temperature, and sweating. Prompt treatment is necessary to halt the rapid progression of this disorder. The focus for healthcare providers is availability, access, and administrations of dantrolene sodium, the medication of choice in the treatment of malignant hyperthermia. (Pa Patient Saf Advis 2008 Sep;5[3]:90-5.)

Since June 2004, PA-PSRS has received 15 reports related to malignant hyperthermia (MH), including one death. Six of the reports were classified as near-miss incidents that identified patients with family histories of MH that were revealed after the initial anesthesia visit and before induction of anesthesia. The information was obtained incidentally while staff prepared the patients for their respective procedures. Four of the procedures were cancelled. Some reports specified that the patient would be referred for genetic testing, and others indicated that the procedure would be rescheduled. Other reports documented patients who manifested clinical symptoms of MH and were appropriately treated during surgery. The following deidentified report indicates that the facility may not have been prepared to treat the patient, and the outcome was fatal.

> *The patient developed hyperthermia . . . planned treatment involved administration of medication (dantrolene). Medication was not readily available. Another medication was utilized. [Case resulted in patient death.]*

In contrast, consider the following deidentified case illustrating prompt recognition and treatment of MH. Staff awareness of additional resources and assistance provided by the Malignant Hyperthermia Association of the United States (MHAUS) resulted in decreased patient harm.

> *A healthy [adult patient] was admitted to facility for an [operative procedure]. Anesthesia began in the [operating room (OR) on the hour]. The incision [occurred about 25 to 30 minutes later]. The surgery [proceeded] without issue. However, anesthesia noted an increase in [end tidal carbon dioxide ($ETCO_2$)] and heart rate. These vital signs continued to increase, and MH crisis code was called [about 45 minutes after the start of anesthesia] by the medical director. [MHAUS] hotline was contacted [within one minute] and kept on speaker phone in the OR. Dantrolene regime was initiated, foley [catheter] was inserted, and surgery was aborted. The surgical site was closed, and a dressing was applied. Laryngeal mask airway was removed, and the patient was intubated with endotracheal tube. [Emergency] 911 was called for advanced life support transport [to the medical center]. Patient responded to treatment with decrease in $ETCO_2$ and heart rate. Patient was stabilized and transferred to [medical center an hour after crisis identified].*

Recognition and Education

Healthcare providers may have limited knowledge of MH and subsequent treatment modalities. In 1960, when MH was first recognized as a complication of anesthesia, the case-fatality rate was 70%.[1,2] Today, with education of healthcare providers about the manifestations of MH and treatment with dantrolene sodium, the mortality rate is less than 5%.[1,2] While its occurrence is rare, development of MH may be sudden and dramatic with rapid progression of symptoms resulting in death.[1] There is a wide range of occurrence rates in the literature: from 1:10,000 to 1:150,000 in adult patients receiving general anesthesia.[1] Prompt identification and treatment are essential to avoid harm or death.[1,3] The deidentified events reported through PA-PSRS are presented in the box article "Malignant Hyperthermia Events Reported through PA-PSRS."

Diagnosis

The gold standard used to determine an individual's susceptibility to MH is an invasive muscle contracture test performed on freshly biopsied muscle: the caffeine-halothane contracture test (CHCT).[4] The sensitivity of CHCT is 97%, but the specificity is lower with approximately 22% of patients having a false-positive result.[4] However, the test is only available at limited locations in the United States and Canada.[4] Additionally, the cost is prohibitive at $6,000 per test, which may not be reimbursed by third-party payers.[4] After years of research involving scientists from many countries, a DNA-based blood test was introduced

 ©2008 Pennsylvania Patient Safety Authority

in the United States by a commercial biotechnology company and a university-based DNA diagnostic laboratory. The test is also available in Europe. Support for the initiation of testing was derived in part from MHAUS. The test in its present form is able to identify up to 50% of MH-susceptible individuals.[4] If a person is known to have a family history of MH, a DNA change (mutation) for MH may be identified. However, the absence of the mutation does *not* mean that patients are not at risk for MH. Although this test does not replace the CHCT, it is the first inexpensive readily available test.[4]

Risk Factors

Risk factors for MH include family history, myopathies, and musculoskeletal disorders such as congenital ptosis and kyphoscoliosis.[3] Individuals with central core disease and/or multiminicore disease, both congenital myopathies, are also susceptible to MH.[5,6] Additionally, athletic young males are more susceptible to MH.[3] However, manifestations of this disorder are not predictable based on family history or previous exposures to anesthesia.[1] Therefore, early recognition is the key to preventing a fatal outcome. Clinical signs may vary considerably in severity and may appear at various times during administration of anesthesia and the postoperative period.[3,7] The Table identifies signs and symptoms that may alert providers to the onset of this disorder.

Treatment

MH is triggered by a variety of anesthetic agents.[3] These include volatile agents such as halothane, suxamethonium, isoflurane, enflurane, desflurane, and sevoflurane.[2] Once MH is identified, begin resuscitative measures immediately. Treatment includes administration of dantrolene sodium, providing 100% oxygen via an endotracheal tube, discontinuing all anesthetic agents, lowering body temperature, and obtaining blood specimens.[3] Potentially abnormal lab values such as hyperkalemia and hypercalcemia may require additional pharmacological treatment.

Dantrolene sodium is the drug of choice for the treatment of MH. It reverses the calcium accumulation within skeletal muscle, resulting in reversal of the condition.[2,3] For MH crisis, dantrolene sodium 2.5 mg/kg is administered by continuous rapid intravenous (IV) push and may be followed with 1 to 2.5 mg/kg every 10 minutes until symptoms subside or the condition is under control.[7,8] During the post-crisis period, administer 4 to 8 mg/kg/day orally in four divided doses or administer 1 mg/kg intravenously and titrate as the clinical situation dictates for one to three days after the onset of symptoms to prevent relapse.[3,8]

After an MH crisis, the patient should be closely monitored in an intensive care unit.[3] Key elements include monitoring creatine kinase (CK) levels to assess kidney function and obtain a coagulation profile to rule out disseminated intravascular coagulation—a known complication of MH crisis.[1-3] Prior to discharge, counsel the patient and family regarding MH and provide written educational materials and contact information for MHAUS. [3]

Table. Clinical Signs of Malignant Hyperthermia

EARLY SIGNS	LATE SIGNS
Increased end tidal carbon dioxide ($ETCO_2$)	Cardiac arrest
Skeletal muscle rigidity	Disseminated intravascular coagulation
Muscle spasm	Myoglobinuria
Tachycardia	Elevated creatine phosphokinase
Metabolic and respiratory acidosis	Elevated temperature
Tachypnea	Hypocalcemia or hypercalcemia
Sweating	Mottled cyanosis

Sources: Neacsu A. Malignant hyperthermia. *Nurs Stand* 2006 Mar 22;20(28):51-7; McNeil B. Malignant hyperthermia. *Br J Perioper Nurs* 2005 Sep;15(9):376-7, 379-82; Ali SZ, Taguchi A, Rosenberg H. Malignant hyperthermia. *Best Pract Res Clin Anaesthesiol* 2003 Dec;17(4):519-33.

Risk Reduction Strategies

Strategies to reduce the potential for harm and provide safe quality care to surgical patients include educating staff, conducting preoperative screening for MH, and implementing processes to ensure that staff are prepared to treat patients who develop MH.

Education

Education efforts include perioperative staff, are ongoing, and focus on describing MH, its clinical manifestations, and treatment.[3] A team approach, similar to the response to a cardiopulmonary arrest, facilitates efficient, effective care in this emergency situation. The following strategies may reinforce perioperative staff preparedness for a MH crisis:

- Provide education sessions for all surgical staff.[8]
- Conduct annual drills that include didactic information and simulation with a patient who develops symptoms of MH.
- Assign specific responsibilities to each operative team member to perform when an MH crisis occurs.
- Provide MH emergency management kits to the anesthesia department. MH kits include airway management supplies and medications.[3]
- Provide all operative staff with pocket-size guides about dantrolene sodium, including indications, dosage and administration, and adverse reactions of dantrolene sodium.

 ©2008 Pennsylvania Patient Safety Authority

Malignant Hyperthermia Events Reported through PA-PSRS

PA-PSRS has received 15 reports related to malignant hyperthermia since June 2004. These deidentified cases illustrate the types of issues reported.

The six reports below identify a family history of malignant hyperthermia. Of these, four resulted in cancellation of the procedure at that time and place, one resulted in transfer to controlled setting for the procedure to be performed on the same day, and the other patient had surgery without incident. Four of these six events were in ambulatory facilities.

Upon admission, the patient described an allergy to sodium pentathol. Patient had previous surgeries without complication. When anesthesia visited the patient in the preoperative area, nothing else was mentioned. When taken to the [operating room (OR)], the patient elaborated to the certified registered nurse anesthetist that [an older relative] had died during surgery. Patient stated "he burned up." Malignant hyperthermia testing on patient was never done to rule it out.

After an intravenous (IV) catheter was started in preparation for the [operative procedure], the anesthesiologist discovered while talking to patient that an [older relative] had severe anesthesia allergy and that patient had never been tested for malignant hyperthermia. Anesthesiologist cancelled case until further information is gathered and will perform the procedure in a hospital setting. [Patient did return] preoperative phone call to obtain this information prior to surgery.

Parent reported . . . that procedure had been cancelled for the second time in past [few] months. Procedure was cancelled due to concern about anesthesia/sedation reaction. Patient's [older relative] has history of malignant hyperthermia, and patient must have sedation/anesthesia administered in controlled setting. Appointment was cancelled due to known history without special precautions taken. . . .

When anesthesia consult was conducted, with family being present, [sibling] stated . . . "I have had high fevers with general anesthesia." Anesthesiologist suspected malignant hyperthermia and wanted patient transferred to hospital so procedure could still be done today.

Patient prepared for surgery, and during anesthesia interview the patient's [spouse] mentioned that patient's [sibling] had malignant hyperthermia during surgery. Information was verified and after discussion with surgeon, the case was cancelled for this day. Patient cooperative and will be rescheduled for a later time.

Patient had surgery. Patient had family history of malignant hyperthermia and needed to have urinalysis results prior to being discharged. There was a delay in receiving the results. Investigation revealed that only a urine culture was ordered, not a urinalysis. When this was realized, hematology lab obtained urinalysis results from the existing urine sample. The patient was discharged to home after results were available.

The nine reports below indicate patients who were diagnosed as having malignant hyperthermia: four of the patients were male and five were female. The ages ranged from 6 to 72, with a median of 40. Five of the reports referred to treatment, with four specifically mentioning dantrolene. Eight of the nine cases occurred in hospitals. There was one death as noted in the main text, which specifically mentioned that dantrolene was not readily available.

- Showcase posters describing the signs and symptoms of MH.
- Display posters with the MHAUS hotline number (1-800-644-9737 or 1-800-MH HYPER) in critical areas of the surgical department.

Screening

Screening is a holistic process. Healthcare providers, particularly anesthesia providers, may incorporate an anesthetic history as described below in the standard preoperative screening process.

- Obtain a thorough medical history.[2]
- Obtain an anesthetic history to identify patients at risk for MH:[2]
  - Has the patient had general anesthesia before? If yes, what, if anything, happened?
  - If the patient has not had general anesthesia before, does the patient know of a blood relative who had a bad reaction to anesthesia? If the answer is yes, consider testing for MH susceptibility.
- Perform a physical examination.[2]
- Assess airway, and identify smoking history and other respiratory illnesses.[2]
- Obtain and/or review laboratory results for complete blood count, liver function tests, a comprehensive metabolic panel, CK, and a urine analysis.[2] Late signs of MH may include abnormal lab values, including hyperkalemia, hypercalcemia, and elevated CK.[2]
- Obtain baseline 12-lead electrocardiogram.[2]
- Obtain preoperative baseline vital signs, including height and weight, blood pressure, heart rate, respirations, and temperature.[2]

Treatment

Treatment of MH requires rapid interventions to stop disease progression and prevent complications. Call the MHAUS hotline as identified previously. In

 ©2008 Pennsylvania Patient Safety Authority

Several malignant hyperthermia events were treated with dantrolene.

Patient developed hyperthermia . . . planned treatment involved administration of medication (dantrolene). Medication was not readily available. Another medication was utilized. [Case resulted in patient death.]

A healthy [adult patient] was admitted to facility for an [operative procedure]. Anesthesia began in the [OR on the hour]. The incision [occurred about 25 to 30 minutes later]. The surgery [proceeded] without issue. However, anesthesia noted an increase in end tidal carbon dioxide ($ETCO_2$) and heart rate. These vital signs continued to increase, and MH crisis code was called [about 45 minutes after the start of anesthesia] by the medical director. [MHAUS] hotline was contacted [within one minute] and kept on speaker phone in the OR. Dantrolene regime was initiated, foley [catheter] was inserted, and surgery was aborted. The surgical site was closed, and a dressing was applied. Laryngeal mask airway was removed, and the patient was intubated with endotracheal tube. [Emergency] 911 was called for advanced life support transport [to the medical center]. Patient responded to treatment with decrease in $ETCO_2$ and heart rate. Patient was stabilized and transferred to [medical center an hour after crisis identified].

Patient had operative procedure and was discharged home in stable condition. The patient was found unresponsive at home the following day and was readmitted. Lab values were elevated. Anesthesia determined patient may have malignant hyperthermia. Patient was subsequently discharged.

During closure of procedure, patient developed signs of malignant hyperthermia. Patient received initial dose of dantrolene sodium and necessary treatment in OR and was transferred to the [intensive care unit (ICU)].

[Increased] temperature, [increased] heart rate, [decreased] blood pressure immediately post op elective . . . procedure. Identified as probable malignant hyperthermia and treated immediately according to . . . policy. No long-term sequelae.

Patient presented for [procedure]. [During] postoperative [period, the patient] developed increased heart rate (130s to 140s) [with] temperature of 37°C. Urine is also positive for blood in postanesthesia care unit. There is a strong history of malignant hyperthermia and [patient] was admitted to ICU for observation. In ICU, vital signs were stable with good oxygen saturation, and urinalysis was negative for any red blood cells. Patient was discharged to home later [that day].

Patient received 300 mg of succinylcholine within an eight-hour period. While [this] drug can sometimes be associated with malignant hyperthermia, his temperature maxed out at [101 to 102° F] with no evidence of rigidity and no hemodynamic instability. Patient clearly does have rhabdomyolysis and is most likely related to succinylcholine. The physician monitored and reviewed. . . . Patient had not received [this] drug previously. . . .

Patient to the OR for [operative procedures]. Anesthesia medications [given] were Versed® 2 mg and Fentanyl total of 450. Patient was administered dantrolene 1 mg/kg IV [for probable malignant hyperthermia] with a decrease in temperature temporarily, and then [was given] cooled fluids and cooling blanket. No further orders at this time.

Patient received 150 mg succinylcholine (rapid sequence intubation) and subsequently was diagnosed as having malignant hyperthermia.

addition, implement the following if patients exhibit clinical signs of MH:[3]

- Withdraw all anesthetic agents.
- Administer nontriggering agents such as sedative-hypnotic agents to maintain unconsciousness.
- Stop surgery as quickly as possible.
- Alert the entire operative department to the situation.
- Assign team members to respond and care for the patient.
- Intubate the patient if not already done, and hyperventilate with 100% oxygen.
- Administer dantrolene sodium as indicated.
- Monitor core body temperature in addition to blood pressure and heart rate and rhythm.
- Lower the temperature in the OR, and cool the patient with cold packs to the groin, axilla, and neck.
- Administer IV fluids to maintain urine output.
- Obtain CK and coagulation profile.
- Obtain arterial blood gas.
- Monitor urine color and amount per hour.
- Assess and correct metabolic acidosis.
- Administer insulin and glucose to correct hyperkalemia.
- Monitor central venous pressure.

Conclusion

Prompt identification of MH and treatment are essential to minimize patient harm. Knowledge of the wide variation of symptoms that may present during administration of anesthesia is vital for healthcare providers to initiate treatment. The focus for healthcare providers is availability and administrations of dantrolene sodium. In addition to knowledge of MH and its treatment modalities, it is essential for perioperative staff to have access to other valuable resources. MHAUS provides information and support to healthcare providers and patients, including evidence-based

 ©2008 Pennsylvania Patient Safety Authority

The Malignant Hyperthermia Association of the United States: Services and Research

The Malignant Hyperthermia Association of the United States (MHAUS) was established in 1981 to educate both healthcare professionals and lay communities. Its mission is to reduce death and injury from malignant hyperthermia (MH) by improving medical care related to MH, providing support information to patients, and improving the scientific understanding and research related to MH and other heat-related syndromes.

Highlights of Services and Educational Materials

- The MHAUS hotline, 1-800-MH HYPER, provides medical professionals with access to anesthesiologists who specialize in MH-crisis treatment 24 hours a day, 365 days per year. These anesthesiologists provide expertise and support for successfully managing an MH crisis.
- MHAUS publishes a quarterly newsletter, the *Communicator*, providing the latest news on MH.
- MH procedure manual is a new program offering comprehensive protocols and a training video for use in hospitals, ambulatory surgery centers, and office-based surgery practices.
- A variety of educational information is available at the association's Web site (http://www.mhaus.org).
- Emergency medical identification tags, to alert healthcare providers to a patient's MH status, may be obtained through MHAUS.

Scientific Research

MHAUS maintains the North American MH Registry (http://www.mhreg.org), which is used to analyze and disseminate patient-specific clinical and laboratory information of MH-susceptibility to scientific investigators and physicians caring for MH-susceptible patients.

Source: Malignant Hyperthermia Association of the United States (MHAUS) [Web site]. [cited 2008 March 21]. Available from Internet: http://www.mhaus.org.

interventions. For more information, see "The Malignant Hyperthermia Association of the United States: Services and Research."

Notes

1. Ali SZ, Taguchi A, Rosenberg H. Malignant hyperthermia. *Best Pract Res Clin Anaesthesiol* 2003 Dec;17(4):519-33.
2. Neacsu A. Malignant hyperthermia. *Nurs Stand* 2006 Mar 22;20(28):51-7.
3. McNeil B. Malignant hyperthermia. *Br J Perioper Nurs* 2005 Sep;15(9):376-7, 379-82.
4. Litman RS, Rosenberg H. Malignant hyperthermia: update on susceptibility testing. *JAMA* 2005 Jun 15;293(23):2918-24.
5. Quinlivan RM, Muller CR, Davis M, et al. Central core disease: clinical, pathological, and genetic features. *Arch Dis Child* 2003 Dec;88(12):1051-5.
6. Zhou H, Brockington M, Jungbluth H, et al. Epigenetic allele silencing unveils recessive RYR1 mutations in core myopathies. 2006 Nov;79(5):859-68.
7. Noble K. Malignant hyperthermia: hot stuff! *J Perianesth Nurs* 2007 Oct;22(5):341-5.
8. Malignant Hyperthermia Association of the United States (MHAUS) [Web site]. [cited 2008 March 21]. Available from Internet: http://www.mhaus.org.

(See Self-Assessment Questions on next page.)

 ©2008 Pennsylvania Patient Safety Authority

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. All of the following are clinical manifestations of malignant hyperthermia (MH) EXCEPT?
   a. Increased temperature
   b. Tachycardia
   c. Fluctuating blood pressure
   d. Fine muscle twitching and rigidity
2. Which is the definitive means to determine the presence of MH?
   a. DNA analysis
   b. Caffeine-halothane contracture test
   c. Ionized calcium levels
   d. 12-lead electrocardiogram
3. Dantrolene sodium administered by continuous rapid intravenous (IV) push is the treatment of choice for MH.
   a. True
   b. False
4. The components of the treatment plan when MH is suspected and/or diagnosed include which of the following?
   a. Withdrawing all anesthetics and administering 100% oxygen
   b. Discontinuing IV fluids and assessing urine output
   c. Obtaining 12-lead electrocardiogram to identify and treat arrhythmias
   d. Maintaining temperature in the operating room
5. All of the following risk reduction strategies may reduce harm to patients that develop MH EXCEPT?
   a. Conducting annual drills and providing MH emergency management kits to the surgical team
   b. Displaying posters that include the clinical manifestations of MH and the Malignant Hyperthermia Association of the United States hotline number.
   c. Cancelling all procedures on patients with a family history of MH
   d. Obtaining an anesthesia history that identifies any previous reactions to anesthesia

 ©2008 Pennsylvania Patient Safety Authority

Hazardous Spills: The Safe Handling of Hazardous Drugs

ABSTRACT

Healthcare practitioners may underestimate the exposure risk associated with hazardous drugs. The risk of exposure extends along the drugs' entire life cycle, including the manufacturing, transporting, dispensing, and administering processes. The safe handling of hazardous drug spills is uniquely different from other healthcare spills, and exposure extends beyond patients and healthcare practitioners because nonclinical staff are often involved with the containment and disposal of spills. PA-PSRS has received more than 40 reports of patients and staff exposure to hazardous drugs. Many events involved intravenous (IV) tubing disconnections resulting in hazardous drugs leaking to the floor, the patient, hospital gowns, and linens. Many exposure incidents were attributed to IV port or site leaks and involved IV spiking issues, resulting in large hazardous spills. Risk reduction strategies include developing a hazardous drugs program; encouraging personnel compliance in the storing, dispensing, transporting, and administering of these medications; managing spills; and disposing of hazardous drugs in such a way that the most appropriate guidelines are used to minimize exposure. (Pa Patient Saf Advis 2008 Sep;5[3]:96-9.)

Accidental patient and staff exposures during hazardous drug administration have been reported through PA-PSRS. These exposures increase the potential for harm to patients *and* staff. The most often referred to U.S. guidelines for the safe preparation, dispensing, and administration of hazardous medications are from the National Institute for Occupational Safety and Health (NIOSH), American Society of Health-System Pharmacists (ASHP), Oncology Nursing Society (ONS), and Occupational Safety and Health Administration (OSHA).[1-4] There have been 42 reports of accidental hazardous drug events submitted through PA-PSRS since the program's inception in 2004. Two-thirds of the reported events were attributed to intravenous (IV) tubing disconnections, resulting in hazardous drugs leaking to the floor, the patient, hospital gowns, and linens. The remaining reported events were attributed to IV port or site leaks, IV spiking, and other issues (see Table). One-third of reported events involved volume amounts ranging from 7 mL to the entire contents of the medication IV bag, resulting in large hazardous spills.

While there are many helpful strategies for inpatient, outpatient, and office-based healthcare facilities to apply to the safe handling of hazardous drugs, the first strategy is to recognize the problem. Facilities may consider developing programs for the interdisciplinary safe handling of hazardous drugs that incorporate national guidelines and outline policies and personnel compliance.

In 2004, the NIOSH Working Group on Hazardous Drugs revised the 1990 ASHP hazardous drug definition to include one or more of the following criteria:[1,2,5]

- Carcinogenicity
- Teratogenicity
- Reproductive toxicity
- Organ toxicity at low doses
- Genotoxicity
- Structure or toxicity similar to drugs classified as hazardous using the above criteria

While the ASHP, OSHA, NIOSH, and ONS guidelines for the safe handling of hazardous drugs are readily available, the application of these guidelines is inconsistent, resulting in increased incidence of hazardous drug exposure. Research has revealed measurable levels of hazardous drugs in the urine of healthcare providers who are involved throughout different stages in the drugs' life cycles.[2,5,6] The life cycle of a hazardous drug begins at manufacture and ends at waste disposal in patient care units, outpatient facilities, office-based practices, and home care.[6,7] Guidelines now include cradle-to-grave considerations for hazardous drugs because some chemotherapy agents can be administered for noncancerous conditions, thus increasing exposure for healthcare practitioners and patients and their families.[6] Exposure extends to surfaces such as countertops and floors and to the arms and hands of nurses.[8] Drug residue inadvertently left on the outside of drug vials during the manufacturing process can also contribute to hazardous drug exposures.[8] Healthcare providers' hazardous drug exposures can occur by means of inhalation, dermal contact, oral intake, and injection, as well as exposure to drug vaporization.[5,6,8,9] Bodily fluids of patients receiving hazardous medications are also potential sources of exposure. Some research indicates that dermal and inhalation exposure can

Table. Hazardous Spills Reported to PA-PSRS

TYPE OF HAZARDOUS SPILL	NUMBER OF SPILLS REPORTED	PERCENTAGE (%)
Tubing disconnect	27	64%
Intravenous port/ site leak	5	12%
Spiking issues	4	10%
Other	6	14%
Total	42	100%

 ©2008 Pennsylvania Patient Safety Authority

be attributed to the act of removing bed linens, decanting urine, or cleaning toilets contaminated with hazardous drugs, any of which could potentially expose environmental services and housekeeping staff as well as other nonclinical employees.[10]

Consider these examples submitted through PA-PSRS:

> *The patient removed his IV [containing] docetaxel, an antineoplastic agent, while in the bathroom, spilling approximately 20 cc to 30 cc on the floor. Physician was notified, and the IV was restarted.*

> *Patient dislodged IV while sleeping. Approximately 30 cc of Taxol® leaked onto patient's arm and clothing. Nurse stopped infusion, used "chemo spill kit" to clean patient, and disposed of clothing. Treatment resumed after new IV started.*

Still other accidental exposures occur when contaminated surfaces are touched during the preparation, administration, or disposal of hazardous drugs.[6,10,11] Oral exposure may occur from hand-to-mouth contact.[6] Crauste-Manciet et al.[12] suggest that hands have been identified as the major route of contamination. Other research reveals that hands, forearms, and foreheads account for 87% of cyclophosphamide (i.e., an antineoplastic alkylating agent) total body exposures.[10,12] Drug reconstitution, transfer between containers, spiking and unspiking IV containers, priming IV tubing, and connecting or disconnecting tubing or syringes from injection ports have also resulted in leaking and surface contamination.[5]

Other examples from reports submitted through PA-PSRS include the following:

> *Patient was to receive chemo. When the nurse spiked the bag, it began to leak. This resulted in the bag of chemo being wasted, and a new one was prepared. The dose of chemo was administered 90 minutes later. Staff followed all procedures related to chemo spillage, which was contained to the medication room. No harm came to the patient due to the slight delay in administration of the dose.*

> *When the patient arrived, the IV started beeping. The chemotherapy bottle was found dripping onto the IV pole and the floor. The spike had come out of the bottle. The nurse was notified and assessed the situation and reconnected the chemotherapy fluid. A chemo spill kit was used to clean the area, and security was alerted according to the spill kit directions. There was no apparent patient or staff injury.*

> *When the nurse entered patient's room during chemo infusion, she noted that the bed linens were wet. Upon further investigation, it was noted that the patient's Cytosar-U tubing had become disconnected and was infusing on the bed. The physician was notified, and the sterile tubing was reconnected. Patient was showered, and area was cleaned according to chemo spill protocol. Physicians recalculated rate so that patient would still receive desired dose of Cytosar-U. Parent notified as well. No further interventions required.*

> *IV line connection became disconnected, chemotherapy meds spilled onto patient's bed.*

> *Patient called nurse stating her sleeve was wet. Taxol was disconnected. Physician was notified. Approximately 50 cc of fluid spilled.*

> *5 cc of busulfan chemo spilled on floor when tubing [was disconnected]. Chemo spill kit used to clean up spill. [Environmental services] cleaned floor following cleanup.*

> *Patient was receiving IV chemotherapy. While patient was sleeping, line became disconnected and chemo infusion spilled on floor. Chemo spill kit was used to clean up.*

> *Tubing disconnected, and Taxol® spilled on bed. Patient was removed from bed and his clothes and linens were removed. Bed was cleaned by housekeeping.*

While most IV equipment has been designed with patient safety in mind, hazardous spills continue to occur. Leaking and spills from needleless IV connectors are discussed in the following reports submitted through PA-PSRS:

> *Nursing staff found chemotherapy infusion tubing wet and approximately 15 cc to 20 cc of fluid on the floor. No cracks or defects were noted in the tubing or the medication bag. Chemo spill kit was used to clean area. Environmental health services cleaned entire floor. The patient remained in bed during the entire cleanup. Physician was notified. No patient injury.*

> *Patient presented to [emergency room]; [patient] had a history of cancer and was receiving 5-FU [fluorouracil] through port when leakage was noticed. Nurse supervisor notified security and maintenance. Oncologist was notified. Spill was cleaned according to policy and protocol. Patient had port removed and skin cleansed. Linens and nightgown were placed in red bags per policy.*

> *Patient with peripheral IV infusing 5-FU in forearm. Leakage noted from IV. Infusion stopped, and IV discontinued and removed. Small contact of drug with skin and linen only. Skin cleansed, and linens removed per policy. Doctor notified. No injury to skin noted. No patient injury noted.*

Risk Reduction Strategies

Although the 2004 NIOSH guidelines outline the safe handling of hazardous drugs, inconsistent use of these strategies continues. Inpatient, outpatient, and office-based healthcare facilities may consider developing facility-specific protocols and policies to facilitate consistent approaches to the safe handling of hazardous drugs. Consider incorporating the following elements into protocols and practice.

Safe Handling of Hazardous Drugs Program Development

Develop a program for the interdisciplinary safe handling of hazardous drugs that includes initial and

 ©2008 Pennsylvania Patient Safety Authority

ongoing education and competencies for all healthcare staff. Include ongoing education for nonclinical personnel who are involved with hazardous spill cleanup and disposal. Encourage wide availability of policies and procedures, particularly at community-based practices; one study reported that hazardous drug policies and procedures were available in hospitals significantly more than in community-based practices.[7] Consider employing the pharmacy and therapeutics committee to develop and annually update a list of organization-specific hazardous drugs, as well as policies, procedures, and revisions, for dissemination to the pharmacy and appropriate patient care areas. Make material safety data sheets or drug inserts readily available, and update on an annual basis to provide drug-specific resources for healthcare staff if accidental hazardous exposures occur.

Personnel Compliance

Storing hazardous drugs. Evaluate and monitor the current hazardous drug storage practices and equipment in the pharmacy and patient care areas. Hazardous medications require hazardous drug label warnings and safe storage in segregated areas in pharmacy and patient care units. Use personal protective equipment (PPE), including wearing chemical protective gowns and two pairs of gloves that are changed after 30 minutes or whenever a tear, a puncture, or contamination occurs.[1-3,9] Spill kits must be readily available wherever hazardous medications are stored.

Preparing hazardous drugs. Evaluate and monitor the current work practices, equipment used, and physical layout in which hazardous drugs are prepared. Don PPE, such as gowns and two pairs of gloves that are changed every 30 minutes or whenever a tear, a puncture, or contamination occurs.[1-3,9] The likelihood of permeation through two pairs of gloves is low, and the second pair of gloves adds protection from contamination of the healthcare providers' hands when removing gloves. Keep hazardous drug waste containers and spill kits readily available in areas where hazardous drugs are prepared.[9] Maintain environmental/ventilation controls by using a pharmacy-dedicated biological safety cabinet (BSC) with a downward flow and a high-efficiency particulate-air filter. A closed system transfer device adds additional protection. If IV tubing is attached in the BSC, care must be taken to avoid contamination of the tubing with the hazardous drug from the surface of the gloves or the BSC.[1,2,9] Strategies for preparing hazardous drugs by pharmacy staff would include priming of IV tubing with nondrug solution to prevent the risk of hazardous drug exposure in a patient's room.

Transporting hazardous drugs. Transport hazardous medications safely from the pharmacy to patient care areas in properly labeled containers. The precautions for staff who handle and transport hazardous medications from the pharmacy to patient care areas include donning two pairs of gloves.[1-3,9] Place medications in clear sealable bags to facilitate verification of the bag's contents without drug removal to minimize exposure risk. The use of pneumatic tube systems with these drugs is not advised due to the potential for hazardous spills. (See the March 2008 *Pennsylvania Patient Safety Advisory* article, "Pneumatic Tubes: A Possible Patient Safety Vacuum?" available online at http://www.psa.state.pa.us/psa/lib/psa/advisories/v5n1march_2008/mar_2008_v5_n1_article_pneumatic_tubes.pdf.)

Administering hazardous drugs. Keep hazardous drug waste containers and spill kits readily available in patient care areas where hazardous drugs are administered. Perform all work below eye level to reduce eye and facial splash potential.[1,2] Use only needleless devices with closed fittings, syringes, infusion tubing, pumps, and closed systems with locking connections when administering these drugs intravenously.[1-3,6,9] Pharmacy staff can complete priming of IV tubing with nondrug solution before drug preparation to prevent the nursing staff from attempting to prime tubing in the uncontrolled environment of a patient's room.[1-3,6,9] To prevent unintended exposure from leaking of residual fluid once an IV is attached, avoid disconnecting, removing, or unspiking the tubing.[1,2,9] PPE is essential and includes two pairs of gloves, a gown, and appropriate eyewear and face shield as needed to avoid hand, eye, mouth, or nasal exposure.[1-3,9] Place a plastic-backed absorbent pad under the administration area to absorb leaking and prevent patient dermal contact.[1,2] Wash hands with soap and water after glove removal.[1,2] Dispose of all PPE in labeled *yellow* hazardous waste containers.

Managing spills and disposing of hazardous drugs. Review the availability of spill kits in your facility near all potential exposure sources. Hazardous spills are considered small when their volume is less than 5 mL or 5 gm outside the BSC; spills are considered large when volumes are greater than 5 mL.[2,4,7,9] When managing small and large spills and disposing of hazardous drugs, wear essential PPE, including two pairs of gloves, a gown, appropriate eyewear, and, if necessary, a NIOSH-approved respirator appropriate for exposure to hazardous drugs. Also, use plastic backed spill-control pillows or absorbent towels for larger spills for employee protection when managing hazardous drug spills.[1-4,9] Decontaminate all interior BSC surfaces after spill cleanup of greater than 150 mL or the contents of one vial.[1-4] Protect employees handling hazardous drug waste from potential exposure. When handling linens or decanting urine or feces from patients who received hazardous drugs within the past 48 hours, staff are best protected by wearing two pair of gloves, a disposable gown, and appropriate eyewear and face shield if splashing is possible because surgical masks do not provide adequate protection from splashes to the mouth, nose, and mucous membranes.[1,2,4,8] Dispose of hazardous drug waste in labeled *yellow* hazardous waste containers; it is managed differently than other medical infectious (i.e., *red* bag) and noninfectious waste.[1,2,4,9] Wash equipment surfaces that come in contact with hazardous drugs

 ©2008 Pennsylvania Patient Safety Authority

with detergent, sodium hypochlorite solution (bleach solution), and a neutralizer.[1]

Conclusion

Practice guidelines for the safe use of hazardous drugs exist, but inconsistent implementation of these guidelines can lead to inadvertent patient and staff exposure. Inpatient, outpatient, and office-based healthcare facilities may consider developing facility-specific protocols and policies to facilitate consistent approaches to the safe handling of hazardous drugs. Risk reduction strategies include the development of the safe handling of hazardous drugs program, which incorporates guidelines for personnel compliance. The guidelines encompass the entire drug life cycle, including manufacturing, transporting, dispensing and administering these medications. Consistent managing of spills and disposing of hazardous spill cleanup materials will minimize risks to patient and staff in areas where these medications are used.

Notes

1. National Institute for Occupational Safety and Health. U.S. Department of Health and Human Services. Preventing occupational exposure to antineoplastic and other hazardous drugs in health care settings [alert online]. No. 2004-165. 2004 Sep [cited 2008 Feb 22]. Available from Internet: http://www.cdc.gov/niosh/docs/2004-165/.
2. Chen DF, Thompson KK. ASHP guidelines on handling hazardous drugs. *Am J Health-Syst Pharm* 2006 Jun 15;63(12):1172-93.
3. Oncology Nursing Society [clinical alert online]. [cited 2008 Feb 22]. Available from Internet: http://www.ons.org/publications/books/update.shtml.
4. Occupational Safety and Health Administration. Controlling occupational exposure to hazardous risks. Chapter 2, section VI. In: Occupational Safety and Health Administration (OSHA). OSHA technical manual, TED 1-0.15A [online]. OSHA 1999 [2008 Feb 26]. Available from Internet: http://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html.
5. Polovich M. Safe handling of hazardous drugs. Online J Issues Nurs 2004 Sep 30 [cited 2008 Feb 13]. Available from Internet: http://nursingworld.org/MainMenuCategories/ANAMarketplace/ANAPeriodicals/OJIN/TableofContents/Volume92004/Number3September30/HazardousDrugs.aspx.
6. Connor TH, McDiarmid MA. Preventing occupational exposures to antineoplastic drugs in health care settings. *CA Cancer J Clin* 2006 Nov-Dec;56(6):354-65.
7. Martin S, Larson E. Chemotherapy-handling practices of outpatient and office-based oncology nurses. *Oncol Nurs Forum* 2003 Jul-Aug;30(4):575-81.
8. Fransman W, Vermeulen R, Kromhout H. Occupational dermal exposure to cyclophosphamide in Dutch hospitals: a pilot study. *Ann Occup Hyg* 2004 Apr;48(3):237-44.
9. Polovich M, Blecher CS, Glynn-Tucker EM, et al. *Safe handling of hazardous drugs*. Pittsburgh (PA): Oncology Nursing Society; 2003.
10. Gambrell J, Moore S. Assessing workplace compliance with handling of antineoplastic agents. *Clin J Oncol Nurs* 2006 Aug;10(4):473-7.
11. Mason HJ, Blair S, Sams C, et al. Exposure to antineoplastic drugs in two UK hospital pharmacy units. *Ann Occup Hyg* 2005 Oct;49(7):603-10.
12. Crauste-Manciet S, Sessink PJ, Ferrari S, et al. Environmental contamination with cytotoxic drugs in healthcare using positive air pressure isolators. *Ann Occup Hyg* 2005 Oct;49(7):619-28.

 ©2008 Pennsylvania Patient Safety Authority

Hand Hygiene Practices and the Use of Alcohol-Based Sanitizers

Hand hygiene, a term applied to either a thorough washing of hands with soap and water for at least 15 seconds or the application of 3 to 5 ml of an alcohol-based antiseptic solution, has been reported as the most significant method to reduce healthcare-associated infections (HAIs).[1] The Centers for Disease Control and Prevention (CDC) estimates that approximately 90,000 patients die every year as a result of HAI acquisition.[2] In 2006, the Pennsylvania Health Care Cost Containment Council reported that more than 30,000 patients acquired HAIs in Pennsylvania, a rate of 19.2 per 1,000 cases, and patients with hospital infections died at a rate nearly 6 times that of uninfected patients.[3]

Background

The concept of handwashing as a method of infection control dates back to 1843, when Oliver Wendell Holmes Sr., MD, authored the "The Contagiousness of Puerperal Fever" in the *New England Quarterly Journal of Medicine*.[4] The essay addressed Holmes' perception that the degree of contagiousness highly suggests patient-to-patient carriage by physicians and nurses. Around the same time, Ignaz Philipp Semmelweis, MD, a Hungarian obstetrician, discovered that "hand washing was an effective method to reduce the death rate due to childbirth fever or puerperal sepsis."[5] Semmelweis enforced antiseptic practices among his students, and he reduced the death rate in the postpartum population from 12% to 1% in two years. Both physicians encountered significant resistance to this practice.

During 2002, CDC, in collaboration with the Society for Healthcare Epidemiology, the Association of Professionals in Infection Control and Epidemiology, and the Infectious Disease Society of America, released its updated *Guideline for Hand Hygiene in Health-Care Settings.* Included in these guidelines was the strong recommendation for routine use of alcohol hand sanitizers in clinical settings.[6] Similar to findings of Holmes and Semmelweis, the guideline supports hand hygiene as an evidence-based practice to reduce HAIs as part of a multifaceted approach.[7]

HAIs have a global impact on healthcare delivery systems. The World Health Organization (WHO) addressed these issues in 2007 with the *WHO Guidelines on Hand Hygiene in Health Care.*[8] The international recommendations came on the heels of another WHO campaign, Global Patient Safety Challenge 2005-2006: Clean Care is Safe Care, which collectively supports fundamental principles to improve universal health and well-being.

Hand Hygiene Compliance Issues

One of the most significant challenges for infection preventionists (formerly known as infection control practitioners) is the lack of overall compliance among healthcare workers in all healthcare settings, resulting in unacceptably low rates of adherence to guidelines and practice.[9] A review of reports submitted through PA-PSRS revealed violations in hand hygiene practices, whereby healthcare workers (i.e., physicians, laboratory and radiology personnel) entered patient rooms, rendered care, and left without washing their hands. This included patients in contact isolation. In a 1999 study by Pittet et al., 2,834 observed opportunities for handwashing revealed an average compliance rate of 48%. Nurses had the highest rate of compliance compared to physicians, nursing assistants, and other healthcare workers.[10] For the most part today, the rate of hand hygiene compliance remains at less than 50% except in hospitals that have instituted extremely aggressive campaigns such as the University of Pittsburgh Medical Center, Shadyside Campus. In 2005, the hospital launched a highly visible program including promoting the use of alcohol hand sanitizer. After four months, hand hygiene compliance had risen from 17% to 60%.[11] Now, the center's overall compliance rate is consistently greater than 90%.

System Failures and Barriers to Effective Hand Hygiene

System failures encourage poor compliance by healthcare workers. Healthcare facilities (hospitals and nursing homes) need to design user-friendly, easily accessible, and simple but effective hand hygiene systems. Well-designed systems in conjunction with other pertinent factors, will ultimately lead to motivation with resultant individual accountability and compliance. Several observational studies have determined that noncompliance is multifaceted, and breaking down the barriers is critical to a successful program.[12-14] The following barriers are most commonly reported:

- Lack of institutional commitment
- Skin irritation, mainly as a result of handwashing with soap and water
- Time constraints, particularly when handwashing
- Inconvenient location and insufficient numbers of sinks
- Frequent lack of supplies (e.g., soap, paper towels)
- False sense of security with glove use
- Interference with worker-patient relation (hand hygiene creates a brief interruption of care)
- Forgetfulness
- Lack of guidance
- Lack of effective educational programs
- High workload and understaffing
- Lack of scientific information demonstrating impact of improved hand hygiene on hospital infection rates

 ©2008 Pennsylvania Patient Safety Authority

Components of a Successful Hand Hygiene Program

Changing behavior is complex, and facility-wide acceptance is imperative. Infection control personnel play a key role in assisting administration with the design of an effective program. Providing evidence to facility administrators about new approaches can aid in meeting HAI reduction and prevention goals. How-to guides such as the toolkit and guide produced by the Institute of Healthcare Improvement have assisted hospitals in achieving far higher compliance rates.[15,16] Components of a successful system include the following:

- Institutional commitment
- Establishment of policies and procedures for hand hygiene
- Active participation in promotion at the individual and institutional/system level
- Designated champions
- Ongoing staff and patient education, including technique for handwashing and alcohol sanitizer use
- Routine monitoring and assessments with feedback (quality improvement tools)
- Readily available sinks, paper towels, and alcohol-based rubs
- Reminders such as posters and screen savers
- Personal accountability
- Sanctions for noncompliance
- Reward and recognition for good performers

Alcohol Hand Sanitizers and Their Role in Hand Hygiene Compliance

Use of alcohol hand sanitizers appears to be superior to traditional handwashing when the caregiver's hands are not visibly soiled. Sanitizers are less irritating, require less time, act faster, have rapid bactericidal action (except for *Clostridium difficile* and spore-producing organisms), are active against the most clinically important organisms (viruses, yeasts, fungi), and contribute to improved compliance. A systematic review of the efficacy of alcohol hand sanitizers revealed that the overall compliance for hand hygiene appears to be improving since the introduction of these products and the strong endorsement in CDC's 2002 guidelines.[17-19] The review concluded that while hand hygiene involving alcohol hand sanitizers is increasing, relatively few well-designed studies to date reveal a reduction in the overall incidence of HAIs as a result. However, one experimental trial/study in a hospital setting demonstrated that if staff can be convinced to use alcohol hand sanitizers to a significant degree, the rate of HAIs will decrease significantly, especially if it is part of a multifaceted approach to HAI reduction.[20] It is important to note that alcohol hand sanitizer products within the United States usually contain 60% to 95% ethanol or isopropanol, with 60% to 70% formulations being most commonly used.[21]

Alcohol hand sanitizer factors that increase hand hygiene compliance include the following:

- Ease of use
- More readily available than sinks
- Less skin irritation than handwashing because of the absence of harsh chemicals as well as the addition of emollients
- Rapid evaporation
- Less time consuming than handwashing
- More efficacious, mainly due to increased use versus regular handwashing

Risk Reduction Strategies

Approximately 165 years have passed since Holmes and Semmelweis first made the connection between handwashing and infection prevention. While there has always been the need for compliance, today with the prevalence of multidrug-resistant organisms, such as methicillin-resistant *Staphylococcus aureus*, the need for risk reduction strategies is critical.

All healthcare facilities, including acute care hospitals and nursing homes, must create their own action plans with specific risk reduction strategies that include but are not limited to the following:

- Audit the current rate of hand hygiene compliance.
- Set a target rate and time frame for improvement.
- Provide appropriate hand hygiene education to all providers of patient care.
- Encourage, reward, and recognize staff input and ideas for improving hand hygiene compliance.
- Allocate sufficient funds, and appoint unit champions.
- Survey the environment, and determine placement at point of care for the alcohol sanitizer dispensers.
- Encourage patient input on the overall plan to improve hand hygiene compliance.

Ultimately, compliance with hand hygiene needs to become part of a culture of patient safety. Healthcare advances, including alcohol hand sanitizers, have made it possible for facilities to provide the necessary components for facilitywide compliance. Effective systems as described above together with alignment of frontline team members, strong educational programs, and consistent personal accountability by all staff can help achieve 100% compliance with hand hygiene, which is a vital component of the nationwide HAI reduction initiative.[22]

In his recently published book, *Results That Last: Hardwiring Behaviors That Will Take Your Company to the Top*, Quint Studer, a consultant whose firm implements evidence-based leadership systems, quoted a colleague who stated that "what we permit, we promote." If we permit low rates for compliance with hand hygiene, are we promoting infections?[23] Facilities can look at this issue and commit to improving

 ©2008 Pennsylvania Patient Safety Authority

patient care by promoting hand hygiene compliance today.

Notes

1. Reduction in central line-associated bloodstream infections among patients in intensive care units—Pennsylvania, April 2001-March 2005. *Morb Mortal Wkly Rep* 2005 Oct; 54(40):1013-6.
2. McKibben L, Horan T, Tokars JI, et al. Guidance on public reporting of healthcare-associated infections: recommendations of the Healthcare Infection Control Practices Advisory Committee. *Am J Infect Control* 2005 May;33(4):217-26.
3. Pennsylvania Health Care Cost Containment Council. Hospital-acquired infections in Pennsylvania; calendar year 2006 [online]. 2008 Apr [cited 2008 Jul 21]. Available from Internet: http://www.phc4.org/reports/hai/06/docs/hai2006report.pdf.
4. Holmes OW. The contagiousness of puerperal fever. *New Eng Q J Med Surg* 1:503-30, 1842-3.
5. Semmelweis I. The etiology, concept and prophylaxis of childbed fever [excerpts]. In: Buck C, Llopis A, Najera E, Terris M, ed. *The challenge of epidemiology—issues and selected readings.* Washington: PAHO Scientific Publication; 1988:46-59.
6. Centers for Disease Control and Prevention (CDC). Guideline for hand hygiene in health-care settings. 2002.
7. Rotter ML. Semmelweis' sesquicentennial: a little-noted anniversary of handwashing. *Curr Opin Infect Dis* 1998 Aug;11(4):457-60.
8. World Health Organization. WHO Guidelines on Hand Hygiene in Health Care (Advanced Draft). Geneva: World Health Organization: 2006.
9. Boyce JM. It is time for action: improving hand hygiene in hospitals. *Ann Intern Med* 1999 Jan 19;130(2):153-5.
10. Pittet D, Mourouga P, Perneger TV. Compliance with handwashing in a teaching hospital. Infection Control Program. *Ann Intern Med* 1999 Jan 19;130(2):126-30.
11. Institute for Healthcare Improvement. The sounds of two hands washing: Improving hand hygiene [online]. [cited 2008 Aug 18]. Available from Internet: http://www.ihi.org/IHI/Topics/CriticalCare/IntensiveCare/ImprovementStories/FSSoundofTwoHandsWashing.htm.
12. Pittet D. Improving adherence to hand hygiene practice: a multidisciplinary approach. *Emerg Infect Dis* 2001 Mar-Apr;7(2):234-40.
13. Larson EL, Bryan JL, Adler LM, et al. A multifaceted approach to changing handwashing behavior. *Am J Infect Control* 1997 Feb;25(1):3-10.
14. Goldmann D. System failure versus personal accountability—the case for clean hands. *N Engl J Med* 2006 Jul;355(2):121-3.
15. Institute for Healthcare Improvement. How-to guide: improving hand hygiene [online]. [cited 2008 Aug 18]. Available from Internet: http://www.ihi.org/IHI/Topics/CriticalCare/IntensiveCare/Tools/HowtoGuideImprovingHandHygiene.htm.
16. The Society for Healthcare Epidemiology of America. How-to guide: improving hand hygiene: a guide for improving practices among health care workers [online]. [cited 2008 Aug 19]. Available from Internet: http://www.shea-online.org/Assets/files/IHI_Hand_Hygiene.pdf.
17. Picheansathian W. A systematic review on the effectiveness of alcohol-based solutions for hand hygiene. *Int J Nurs Pract* 2004 Feb;10(1):3-9.
18. Carr MP. Waterless hand washing: a new era in hand hygiene. *J Pract Hyg* 2004 Mar-Apr:13(2):33-6.
19. Zoutman D, Matlow A. Alcohol hand sanitizers: an examination of the evidence of their efficacy. *Can J Infect Control* 2003 Spring:8-9.
20. Pittet D, Hugonnet S, Harbarth S, et al. Effectiveness of hospital-wide programme to improve compliance with hand hygiene. Infection Control Programme. *Lancet* 2000 Oct;356(9238):1307-12.
21. Malik YS, Maherchandani S, Goyal SM, et al. Comparative efficacy of ethanol and isopropanol against feline calicivirus, a norovirus surrogate. *Am J Infect Control* 2006 Feb;34(1):31-35.
22. Larson E. State-of-the science—2004: time for a "No Excuses/No Tolerance" (NET) strategy. *Am J Infect Control* 2005 Nov;33(9):548-57.
23. Studer Q. Results that last: hardwiring behaviors that will take your company to the top. Hoboken (NJ): John Wiley & Sons, Inc; 2007.

 ©2008 Pennsylvania Patient Safety Authority

Quarterly Update on the Preventing Wrong-Site Surgery Project

A revised graph of the number of reports of wrong-site surgery events by quarter has been extended to include data through the second quarter of 2008 and updated on the Pennsylvania Patient Safety Authority's Web site (see Figure).* Increased numbers for previous quarters are the result of belated reports. The marked volatility, from 16 to 24 to 11 to 21 reports per quarter, indicates the lack of systems; systems produce reproducible results. Of interest, approximately 38% are reports of wrong-site injections.

The indemnity for claims paid by physician insurers for wrong-site surgery is impressive, although the likelihood of a paid claim is small. Based on information from the Physician Insurers Association of America,[1] of 487 claims related to wrong-site surgery reported over 10 years (1998 to 2007), oral surgeons were collectively the least likely to have or pay a claim against them; orthopedic surgeons were collectively the most likely (see Table 1).

Adjusting all paid claims to 2008 dollars, the overall average indemnity paid for a claim of wrong-site surgery was $146,201 (see Table 2), with the highest average indemnity paid by neurosurgeons at $425,677 and the second highest by urologists at $306,460.[1] According to Mody et al., spinal surgeons, which include neurosurgeons, are also the most likely to perform wrong-site surgery. Mody et al. found that 50% of all spinal surgeons reported performing wrong-site surgery during their careers.[2]

Interestingly, only 62% of claims were paid. Kwaan et al. estimated that a (nonspinal) wrong-site surgery was reported to a malpractice insurer for every 112,994 operations.[3] Making some rough assumptions, such as reports to a malpractice insurer are equivalent to claims, a surgeon performing surgery other than spinal surgery would pay a claim for wrong-site surgery approximately every 182,000 operations. At an amortized cost of less than one dollar per operation, combined with the time needed for a surgeon to properly follow the Joint Commission's Universal Protocol described in the June 2008 *Pennsylvania Patient Safety Advisory*,[4] the rationale for taking the time to prevent this rare event is ethical, not economic. As mentioned in the June 2008 *Advisory*,[4] in order to maximize compliance, facilities should work with surgeons to develop processes that minimize the time needed for the surgeon to *properly* follow the Universal Protocol.

Standardized, detailed wrong-site surgery reports have now been submitted by cooperating facilities for a year in follow-up to reports of both near-miss and actual wrong-site events. This prospective comparison of near-miss to actual wrong-site events has been closed as of the end of August. The December 2008 *Advisory* will include the final report on the results of comparing the processes that were and were not significantly associated with trapping the error before harm occurred.

Figure. PA-PSRS Wrong-Site Surgery Reports by Quarter

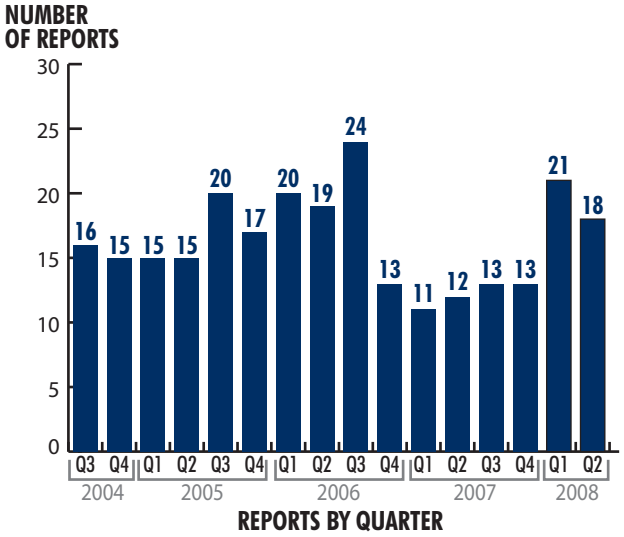


Table 1. Relative Ratios of Claims and Paid Claims by Specialties, Compared to the Specialty with the Collective Minimum Number

SPECIALTY	RATIO CLAIMS (CLOSED)	RATIO PAID CLAIMS
Oral surgery (baseline for each column)	1	1
Otorhinolaryngology	4	5
Anesthesiology	7	5
Ophthalmology	7	11
Plastic surgery	9	14
Cardiovascular and thoracic surgery	17	14
Urologic surgery	12.5	15
Obstetric and gynecologic surgery	14	17
General and colorectal surgery	43.5	57
Neurosurgery	40	60
Orthopedic surgery	88.5	126

Source: Special request, wrong patient—ECRI Institute: wrong patient or wrong body part by specialty and year, 2008, Physician Insurers Association of America.

* The Pennsylvania Patient Safety Authority maintains an online collection of articles, educational resources, and data pertaining to wrong-site surgery. This collection, titled "Preventing Wrong-Site Surgery," is available at http://www.psa.state.pa.us/psa/cwp/view.asp?a=1293&q=448010.

©2008 Pennsylvania Patient Safety Authority

Table 2. Percentage of Claims Paid and Average Payment for Paid Claims, Adjusted to 2008 Dollars, by Specialty and Overall

SPECIALTY	% OF CLAIMS PAID	AVERAGE INDEMNITY
Oral surgery	50	$ 16,254
Anesthesiology	36	$ 40,129
Otorhinolaryngology	63	$ 71,467
General and colorectal surgery	66	$ 90,467
Obstetric and gynecologic surgery	61	$ 95,693
Plastic surgery	78	$ 98,416
Orthopedic surgery	71	$133,047
Ophthalmology	79	$148,283
Urologic surgery	60	$182,317
Cardiovascular and thoracic surgery	41	$306,460
Neurosurgery	75	$425,677
Average for all operative specialties	62	$146,201

Source: Special request, Wrong patient—ECRI Institute: wrong patient or wrong body part by specialty and year, 2008, Physician Insurers Association of America.

Although the number of reports of wrong-site surgery events submitted through PA-PSRS by quarter has not improved, results from an improvement collaborative implemented by the Health Care Improvement Foundation (HCIF) are encouraging. The HCIF collaborative was sponsored by the Partnership for Patient Care, a multiyear patient safety initiative funded by Independence Blue Cross and participating hospitals and health systems. The goal of the HCIF collaborative was to improve the Universal Protocol process in operating suites.[5] Thirty facilities in the Delaware Valley region of the state (Philadelphia and its suburban counties) participated in a comprehensive program that included baseline surveys of processes and observations of practices, didactic education, technical assistance, workshops, conference calls devoted to each of the three elements of the Universal Protocol, and follow-up surveys of processes and observations of practices. The facilities shared with each other their experiences of successful and unsuccessful attempts to correct identified weaknesses in their processes.

Some of the improvements in compliance of policies and practices could be linked to compliance levels for the Pennsylvania Patient Safety Authority's Self-Assessment Checklist for Program Elements Associated with Preventing Wrong-Site Surgery that were submitted by facilities that had no reports of wrong-site surgery. Some could be linked to compliance levels for near misses that have been reported with the ongoing comparison of near-miss and wrong-site surgery events that facilities throughout Pennsylvania have submitted through PA-PSRS, as reported in the June 2008 *Advisory*.[4] Out of seven possible links between the different programs, the HCIF collaborative facilities showed improvements in four areas from below to above the PA-PSRS baseline for reports associated with no wrong-site surgery. In two areas, the improvement approximated the baseline (93% compliance versus 94% baseline compliance and 99% compliance versus 100% baseline compliance). In all six of these areas, the final compliances were over 90%. One of the seven areas that could be linked was the surgeon explicitly encouraging members of the operative team to speak up if concerned. The HCIF collaborative facilities showed improvement from 55% to 63%, but did not approach the baseline

Enter the Time-Out in the OR Competition

Does your facility have a particularly good script for the time out in the operating room (OR)? If so, please enter the Time-Out in the OR competition. Here's what you have do:

Write down your script for a Time-Out in the OR for Mary Jones' (MR# 007) Left Total Hip Replacement as if it were a Shakespearean play. For example:

> ***Circulating nurse:*** *"Time-out. We are doing a left total hip replacement on Mary Jones, medical record number 007; is that right?"*
>
> ***Surgeon:*** *"Right."*
>
> ***Anesthesia provider:*** *"Agree."*

Submit the script in a Microsoft Word document or its electronic text equivalent to JClarke@ecri.org before December 1, 2008.

The entries will be posted for peer review and comments. The winning entries will be determined by a vote of your peers, posted on the Pennsylvania Patient Safety Authority Web site, and profiled in an upcoming issue of the *Advisory*.

This is your opportunity to share your expertise with others.

 ©2008 Pennsylvania Patient Safety Authority

compliance of 76% for PA-PSRS reports associated with no wrong-site surgery.[4] The results suggest that assessment of a facility's Universal Protocol process can identify weaknesses that can be strengthened to match facilities that have not reported wrong-site surgery. A form for observing compliance with the Universal Protocol process can be found on the Pennsylvania Patient Safety Authority's Web site.

Facilities with specific problems or questions concerning wrong-site surgery are welcome to submit comments or specific inquiries. Communications should be directed to John Clarke, MD, FACS, Clinical Director of the Pennsylvania Patient Safety Authority at (866) 316-1070 or JClarke@ecri.org.

Notes

1. Special request, Wrong patient—ECRI Institute: wrong patient or wrong body part by specialty and year, 2008, Physician Insurers Association of America.

2. Mody MG, Nourbakhsh A, Stahl DL, et al. The prevalence of wrong level surgery among spine surgeons. *Spine* 2008 Jan 15;33(2):194-8.

3. Kwaan MR, Studdert DM, Zinner MJ, et al. Incidence, patterns, and prevention of wrong-site surgery. *Arch Surg* 2006 Apr;141(4):353-8.

4. Pennsylvania Patient Safety Reporting System. Quarterly update on the preventing wrong-site surgery project. Pa Patient Saf Advis [online] 2008 Jun. [cited 2008 Aug 5]. Available from Internet: http://www.psa.state.pa.us/psa/lib/psa/advisories/v5n2june_2008/jun_2008_v5_n2.pdf.

5. The Health Care Improvement Foundation. Wrong-site surgery [patient safety topic online]. 2008 [cited 2008 Aug 5]. Available from Internet: http://www.hcifonline.org/section/topics/patient_safety/wrong_site_surgery.

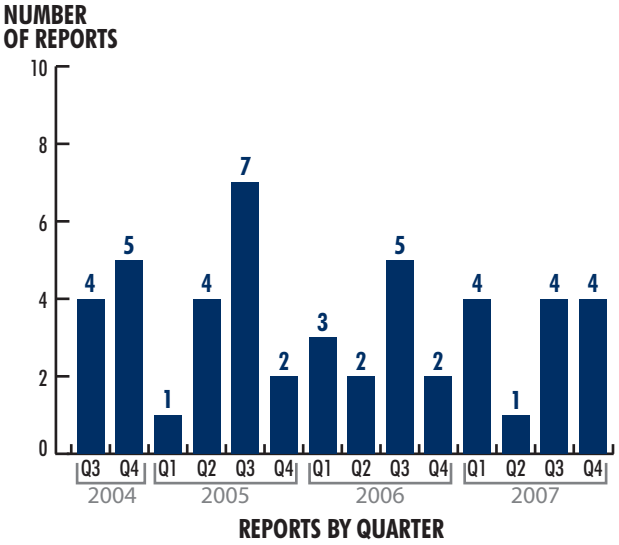
 ©2008 Pennsylvania Patient Safety Authority

Still Not Seeing Clearly—A Second Look at Intraocular Lens Implant Events

In the March 2005 issue of the *Patient Safety Advisory*, an article reviewed the Serious Events and Incidents reported through PA-PSRS regarding eye surgery. Two distinct patterns were identified at that time: (1) wrong-side surgery and (2) incorrect intraocular lens (IOL) implants.[1] This follow-up article looks at the frequency of incorrect IOL placement events since the inception of PA-PSRS to discuss the identified process issues that may have contributed to the surgical error and the risk reduction strategies that are being implemented to reduce the incidence of further events.

Since PA-PSRS began in June 2004 through December 2007, 48 cases involving implantation of the wrong IOL have been reported. The number of these events has remained on average about 10% of all lens-related events per year. In 32 of these events, patients required a second procedure to implant the correct IOL. Four of the patients did not require surgical intervention, and reports of the remaining 12 cases did not include this information (see Figure).

Figure. PA-PSRS Wrong Intraocular Lens Implant Reports by Quarter



Lessons Learned

Cataract surgery patients, in most instances, are scheduled back-to-back. The patients are quite similar. If staff skip steps in the verification of the IOL, surgical errors can result.[2,3]

> *The doctor pulled the patient's office chart and the lens he would be using for the case. The doctor checked the lens with the office chart. A 23.0 diopter lens was inserted. Postoperatively, the doctor realized he had pulled the wrong patient's chart. The patient was to receive an 18.0 diopter lens. Additional surgery was necessary to remove the incorrect lens and implant the correct one.*

> *Two patients were scheduled for cataract surgery. It was decided to do the second patient first. The time-out was proper, and the proper patient, site, and surgery were done. However, the lens implant for the first patient scheduled was implanted in the second patient.*

In the reports, the facilities identified several issues that led to implanting the wrong IOL. The event data shows that the verification process is central in the majority of the reports. Issues identified included the following:

1. The physician or his or her office staff gave information from the wrong patient's office chart regarding the lens to be used.
2. The surgeon/resident/other team members were inattentive during the time-out.
3. The surgeon's office record was not available in the operating room (OR) to review during the time-out.
4. The nurse picked up the wrong lens.
5. OR staff members used information from the wrong patient's medical record.
6. More than one lens was available in the OR.
7. The sequence of the scheduled patients was changed without corresponding changes to their respective verification processes.

Changes Going Forward

Events that result in implanting the wrong IOL can be reduced by following strict policies of checking and double-checking that the correct IOL is being used.[4] The Joint Commission requires that the time-out performed immediately before starting the procedure will include confirmation that the correct implant is ready for use.[5] The American Association of Ophthalmologists (AAO) has made suggestions to reduce instances of wrong IOL implants consistent with the guidance provided by the Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery™.[6] These suggestions focus on the importance for the surgeon and OR personnel to develop good and consistent communication processes surrounding the verification of the IOL before implantation.[1] AAO's suggestions were reprinted in the aforementioned March 2005 *Advisory* article (http://www.psa.state.pa.us/psa/lib/psa/advisories/v2n1march2005/vol_2-1-march-05-article_f-eye_surgery.pdf).

After implanting the wrong IOL, one Pennsylvania facility took specific steps to reduce the risk of this error recurring. The facility conducted a root-cause analysis that showed that the staff had multiple inconsistent processes for verifying the IOL before

 ©2008 Pennsylvania Patient Safety Authority

implantation. The facility standardized on a single process with which all staff was to comply. The facility has found that implementing and following a consistent process has been effective in reducing the risk of implanting the wrong IOL. The implemented process is as follows:

- The surgeon sends the office chart, which includes the A-scan, to the OR before the surgery.
- During the preoperative visit on the day of surgery, the circulating nurse verifies that the A-scan is in the record and is the correct scan for patient undergoing the procedure.
- Immediately before the surgery, the surgeon visits the patient, reviews the A-scan, selects the lens, and hands the lens to the circulating nurse. Preselection of the lens has been eliminated because a change in schedule may lead to the wrong lens being set up for the wrong patient.
- Once in the room, the time-out is performed with the entire OR team. The patient, procedure, site, and lens are verified by the surgeon and the scrub nurse. The staff has the patient's office chart, surgical medical record, lens, and lens box available to review during the time-out.
- The circulating nurse and surgeon double-check the IOL power together before beginning the surgery.

Other healthcare facilities in Pennsylvania include the following steps in their verification process:

1. Only the current surgical patient's medical record will be in the OR.
2. Only the current patient's IOL will be in the room at the time of surgery.
3. The time-out process will include the medical record from the physician's office, with lens model and diopter clearly documented.
4. The surgeon will select and pull the lens and place it on the patient's medical record before the procedure and announce it to the nurse when handing it into the sterile field.

Conclusion

The IOL verification process begins in the physician's office and ends with the correct lens being implanted. The information gathered from these PA-PSRS events may assist healthcare facilities in evaluating processes and preventing adverse events. Reducing the incidence of wrong IOL implantation is a team effort. The importance of developing a verification process within a facility that is followed by the entire surgical team is crucial in reducing these surgical errors.

Notes

1. Pennsylvania Patient Safety Reporting System. Focusing on eye surgery. *PA PSRS Patient Saf Advis* 2005 Mar; 3(1):12-4.
2. Ronge LJ. Human error during cataract surgery: right patient, wrong lens. EyeNet Magazine [online]. 2006 Mar [cited 2008 Jan 17]. Available from Internet: http://www.aao.org/aao/publications/eyenet/200603/index.cfm.
3. Jin GJ, Crandall AS, Jones JJ. Intraocular lens exchange due to incorrect lens power. *Ophthalmology* 2007 Mar; 114(3):417-24.
4. Laber D. Intraocular lenses: incorrect power calculations analyzed. EyeWorld [magazine online]. 2006 Aug [cited 2008 Jan 17]. Available from Internet: http://www.eyeworld.org/article.php?sid=3310.
5. Joint Commission. Implementation expectations for the universal protocol for Preventing Wrong Site, Wrong Procedure And Wrong Person Surgery™ [online]. 2003 [cited 2008 Jan 17]. Available from Internet: http://www.jointcommission.org/NR/rdonlyres/DEC4A816-ED52-4C04-AF8C-FEBA74A732EA/0/up_guidelines.pdf.
6. American Academy of Ophthalmology, American Society of Ophthalmic Registered Nurses, American Association of Eye and Ear Hospitals. Patient Safety Bulletin. Minimizing wrong IOL placement [online]. 2005 [cited 2008 Apr 4]. Available from Internet: http://one.aao.org/CE/PracticeGuidelines/Patient_Content.aspx?cid=38305f4c-4cb4-406a-953f-fc193cf2ade3.

Reviewer Commentary:

At Wills Eye Hospital and also our ambulatory surgery center, we have the doctors fill out a preferred lens form for each patient. The form is then faxed to the facility prior to surgery. The lens is selected by the nurse in the operating room. The lens is then verified the day of surgery with the nurse and the doctor, and the doctor signs off that the correct lens has been picked and inserted.

Michael L. Kay, MD
Wills Eye Hospital

 ©2008 Pennsylvania Patient Safety Authority

Forcing Functions of Antibiotic Prophylaxis

Editor's Note:

This text was abstracted from Whitman G, Cowell V, Parris K, et al. Prophylactic antibiotic use: hardwiring of physician behavior, not education, leads to compliance. J Am Coll Surg 2008 Jul;207(1):88-94. *The article described a successful program at Temple University Hospital.*

Introducing certain forcing functions can help improve physician behavior associated with use of prophylactic antibiotics in preventing surgical site infections, according to the results of a study undertaken at Temple University Hospital. The study addressed correct selection, appropriate timing of administration, and appropriate postoperative cessation of antibiotics.

The authors reviewed prophylactic antibiotic administration documented in the charts of more than 1,600 patients cared for between March 2005 and March 2007. Three patient variables were noted: (1) prophylactic antimicrobial regimen consistent with published guidelines, (2) parenteral antimicrobial prophylaxis initiated within one hour before incision, and (3) prophylactic antimicrobials discontinued within 24 hours after the procedure. The authors then devised processes to improve compliance (beyond educating residents and faculty). The processes were as follows:

Appropriate selection. Department-specific preoperative order forms were developed that limited choices to appropriate antibiotic prophylaxis selection (i.e., only prophylactic antibiotics recommended by the national Surgical Care Improvement Project). Compliance with appropriate selection increased from 76% to 91%.

Preoperative timing of administration. The practice of administering preoperative antibiotics within one hour before the procedure has previously been demonstrated to lower wound infection rates by as much as 80%. In response to variances in timing of initial dose, responsibility for confirming antibiotic administration during the time-out was assigned to the anesthesiologist (i.e., according to hospital policy, the time-out occurs in the operating suite before the patient is draped and in the presence of the surgeon, anesthesiologist, and nursing staff). Confirmation of antibiotic administration became part of the time-out checklist, and the time of administration and choice of antibiotic were documented. Compliance with timing of administration increased from 55% to 95%.

Postoperative cessation. To prevent further dose of prescribed antibiotics being administered more than 24 hours after the procedure (resulting from an order similar to the following: "antibiotic IV now and q 8 hours x 3 doses"), a postoperative pathway was implemented in the facility's electronic medical record. If the pathway is used, the order for postoperative antibiotics limits administration to 16 hours from the initial dose. With the use of this pathway, compliance with postoperative cessation of antibiotics increased from 60% to 86%.

Limitations of the study included that study design did not allow for a control group and that physician awareness of importance of correct administration of prophylactic antibiotics may have increased during the study period.

 ©2008 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.psa.state.pa.us.
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

PA PSRS
Pennsylvania Patient Safety Reporting System

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 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 PA-PSRS program, 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 PA-PSRS program or the Patient Safety Authority, see the Authority's Web site at www.psa.state.pa.us.

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.