PENNSYLVANIA PATIENT SAFETY ADVISORY

PATIENT SAFETY AUTHORITY
An Independent Agency of the Commonwealth of Pennsylvania

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

Vol. 8, No. 3

September 2011

OBJECTIVE

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

PUBLISHING INFORMATION

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

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

SUBSCRIPTION INFORMATION

This publication is disseminated by e-mail at no cost to the subscriber. To subscribe, go to http://visitor.constantcontact.com/d.jsp?m=1103390819542&p=oi.

INDEX INFORMATION

The *Pennsylvania Patient Safety Advisory* is indexed in NLM Catalog (http://www.ncbi.nlm.nih.gov/nlmcatalog), a service of the U.S. National Library of Medicine and National Institutes of Health.

The *Advisory* is also indexed in the CINAHL® Plus and CINAHL Plus with Full Text databases.

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Ambulatory Surgery Facilities: A Comprehensive Review of Medication Error Reports in Pennsylvania

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ABSTRACT

Pennsylvania ambulatory surgery facilities (ASFs) submitted 502 medication error reports to the Pennsylvania Patient Safety Authority from June 28, 2004, through December 31, 2010. The most common types of medication errors reported by ASFs to the Authority included drug omission, wrong drug, and monitoring error/documented allergy. The predominant routes of administration associated with wrong-drug errors were intravenous (IV) and ophthalmic. More than one-third of IV wrong-drug errors involved high-alert medications. Unlike previously reported confusion between eye drops of similar pharmacologic categories, three-quarters of wrong-drug errors involving ophthalmic products were mix-ups between eye drops of different pharmacologic categories. Strategies to prevent wrong-drug errors, especially for high-alert medications in the perioperative area, can be prioritized to prevent harm to patients undergoing procedures in ASFs, such as requiring labels on all medications, medication containers (e.g., syringes, medicine cups, basins), or other solutions on and off the sterile field; differentiating look-alike products by highlighting distinguishing information on the label; and purchasing eye drops within a class from different manufacturers. (Pa Patient Saf Advis 2011 Sep;8[2]:85-93.)

INTRODUCTION

According to the Pennsylvania Department of Health Bureau of Health Statistics and Research, the Commonwealth had licensed 265 ambulatory surgery facilities (ASFs), which performed more than 960,000 procedures between July 1, 2008, and June 30, 2009.[1] ASFs offer services including general surgical, orthopedic, gynecological, urologic, eye, and endoscopic (e.g., colonoscopies, upper gastrointestinal endoscopies) procedures. These were performed by more than 7,000 medical staff with clinical privileges, most commonly in anesthesiology, ophthalmology, and orthopedic surgery. Despite the variety of services provided by ASFs, the types of medications used are usually limited to antibiotics and intravenous (IV) fluids, as well as many high-alert medications such as analgesics, sedatives, local and general anesthetics, and paralytics.

The National Quality Forum (NQF) recently approved for endorsement a list of 29 serious reportable events (SREs) in healthcare, outlined in the forthcoming report, Serious Reportable Events in Healthcare—2011 Update: A Consensus Report. As a part of this update to the original SREs in 2002, NQF has added three new care settings, including ambulatory surgery centers.[2]

There is little in the literature that quantitatively addresses medication errors occurring in ambulatory surgical settings, although a 2005 MedMarx report from the United States Pharmacopeia specifically addresses the outpatient surgery setting.[3] Therefore, this article analyzes events reported to the Pennsylvania Patient Safety Authority to determine the most common types of events, patient populations involved, and medications involved, as well as to comprehensively review event descriptions in reports to determine specific and common issues affecting ASFs.

MEDICATION ERRORS IN PENNSYLVANIA ASFs

Pennsylvania ASFs submitted 502 medication error reports to the Authority from June 28, 2004, through December 31, 2010. Categorization of the reports by harm score, which is adapted from the National Coordinating Council for Medication Error Reporting and Prevention harm index,[4] shows that 91% (n = 457) of the events reached the patient (harm index = C to I). ASFs reported that 3.6% (n = 18) of the events resulted in patient harm (harm index = E to I), which is significantly higher than the overall rate for all medication error reports from reporting acute care facilities (0.6%). The 2005 MedMarx report showed that almost 3% of reported errors resulted in harm, and three events required life-sustaining interventions to preclude death.[3]

Department of Health data shows treatment at ASFs by population as follows: 57.6% adults (ages 18 to 64), 37.7% elderly (65 or older), and 4.7% pediatrics (younger than 18).[1] Nearly half of the events reported to the Authority, 49% (n = 246), involved the adult population, while 40.2% (n = 202) involved the elderly. Almost 11% (n = 54) of reports involved the pediatric population, more than double the percentage treated in ASFs.

The medications mentioned in reports are representative of the variety of services provided by ASFs. The most common routes of administration reported were IV (46%, n = 231), ophthalmic (23.9%, n = 120), and oral (14.1%, n = 71). The most common classes of medications (see Table 1) were antibiotics (33.9%, n = 170), local anesthetics (8%, n = 40), and corticosteroids (4.6%, n = 23), while the most common specific medications listed were ceFAZolin (15.3%, n = 77), vancomycin (4%, n = 20), and midazolam (4%, n = 20). Multiple products (e.g., the combination of fentaNYL and midazolam) were also reported (5%, n = 25). The 2005 MedMarx report found that the most common medications

Table 1. Predominant Classes of Medications Mentioned in Events in Ambulatory Surgical Facilities, June 28, 2004, through December 31, 2010 (296 of 502 events)

MEDICATION	NUMBER	% OF TOTAL REPORTS (*N* = 502)
Antibiotics	170	33.9%
Local anesthetics*	40	8.0
Corticosteroids	23	4.6
Opioid analgesic combinations*	23	4.6
Benzodiazepines*	21	4.2
Nonsteroidal anti-inflammatory agents (NSAIDS)	19	3.8

* High-alert medication

involved in errors were ceFAZolin (14.7%, *n* = 488), midazolam (3%, *n* = 100), and morphine (2.9%, *n* = 96).[3]

Drug Omission Errors

Surgical site infections (SSIs) are a major contributor to patient injury, mortality, and healthcare costs. Despite evidence of effectiveness of antimicrobials to prevent SSIs, studies have demonstrated inappropriate timing, selection, and excess duration of administration of antimicrobial prophylaxis. Omitting preprocedural antimicrobial products has been linked to surgical site infections.[5] Antimicrobial prophylaxis, such as ceFAZolin, initiated before a procedure reduces surgical wound infections, especially when administered within one hour before the surgical incision.

A national, retrospective, cohort study with medical record review that measured the proportion of patients who had parenteral antimicrobial prophylaxis initiated within one hour before the surgical incision showed that an antimicrobial dose was administered to only 55.7% of patients.[6]

When looking at the stages of the medication use process for a procedure in an ASF, drug omissions most commonly took place during the preoperative stage (60.4%, *n* = 81) and the postoperative stage (17.9%, *n* =24), according to events reported to the Authority. Overall, antibiotics were the most common class of medications omitted (53.7%, *n* = 72), with ceFAZolin the most commonly omitted within that class (70% of all antibiotics, *n* = 35). Benzodiazepines were the second most frequently omitted class of medications (6%, *n* = 8), with midazolam accounting for 87.5% (*n* = 7) of the omitted benzodiazepines.

Review of the drug omission event details found that 91% (*n* = 122) of the events involved a breakdown in the communication of orders or overlooking the preoperative orders.

> *[An elderly] patient was admitted for [a procedure]. The admitting nurse transcribed the preoperative orders. The physician prescribed a preoperative antibiotic (ceFAZolin) after the orders were transcribed by the nurse. There was no verbal notification to the nurse. The PACU [postanesthesia care unit] nurse discovered that the order was not given. [The nurse] notified the physician and the medication was given in the PACU.*

Wrong-Drug Errors

The routes of administration for medications associated with wrong-drug errors primarily involved ophthalmic (42%, *n* = 47) and IV (40.2%, *n* = 45) products. Based on the description of the events, it appears that most of the wrong-drugs errors involved choosing the wrong product (86.6%, *n* = 97) with no contributing factors mentioned.

When looking solely at the wrong-drug errors involving IV medications, 37.8% (*n* = 17) involved high-alert medications such as fentaNYL, EPINEPHrine, ketamine, meperidine, and morphine.

> *Anesthesia signs out a drug box each morning. The drug box contains fentaNYL 200 mcg/2 mL (10 vials), midazolam 2 mg/2 mL (10 vials), and ketamine 500 mg/5 mL (2 vials). The ketamine was recently added to the drug box. The doctor stated he was not aware that ketamine was in the box. He drew up the ketamine and administered it as if it were fentaNYL. He labeled the syringe "Fentanyl." The patient was not arousing in the recovery area as anticipated and the doctor was informed of this. The error was realized when the drug box was checked back in by two staff nurses; the fentaNYL and the ketamine counts were incorrect.*

> *A nurse was asked to obtain EPINEPHrine 1:10,000 and could not locate the drug in the room. The nurse left the room to procure the medication. Upon opening the medication cabinet, she obtained a vial that was thought to be labeled as "1:10,000." The medication was mixed with normal saline and administered to the patient. After the patient left the room, the nurse manager was in the room assisting the staff to look for EPINEPHrine in the medication drawer. The nurse manager noted that heparin vials were inadvertently placed in the drawer and brought this to the nurse's attention. The nurse looked in the sharps box and discovered that she had handed the scrub nurse heparin instead of EPINEPHrine.*

Decadron® 4 mg was prepared in a syringe to give to patient. A syringe of fentaNYL was at the bedside from a previous pain medication injection. Both syringes were labeled as to the contents. FentaNYL was given in error (meant to give Decadron). The error was realized as soon as the meds were given when the nurse saw "fentanyl" on the syringe. The physician was immediately notified and Narcan® was given.

An at-risk behavior that contributes to wrong-drug medication errors in the perioperative setting involves the failure to label stainless steel bowls that hold medications before they are drawn up into a syringe and injected into the patient. Data from the 2004 Institute for Safe Medication Practices (ISMP) Medication Safety Self -Assessment® for Hospitals indicated that only 41% of hospitals always labeled medications and solutions used in operating room (OR) settings.[7] An alarming 18% of hospitals did not label containers at all, and another 42% applied labels inconsistently. Also in 2004, a 69-year-old Seattle woman died largely because of unlabeled basins of solution in the interventional radiology procedure room. During coil placement under cerebral angiography to repair a brain aneurysm, the patient was accidentally injected with a topical antiseptic solution, chlorhexidine, instead of contrast media. Both solutions were clear and available on the sterile field in unlabeled basins. The hospital's decision to switch antiseptics from a brown povidone-iodine solution to a clear chlorhexidine solution resulted in a latent failure—two look-alike clear solutions previously distinguished by color on the sterile field. This latent failure was revealed when the unlabeled solution basins were mixed up.[8,9] In another example, an event was reported to ISMP in which an unlabeled basin contained lidocaine and another unlabeled basin contained ethyl alcohol. Although both solutions were clear, which increased the risk for confusion, staff relied on location in the sterile field to identify the substances. This time, ethyl alcohol was mistakenly drawn into a syringe and injected into the patient's face instead of lidocaine. The patient suffered from partial facial paralysis and unknown long-term consequences.[7] In 2006, The Joint Commission established a National Patient Safety Goal that required organizations to label all medications, medication containers (e.g., syringes, medicine cups, basins), and other solutions on and off the sterile field in perioperative and procedural areas.[10]

Similar events reported to the Authority include the following:

During fracture nasal procedure, the surgeon requested bupivacaine 0.25% with EPINEPHrine. The surgical technician drew up the medication from the OR table into a syringe. The surgeon administered the medication intranasally. When preparing to soak the Cottonoids® in a [nasal vasoconstrictor] solution, the surgical technician discovered she had only a small amount of [that solution] left in the medication container. The bupivacaine medication container was still full. The surgeon was notified that the [nasal vasoconstrictor] was possibly administered instead of the bupivacaine as requested and the anesthesiologist was notified. Later, the patient was transferred to the critical care unit at the acute care facility.

Wrong-Drug Errors Involving Ophthalmic Products

There is a long, documented history of confusion between eye drop containers due to similarity in product packaging. In 1996, the American Academy of Ophthalmology urged manufacturers to convert to a uniform color-coding system, based on therapeutic class, for eye solutions and ointments; the U.S. Food and Drug Administration and manufacturers of these products later agreed to this.[11] For example, the caps and carton labels for anti-infective ophthalmic medications are tan. Mydriatics and cycloplegics are coded red, miotics are green, beta-blockers are yellow or blue, and so forth. The proponents of the color-coding system argue it helps ophthalmologists and patients quickly differentiate medications. Although it is intended to be an actual color-code system as defined above, in reality it is more likely that practitioners use the colors to differentiate products rather than to identify products by pharmacologic class. However, this color-coding system may contribute to errors if healthcare practitioners confuse similar-appearing products in the same class. Color-coding may work well in an office setting or in the patient's home, but when similar corporate logos, fonts, and package sizes are factored in (see Figure), color-coding may not be safe in pharmacies, patient care areas, or procedure areas where greater numbers of medications are stored.[12] Errors have happened when dispensing and administering these products on nursing units, in ophthalmology clinics, and in hospital and ambulatory care pharmacies.[13] The following is an example reported to the Authority:

Preoperatively, the physician prescribed eye drops for cataract surgery. The bottle of Cyclogyl® 15 mL has a red top. Tropicacyl® has same size bottle and color lid. The Cyclogyl drops were inadvertently placed into the eye instead of Tropicacyl.

Contrary to the previously reported confusion between eye drops of similar pharmacologic categories, 74.5% (n = 35) of the wrong-drug errors involving ophthalmic products submitted to the Authority involved mix-ups between eye drops of *different* pharmacologic categories; 82.9% (n = 29) of these reports specifically mention situations of product selection errors, although additional contributing factors may have led to the error.

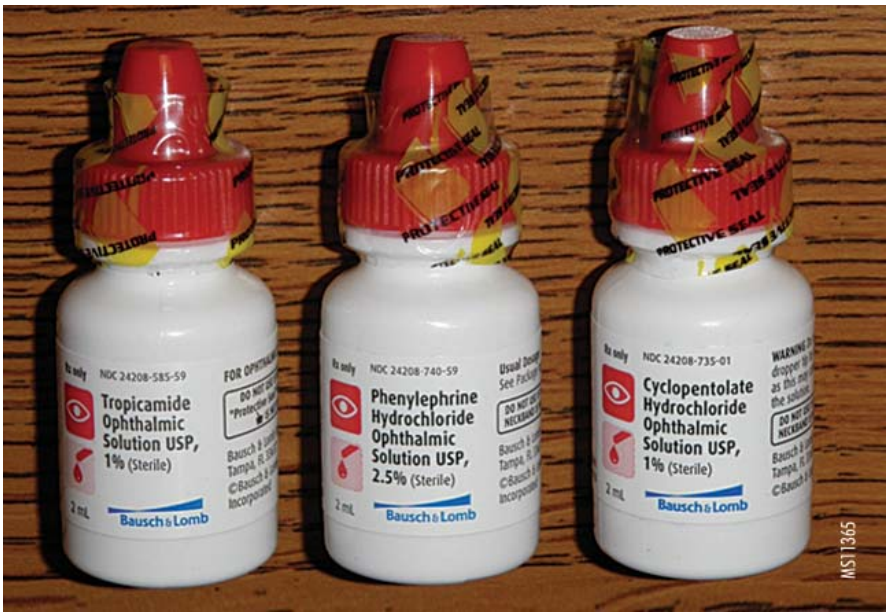
A patient was scheduled for a YAG laser peripheral iridotomy. A nurse administering eye drops was preparing more than one patient for YAG laser procedures at the same time. The nurse did not check the written medication order immediately prior to administering the eye drops and thought the patient was [scheduled] for YAG laser capsulotomy (phenylephrine 2.5% and tropicamide 1%) instead of YAG laser peripheral iridotomy. The nurse accidentally administered the routine eye drops for the capsulotomy procedure. The doctor was notified immediately and the patient was ordered that the left eye should be irrigated and 3 drops of 2% pilocarpine, followed by 1 drop of 2% pilocarpine and 1 drop of 0.5% Iopidine® to left eye in 5 minutes.

Proparacaine drops were to be placed into the operative eye prior to eye preparation. Instead, the pilocarpine eye drop was instilled after surgery. Both eye drop bottles were sitting on the eye cart. The nurse picked up pilocarpine instead of proparacaine and did not register the mistake until after the eye drop was instilled. Both [bottles] were sitting in close proximity of each other for the case and both bottles are quite similar looking (but not alike).

Errors Involving Documented Drug Allergies

When reviewing event descriptions for event reports classified as "other" (n = 107), analysts found that 33.6% (n = 36) indicated that a patient received a medication to which he or she had a documented allergy, similar to what was reported by the Authority in September 2008.[14] In addition, a review of the wrong-drug events revealed another 14 events in which a patient almost or actually received a medication to which he or she had a history of allergies. Facilities also reported 36 events with the event type "monitoring error/documented allergy," for a total of 86 events that described errors involving documented drug allergies (see Table 2). These 86 events account for 17.1% of all medication errors reported by ASFs. The most common drug classes involved in these events were antibiotics (46.5%, n = 40), contrast media (8.1%, n = 7), and antiseptics (7%, n = 6).

Figure. Look-Alike Eye Drop Bottles



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A patient was interviewed prior to the procedure by the circulating nurse. The patient denied any allergies when asked, but had a red medication allergy bracelet on. The bracelet said "powdered gloves," and the patient said that she did indeed have an allergy after denying it previously. The OR nurse then asked if the patient had any allergies to betadine, iodine, or shellfish. The patient stated "no." The patient was taken back to the OR and the nurse started prepping the operative site with betadine. The patient then stated that the nurse should stop because she is allergic to the prep.

Patient had a documented allergy to IV dye on the chart. The patient also had an allergy band on her wrist which was placed by preoperative staff. The OR nurse confirmed the allergy with the patient during preoperative questioning. During the procedure, the medication was dispensed to the physician by the OR nurse and the medication was administered to the patient by the physician. The OR nurse realized the error immediately after the procedure. The patient was taken to the PACU and monitored. She was given Benadryl® and Decadron in the PACU.

A surgeon's postoperative instructions included "Diamox Sequel® 500 mg for one dose" to be administered except in the case if patient was allergic to sulfa. Patient received a one-time dose of Diamox 500 mg [a sulfa derivative] and there was documentation indicating that patient was allergic to "sulfa" drugs. Patient also had an allergy bracelet indicating sulfa allergy. After a follow-up phone call to the patient and family, it was found that the patient did present with a delayed

Table 2. Predominant Medication Error Event Types Associated with Ambulatory Surgery Facilities, June 28, 2004, through December 31, 2010 (453 of 502 events)

EVENT TYPE	NUMBER	% OF TOTAL REPORTS (*N* = 502)
Drug omission	134	26.7%
Wrong drug	112	22.3
Monitoring error/documented allergy	86	17.1
Extra dose	21	4.2
Wrong dose/overdosage	18	3.6
Wrong dose/underdosage	11	2.2
Other	71	14.1

allergic reaction to the medication given (Diamox) in which the patient/family reported facial swelling, which is now subsiding.

The analysts note that it is the responsibility of the prescriber to check for allergies and not write an order to administer a medication "unless the patient is allergic."

RISK-REDUCTION STRATEGIES

ASFs can strive to identify system-based causes of the medication errors that occur and implement effective risk-reduction strategies to prevent harm to patients. Although many of the events reported to the Authority were not explicit in revealing all the causes and contributing factors of drug omissions, wrong–drug errors, and documented allergies, healthcare facilities may consider the strategies described below, which are based on a review of events reported to the Authority, observations from ISMP, and recommendations in the literature.

Antibiotic Omission

Strategies designed to improve compliance with prophylactic antibiotic administration within 60 minutes of initial incision include the following:[15]

— Use prompts in the electronic documentation of perioperative care regarding prophylactic antibiotics that include antibiotic selection and time of administration. The electronic chart may include a question asking if antibiotics had been ordered.

— Review preoperative standing order forms for select surgical diagnoses to ensure they include preoperative antibiotic administration, as well as the specified antibiotic and timing for surgical procedures for which preoperative antibiotics are recommended.

— In the preoperative holding area, introduce a process to screen preoperative antibiotic orders according to national guidelines and immediately notifying physicians of problems. Assign responsibility to the preoperative holding-area staff for ensuring that patients have orders for preoperative antibiotics. Incorporate a check by anesthesia and OR staff to verify appropriate preoperative antibiotic therapy has been initiated or completed.

— Change the preoperative processes for antibiotic administration. One organization determined the average time from when the patient enters the OR to when the initial incision was made, which for all procedures ranged from 20 to 30 minutes. Based on this information, the organization's SSI improvement team determined that the anesthesia care provider should administer the antibiotics immediately before the patient leaves the preoperative holding area. This process change enabled healthcare practitioners to consistently administer antibiotics within 60 minutes of the initial incision.

Wrong-Drug Errors

Although there were few reported cases of unlabeled bowls or syringes, organizations should have policies and procedures for the safe labeling of medications and solutions used on a sterile field. The Joint Commission National Patient Safety Goal NPSG.03.04.01 mandates such labeling in both inpatient and outpatient settings and requires the following in perioperative and other procedural settings both on and off the sterile field:[16]

— Label medications and solutions that are not immediately administered.

— Label any medication or solution that is transferred from the original packaging to another container.

— Verify all medication or solution labels both verbally and visually. Verification is done by two individuals qualified to participate in the procedure whenever the person preparing the medication or solution is not the person who will be administering it.

Strategies to improve the labeling of medications on a sterile field as well as to prevent wrong-drug errors include the following:[17,18]

Provide labels. Make labeling easy by using sterile markers, blank labels, and preprinted labels (prepared by the facility or commercially available) that can be opened onto the sterile field during all procedures.

Require labels. Require labels on all medications, medication containers (e.g., syringes, medicine cups, basins),

or other solutions on and off the sterile field, even if only one medication or solution is involved. Also require labels on all solutions, chemicals, and reagents (e.g., formalin, saline, Lugol's solution, radiocontrast media) that are used in perioperative units.

Differentiate look-alike drug names and products. If drug or solution names or packaging are similar, use tall man lettering (e.g., EPINEPHrine) on the labels to differentiate them, or highlight or circle the distinguishing information on the label. For example, consider purchasing skin antiseptic products in prepackaged swabs or sponges to clearly differentiate them from medications or other solutions and eliminate the risk of accidental injection.

Confirm medications and labels. Require the scrub person and the circulating nurse to concurrently verify all medications and solutions visually and verbally by reading the product name, strength, and dosage from the labels. (If there is no scrub person, the circulating nurse can verify the medication or solution with the licensed professional performing the procedure.) When passing a medication to the licensed professional performing the procedure, visually and verbally verify the medication, strength, and dose by reading the label aloud. The healthcare practitioner administering the medication also can read the product label to verify that it is the correct medication.

Standardize medications. Standardize and limit the variety of strengths and concentrations of medications as much as possible. Communicate any changes in available strengths and concentrations to front-line staff.

Storage of medications. Store medications safely with consideration given to separate look-alike products. This includes separating by generic name and packaging to the extent possible.

Perhaps the best way to prevent mix-ups of ophthalmic products is to avoid purchasing all eye drops from one manufacturer and to purchase drugs within a class from different manufacturers.[13]

Documented Allergies

As mentioned in the September 2008 *Pennsylvania Patient Safety Advisory* article, "Medication Errors Associated with Documented Allergies," specific strategies to prevent the prescribing and administration of medications to patients with documented allergies include the following:[14]

- 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 any reaction (e.g., front of medical record, on top of order forms, computer screens, assessment forms). This location can be standardized and used by all staff in the facility. Alert staff to always refer to these areas for reliable information.
- Consider adding prompts in consistent locations to document allergy information, and include clearly visible and prominently placed allergy prompts at the top of every page of all prescriber order forms (including blank, preprinted, and verbal order forms).
- On a patient's admission to the facility, list allergies, describe the reaction to the allergen, and, if possible, record the date that the reaction took place on all admission forms. Have appropriate staff consistently transfer this information to subsequent 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 or transcribing a verbal order for a medication.
- Educate prescribers and nurses about medication allergies. These efforts can include organization-specific procedures such as where to document or find patient allergy information, as well as how to access important drug information that includes common allergies, cross allergies, and multi-ingredient drug products that may have implications for common drug allergies.
- Use information published by the Authority to identify problem areas, processes, or medications and to determine the types of events that occur within the facility.
- Measure the use of trigger drugs used to treat allergic reactions (e.g., diphenhydrAMINE, methylPREDNISolone, EPINEPHrine) to increase detection of possible preventable adverse drug events and determine whether patients with documented allergies are erroneously receiving medications. Collection of trigger data could be incorporated into the order-screening processes or accomplished by those who routinely review patient records, such as quality managers or case managers.

CONCLUSION

In Pennsylvania ASFs, 502 medication errors have been reported. The predominant types of medication errors are drug omissions, wrong-drug errors with IV and ophthalmic products, and prescribing and administering of medications to patients with documented allergies. Use of strategies to prevent wrong drug errors, especially with high-alert medications in the perioperative area, can help prevent harm to patients undergoing procedures in ASFs.

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LEARNING OBJECTIVES

— Recognize the predominant types of medication errors associated with ambulatory surgery facilities (ASFs), according to reports submitted to the Pennsylvania Patient Safety Authority.

— Recall the most common classes of drugs involved in medication errors in ASFs.

— Identify factors frequently involved in wrong-drug medication errors in ASFs.

— Distinguish between effective and ineffective risk reduction strategies for ASF practitioners to promote the safe use of medications.

SELF-ASSESSMENT QUESTIONS

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

1. The most frequently reported type of medication errors occurring in ASFs is _____.
   a. extra dose
   b. drug omission
   c. wrong drug
   d. other
   e. monitoring error/documented allergy
2. All of the following are true about wrong-drug errors in ASFs EXCEPT:
   a. More than 40% of wrong-drug error reports mention ophthalmic products.
   b. An at-risk behavior that contributes to wrong-drug medication errors in the perioperative setting involves the failure to label stainless steel bowls that hold medications.
   c. High-alert medications were involved in more than 37% of wrong-drug errors involving intravenous products.
   d. Analysis of Authority reports involving wrong-drug errors found that nearly 90% of reports did not indicate contributing factors.
   e. More than 74% of wrong-drug error reports involving ophthalmic products involved mix-ups with products of similar pharmacologic categories.
3. All of the following are effective strategies to reduce the risk of wrong-drug medication errors in ASFs EXCEPT:
   a. Purchase sterile markers, blank labels, and preprinted labels prepared by the facility or commercially available that can be opened onto the sterile field during all procedures.
   b. Avoid purchasing all eye drops from one manufacturer, especially drugs within the same pharmacologic class.
   c. Require labels on all medications, medication containers (e.g., syringes, medicine cups, basins), or other solutions on and off the sterile field.
   d. Verification of medication labels should be done by an individual qualified to participate in the procedure.
   e. Differentiate look-alike drug names and products by using tall man lettering (e.g., EPINEPHrine) or highlighting or circling the distinguishing information on the label.
4. Which of the following is the predominant class of medications mentioned in medication errors reported by ASFs?
   a. Opioid analgesic combinations
   b. Neuromuscular blocking agents
   c. Corticosteroids
   d. Antibiotics
   e. Benzodiazepines

SELF-ASSESSMENT QUESTIONS (CONTINUED)

Case Scenario 1

A surgeon's postoperative instructions included "Diamox Sequel® 500 mg for one dose" to be administered except in the case if patient was allergic to sulfa. Patient received a one-time dose of Diamox 500 mg (a sulfa derivative) and there was documentation indicating that patient was allergic to "sulfa" drugs. Patient also had an allergy bracelet indicating sulfa allergy. After a follow-up phone call to the patient and family, it was found that the patient did present with a delayed allergic reaction to the medication given (Diamox) in which the patient/family reported facial swelling, which is now subsiding.

5. Which of the following strategies would *not* help prevent the above scenario from occurring?
   a. Avoid writing an order to administer a medication with a conditional statement such as "unless the patient is allergic."
   b. Standardize the location where a patient's complete allergy information, including descriptions of the reaction, appears (e.g., front of medical record, on the top of order forms, computer screens, assessment forms).
   c. Measure the use of trigger drugs used to treat allergic reactions (e.g., diphenhydrAMINE, methylPREDNISolone, EPINEPHrine) to increase detection of possible preventable adverse drug events.
   d. Have appropriate staff consistently transfer allergy information obtained on admission to subsequent forms and place the completed forms into the charts so that they are readily accessible.
   e. Provide prescribers and nurses access to important drug information that includes common allergies, cross allergies, and combination drug products that may have implications with common drug allergies.

Case Scenario 2

An elderly patient was admitted for a procedure. The admitting nurse transcribed the preoperative orders. The physician prescribed a preoperative antibiotic (ceFAZolin) after *the orders were transcribed by the nurse. There was no verbal notification to the nurse. The postanesthesia care unit (PACU) nurse discovered that the order was not given. The nurse notified the physician and the medication was given in the PACU.*

6. Which of the following strategies would *not* help prevent the above scenario from occurring?
   a. Use prompts in the documentation of perioperative care regarding prophylactic antibiotics that include antibiotic selection and time of administration.
   b. Use verbal orders to communicate preoperative antibiotic orders between prescribers and nurses.
   c. Incorporate a check by anesthesia and operating room staff to verify appropriate preoperative antibiotic therapy has been initiated and/or completed.
   d. Review preoperative standing order forms for select surgical diagnoses to include preoperative antibiotic administration as well as the specified antibiotic and timing for surgical procedures for which preoperative antibiotics were recommended.
   e. Assign responsibility to the preoperative holding area staff for ensuring that patients have orders for preoperative antibiotics.

Making Patient-Controlled Analgesia Safer for Patients

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ABSTRACT

The Pennsylvania Patient Safety Authority has received approximately 4,500 event reports associated with patient-controlled analgesic (PCA) pumps (June 2004 through May 2010). PCA infusion pumps allow patients to self-administer doses of pain-relieving medication as needed, rather than having to summon a caregiver. The most significant risk when using these pumps is overmedication leading to opioid-induced respiratory depression. This article assesses this and other risks associated with PCA therapy reported to the Authority. It reviews ways to prevent adverse events. (Pa Patient Saf Advis 2011 Sep;8[3]:94-9.)

Patient-controlled analgesic (PCA) infusion pumps allow patients to self-administer opioid analgesics within the limits prescribed by a physician or other licensed professional. PCA therapy is used for postoperative, obstetric, terminally ill, and trauma patients. PCA pumps deliver solutions intravenously, subcutaneously, or epidurally and allow patient activation by means of a pendant button on a cord connected to the pump or a button directly on the pump. Accidental overdoses by patients are prevented by lockout features on the pump and by the fact that heavily sedated patients will be too somnolent to self-administer more analgesics.

The programmable features of pumps allow the clinician to select the drug concentration, patient bolus dose, lockout interval between patient-controlled boluses, and a continuous (basal) rate. Drug concentration is typically specified in mg/mL, the patient-activated bolus dose is specified in mg, and lockout intervals between patient boluses are programmed in minutes. If a continuous rate is ordered, it would be in mg/hr or mcg/hr.

PCA pumps come in two main styles: larger pole-mounted pumps and smaller ambulatory-style pumps. Pole-mounted pumps are intended for bedside use, often in an inpatient setting; most offer limited ambulation time. They emphasize function for complex care, with larger display screens and easy-to-navigate menus that guide the clinician through the programming process. These pumps generally offer more computing power and therefore more comprehensive features, functions, and event logs, and typically can only deliver medications that are available in prefilled vials or syringes. Ambulatory-style pumps are intended to be carried by the patient to allow ambulation in inpatient, outpatient, and home care settings; they may also be clamped to an intravenous (IV) pole. They typically deliver fluid from small bags or cassettes and emphasize portability and simplicity of programming.

A dose error reduction system (DERS) is a critical element in detecting and preventing errors in prescribing and programming. Devices with this functionality are commonly referred to as "smart" pumps because they can compare programmed parameters (e.g., dose, concentration) against preset limits stored in a drug library; the limits are specific to each drug and clinical location. If a clinician tries to program a dose outside the limits, the device alerts the clinician and either requires the program to be changed to something within the limits (these are referred to as "hard" limits) or allows the clinician to continue with the programmed infusion after acknowledging the alert ("soft" limits).

OVERVIEW OF PCA INFUSION ERRORS

The first six years of Pennsylvania Patient Safety Authority data (June 2004 through May 2010) contain approximately 4,500 reports associated with a PCA pump. (In the initial search, "PCA" was used for *patient care assistant* in approximately 20% of the reports.) Many of the reports related to patient-controlled analgesia reflected confusion about the infusion order but did not identify a source of error. Other reports documented problems common to any infusion therapy: infiltration, tubing disconnection, medication leakage, and delay in therapy when a pump was unavailable. Delivering the wrong medication or the wrong amount are also reported for all infusion pumps, but the use of PCA pumps entails more hazards than use of other types of pumps. PCA pumps are used with potent opioids, so even small errors can lead to serious patient harm. For example, although it is counterintuitive, an erroneously programmed low drug concentration will cause a pump to deliver an excessive amount of the drug, causing an overdose.[1] Or, the concentration could be programmed as ordered but a vial or bag with a higher concentration could be selected and connected to the pump.

The U.S. Food and Drug Administration's (FDA) Manufacturer and User Device Experience (MAUDE) database reveals that reports of PCA-related device events are three times as likely to result in injury or death as reports of device events involving general-purpose infusion pumps. Authority analysts searched for all reports in the MAUDE database (as of January 31, 2011) for devices by both FDA product code and outcome (i.e., outcome = death *or* injury). Of 4,230 reports for product code MEA (PCA pumps), 826 (19.5%) resulted in injury or death. Of 48,961 reports for product code FRN (general-purpose pumps), 3,240 (6.6%) resulted in injury or death. This may be due to the exclusive use of high-risk analgesics in PCA pumps.

Opioids commonly used in PCA therapy, such as morphine, HYDROmorphone, and fentaNYL, are considered to be high-alert medications.[2] Approximately one of four events reported to the Authority involved high-alert medications. Of those reports, 44% involved pain management medications often used for PCA, including morphine, HYDROmorphone, meperidine, and fentaNYL.[3] In addition, Authority data indicates that 21% of look-alike name errors involved opioids and included name confusion among morphine, HYDROmorphone (Dilaudid), and meperidine (Demerol).[4]

During a recent six-month period (December 2009 through May 2010), approximately 70% of the PCA therapy related reports to the Authority were attributable to errors associated with pump use (e.g., misprogrammed doses and concentrations, installation of the wrong drug or concentration). Naloxone (Narcan) was administered to reverse an opioid overload in more than 10% of these reports. Misprogramming of the PCA pump is by far the most frequently reported practice-related issue surrounding PCA therapy.[5] The following examples from Authority reports illustrate some of the ways PCA errors may occur, including misinterpreting orders, pump misprogramming (e.g., concentration, bolus dose, lock-out interval), and running the wrong drug or concentration:

> *PCA was ordered for morphine 1 mg dose, 8 minute lock-out with 10 mg hourly limit. PCA morphine concentration comes as 1 mg/ml standard. PCA [pump] was programed as morphine 1 mg dose, 8 minute lock-out with 10 mg hourly limit with a 0.25 mg/ml concentration. At the set concentration, the PCA [pump] delivered 4 ml for 1 mg dose when it should have delivered 1 ml for 1 mg dose, therefore giving 4 times the ordered dosage each time.*

> *I went to verify orders for this patient and noticed that the patient's HYDROmorphone PCA, patient administered dose, was increased from 0.25 mg to 2.5 mg. I called the nurse to check if she knew the rationale for such a large dosage increase. She thought this seemed inappropriate and spoke with the physicians who were rounding at the time. The physician had intended to order 0.25 mg rather than 2.5 mg. The order was corrected.*

> *Patient received from the PACU [postanesthesia care unit]. PCA documented as started by this RN [registered nurse]. Upon receiving the patient, the PCA was set as a 5 ml dose [0.2 mg/mL HYDROmorphone] with 10 minute lockout time; however, it was ordered as 1 ml dose with 5 minute lockout. Nurse practitioner was notified.*

> *PCA was discontinued and it was found to have incorrect medication given. The patient was ordered HYDROmorphone PCA, but morphine was infusing. The pharmacy was notified.*

> *We discovered the incorrect PCA settings during rounds. The HYDROmorphone syringe was the correct concentration. The settings for the PCA were ordered in ml–1 ml/6 min/0 basal/10 ml hourly limit–but the pump was set in mg–1 mg/6 min/0 basal/10 mg hourly limit. The patient was a little sleepy but easily arousable, with an O_2 saturation of 95% and adequate respirations. Upon questioning, the RN caring for the patient stated that the prior PCA pump was malfunctioning. She got another PCA pump and reprogrammed it but did not have another RN verify that she did reprogram the replacement pump properly.*

Authority reports also illustrate several reasons why physiologic monitoring may be desirable during PCA. Respiratory depression is likely to occur when one or more medications (e.g., other central nervous system depressants or other opioids by other routes of administration) are intentionally or inadvertently given to a patient who is also receiving an opioid via a PCA pump. Reports also reveal programming errors that were not detected despite a double check by another nurse or during two shifts. Two reports illustrate how monitoring helped alert clinicians in time to resuscitate patients with naloxone.

> *A code was called for patient who was not breathing. Patient was found being assisted with her respirations with bag-valve-mask ventilation by respiratory therapy techs. She was unresponsive and not breathing adequately. She was given large amounts of sedation throughout the day. From 0800 to 1600, the patient had received 200 mcg IV fentaNYL via PCA pump; she also received, at 1200, 30 mg of po oxycodone SR (sustained release). Then at 1700 she received 5 mg Dilaudid IV push. At 1800, a code was called for respiratory arrest, and the patient required transfer to ICU after for monitoring. She had been reversed and recovered with the use of IV Narcan.*

A patient was admitted after an automobile accident. The patient went to OR. An order for Dilaudid 1 mg IV every 4 hours as needed for pain and oxycodone 12 mg PO BID x 6 doses was made at 1700 post-operatively. The patient was agitated and had pinpoint pupils. An order to d/c [discontinue] the PCA was made at 1900 and it was to be started the next am. At 2000, Narcan 0.5 mg IV was to be given and repeated as needed to reverse narcotic effects as per order written in the chart. After Narcan was given, the patient was much more oriented and alert.

Patient is on a PCA and I also gave Percocet in the morning for pain. No other narcotics should have been given with the morphine PCA.

Dilaudid PCA programmed incorrectly by RN: drug concentration entered as 0.1 mg/ml instead of the actual 1 mg/ml. As a result of this error, the patient received more drug than intended over an 8-hour period before the error was detected. This error was not detected as part of the double-checks performed at initial pump setup or change of shift. Patient became symptomatic and required Narcan and supplemental oxygen. The patient did not require transfer to a higher level of care.

The patient had a PCA morphine infusing, 0.2 mg patient bolus was ordered and 2 mg patient bolus was being infused. Pharmacy was called to double check concentration and physician assistant was notified of error. Error went through two shift changes.

[A patient with a] known history of sleep apnea on PCA morphine developed respiratory arrest. [The patient was] initially on 2 mcg basal, up to 2.5 mcg when unable to achieve pain control. The patient was then sleeping, and was easy to arouse for 6 hours. Alarm sounded, O_2 saturation low; staff rechecked patient and found her unarouseable; respiratory code called. PCA was stopped; Narcan was given twice with return to 97% saturation.

Patient on PCA post total knee arthroplasty. Noted to have snoring respirations, low pulse oximetry, somnolent. Given Narcan 0.2 mg IVP, more alert, responds to questions, pulse ox returned to 97%.

FACTORS THAT CONTRIBUTE TO ERRORS WITH PCA THERAPY

Improper Patient Selection

An important safety feature with demand PCA (PCA therapy without a basal rate) is that the patient delivers each dose. For this reason, candidates for PCA should have the mental alertness and cognitive ability to manage their pain and communicate their pain level to their caregiver. However, the benefits of PCA have led some healthcare providers to extend its use to less-than-ideal candidates (e.g., young children, confused elderly patients). Oversedation also has occurred in less-than-ideal candidates who are at risk for respiratory depression because of comorbid conditions such as obesity, asthma, or sleep apnea or use of concurrent drugs that potentiate opioids. However, even when these factors are identified and considered, patients respond to opioids in different ways, and what is a safe dose for most patients can cause dangerous reactions in a small percentage of the population.[6]

Prescription Errors

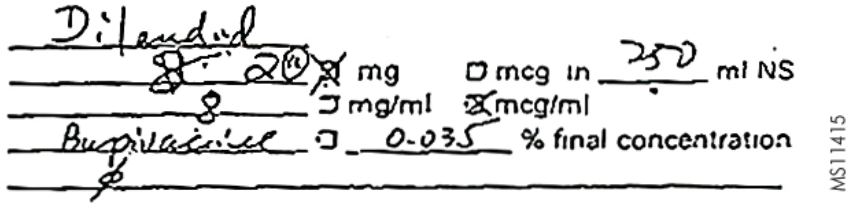
The PCA order itself can be a source of error. Prescribers have made mistakes in converting oral opioid doses to the IV route; most problematic is HYDROmorphone, which has an oral to IV conversion range of 3:1 to 5:1.[7] Errors in selecting an opioid that is not appropriate for the patient, such as prescribing meperidine for individuals with renal impairment, have also been made. Occasionally, one opioid has been prescribed, but the dose has been for a different opioid.[6]

Even with correct PCA orders, clinicians have been known to miscommunicate orders, sometimes leading to serious errors. Concurrent orders for other opioids while PCA is in use have resulted in opioid toxicity. Problems also have occurred when patients are started on PCA therapy but have a documented allergy to the ordered medication. One example includes an order that was given for a "stat" dose of morphine, but the patient had a documented allergy to this drug. Fortunately, a pharmacist caught the error and contacted the physician, but not before the nurse used the override function to remove morphine from the automated dispensing cabinet and administered the drug to the patient.[6]

Errors have occurred even with the use of facility-defined PCA order forms. In one case reported to the Institute for Safe Medication Practices (ISMP), a 70-year-old patient received a tenfold overdose of HYDROmorphone. A physician prescribed PCA using HYDROmorphone 2 mg in 250 mL of normal saline 0.9% injection, creating a concentration of 8 mcg/mL. While writing the order on a preprinted form, he mistakenly entered the 8 mcg/mL concentration on the wrong line. He quickly recognized the mistake, scribbled over the erroneous entry, and wrote the correct value of 2 mg in 250 mL. He then initialed and circled the change.[6] (See Figure.)

The pharmacist misinterpreted the circled initials as a zero and dispensed 20 mg of HYDROmorphone in 250 mL normal saline, yielding a concentration of 80 mcg/mL. The bag was labeled as "20 mg/250 mL NS," but the concentration on the order was entered as "8 mcg/mL." Before administration, two nurses checked the bag using the original order, but they only verified the labeled

Figure. Patient-Controlled Analgesic Order



Circled orders on patient-controlled analgesic order caused 2 mg to be interpreted as 20 mg, which is a concentration that is 10 times greater than intended.

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concentration, and the error was not noticed because the concentrations on the order form and on the mislabeled bag were the same. Later, the night nurse found the error while checking the bag against the original entire order.[6]

Drug Product Mix-Ups

Some opioids used for PCA have similar names and packaging, which has led to drug selection errors. Errors have occurred when prefilled vials of meperidine and morphine have been packaged in similar-looking boxes. Morphine is available in prefilled vials in two concentrations, but the packaging may not allow quick differentiation of the strengths.[6]

Pharmacy-applied labels may look similar on extemporaneously prepared syringes or bags. Since opioids are typically in unit stock, when a new order is written, the nurse sees the order and takes the medication out of the automated dispensing cabinet, frequently with no independent double check. These errors are rarely detected and can lead to significant overdoses.[6]

Name similarities also have led to inadvertent mix-ups between morphine and HYDROmorphone or the mistaken belief that HYDROmorphone is the generic name for morphine. Thirty-two percent of the opioid look-alike-name events reported to the Authority have involved these two drugs. Contributing factors include the fact that both drugs are available in prefilled syringes in concentrations of 1 mg/mL, 2 mg/mL, and 4 mg/mL. As the estimated relative potency of IV HYDROmorphone to morphine is 7.5:1, these mix-ups can easily be fatal.[7]

Patient harm has occurred with mix-ups between other pairs of opioids. In one report to ISMP, a pharmacist drew 50 mg of 10 mg/mL HYDROmorphone from a 5 mL ampule to prepare two epidural PCA orders for 500 mcg of 50 mcg/mL fentaNYL. As a result, two women received opioid overdoses while in labor, and they and their babies developed respiratory difficulties.[6]

PCA by Proxy

Patients may be harmed even if the pump's programming matches the medication order. The effects of opioids may be difficult for caregivers to anticipate: a dose that is sufficient for one patient may oversedate another. Reports also indicate that PCA pump patients have received dangerous and even lethal amounts of opioids when family members or clinicians activated the pump's delivery request button on the patient's behalf (i.e., PCA by proxy).

It is essential, therefore, that clinicians be aware that allowing anyone other than the patient to press the delivery request button is a clear contraindication of PCA therapy and has been strongly warned against by the Authority, ECRI Institute, ISMP, and the Joint Commission.[5,8-10]

RISK REDUCTION STRATEGIES

Reducing Error through Standardized Protocols

One way to minimize adverse events and medication errors with opioid PCA is through the use of standardized protocols.[1] Some facilities have adopted facility-wide protocols for programming PCA pumps. The protocols may include standardized drugs, concentrations, and dosing regimens for typical patient characteristics—for example, protocols labeled "Morphine Post-Op" for standard postoperative pain control or "Morphine, Opioid-Tolerant" for patients who require higher doses of drug to achieve adequate pain relief. Dosing protocols are implemented in the form of either a preprinted order sheet or a preset list in an order entry system.

Using standardized protocols reduces medication errors by limiting the number of choices a physician needs to make when prescribing (e.g., deciding between a 1 mg bolus with 5-minute lockout and a 2 mg bolus with 10-minute lockout) and by reducing transcription and programming errors related to hard-to-read orders. Hospitals can also use dosing protocols to standardize on one or a few concentrations of each drug, reducing the likelihood of medication errors due to selecting the wrong-drug concentration when obtaining a drug vial or entering the concentration into the pump. Many of the risk reduction strategies presented in the September 2010 *Pennsylvania Patient Safety Advisory* article "Adverse Events with HYDROmorphone: How Preventable Are They?" are also applicable.[7]

Monitoring during PCA

The primary concern with opioid oversedation is respiratory depression and even respiratory arrest. The usual approach to minimizing this risk is to have nursing periodically assess patients on PCA. In addition, pain scores are crucial, because

pain is recognized as the "fifth vital sign" and is the therapeutic monitoring parameter to determine dose adjustments (either increase or decrease). ISMP has noted that the common practice of assessing the patient while interacting with him or her is inadequate since an overly sedated patient can be aroused and respond to questions but will fall back into oversedation when the nurse leaves. Accordingly, ISMP recommends observing the patient unobtrusively and noting both respiratory rate and depth of respiration in the absence of any stimulus.[11]

Continuous monitoring is another tool to reduce the risk of oversedation. Pulse oximetry is ubiquitous, easy to use, and relatively inexpensive. A recent study using continuous pulse oximetry monitoring in an orthopedic unit (where patients frequently receive PCA therapy and are not typically connected to physiologic monitoring) concluded that it resulted in reduced need for rescues and intensive care unit transfers.[12] Pulse oximetry is also recommended for selected patients receiving epidural or spinal opioids.[13]

However, while useful, pulse oximetry does not measure ventilation. Since oxygen saturation is a lagging indicator of respiration, pulse oximetry may not indicate a problem early enough for effective intervention. Pulse oximetry is even more problematic for patients who are receiving supplemental oxygen, since they may be adequately oxygenated even with dangerously depressed ventilation. Capnography, or end-tidal carbon dioxide monitoring, allows clinicians to track several indicators, but for purposes of PCA it is primarily used as a reliable monitor for respiratory rate, including apneic episodes. The Anesthesia Patient Safety Foundation (APSF) advocates monitoring both oxygenation and ventilation in all patients receiving PCA.[14] However, APSF also recognizes that universal monitoring will not be implemented immediately and therefore suggests using available monitors for the highest risk patients on PCA—in particular those with obstructive sleep apnea—in the short-term.

At an October 2010 infusion device summit cosponsored by the Association for the Advancement of Medical Instrumentation and FDA, the Veterans Health Administration stated that PCA pumps with an *integrated* end tidal carbon dioxide monitor could have prevented 60% of adverse events identified in 69 root cause analyses related to PCA pumps.[15] In addition to alarming, an integrated monitor would halt further opioid delivery by deactivating the pump.

Special Precautions

Healthcare facilities may consider implementing special precautions when administering opioids to patients with PCA pumps, including the following:

1. Limit choices by minimizing the variety of medications and concentrations used for PCA.[6]
2. Restrict fentaNYL PCA administration to anesthesia or pain management team members only.[6]
3. When available use "smart" PCA pumps that can alert clinicians to potential programming errors.[6]
4. It is desirable to match the sequence of information that appears on PCA medication labels and order sets with the sequence of information that must be entered into the PCA pump.[6]
5. Drug names are less likely to be confused if tall man lettering is used (e.g., HYDROmorphone).[5]
6. Patients must be cognitively, physically, and psychologically capable of understanding the concepts of PCA.[10]
7. Clearly define a manual *independent* double-check process for clinicians to follow when verifying PCA medications, pump settings via a confirmation screen, the patient, and line attachments.[6]
8. If a patient is not responding to PCA doses, consider the possibility of an error, especially before administering a bolus dose. In particular, independently double-check the drug, concentration, pump setting, and line attachment.[6]
9. Ensure that oxygen and naloxone are readily available where opioids are administered.[2]
10. Educate patients about the proper use of PCA (e.g., during a preoperative testing visit) before initiation when patients are not too groggy to understand.[6]
11. Warn family members and visitors about the danger of PCA by proxy.[6]
12. When possible, continuously monitor patients at risk for respiratory depression (e.g., patients with comorbid conditions or who are receiving concurrent drugs that potentiate opioids).[13,14]

CONCLUSION

PCA therapy is an effective way to provide pain management. However, reports to the Authority illustrate the multiple ways that errors with PCA happen frequently, sometimes with tragic consequences. Although smart infusion pumps can help detect medication errors, and patient monitoring can detect the results of errors, clinicians should nevertheless question orders for drugs or doses that are illegible or appear unsafe, ensure that the correct concentration has been selected, request independent double checks of pump programming, use proper patient identification techniques, and periodically assess patient vital signs and level of sedation.

Error-reduction strategies for PCA therapy should include a balanced approach of practice-related, system-related, product-related, and device-related efforts. By embracing proven prevention strategies, healthcare facilities can help reduce the risks associated with this technology and improve patient safety.

NOTES

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Central-Line-Associated Bloodstream Infection: Comprehensive, Data-Driven Prevention

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ABSTRACT

Central venous catheters provide necessary vascular access; however, their use places patients at risk for infection. Central-line-associated bloodstream infection occurs when there are lapses in care in insertion and maintenance. It is essential that a comprehensive infection prevention program be data driven. During calendar year 2010, of Pennsylvania acute care facilities that had submitted central venous catheter insertion dates to the National Healthcare Safety Network, 71.7% reported that central-line-associated bloodstream infections occurred more than five days after insertion. Biofilm formation in the internal lumen and subsequent late onset of bacteremia (after five days) may signify failure in central line maintenance practices. Pennsylvania's data suggests that healthcare facilities need to focus greater attention on catheter maintenance, in addition to complying with best practices during insertion. (Pa Patient Saf Advis 2011 Sep;8[3]:100-4.)

INTRODUCTION

Central venous catheters (CVC) provide necessary access to the bloodstream; however, their use places patients at risk for central-line-associated bloodstream infection (CLABSI).[1] The two phases, insertion and maintenance, of CVC life and associated CLABSI prevention strategies may challenge infection preventionists when assigning resources to the CVC phase that is causing suboptimal CLABSI rates. A survey of Society of Healthcare Epidemiology of America (SHEA) members found that hospital epidemiology and infection control departments experienced an increase in responsibilities and scope, while in many instances resources were below levels recommended by expert panels in the peer-reviewed literature.[2] Designing systems for preventing CLABSI and auditing compliance with best practices can be daunting without appropriate resources. Data interpretation can help in the design of effective CLABSI prevention programs and prove to be an ally when resources are not available, are not allocated appropriately, or are underutilized. Pennsylvania Patient Safety Authority analysts have captured data that may help determine whether an institution should focus resources on a specific phase of CVC life to prevent CLABSI.

BACKGROUND

There are two types of CVC: short-term and long-term. Short-term catheters are commonly used in acute care or emergent settings and dwell for 10 days or less. Long-term catheters typically remain in place for more than 10 days.[3] Long-term catheters usually contain implanted cuffs and include devices like ports, making them more complex than short-term catheters. Peripherally inserted central catheters (PICCs) have traditionally been considered long-term devices but are becoming more prevalent in acute care settings. Data collected from outpatient and inpatient studies suggests that the risk for infection associated with PICC use is similar to that for cuffed or tunneled catheter use.[3]

The common risk factor for infection among CVC types is catheter dwell time; the longer the dwell time and the greater the use, the higher the risk for infection. Mermel and Maki analyzed the pooled data from four prospective studies that noted the outcomes of 988 Swan-Ganz catheters and concluded that Swan-Ganz catheters, because of infection risk, should be short-term lines, used for no longer than four days except in extenuating circumstances.[4]

Microbes can be introduced into the patient from the patient's skin, the environment, or healthcare workers' hands during initial CVC insertion or at any point during use of the CVC. Introduction of organisms into or onto the CVC can precipitate biofilm formation. Microbial biofilm develops when microorganisms irreversibly adhere to and form a structural matrix on a surface.[5] CVC surfaces are at risk for biofilm formation wherever they are in a resource-sustainable environment. CVC surfaces come in contact with such an environment when the patient's blood contacts the exterior surface (extraluminal) or the interior channel (intraluminal) of the catheter that is used to administer fluids, medications, blood, or other intravascular therapies. Bloodstream infections related to long-term CVC use are almost always a result of intraluminal biofilm development.[6,7] Examining how, when, and where biofilm forms can provide insight into CLABSI prevention strategies at both phases of CVC life.

CLABSI PREVENTION: INSERTION AND MAINTENANCE

CLABSI may occur as a result of lapses in care in insertion or maintenance; therefore infection prevention strategies focus on these areas. Lapses in care surrounding insertion happen over a short period, from seconds to hours, setting up an environment

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for inoculation with bacteria and the potential for conditions that aid extraluminal biofilm formation.[5] Opportunities for failure in the maintenance phase are numerous and have days to months to precipitate intraluminal-sourced CLABSI.[6,7] For example, in the pediatric population, McKee alludes to maintenance failures by stating that improving practices for central line insertion leads to a reduction in CLABSI, but not its elimination.[8] If proper insertion is the foundation of a strong CLABSI prevention program, then solid maintenance practices are essential to protect patients from infection.

Insertion

The intensive care unit (ICU) project of the Michigan Health and Hospital Association (MHA) Keystone Center for Patient Safety and Quality, funded by the Agency for Healthcare Research and Quality (AHRQ), was able to achieve impressive results with relatively simple interventions. The interventions included the use of an insertion checklist, hand hygiene, chlorhexidine for skin preparation, appropriate site selection, maximal barriers, daily review of line necessity, and a maintenance protocol. During the project, participants were able to maintain very low infection rates for extended periods.[9] Many CLABSI prevention programs have been modeled after this study, using the insertion protocol, insertion checklist, and daily goal sheets. These selected interventions are relatively inexpensive and simple to implement, but they focus on CVC insertion. Many regulatory bodies now require compliance with these practices, heavily weighting the insertion phase of CVC care. Since January 2010, the Joint Commission has required hospitals to use a standardized supply kit or cart, a catheter checklist, and a standard protocol for insertion.[10] These insertion requirements are the foundation of CLABSI prevention but do not constitute a complete prevention program.

Maintenance

Insertion is a quick procedure performed by a small group of providers that must adhere to a proven set of best practices. Maintenance of the line occurs over many hours to months and involves a host of individuals (e.g., nurses, physicians, caregivers, patients, and families), all of whom have a hand in causing or preventing the development of CLABSI. Practices that limit the introduction of organisms into the CVC have been a focus of CLABSI prevention, specifically when the catheter is accessed by the healthcare professional. Failure to disinfect hubs and caps, for example, can lead to the development of intraluminal biofilm, which may lead to infection. Microbial biofilms on the intraluminal surface originate from microorganisms transported through contaminated injection ports, needleless connectors, stopcocks, and catheter hubs.[11] The CVC hub, needleless cap, and intraluminal surfaces of CVCs are a potential source of CLABSI.[7] Safdar and Maki report that after changing CVC insertion protocols in an ICU to chlorhexidine (CHG) skin antisepsis and a CHG dressing, CLABSI shifted from extraluminal sources to intraluminal sources.[12] Extraluminal contamination can be minimized if staff performs adequate skin antisepsis and applies an occlusive dressing including a CHG delivery method (sponge or other product).

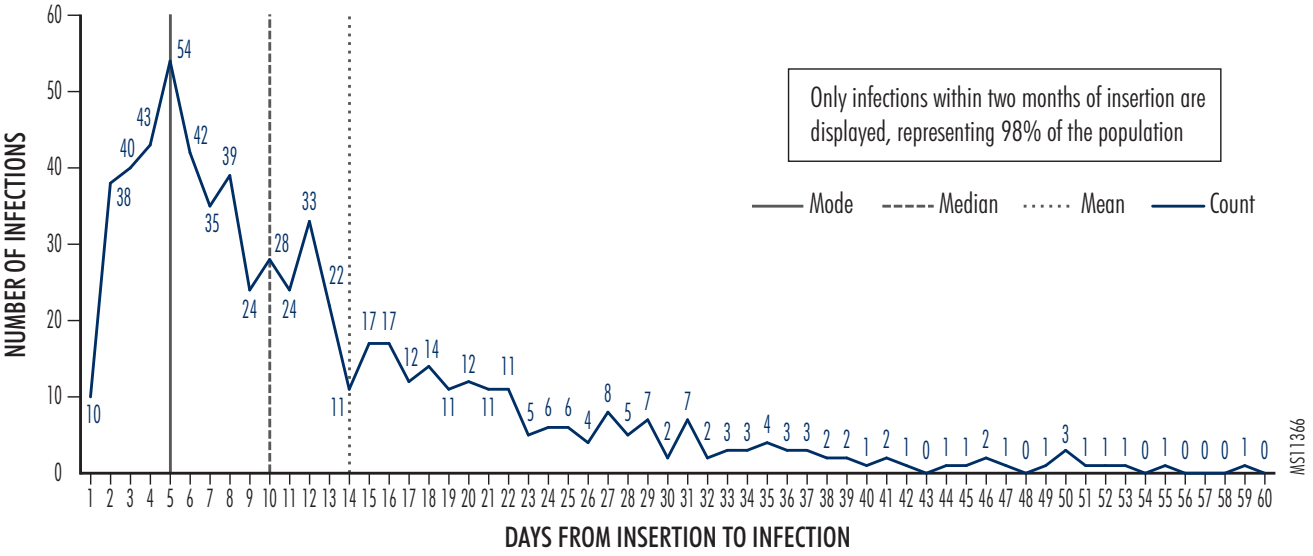
Maintenance of the CVC is essential for building a program that is resistant to the late development of CLABSI. Opportunities for intraluminal contamination are more frequent after the line is in use. During a root-cause analysis conducted to identify sources of CLABSI in Canadian pediatric ICUs, investigators found several causal factors, including positive pressure needleless caps on PICC s and an excessive number of ports on infusion systems. In addition, they noticed inconsistent practice, line necessity based on limited alternatives for intravenous access, and inadequate monitoring, all of which contributed to development of CLABSI. [13] "There are many procedures, many steps, and many personnel that are involved in the placement, care and maintenance of central venous catheters,"[14] said Neil Fishman, MD, past president of SHEA.

How healthcare providers interact with the CVC has direct impact on care failures experienced by the patient. For example if a caregiver does not thoroughly disinfect the hub and needleless connector of a CVC with an antiseptic, organisms could be injected into the CVC and precipitate the formation of biofilm.[15] Ryder notes that the internal lumen can be the primary source of bacteremia in short-term catheters as early as day 5 postinsertion.[6] Causal or preventative opportunities begin the minute the decision is made to place a central line in a patient.

METHODS

Using fields readily available in the NHSN data analytics function tab, Authority analysts queried the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) database to determine the date of infection event from the documented date of insertion for CVCs in Pennsylvania's acute care facilities from January through December 2010, as of March 22, 2011. Date of CVC insertion and date of infection event were the two fields chosen to isolate data related to the determination of early- versus late-onset CLABSI. It is important to note that the date of insertion field in the NHSN reporting system is not a mandatory field. Analysts excluded events when insertion-to-event times were less than one day. Analysts also excluded events with blank fields, missing data, or dates in reverse order. The final sample size included 653 events. Authority analysts have chosen a cut point after day 5 that would most likely indicate intraluminal biofilm formation caused by maintenance failures.[6]

Figure 1. Time Distribution of CLABSI: Pennsylvania NHSN Facilities 2010



RESULTS

According to Authority analysis of 2010 event reports, the majority of CLABSIs occurring in Pennsylvania acute care facilities have been late in onset: of the 653 central-line-related infection events reported to NHSN in 2010 by Pennsylvania facilities, 468 (71.7%) occurred after day five (see Figure 1). Pennsylvania facilities may need to direct their resources toward maintaining CVCs.

Figure 2 represents 104 Pennsylvania facilities that reported data for both CLABSI and time of CVC insertion in 2010. Individual facilities were listed based on total number of infections, then numbered and deidentified. This distribution of infection implicates maintenance as the phase in which CLABSI most likely is developed.

DISCUSSION

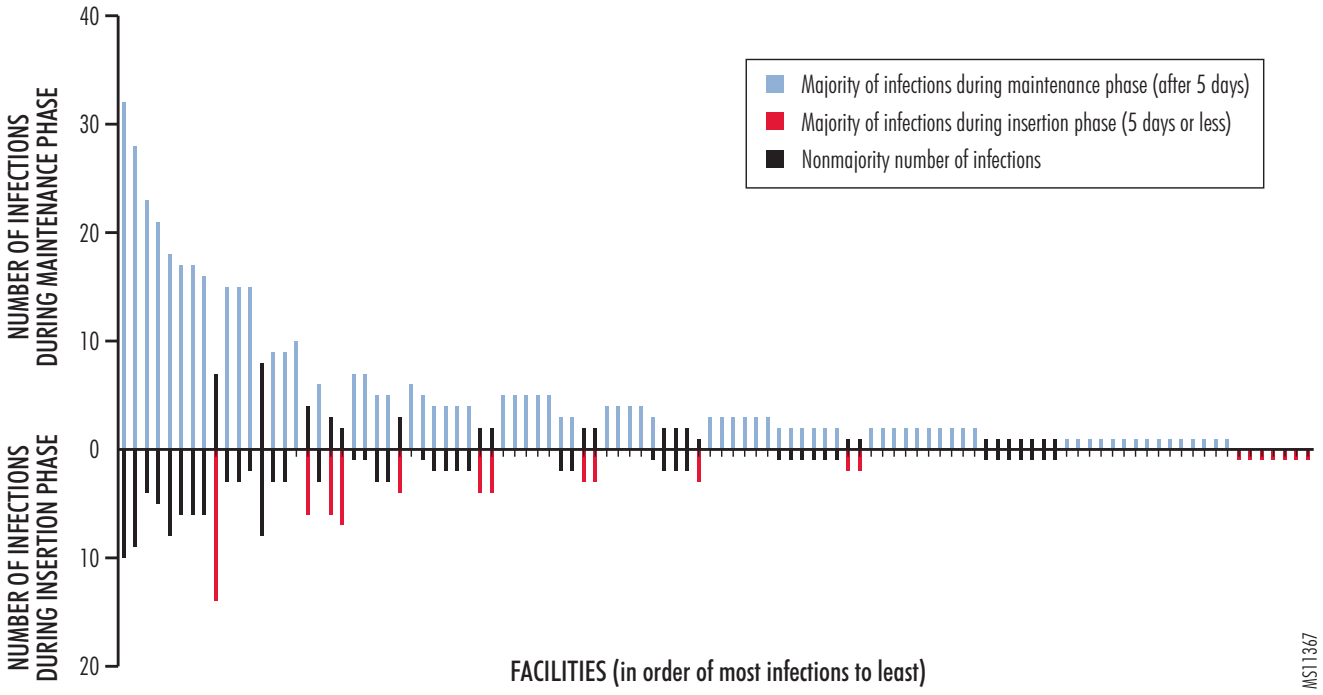
Data points for catheter dwell time to infection event, combined with published time lines on pathogenesis of intraluminal versus extraluminal biofilm formation, can help allocate resources that focus on corrective actions. Data-driven decisions, data-based interventions, and corrective actions can be directed at the specific time at which CLABSI develops. Utilizing time-to-infection data will have a significant effect on a facility's CLABSI prevention program, especially if resources are scarce. If there are more breaches in compliance with insertion practices, the incidence of infection will increase early in the life of the CVC. If infections are occurring later in the life of the CVC, breeches in the care and maintenance of CVCs may be implicated.

The MHA project allocated significant resources and funds to a CLABSI prevention infrastructure (AHRQ financially supported the majority of the project). In addition to the recommended evidence-based procedures for CVC insertion and daily goal sheets, the MHA study implemented a comprehensive program that addressed a culture of safety in the units where data was collected. Pronovost et al. note the importance of an infrastructure used to monitor CLABSI rates and the use of a staff of hospital-based infection preventionists for this study. They note that similar infrastructure does not exist for most other issues related to patient safety.[9] Despite the possibility of infrastructure differences, each facility in Pennsylvania can use its own data and determine which way it believes the scale is tipped. If the majority of infections occur before or on day 5, insertion bundle compliance may be worth auditing more closely; conversely, if the majority of infections occur after five days postinsertion, perhaps care and maintenance practices should be monitored. When a facility knows where to allocate resources, infection prevention measures can be implemented to effectively reduce infection rates.

The following links from CDC provide information on isolating facility-specific data from NHSN for analysis:

— Quick Tips: Run and Modify Output http://www.cdc.gov/nhsn/PDFs/AnalysisBasics.pdf

Figure 2. Time to CLABSI as Reported by Pennsylvania NHSN Facilities in 2010: Insertion versus Maintenance



— NHSN Analysis: Advanced Features & Terminology http://www.cdc.gov/nhsn/wc_Analysis_Advan_Features.html

— NHSN Analysis: Advanced Features & Terminology: Training Session for NHSN Hospitals, December 19, 2006 http://www.cdc.gov/nhsn/PDFs/slides/NHSN_trainingDec19PAandMAAnalysis.pdf

To help Pennsylvania facilities assess their overall CLABSI prevention programs, the Authority maintains a CLABSI prevention toolkit, available at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/clabsi/Pages/home.aspx.

CONCLUSION

The CLABSI data presented here by Authority analysts is a glimpse into the meaningful use of event data collected by dedicated Pennsylvania infection preventionists and others. Given the available sample size, the Authority believes that facilities are putting time-to-infection data to use. Infection preventionists have invested a great deal of effort uploading infection-related event data. All infection types can benefit from like analysis and interpretation. Event reporting is mandatory, and reported data is a powerful assessment tool that needs to be continually used by facility-level infection preventionists and all disciplines for the safety of Pennsylvania patients. The effectiveness of intervention and applied resources is compelling. Pennsylvania's data suggests that healthcare facilities need to focus greater attention on catheter maintenance, in addition to complying with best practices during insertion.

NOTES

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Physiologic Alarm Management

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In response to an inquiry, analysts from the Pennsylvania Patient Safety Authority queried the Authority's reporting system database for event reports of patient deaths related to physiologic alarm monitoring from June 2004 through December 2010. Using the keywords *alarm, monitor, ECG* [electrocardiogram], *telemetry, pulse-ox, and defibrillator* in combination with *intensive care unit* or *telemetry unit*, where death was mentioned or harm score signified death (i.e., "I"), staff identified 187 reports. Thirty-five of the event reports indicated that patient death was related to some aspect of physiologic alarm management. The 35 event reports referenced the following types of monitoring equipment:

- Blood pressure machine (*n* =1)
- Bilevel positive airway pressure machines (*n* = 2)
- Ventilators (*n* = 4)
- Telemetry monitors (*n* = 28)

The reports were categorized as either equipment (*n* = 4) or human (*n* = 31) failures (see Table 1).

HUMAN FAILURE

Equipment Not Connected

Forty-five percent (*n* = 14) of the human failures were related to disconnected monitoring equipment. Eight of the cases concerned patients found in rooms with disconnected equipment, including the following:

> *The nurse went in to check on the patient. [Patient was] put back on monitor, patient was in asystole. A code was called, [and staff were] unable to resuscitate patient . . .*
>
> *[Elderly] female brought to emergency department [ED] . . . She was inadvertently off telemetry when she was found unresponsive and expired . . .*
>
> *A patient was admitted through the ED . . . Admission orders include telemetry monitoring–nurse entered room and found patient unresponsive. A code was called and the patient was transferred to the intensive care unit. Later, [the patient] coded again and expired. . . . Discovered that telemetry monitoring was never initiated on admission to floor . . .*
>
> *A nurse responded to the patient's IV [intravenous] pump alarm and found the patient unresponsive and pulseless. Cardiac leads were found to be disconnected from the monitor cable. The physician was immediately notified . . . the patient was pronounced dead.*

Physiologic monitoring systems generate visual and audible alarm signals based on changes in patient physiologic conditions that exceed established alarm criteria for a specific patient or a particular patient population.[1] When monitoring equipment disconnects, or is left unconnected from the patient, important safety signals are not generated.

Monitoring Equipment during Diagnostic Testing

Six of the reports concerned patients who had been transported out of the unit for diagnostic tests, including the following:

> *The patient [required transfer to a higher level of] care. While preparing for transfer, the patient was discharged from the stationary telemetry, [so the patient could] be placed on a portable monitor. Prior to placement of the portable monitor [after approximately*

Table 1. Patient Deaths Related to Physiologic Alarm Monitoring, Human versus Equipment Failures, Reported to the Authority, June 2004 through December 2010

FAILURE	NUMBER
STAFF	
Equipment not connected	14
Monitoring equipment during diagnostic testing	6
Inadequate response to alarms	6
Alarms silenced	4
Unknown	1
Total	**31**
EQUIPMENT	
Home equipment used in hospital without alarm capability	2
Manufacturer default setting caused battery to power down	1
Possible ventilator unit failure	1
Total	**4**

12 minutes], the patient was found unresponsive. . . . The patient was resuscitated and transferred and the patient expired . . .

The patient was received in CT [computed tomography] suite and placed on the scanner. No monitoring of vital signs was performed in radiology; the patient had been on a telemetry unit. When the patient was placed back in the radiology waiting area, the family alerted staff to the absence of respirations. Unsuccessful resuscitation efforts . . .

The patient was taken to radiology for an x-ray. Upon return to the ED, the patient was not placed [back on] the cardiac monitor. Approximately twenty minutes [later], the patient was found unresponsive and pulseless . . . the patient expired.

A telemetry patient was transported unaccompanied by nursing to CT [computed tomography], contrary to unit policy. After the CT [scan] was completed the patient was awaiting transport and was discovered unresponsive . . .

A key function of monitoring systems is to alert appropriate staff to a change in patient condition so that staff can promptly intervene with the appropriate care.[1] When patients are transported without monitoring systems, or when they are left unmonitored before, during, or after diagnostic tests, staff is deprived of both audible and visual cues that would alert them to deterioration in patient status. While it is not possible to know with certainty that these patients would have survived if staff had received timely alarm cues, the event reports do illustrate the dangers of patient transport without necessary monitoring equipment.

Inadequate Response to Alarms

Six event reports concerned inadequate response to the physiologic alarm. In four events, the nurse assigned to the patient was busy caring for another patient and did not or could not respond to the alarm in a timely manner. In one case, a patient walked off the telemetry unit and entered an unmonitored area of the facility. In another case, a team of healthcare providers was in the room when the ventilator alarm sounded and yet did not appear to respond quickly to the alarm, for reasons that were not clarified within the event report. However, the report did recommend training to avoid "desensitization to alarms."

Alarms Silenced

Alarms were silenced in four events reported to the Authority. Three events involved telemetry alarms. In one event, a telemetry technician silenced the alarm of a patient with metastatic disease. In the second event, the floor nurse had silenced the telemetry alarm in the room and was relying solely on the telemetry technician (who was performing additional duties while watching the monitors) to relay alarm information. The third event involved a patient in the critical care unit, whose nurse silenced the telemetry alarms. A resident found the patient unresponsive approximately 40 minutes after the nurse documented her assessment. Finally, a noninvasive blood pressure monitoring system had been silenced and the patient was found hypotensive and hypothermic; resuscitation efforts were unsuccessful.

EQUIPMENT FAILURES

Four of the events reported to the Authority were related to equipment failures. In two of the cases, patients came to the hospital with bilevel positive airway pressure machines that did not have alarm capabilities. Both patients' equipment failed and both were found after telemetry technicians alerted staff to abnormal heart rates. In the third case, a default setting by the telemetry manufacturer to conserve battery power caused telemetry units to automatically power down after ten minutes of nonusable waveform. In this instance, the battery needed to be manually removed and replaced to restart accurate telemetry monitoring. The

fourth case concerned a possible ventilator unit failure.

FACILITY SPECIFIED CONTRIBUTING FACTOR DATA

The Pennsylvania facilities reported 102 potential contributing factors associated with the 35 events (see Table 2). The categories with the highest number of factors were communication problems between providers (*n* = 14; 13.7%), workplace distraction and interruptions (*n* = 14; 13.7%), procedures not followed (*n* = 12; 11.8%), and training issues (*n* = 8; 7.8%).

The Authority previously published information on physiologic alarm management. Several risk mitigation strategies were included in the publication, all of which remain important in light of these recent findings:[1]

- Placing slave displays and alarm enunciators in strategic locations throughout a telemetry care area
- Developing a protocol for setting the volume level of an alarm to higher than the minimum audible level that can be heard in a typical environmental noise level for given care area (the volume level setting will be specific to the noise level for each healthcare facility's care area environment)
- Developing standardized practices for periodic ECG-electrode and lead-set inspection and replacement and proper electrode-site skin preparation
- Developing a protocol that requires prompt response for all alarm conditions (low-, medium-, high-priority alarms)
- Developing a protocol that establishes alarm limit default settings based on a particular patient population in a given care area
- Developing protocols that establish criteria for when and how to adjust alarm default limits per patient condition

Table 2: Potential Contributing Factors to Patient Deaths Related to Physiologic Alarm Monitoring Reported to the Authority, June 2004 through December 2010

POTENTIAL CONTRIBUTING FACTOR	NUMBER
Team	
Communication problems between providers	14
Shift change	4
Cross-coverage situation	2
Unplanned workload increase	2
Total	**22**
Work Environment	
Distractions/interruptions	14
Limited access to patient information	3
High noise level	2
Equipment availability	2
Total	**21**
Task	
Training issues	8
Cardiac/respiratory arrest situation	7
Emergency situation	2
Inexperienced staff	1
Order-entry system problem	1
Total	**19**
Staff	
Inadequate system for covering patient care	3
Issues related to proficiency	3
Use of float staff	2
Insufficient staffing	2
Total	**10**
Patient Characteristics	
Patient compliance	7
Patient understanding	2
Total	**9**
Organizational/Management	
Procedures not followed	12
Unclear policies and procedures	5
Inadequate bed availability	2
Lack of policies and procedures	1
Presence of boarding patients	1
Total	**21**

— Developing protocols to delineate responsibility for primary alarm response and to establish tiers of backup alarm coverage

Alarm management is a critical issue for all Pennsylvania facilities. The 35 patient deaths and 102 associated potential contributing factors that were reported to the Authority illustrate a wide variety of reasons for alarm management failure and suggest focus areas for improved alarm management strategies. Basic staff interventions (i.e., education regarding physiologic alarms, clear lines of responsibility for responding to alarms, discouraging silenced alarms) can be paired with equipment management interventions (i.e., scheduled equipment testing, replacement, and battery change; alarm audibility testing; policies for alarm default limits) for maximum impact. Facilities can also monitor for alarm desensitization in both primary care staff and remote monitoring technicians.

NOTE

1. Alarm interventions during medical telemetry monitoring: a failure mode and effects analysis [online]. Pa Patient Saf Advis 2008 Mar [cited 2011 Aug 3]. Available from Internet: http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2008/mar5(suppl_rev)/Pages/mar5(supplrev).aspx.

Quarterly Update: What Might Be the Impact of Using Evidence-Based Best Practices for Preventing Wrong-Site Surgery?

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The mysterious two-year cycle of wrong-site surgery reports continues, with the second lowest quarterly total to date (see Figure). As usual, this quarterly report has been updated to include any belated additions and corrections from previous quarters.

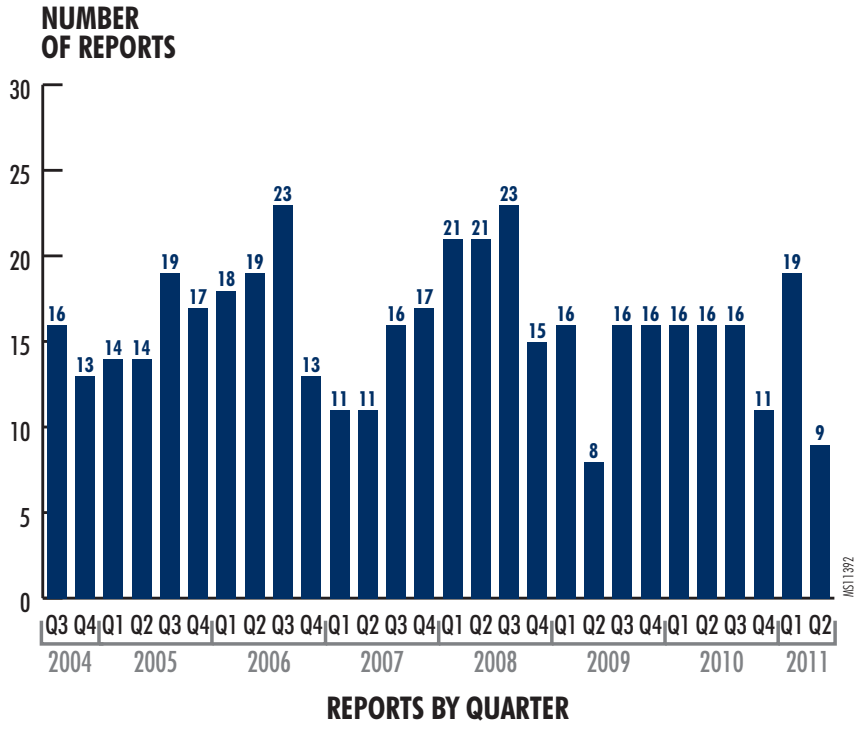
Two near-miss reports submitted to the Pennsylvania Patient Safety Authority exemplify the value of preventive measures. The first, a good catch, highlights the value of the time-out. The second shows how the problems of rationally addressing remote access to the operative site, such as with laparoscopic or endovascular surgery, has been resolved within one facility.

> *A patient's incorrect leg was prepped and draped for surgery. The error was noticed during time-out; no incision was made. The patient's leg was not marked in pre-op. The nurse did not check to ensure leg was marked prior to taking the patient to the OR [operating room]. During the "time out," it was noted that incorrect leg was prepped and draped. The drapes were taken down; the patient's correct leg was prepped and draped. A new time-out was completed and all documents were rechecked.*

> *A patient's surgical consent read "right femoral angiogram." The patient stated we were operating on the left leg. The patient and doctor spoke and signed a new consent for the correct leg. The new consent read "left leg angiogram via right groin approach." The patient, doctor, and a witness agreed and signed the new consent.*

This article examines the possible impact of each previously proposed best practice principle for preventing wrong-site surgery.[1,2] Authority analysts did a subjective analysis of the narratives of the 444 wrong-site surgery reports from June 28, 2004, through June 30, 2011, to identify possible best practice principles for reducing risk suitable for

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



Scan this code with your mobile device's QR Reader to access the Authority's wrong-site surgery prevention toolkit.

each scenario. One or more principles may be effective independently or in combination for each scenario. The narrative was too sparse to give any clues about specific best preventive practices for 13 of the 444 reports, leaving 431 reports that were analyzed further. The results of a subjective analysis of the possibility for each principle to help prevent the wrong-site surgery are presented in the Table. The possibility of multiple principles helping individually or collectively was present for most of the narratives assessed. (A flowchart detailing this subjective analysis is available exclusively on the Authority's website.)

The most common best practice principle considered was the provider (the surgeon doing the procedure or the anesthesiologist doing the block) verifying the information in the documents and the mark with the patient. This was considered a preventive measure when the narrative suggested that the provider had not taken active responsibility before the time-out to ensure that the information that was the basis of the procedure was correct. This scenario was considered possible in 312 of the 431 reports (72%).

The information about the correct site that might have prevented the provider from making a wrong-site error was likely present on the schedule, the history and physical examination, the consent, the office records (on occasion), and/or the preoperative imaging studies (on occasion). Confirming the correct site marking with the patient and initializing the mark is proof of that verification.

Of the remaining 119 narratives, the use of intraoperative imaging verification for location of the target anatomic structure was the next most common best practice principle, considered a possible preventive measure in 53 of the remaining reports. There were very few connections between this best practice principle and the other 20. Overall, 61 of the 431 reports (14%) were considered to possibly benefit from this best practice: 46 wrong-level spinal surgeries, 14 stents placed in the wrong ureter, and 1 resection of the wrong rib. The distribution in the subset of 53 was similar. In the subset, no other best practice principles for preventing wrong-site surgery were identified in 49 of the 53 reports.

Table. Possible Impact of Best Practice Principles for Preventing Wrong-Site Surgery

POSSIBLE IMPACT	BEST PRACTICE PRINCIPLE*	NUMBER OF REPORTS	PERCENTAGE (*N* = 431)
1	6. Provider verifies	312	72%
2	17. All engaged	310	72
3	15. Reference mark	300	70
4	19. Voice concerns	292	68
5	12. Circulator verifies	286	66
6	14. Stop activities	280	65
7	10. Confirm mark	248	58
8	11. Mark with provider's initials	237	55
9	2. Site on history and physical	192	45
10	13. Time out for each procedure	173	40
11	1. Site on schedule	158	37
12	3. Site on consent	151	35
13	16. Active responses	110	26
14	21. Verify with images	61	14
15	18. Provider empowers	59	14
16	5. Access office records	44	10
17	9. Provider resolves discrepancies	26	6
18	20. Address concerns	11	3
19	4. Reconcile discrepancies	9	2
20	7. Ask active questions	8	2
21	8. Two identifiers	6	1
	Other	8	
	Unknown	13	

* See "Identified Best Practices Principles for Preventing Wrong-Site Surgery" in this article.

Consideration of intraoperative imaging verification for location of the correct level for spinal surgery is part of the North American Spine Society Clinical Care Checklist for Safety to Prevent Wrong-Site Surgery (see "Identified Best Practices Principles for Preventing Wrong-Site Surgery").[3] Best practice includes a radiograph after surgical exposure of the operative site, using markers that do not move, with a radiologist's reading, in addition to the surgeon's. Two of the narratives indicated a correct reading from a radiologist after the fact.

Use of the same principles to prevent wrong-side ureteral stenting was supported with evidence in the March 2010 *Pennsylvania Patient Safety Advisory*.[4]

For the remaining 66 narratives, the next most common best practice principles

that were considered as possible preventive measures involved doing a proper time-out (Principles 12 through 20). The best practice principles for a proper time-out were considered for 48 of these remaining narratives. The best practice principles, chronologically, are as follows:

— The circulating nurse verifies the patient's information when bringing the patient into the OR. This verification makes the nurse independently informed about what the physician should be doing during the procedure. Ideally, the other team members are informed by the physician during a preoperative briefing before the final time-out.
— Formal time-outs should be done for each invasive procedure, including preoperative radiological procedures for breast and other cancer procedures, anesthetic blocks, and second procedures under the same anesthetic. The report narratives frequently stated that a time-out had not been done. The need for a formal time-out was considered for 109 wrong-site anesthetic blocks and 3 wrong-site radiological procedures before definitive surgery.
— The members of the team involved in the procedure should bring independent knowledge to the time-out, should be engaged in the time-out, and should speak for the benefit of the patient and provider if their knowledge differs from that of any other member of the team. Engagement means more than witnessing a ritual. Engagement means stopping other activities to focus on the verification of information. It means each team member communicating his or her understanding of the information being verified, not passively supporting another person's understanding. It means addressing concerns.

The most common single practice principle considered for a proper time-out was explicitly referencing the site marking in the prepped and draped surgical field during the time-out, considered in 43 of these remaining 66 narratives.

The addition of considering proper verification of the patient's information by the circulating nurse, in an additional 4 narratives, and empowering team members to speak up identified these 48 remaining narratives for which best practice principles for time-outs might be maximally effective for preventing wrong-site surgery.

Of the remaining 18 narratives, the remaining best practice principles that were considered were the expectation that the appropriately specific information about the operation and the site of the operation would be available for verification on all critical documents, including the operative schedule, the history and physical examination, and the informed consent. If the information is not available from the history and physical examination in the facility's medical record, it should be available from the surgeon's office records. Critical radiology and pathology reports should be available, as should images, where appropriate, for proper verification of all the patient's information by multiple team members before the patient enters the operating room.

Ensuring patient information adequate to inform team members for a proper verification was considered the best practice principle for 13 of the remaining 18 narratives. The need for information from the history and physical examination was considered a common possible source of preventing wrong-site surgery for 12 of the 13 narratives, with information from the office records or consent the possible source for 1.

Only five wrong-site narratives involved unusual situations not covered by the best practice principles that have been identified:

— Two vascular access devices placed in less preferred arteries instead of more preferred veins
— An operation based on an incorrectly dictated pathology report
— A selective abortion with multiple fetuses
— Regrasping an adjacent left-side anatomic structure after localizing the intended right-side anatomic structure

Three other unusual situations were considered additional factors among the 426 patients with one or more identified best practice principles: failure to correctly map a sentinel node, loss of right-left orientation intraoperatively, and incorrect stereotactic settings.

The original analysis by the Authority in 2007 showed that the two basic reasons wrong-site surgery occurs are misinformation in the patient's records and misperception in the operating room.[5]

This subjective analysis of 444 narratives of wrong-site surgery to consider the possible impact of 21 best practice principles to prevent the specific events revealed four areas of focus for preventing these errors and preventing wrong-site surgery. Chronologically, they are as follows:

1. Use best practice principles to ensure specific patient information is available for team members so they can verify all the information necessary to prevent wrong-site surgery before the patient enters the operating room.
2. The provider performing any procedure should engage in the verification of the patient's information with the patient before the patient enters the operating room to ensure an accurate understanding while preparing the patient for the procedure, during the time-out, and during the procedure.
3. Use best practice principles to inform and engage all team members in the time-out process.
4. Use imaging confirmation intraoperatively where recommended, specifically for spinal surgery.

Providers interested in preventing wrong-site surgery may wish to consider the Joint Commission Center for Transforming Healthcare Wrong Site Surgery Project: Reducing the Risk of Wrong Site Surgery.[6]

IDENTIFIED BEST PRACTICES PRINCIPLES FOR PREVENTING WRONG-SITE SURGERY

Except as noted, the evidence base for the following abridged best practices principles was described in the December 2010 *Pennsylvania Patient Safety Advisory*.[1]

Principle 1. Site on schedule. The correct site of the operation should be specified when the procedure is scheduled.

Principle 2. Site on history and physical. The correct operation and site should be noted on the record of the history and physical examination.

Principle 3. Site on consent. The correct operation and site should be specified on the informed consent.

Principle 4. Reconcile discrepancies. Anyone reviewing the schedule, consent, history and physical examination, or reports documenting the diagnosis, should check for discrepancies among all those parts of the patient's record and reconcile any discrepancies with the surgeon when noted.

Principle 5. Access office records. The surgeon should bring copies of supporting information uniquely found in the office records to the surgical facility the day of surgery.

Principle 6. Provider verifies. All information that should be used to support the correct patient, operation, and site, including the patient's or family's verbal understanding, should be verified by the nurse and surgeon before the patient enters the operating room (OR).

Principle 7. Ask active questions. All verbal verification should be done using questions that require an active response of specific information, rather than a passive agreement.

Principle 8. Two identifiers. Patient identification should always require two unique patient identifiers.

Principle 9. Provider resolves discrepancies. Any discrepancies in the information should be resolved by the surgeon, based on primary sources of information, before the patient enters the OR.

Principle 10. Confirm mark. The site should be marked by a healthcare professional familiar with the facility's marking policy, with the accuracy confirmed both by all the relevant information and by an alert patient, or patient surrogate if the patient is a minor or mentally incapacitated.

Principle 11. Mark with provider's initials. The site should be marked by the provider's initials.

Principle 12. Circulator verifies. All information that should be used to support the correct patient, operation, and site, including the patient's or family's verbal understanding, should be verified by the circulating nurse upon taking the patient to the OR.

Principle 13. Time-out for each procedure. Separate formal time-outs should be done for separate procedures, including anesthetic blocks, with the person performing that procedure.

Principle 14. Stop activities. All noncritical activities should stop during the time-out.

Principle 15. Reference mark. The site mark should be visible and referenced in the prepped and draped field during the time-out.

Principle 16. Active responses. Verification of information during the time-out should require an active communication of specific information, rather than a passive agreement, and be verified against the relevant documents.

Principle 17. All engaged. All members of the operating team should verbally verify that their understanding matches the information in the relevant documents.

Principle 18. Provider empowers. The surgeon should specifically encourage operating team members to speak up if concerned during the time-out.

Principle 19. Voice concerns. Operating team members who have concerns should not agree to the information given in the time-out if their concerns have not been addressed.

Principle 20. Address concerns. Any concerns should be resolved by the surgeon, based on primary sources of information, to the satisfaction of all members of the operating team before proceeding.

Principle 21. Verify with images. Verification of spinal level, rib resection level, or ureter to be stented should require radiological confirmation, using a stable marker and readings, by both a radiologist and the surgeon.

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Evidence for "Best Practice" 21

The North American Spine Society Clinical Care Checklist for Safety to Prevent Wrong-Site Surgery includes consideration of an intraoperative radiograph during surgery, after surgical exposure of the operative site, using markers that do not move, to confirm the vertebral level to be operated on. It also includes consideration of radiologist's reading, in addition to the surgeon's reading.[2]

An analysis of wrong-side ureteral stents revealed 20 reports, accounting for 6% of all 357 wrong-site surgery reports submitted to the Pennsylvania Patient Safety Authority as of the end of 2009.[3] Six stents were placed on the wrong side despite specific reference to doing a time-out. The reports suggested that wrong-side ureteral stenting might have occurred because the intervention on the wrong side occurred after the operation had begun, rather than initially, and that the side of the instrumented ureter may have been known only to the surgeon visualizing the landmarks, not to the other members of the OR team, who had limited views of the procedure, if any. A review of the reports showed that the failure to do intraoperative imaging was cited as a contributing factor in one report. Patients were returned to the OR to correct errors documented by intraoperative radiographs on two occasions and, most certainly, by a postoperative computed tomography scan on a third occasion. An error identified by fluoroscopy was corrected midprocedure. The remaining error was detected by the radiography technician. The analysis suggested that urologists should follow the same principles as vertebral surgeons by obtaining an intraoperative imaging study to confirm proper stent placement, with the interpretation documented at the time. Pregnant patients could have ultrasound imaging.[3]

Notes

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Fostering Safety-Conscious Healthcare Providers: A Leadership Initiative

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INTRODUCTION

Patient safety is a national priority[1-3] and a fundamental part of healthcare[4] that healthcare stakeholders address through a range of activities, including government legislation,[5] accreditation programs,[6] quality improvement initiatives,[7] and research literature.[8] Senior leadership is influenced by these activities while shaping and defining a healthcare facilities' patient safety culture and work environment. Senior leadership is central to a patient safety culture that empowers healthcare workers to maximize their performance in the delivery of safe patient care.[9,10] Yet patient safety is not solely the responsibility of senior leadership; it is the responsibility of the entire healthcare facility.

ORGANIZATIONAL EMPOWERMENT

Patient care delivery is an accumulation of multiple individual decisions made by healthcare workers; one wrong decision can create a situation that leads to an adverse event. Although all healthcare workers set out to deliver safe patient care, the amount of control they have over their work plays a pivotal role in the outcome. The commitment of organizations to a patient safety culture empowers employees to make decisions that result in positive patient safety actions.[11,12] Healthcare workers who can function autonomously yet interdependently within a team are more likely to make sound decisions about the patient care they deliver.

Employee empowerment is not a single activity or goal but an organizational attitude and strategy, created by leadership, that values each individual's contribution to the organization.[13,14] This organizational attitude enables teams and individuals within a team to think critically and act on their own initiative, for example, to question actions or situations that threaten the achievement of organizational outcomes, such as the delivery of safe patient care.[13] An individual's control over and responsibility for decision making is at the core of empowerment.[13,14] It has been shown that employees who have more discretion over their work demonstrate improved feelings of confidence in their work, job satisfaction, commitment, and retention.[9,11,13,14]

Developing an atmosphere of employee empowerment depends on the leader's ability to trust and support his or her employees' expertise, skills, and judgment. The leader functions as a facilitator or coach and in this role establishes a model of team work, sets shared goals, and creates an environment that enables individuals within a team to make decisions so the team can arrive at a set of successful outcomes. Employee empowerment requires leaders to share their power and to acknowledge that employees help the organization to achieve its goals.[13,15] This level of employee-leader interaction should to be introduced incrementally.

For the first six months of 2011, Pennsylvania healthcare facilities reported to the Pennsylvania Patient Safety Authority more than 8,000 near-miss events in which the actions of empowered healthcare workers prevented adverse patient events. Each reported event identifies healthcare workers whose attention to detail and ability to make decisions helped keep their patients safe. The following reported event exemplifies a patient safety action that prevented multiple patient adverse events:

> *A technologist discovered problem with calciums [calcium results] on evening shift following PM [preventive maintenance] on daylight shift, prompting her to rerun QC [quality check], which was out of range. Quality check following PM was acceptable. All patient specimens were sent to another lab for testing. The technologist alerted [the physician] that calcium results may be suspect. The technologist notified Urgicare [*sic*] that the original report was incorrect and relayed the correct results. The physician*

CELEBRATE PATIENT SAFETY ATTAINMENT

The Pennsylvania Patient Safety Authority periodically highlights reports of healthcare workers who take exceptional action to avoid patient safety adverse events. There are many lessons to be learned from the everyday successes of healthcare workers who do the right thing at the right time.

In this issue of the *Pennsylvania Patient Safety Advisory*, a lab technician's astute observation and investigative skills, triggered by suspect lab data, identified the root cause of a potential series of incorrect clinical decisions and actions. This one person prevented multiple patients from inadvertently receiving an incorrect treatment.

The Authority would like to hear from Pennsylvania facilities in which someone's actions resulted in the avoidance of a patient safety adverse event. There are several ways to notify the Authority, including through regular reporting in the Authority's Pennsylvania Patient Safety Reporting System, by notifying the facility patient safety officer, or by contacting a regional Authority patient safety liaison.

assured the technologist that no treatment was initiated based on incorrect results. The next morning, a review of results indicated that the reported glucose was also suspect and was corrected. The senior technologist notified staff of correct results for calcium and glucose.

Further details from the report indicate that the analyzer in question was not used for further testing until the next afternoon, after it was serviced. This technologist's insight and actions prevented several patients from being treated incorrectly based on inaccurate lab test results. All healthcare workers have this potential to keep patients safe, but not all may feel empowered to question and investigate unusual work patterns or potentially dangerous patient care situations. How do individuals within a team setting achieve this level of commitment to patient safety? There are no clear-cut answers; however, there is growing consensus that a strong patient safety culture within an organization can lead to the empowerment of healthcare workers, improved patient safety climates, error reductions, and successful implementation of quality improvement initiatives[11,16-19]

EMPOWERMENT OPPORTUNITIES

Organizations with a positive safety culture and climate provide work environments that are fair and just, support collaboration across rank and discipline, and support life-long learning.[11,17,20,21] An example of this model, "just culture," is a structured process that uses a system approach to evaluate adverse and near-miss events. It advocates for the development of a fair and just environment where suspect actions and decisions regarding the delivery of safe patient care can be evaluated and lessons can be learned.[20,22] Knowledge obtained from evaluations of these actions and decisions can inform and improve employee work processes, thereby improving the delivery of safe patient care.

Creating a just culture that empowers employees is a process as individualized as leadership management styles and is influenced by organizational culture, complexity of work tasks, and level of trust between leaders and employees.[11,13] For example, some leaders may feel comfortable allowing employees to make autonomous decisions in just a few situations, while other leaders may identify a broader set of situations in which employees can make autonomous decisions when performing their jobs.

Following are activities that senior leadership can engage in with employees to foster and build a patient safety culture of empowerment:

- Support employees by providing positive feedback, especially in situations that are questionable, such as when employees question or override authority.[13,14,23,24]
- Devote time to listening to employees and seeking their input on and solutions to identified problems.[14,24]
- When talking with or listening to employees, give them full attention, and attend to body language.[24]
- Provide clear expectations to employees; express trust in their ability to make the right decisions.[13,14]
- Follow through on promises.
- On a case-by-case basis, question or change rules that have been shown to be flawed.
- When possible, allow employees to choose their own path and structure their work, so they can achieve good results while getting the job done.[14]
- Adapt work conditions as demands change; use an incremental process.[12-14]
- Vary levels of empowerment based on job responsibilities and tasks.[13,14]
- Celebrate near misses internally with an employee recognition program.[13,14]
- Consider moving to a just culture.[12]
- Invest in teaching and development of employees to foster their expertise.[12-14]
- Facilitate periodic sharing of information and knowledge about the organization that helps employees understand and contribute to the organization's goals and performance.[13,24,25]
- Explicitly tell staff to speak up if concerned.

CONCLUSION

Employee empowerment is an ongoing process that can improve the delivery of safe patient care. The challenge for leaders in creating an atmosphere of empowerment is to change their approach for relating to their employees. This article provides a list of suggested activities that can move an organization toward empowering its employees, which will improve employee engagement in delivering safer patient care.

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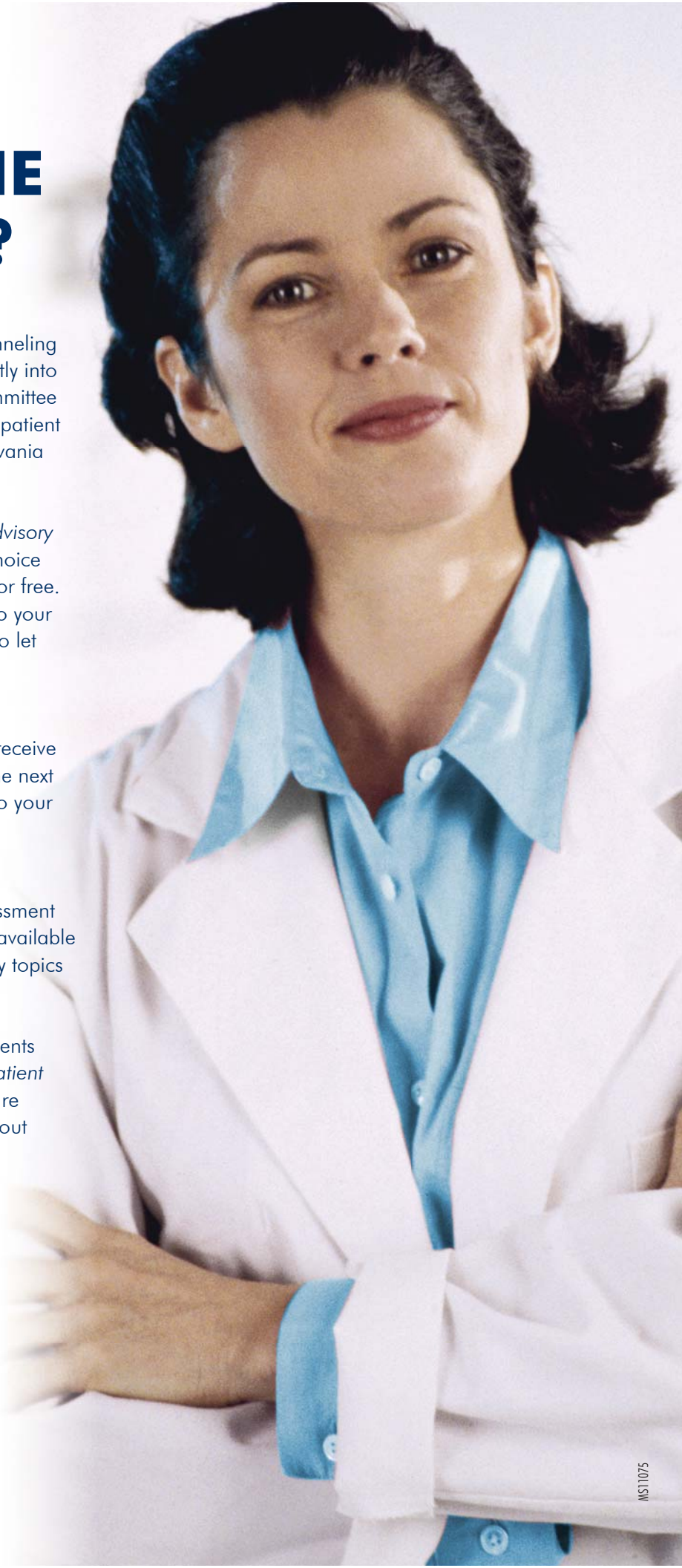
Backed by analysis of real patient safety events and scientific evidence, the *Pennsylvania Patient Safety Advisory* can help improve healthcare delivery systems and educate providers about safe healthcare practices.



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

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