

Patient Safety Authority: Partners in Risk Management

Robert Cole, PhD, Associate Vice President, Outcomes
Bonnie Haluska, RN, Associate Vice President,
Inpatient Services
Kathy Tirpak, Director, Medical Services
Allied Services Rehabilitation Hospital

This contribution from Allied Services Rehabilitation Hospital continues the PA-PSRS Patient Safety Advisory series on leadership perspectives of patient safety. Allied Services was instrumental in a task force initiative to reduce the risks associated with use of color-coded patient wristbands, as reported previously in the December 14, 2005, supplementary Advisory. In the wake of this initiative, at least 10 other states have followed suit to some degree, and Joint Commission has linked to the task force's toolkit at <http://www.jcpatientsafety.org>.

—John R. Clarke, MD, Editor

While there is no single formula to achieve a culture of safety in an organization, one key ingredient that drives and sustains the process is

leadership. As we look back on how we arrived at an open culture of safety and reporting in our organization, we consider the synergistic dynamic between the leadership at our facility and the Patient Safety Authority. Our foundation for change was built on teamwork and the commitment from hospital leadership that focused on patient-centered care and improvement. Our efforts began a little more than a year before mandatory reporting was enacted within the commonwealth when we initiated a project to revamp our incident reporting processes. Over the ensuing year, we saw a convergence of change locally and nationally with the passing of Act 13 and



Robert Cole, PhD

(Continued on page 70)

Drug Labeling and Packaging — Looking Beyond What Meets the Eye

Ambiguous and confusing packaging and labeling as well as look-alike or sound-alike drug names significantly contribute to medication errors. In fact, a frequent (29%) cause of pharmacy drug dispensing errors is failure to accurately identify drugs, usually due to look-alike or sound-alike drug names.¹

Errors may occur when important information is printed in an inconspicuous place on the label, presented in an ambiguous manner, or overshadowed by less important information. The printing on the label may also be less than optimal in size, boldness, or contrast. Ornate graphics, emphasized corporate names, or logos may distract from the primary purpose of the label: to permit the user (i.e., pharmacist, nurse, physician, patient) to identify the name(s), dosage form, and strength of the product. Complicating the situation is that healthcare

practitioners often read labels under less-than-ideal conditions (e.g., in a patient's room at night when lights are dimmed, during emergency situations).

(Continued on page 73)

In This Issue

Patient Safety Authority: Partners in Risk Management (Robert Cole, PhD, Bonnie Haluska, RN, and Kathy Tirpak)	Page 69
Drug Labeling and Packaging — Looking Beyond What Meets the Eye	Page 69
Query on Wrong-Site Surgery	Page 72
Diligence and Design in Behavioral Health Impact Patient Safety	Page 78
Three "Never Complications of Surgery" Are Hardly That	Page 82
The Time for Transfer of Trauma Patients to Accredited Trauma Centers	
Can Impact Quality and Timeliness of Patient Care (Juliet Geiger, RN, MSN)	Page 83
Profitability is Associated with Reporting Patient Safety Events	Page 85
Inadvertent Mix-Up of Morphine and Hydromorphone: A Potent Error	Page 86
Common Medication Pairs that Contribute to Wrong Drug Errors	Page 89
Distribution of Event Types in ASFs versus Hospitals	Page 90
Obstructive Sleep Apnea May Block the Path to a Positive Postoperative Outcome	Page 91
IV Infiltration: Be Alarmed Even When Your Infusion Pump Isn't	Page 97
Preventing Adverse Events Related to Chest Tube Insertion	Page 99
Should Patients be Accompanied When Discharged from Ambulatory Surgery? ..	Page 100
Deaths Following Ambulatory Surgery	Page 104
The Big Picture (Janet Johnston, RN, MSN, JD)	Page 105
Self-Assessment Questions	Page 107

Patient Safety Authority: Partners in Risk Management (Continued)

**Patient Safety Authority
Board of Directors**

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

Patient Safety Authority Staff

Michael Doering, MBA, Executive Director
Laurene Baker, MA, Communications Director
Sharon Hutton, Administrative Assistant
Judith Marpoe, Program Manager

PA-PSRS Patient Safety Advisory Staff

John R. Clarke, MD, Editor

Contributing Editors

Arthur J. Augustine, BS
Mary Blanco, RN, MSN,
Christine M. Callahan, RN, MBA
Hedy Cohen, RN, BSN, MS
Edward Finley, BS
Michael J. Gaunt, PharmD
Matthew Grissinger, RPh
Charlotte Huber, RN, MSN
Janet Johnston, RN, MSN, JD
William M. Marella, MBA
Denise Martindell, RN, JD

Advisors

Michael Cohen, RPh, MS, ScD
Ronni Solomon, JD
Allen Vaida, PharmD

Production Staff

Jesse Munn, BA, Production Editor
John Hall
Miranda R. Minetti, BS

Editorial Policy

PA-PSRS Patient Safety Advisory (ISSN 1552-8596) is published quarterly, with periodic supplements, by the Pennsylvania Patient Safety Authority. This publication is produced by ECRI Institute & ISMP under contract to the Authority as part of the Pennsylvania Patient Safety Reporting System (PA-PSRS).

Copyright 2007 by the Patient Safety Authority. This publication may be reprinted and distributed without restriction, provided it is printed or distributed in its entirety and without alteration. Individual articles may be reprinted in their entirety and without alteration provided the source is clearly attributed.

This publication is disseminated via e-mail. To subscribe, go to <https://www.papsrs.state.pa.us/Workflow/MailingListAddition.aspx>.

Office Location: 539 Forum Building
Harrisburg, PA 17120
Mailing Address: P.O. Box 8410
Harrisburg, PA 17105-8410

Telephone: 717-346-0469

Facsimile: 717-346-1090

Web site: www.psa.state.pa.us

E-mail: patientsafetyauthority@state.pa.us

the initial set of National Patient Safety Goals. As all of these dynamics came together, it reinforced the vision of change underway in our organization. As we retrospectively looked at the impact of the Authority during this period, we found our program benefited in two ways. First, PA-PSRS led us to analyze our data from a different perspective, which allowed us to identify new opportunities for improvement. Second, the Authority offered the ability to learn from the experiences of other facilities by publishing the *PA-PSRS Patient Safety Advisory*.



Bonnie Haluska, RN

Responding to Data

The advent of PA-PSRS led to an expansion of the categories of reportable events at our facility. For example, prior to the implementation of PA-PSRS, our facility did not analyze pressure ulcers with respect to whether they developed pre- or posthospitalization. Through the use of our own data available in PA-PSRS, we began to intensely analyze pressure areas that were pre-existing as compared to those that developed after admission. The necessity for reporting this information combined with the ability to extract and analyze the data allowed our Patient Safety Committee to assess the root causes of skin breakdown that occurred after admission to our facility. This led us to develop new skin protocols that promote a more proactive approach in targeting at-risk patients. Although our initially observed post-admission incidence of skin breakdown was low, we have further lowered that rate by 47% since introducing the revised processes.



Kathy Tirpak

Responding to Advisories

Our patient safety program has also benefited from the Authority sharing “lessons learned” in other facilities in *Advisory* issues. In December 2005, the Authority alerted hospitals to the risks associated with use of color-coded patient wristbands. A statewide survey by the Authority revealed that a significant number of hospitals used color bands to communicate risk, and that there was no standardization in color, even within divisions of the same healthcare systems. As a rehabilitation hospital, with two units in local acute care facilities, this potential for error struck a chord. The review

Acknowledgements

The PA-PSRS staff would like to thank the following individuals, who graciously offered us their insight and/or reviewed selected articles prior to publication:

Warren E. Medina-Riutort, RN, BSN, Patient Safety Manager, Philadelphia VA Medical Center

Wilson C. Po, MD, Assistant Professor of Anesthesiology, Department of Anesthesiology, Penn State Hershey Medical Center

David M. Sine, ARM, CSP, CPHRM, President, Safety Logic Systems

Patient Safety Authority: Partners in Risk Management (Continued)

of the December 14, 2005, supplementary *Advisory* issue at our patient safety meeting in January 2006 launched a community initiative. Within five months, the Color of Safety Task Force, comprised of 11 hospitals from the northeast and central regions of Pennsylvania, was well on its way to developing the first standardized approach to use of color-coded wristbands. Ultimately, the task force developed a toolkit that could be adopted at any facility, and the Authority published a follow-up supplementary *Advisory* outlining the task force's information and risk reduction strategies. Since that date, the information has been used state- and nationwide as a basis for other facilities and agencies. This is now available as a reference document on the Joint Commission International Center for Patient Safety Web site and is listed as a best practice (see <http://www.jcpatientsafety.org>).

PA-PSRS Data and the Patient Safety Authority: Hype or Help?

Without the Patient Safety Authority and PA-PSRS, would we have reached this point? As leaders, we recognize that each resource that plays a role in our patient safety program contributes to improving quality. How we respond is up to us. While the scope and size of organizations and technology vary greatly in Pennsylvania healthcare facilities, we have found the utility of the data from PA-PSRS and the lessons shared in issues of the *Advisory* provide added benefit to our patient safety program, and directly benefit the people we care for. With more

than a half million reports entered thus far, the Authority has the capability to expand their efforts into producing a more detailed database for hospitals to tailor to their facilities' scope of practice.

Going forward, it has been suggested that the Authority develop a standardized "how and when" reporting methodology for hospitals to follow. This would foster a more meaningful benchmark capability for providers interested in comparing their facility's performance to similar institutions. Additionally, the development of a formalized way for hospitals to access standards of care or processes successfully developed in response to "lessons learned" would be an invaluable educational resource.

Even without these enhancements, no available resource to improve patient safety should be discounted. Although we are already subscribing to alerts published by ECRI Institute, the Institute for Safe Medication Practices, and the Joint Commission, the *PA-PSRS Patient Safety Advisory* is yet an additional tool for us to use in evaluating whether we had the same risks present within our organization that other Pennsylvania facilities were experiencing. There was a time when hospitals were reluctant to openly discuss adverse events. Details of these occurrences were "whispered" in fear of punishment and legal retribution. The efforts of the Authority have led to honest sharing of information within and between facilities. Finally, they have us talking out loud.

Authority Board Approves Infection Control Advisory Panel

The Patient Safety Authority's Board of Directors has approved a 13-member panel of infection control experts to help implement Act 52 of 2007. Act 52 was signed into law in July 2007 to help reduce and eliminate healthcare-associated infections in Pennsylvania's hospitals and nursing homes.

Members of the advisory panel include the following:

- Erick J. Bergquist, MD, PhD
- Dorothy Borton, RN, BSN, CIC
- Patrick J. Brennan, MD
- Kenneth Brubaker, MD
- Susan E. Coffin, MD, MPH
- Daniel Haimowitz, MD, FACP, CMD
- Sharon L. Jacobs, RN, MS, CIC
- Emily McCracken, MPH
- S. Candy Mulholland, RN, MSN
- Carlene A. Muto, MD, MS
- Stephen Ostroff, MD
- Abby Weand, RN
- Linda Winston, MSN, CIC

The Authority plans to convene the first meeting of the panel in October 2007. More information on the advisory panel, including responsibilities, selection criteria, and affiliations, is available on the Authority's Web site at <http://www.psa.state.pa.us>. Information on Act 52 is also available.

Query on Wrong-Site Surgery

PA-PSRS Patient Safety Advisory staff recently received a query from a reader in response to the article “Doing the ‘Right’ Things to Correct Wrong-Site Surgery” that appeared in the June 2007 issue. The reader questioned whether the analysis of wrong-site surgery events reported in Pennsylvania and the resulting article adequately addressed the responsibility of physicians in preventing wrong-site surgery. Comments questioning responsibility in wrong-site surgery cases also appeared on the ABC Web site’s “Talk Back” section in response to a *Good Morning America* piece on wrong-site surgery that aired August 9, 2007;¹ this television spot included commentary from John Clarke, MD, editor and clinical director, PA-PSRS.

The emphasis of the *PA-PSRS Patient Safety Advisory* has been on improving healthcare systems so that they can reliably deliver the right care to the right patient at the right time. Educating individual providers about what they can do to prevent or mitigate errors is useful, but not sufficient. It is our position that more improvement comes from improving a system than from improving the performance of individuals within an existing system. Nowhere is this more obvious than with “at-risk behavior.” Individuals should be educated about approaches that increase the risks of error and should be expected not to use them. However, facilities have the responsibility to monitor for at-risk behavior, counsel those who do it, provide encouragements and incentives for low-risk behavior, and provide barriers to keep at-risk behaviors from affecting patients. Examples abound, but one directly related to wrong-site surgery is that some hospitals will not load the scalpel blade into the handle until after the surgeon has done the time-out (see the aforementioned article in the June 2007 *Advisory*). Physicians, frequently not employees of the healthcare facility, should not be participating in at-risk behavior. However, physicians have a relationship with

the facility predicated on explicitly stated behavior, and the facility has a responsibility to its patients to protect them against at-risk behavior by providers, including those on medical staff. We feel that arguments about who has more responsibility for patient safety misses the point that safety is the commitment of a system that includes both facilities and their medical staffs.

The actions of the surgeons in the operating room (OR) were cited as the leading factor in wrong-site surgery in the article (under the section on “System Breakdowns”), and these actions were illustrated by several examples. When we compared 174 wrong-site surgery events with 253 wrong-site surgery near misses, we found that physician behavior in the operating room was the leading cause of wrong-site surgery events. Most of these events (92) involved the behavior of the surgeon in the operating room, with another 29 involving the behavior of the anesthesia provider. This detailed scientific study was presented to the American Surgical Association and was published in the September 2007 issue of the *Annals of Surgery*. Almost all of the recommendations involve actions by the surgeons.² Publication of our analysis in this surgical journal was specifically chosen to reach and influence the thinking of practicing surgeons. PA-PSRS staff hope that facilities will take advantage of the information, which is available electronically (<http://www.annalsofsurgery.com>), to develop a strong working relationship between the OR physicians and support staff to commit to a safe patient experience in the OR.

Notes

1. Talk back [comment section online]. In: Surgical mishaps: wrong-site operations [television transcript online]. ABC News Good Morning America. 2007 Aug 9 [cited 2007 Aug 16]. Available from Internet: <http://abcnews.go.com/GMA/OnCall/story?id=3459845&page=1>.
2. Clarke JR, Johnston J, Finley ED. Getting surgery right. *Ann Surg* 2007 Sep;246(3):395-405.

Ongoing Wrong-Site Surgery Initiative

PA-PSRS staff have started to contact Patient Safety Officers from facilities that submit a report of a near miss or an actual wrong-site surgery with detailed follow-up questions to augment the information submitted in the initial report to PA-PSRS. This information is subject to the same confidentiality protections as all information submitted to the Patient Safety Authority under Act 13 of 2002, the Medical Care Availability and Reduction of Error Act. Taking the time and effort to answer the follow-up questions will be critical to the Authority’s ability to gain further insight on factors that contribute to recovery from wrong-site surgery and barriers to prevention.

Drug Labeling and Packaging—Looking Beyond What Meets the Eye (Continued)

Confirmation bias also plays a role in product mix-ups.² Errors are often induced by familiarity with procedures and materials, coupled with the tendency for people to see what is familiar or what they want to see, rather than what is actually there. Recent healthcare graduates, not yet familiar with many medications, initially will read labels carefully. After a while, they may rely on the appearance of a familiar product and become less vigilant when reading labels. If a drug has distinctive packaging, the potential for mix-ups may be reduced. If several products have similar packaging or if labeling is hard to read, the potential for error involving confirmation bias increases.

There are many factors related to a medication's label or package design that can contribute to errors. This article will focus on some of these factors as seen in PA-PSRS data, including the following issues:

- Readability of labels and packaging
- Expression of the drug's strength or concentration
- Use of color
- Lack of contrast

Readability of Labels and Packaging

Many words or images that routinely appear on medication labels serve to meet regulatory requirements more than the end users' needs. For example, the wording that appears on bags of infusion solutions (i.e., solutions commonly used to provide hydration) is cluttered with irrelevant information, causing further confusion to the practitioners using the product. (See Figure 1.)

Mix-ups between similar solutions are common in the PA-PSRS database. In fact, 8.7% (almost 1,400 reports) of wrong-drug and wrong-concentration errors involve mix-ups between these solutions.

Expression of the Drug's Strength or Concentration

The way a manufacturer presents the strength or concentration of a drug can be confusing and may lead to errors. For example, there have been reports to PA-PSRS and other reporting programs in which the label on a multidose vial expressed the concentration as the amount of active drug per 1 mL (e.g., 1 mg/mL), yet the vial contained more than 1 mL of solution (e.g., 5 mL) and did not indicate the total



Figure 1. Similar Labeling of Hydration Solutions has Led to Many Errors Reported to PA-PSRS. (Liter bags of Dextrose 5% and Sodium Chloride 0.45% with Potassium Chloride 20 mEq on the left and Sodium Chloride 0.9% with Potassium Chloride 20 mEq on the right.) Image provided courtesy of ISMP.

amount of drug in the vial (e.g., 5 mg/5 mL). The following report submitted to PA-PSRS mentioned an event that occurred due to similar circumstances.

Doctor took Kenalog 40 mg/5 mL vial out of Pyxis machine. After the doctor injected the patient's shoulder, he realized that the concentration was 40 mg/mL, and the whole vial (5 mL) was given.

The carton and vial labels of each of these products prominently display 40 mg. But the multidose vial only displays the concentration as a 40 mg/mL rather than 200 mg/5 mL (see Figure 2 on next page). The facility indicated that staff will now store the vials (5 mL and 1 mL) in separate areas in the pharmacy, only the 40 mg/1 mL concentration will be stocked in their Pyxis machine, and bar-code technology will be used to scan all medications prior to stocking the Pyxis machines.

Another report submitted to PA-PSRS mentions an event that occurred with a 20 mL vial of gentamicin that was labeled as 40 mg/mL.

The certified registered nurse anesthetist (CRNA) read the gentamicin vial as 40 mg per 1 mL but gave the entire vial (20 mL or 800 mg). The multidose vial was new to the operating room. When the CRNA became aware of the error, the surgeon was notified immediately. The patient was hydrated to dilute the medication.

Drug Labeling and Packaging—Looking Beyond What Meets the Eye (Continued)

This organization permanently removed the multi-dose vial from the operating room.

In another case reported to the Institute for Safe Medication Practices (ISMP), an order from the emergency department (ED) was received in the pharmacy for “ZEMURON (rocuronium) 40 mg IV now.” A pharmacy technician removed a carton of the drug from the refrigerator to verify what she was entering into the computer. Upon seeing 10 mg/mL prominently displayed on the box (see Figure 3) and the vial, the tech entered an order for 4 vials, believing all were needed for a 40 mg dose. Actually, the vials contained 10 mL with a total of 100 mg per vial. The tech showed the order, label, and four vials to the pharmacist, who also misinterpreted the total dose in each vial and approved delivery to the ED. The total volume in each vial was probably missed

because this information does not appear within the box that lists the concentration. Fortunately, the ED nurse recognized the mistake before administering the drug.³

ISMP believes product labels should prominently display the total contents. Both the total volume and amount in metric weight (e.g., 10 mg/5 mL) and the concentration per milliliter (e.g., 2 mg/mL) should appear side-by-side or one just above the other, within the same border or shaded background, even on multidose vials.⁴

The expression of drug concentrations on package labeling as a percentage or ratio of weight to volume is problematic. For most injectable products, the concentration is expressed in milligrams or micrograms per milliliter (e.g., mg/mL), but the concentration of a few drugs is expressed as a dilution ratio or percentage (e.g., epinephrine 1:1,000, lidocaine 1%). Studies show that prescribers’ knowledge about concentrations expressed as a ratio or percentage is inadequate, even among physicians and emergency medicine residents.⁵⁻⁷ These expressions are commonly used for drugs in resuscitation (e.g., epinephrine, lidocaine, neostigmine, sodium bicarbonate). A wrong dose or life-threatening delay in treatment is possible if these drugs are prescribed in milligrams (which requires knowledge of ratio or percent concentrations and calculations) or milliliters (a problem if multiple concentrations exist). Many reports have been submitted to PA-PSRS and other reporting programs in which undiluted epinephrine 1:1,000 (1 mg/mL) was given intravenously (IV) instead of 1:10,000 (0.1 mg/mL) concentration.⁸ In some of these cases, practitioners did not understand the ratio expression and accidentally prescribed or administered the wrong medications.

The labeling of oral solid dosage forms in unit dose packaging sometimes expresses the amount of drug in a misleading way. For example, Pentasa (mesalamine) 250 mg capsules have been packaged in a two-capsule, unit-dose package labeled “250 mg” (see Figure 4 on next page). It is not clear to health-care practitioners whether the entire package or each capsule contains 250 mg.⁹ Facilities in Pennsylvania have experienced this same problem, as shown in the following reports submitted to PA-PSRS.

Patient’s medication, when scanned, indicated to give four doses. Each scanned pack was two pills, but scanned four packs and administered.



Figure 2. Presentation of the Concentration of Multi-dose Vial of Kenalog 40 mg/mL (200 mg/5 mL) on the Right Led to Error. Packaging provided to PA-PSRS courtesy of a Pennsylvania healthcare facility.



Figure 3. Carton of Zemuron Shows a Concentration of 10 mg/mL, but Each Vial Contains 10 mL (100mg/10mL). Image provided courtesy of ISMP.

Drug Labeling and Packaging—Looking Beyond What Meets the Eye (Continued)

A nurse removed two packages (two capsules of 250 mg per package) of Pentasa from Pyxis, and the patient asked why there was two when he usually gets four. This led to some confusion.

A patient was administered an incorrect dose of Pentasa: 2,000 mg versus 1,000 mg.

Use of Color

Color is present in many ways on the labeling and packaging of medications and is often used to draw attention to information on the label. Unfortunately, the color used on the label sometimes detracts from important information, such as the drug name and strength. Color has been used to systematically classify and identify drug classes.¹⁰ This technique is referred to as “color coding.” This type of system is used for ophthalmic medications in the United States; the caps and labels are color-coded according to their pharmacologic class. Practitioners who know the system can assume that a manufacturer’s



Figure 4. Unit-Dose Package of Pentasa (mesalamine) Contains Two 250 mg Capsules, but Label Does Not Clearly Express the Total Dose. Image provided courtesy of ISMP.

vial with a yellow label means the product is a beta blocker, while a tan label means the product is an anti-infective. The effectiveness of color-coding systems depends on the practitioners’ ability to know and remember what each color represents. However, such color coding can increase the look-alike similarities of different drugs within the same pharmacologic class. Reports submitted to PA-PSRS (such as the following), as well as the U.S. Pharmacopeia-ISMP Medication Errors Reporting Program, describe confusion between these ophthalmic products.

Three eye kits were prepared incorrectly by the pharmacist. Mydracyl 1% (tropicamide) was supposed to be inside the kits; instead, they contained Cyclogyl 1% (cyclopentolate) drops. The nurse gave a patient the incorrect eyedrops. In others cases, the drops were corrected prior to administration. (See Figure 5.)

Problems can also occur with color-code schemes that are applied by users, such as the American Society for Testing and Materials standard for user-applied syringe labels in anesthesiology.¹¹ Some of the label colors reflect characteristics of the drug class.¹² For example, a neon red-orange label used for neuromuscular blockers indicates “danger.” The blue signifies cyanosis of opiate-related respiratory depression. Labels for some antagonists are linked by color to the specific agonist (e.g., naloxone shares the color of opiates) but have diagonal lines printed along the border of the label. Drug names are printed on the labels, which are on rolls mounted alongside one another on a dowel so that anesthesia personnel can easily retrieve the required label.



Figure 5. Two Ophthalmic Products of the Same Pharmacologic Class with Similar Packaging and Color Scheme. Image provided courtesy of ISMP.

Drug Labeling and Packaging—Looking Beyond What Meets the Eye (Continued)

Both of these scenarios demonstrate the problem when label colors identify a drug category, but do not identify a specific drug, strength, or dose contained in a syringe. The following report sent into PA-PSRS describes an error associated with the use of these labels:

At the end of cath lab case, an anesthesia resident was told to administer neostigmine to reverse the patient. The resident administered rocuronium by mistake. Investigation revealed that the attending physician and resident had drawn up the rocuronium and neostigmine prior to the start of the case. Both syringes were labeled; however, the rocuronium preprinted label is white with a red solid line, the neostigmine preprinted label is white with a red hatch-marked line. Resident mistakenly picked the syringe with the red-and-white label but did not read label prior to administration of medication.

Another example of problems associated with the use of color coding has been discussed in a previous issue of the *PA-PSRS Patient Safety Advisory*, in which 10-fold overdoses of insulin occurred due to mix-ups between insulin syringes and 25-gauge tuberculin syringes with needles.¹³

In contrast to color coding, color differentiation can be used to make certain parts of the label stand out or to help differentiate one item from another. One example of this technique involves Adrenalin. The original packaging (see Figure 6) was changed after reports of delays in treatment because of the similarity in packaging between topical Adrenalin, used to stop bleeding, and injectable Adrenalin, used in emergencies such as cardiac arrest and asthma attacks. Medical personnel had unknowingly



Figure 6. Old Packaging for Topical and Injectable Adrenalin, Left, and the Redesigned Products, Right. Image provided courtesy of ISMP.

stocked their emergency box with the topical agent; when they opened the box for emergency treatment, they did not have the product they needed. They wanted the injectable form, but they identified the item by its appearance: the title (Adrenalin Chloride Solution), the distinctive white and dark-red design, the shape of the box, the horizontal bands at the bottom of the label, and the “1:1000” concentration. The distinguishing words (i.e., “Nasal Solution” and “Topical Application” versus “Injection” and “Hypodermic Use”) were relatively small and were not seen. The redesigned packaging is now distinguished by differentiating the products using a sharp color contrast.¹⁴

Lack of Contrast

The lack of contrast in labeling can be problematic, especially on small products. One example of poor contrast leading to confusion between products involves the embossed labeling of low-density polyethylene (LDPE) ampuls of respiratory therapy medications, discussed in the June 2005 issue of the *Advisory*.¹⁵

The potential for error with this type of labeling and packaging is even greater since some manufacturers have introduced injectable products packaged in LDPE ampuls with the same type of labeling, such as heparin for IV flush and Naropin (AstraZeneca’s ropivacaine product), a local anesthetic. AstraZeneca also manufactures Naropin in various strengths (2 mg/mL, 7.5 mg/mL, and 10 mg/mL) in prefilled, Polyamp DuoFit polypropylene containers. Lidocaine is available in the polypropylene packaging as well. These containers, which all look similar, can be mistaken for respiratory medications. It is difficult to see the small, black print placed directly on the clear plastic containers, especially when the container is held against a dark background. (See Figure 7.)

Risk Reduction Strategies

It is not enough to caution healthcare providers to be more careful because it is human nature to identify items by color, shape, type font, symbols used, and other such characteristics. To help minimize errors related to nomenclature, labeling, and packaging, consider the following strategies:

Performing a failure mode and effects analysis (FMEA). Before adding a medication to your organization’s inventory, consider gathering an appropriate interdisciplinary team to perform a FMEA to determine potential pitfalls with that medication. Including evaluation of the look-alike potential of product containers as well as possible areas of storage throughout the organization may be necessary, not just the

Drug Labeling and Packaging—Looking Beyond What Meets the Eye (Continued)



Figure 7. Look-Alike Packaging in LDPE Ampuls. From left, Naropin injection, cromolyn for inhalation, and ipratropium bromide for inhalation. Image provided courtesy of ISMP.

pharmacy. Using FMEA will help identify the necessary steps to reduce the risk of errors.

Reviewing reports from external sources. Regularly reviewing professional literature may help to identify error-prone drug products.

Purchasing from different vendors. To reduce similarities and prevent errors, consider purchasing one product of an identified look-alike pair from a different vendor.

Segregating and labeling. Consider separating and/or clearly differentiating products that are similar.

Building alerts. Building alerts into computer systems may help to remind practitioners about problematic products in your organization.

Using drug dose conversion charts. Because not all healthcare practitioners are familiar with percent or ratio expressions of concentrations or adept at calculating doses of drugs whose concentrations are expressed in this manner, consider using drug dose conversion charts. It is helpful for organizations to create a dose conversion chart reflecting concentrations available in the facility. The chart can be posted on code carts and in other areas where emergency medications may be prepared. A process to ensure

that these dosing charts undergo an approval process prior to use, as well as an updated review or as new products are published, can help keep these charts useful and up-to-date.

Documenting contributing factors. When submitting reports to PA-PSRS, consider taking advantage of the reporting program's capability to track contributing factors to events. Under question 8J, "System Factors Contributing to Medication Error," selecting an applicable item — such as "Dosage form confusion," "Dose and identify checking (e.g., look-alike and sound-alike)," or "Label design" — may help identify products that are involved in multiple events in your facility due to the design of the label or package. Identifying these products and analyzing the contributing factors can assist your quality improvement programs and guide the development for error-prevention strategies.

Notes

1. Leape LL, Bates DW, Cullens DJ, et al. Systems analysis of adverse drug events. ADE Prevention Study Group. *JAMA* 1995 Jul 5;274(1):35-43.
2. Institute for Safe Medication Practices. Safety brief. *ISMP Medication Safety Alert!* 1996 Nov 20;1(23):1.
3. Institute for Safe Medication Practices. No FDA guidance on drug concentration expression. *ISMP Medication Safety Alert!* 2007 Apr 19;12(8):1.
4. Cohen MR, ed. *Medication errors, 2nd edition*. Washington (DC): American Pharmacological Association; 2007:130.
5. Rolfe S, Harper NJ. Ability of hospital doctors to calculate drug doses. *BMJ* 1995 May 6;310(6988):1173-4.
6. Jones SJ, Cohen AM. Confusing drug concentrations. *Anaesthesia* 2001 Feb;56(2):195-6.
7. Nelson LS, Gordon PE, Simmons MD, et al. The benefit of houseofficer education on proper medication dose calculation and ordering. *Acad Emerg Med* 2000 Nov;7(11):1311-6.
8. Pennsylvania Patient Safety Reporting System. Let's stop this "epi"demic!—preventing errors with epinephrine. *PA PSRS Patient Saf Advis* 2006 Sep;3(3):16-7.
9. Cohen MR, ed. *Medication errors, 2nd edition*. Washington (DC): American Pharmacological Association; 2007:131.
10. Institute for Safe Medication Practices. A spectrum of problems with using color. *ISMP Medication Safety Alert!* 2003 Nov 13;8(23):1-2.
11. American Society for Testing and Materials. Standard specifications for user applied drug labels in anesthesiology. D 4774-94. 2000.
12. Foster P. Labeling history reviewed and future explored. *Anesthesia Patient Safety Foundation Newsletter* 2005-2006 Winter;20(4):86-7.
13. Pennsylvania Patient Safety Reporting System. Overdoses caused by confusion between insulin and tuberculin syringes. *PA PSRS Patient Saf Advis* 2004 Oct 28;1(Suppl 1):1-2.
14. Cohen MR, ed. *Medication Errors, 2nd edition*. Washington (DC): American Pharmacological Association; 2007:112.
15. Pennsylvania Patient Safety Reporting System. Poor labeling of respiratory therapy medications can impact patient safety. *PA PSRS Patient Saf Advis* 2005 Jun;2(2):15-6.

Readers interested in medication errors may also wish to see articles beginning on pages 86 and 89 of this Advisory.

Diligence and Design in Behavioral Health Impact Patient Safety

Behavioral health facilities are potentially dangerous places for both patients and staff when patients are looking for the opportunity to inflict harm.¹ Reports submitted to PA-PSRS indicate that patients continue to harm themselves in behavioral health facilities by using structures and objects common to the behavioral health environment, particularly in patient rooms. Indeed, the majority of patients admitted to behavioral health are at risk for harming themselves or others.²

Although no environment of care can be totally safe and free of risk, facilities can reduce the environmental risk factors that have the potential to cause patient harm by comprehensive planning of facility design.^{2,3} This article addresses existing guidance for the adult behavioral healthcare unit that is applicable to designing a new building, renovating space, or maintaining an existing behavioral healthcare program. Risk reduction strategies are presented that focus on safe environmental design, staff education, and patient assessment, as well as communication to patients' families regarding individualized patient care planning, patient safety issues, and community resources.³⁻⁵

Problems

Since its inception in June 2004, PA-PSRS has received more than 1,900 reports related to behavioral health issues, including suicide, self harm, violent behavior, and possession of items not permitted in the behavioral health environment that may contribute to harm (e.g., illegal drugs, prescription medications, razors, belts, shoelaces). There have been five reported suicides, although others may have been submitted only to the Pennsylvania Department of Health as Infrastructure Failures. Of the five suicides reported to PA-PSRS, four were by strangulation using items such as belts, cords, and clothing. The fifth death resulted from an overdose with contraband medication that the patient had hidden.

Examples of suicides reported to PA-PSRS include the following:

Patient was not in his bed for 7:30 a.m. bed check. Staff attempted to get in bathroom door but couldn't open the door. Staff immediately called security, who pushed open the door. Staff and security witnessed the patient falling behind the door as the belt he used to hang himself was released from the top of the closed door. Patient had no pulse or respirations. Paramedics were called, and patient was deceased.

Patient was admitted with paranoia, anxiety, and agitation. When interviewed by the psychiatrist, he denied suicidal ideation. He was observed in the day hall watching TV with other patients in the evening. Later, a housekeeper entered his room and found him hanging by his shirt on the bathroom door. Staff called a code and began cardiopulmonary resuscitation (CPR) immediately. Resuscitation efforts were unsuccessful, and he was pronounced dead.

Patient found on floor in bathroom with no respirations and faint pulse. His pants were around his neck as if he tried to strangle himself. Mouth-to-mouth resuscitation was given, and oxygen administration was initiated. 911 was called. The paramedics arrived and initiated CPR. The patient was transferred to the emergency room (ER) and pronounced dead.

The Joint Commission addressed behavioral health patient safety in goal 15 of the 2007 National Patient Safety Goals, which calls on accredited healthcare facilities to identify safety risks inherent in their patient populations (e.g., patient suicide).³ In a review of suicides reported between 1995 and 2002, the Joint Commission identified the physical environment as a root cause in more than 80% of the reported suicides.¹ Furthermore, in its November 6, 1998, *Sentinel Event Alert*, the Joint Commission reported that 75% of patients committed suicide by hanging.⁶

Elsewhere, patients' access to potentially dangerous objects may indicate problems with staff competence and training, according to root cause analyses conducted over a 44-month period of 17 attempted and completed patient suicides that occurred in a New York health system.³

PA-PSRS reports further demonstrate the resourcefulness of patients determined to harm themselves despite efforts to the contrary. There have been more than 400 reports of patients harming themselves with objects found in the behavioral health environment. Of these reports, more than 30 were related to attempted suicide by strangulation with common objects such as clothing, belts, bed linens, and shoelaces. About 50% of the more than 400 reports indicated that patients lacerated or punctured themselves with items such as pens, pencils, paper clips, razor blades, and kitchen items, as described in the reports below.

Diligence and Design in Behavioral Health Impact Patient Safety (Continued)

Patient was in kitchen area of group room on unit with doctor. The doctor was called away and left the door open. The patient took a glass dish, smashed it, and began cutting herself on the wrist. She then hid fragments of the glass in her clothing and socks. During lunch, she also hid a fork in her pocket.

Roommate reported that patient had shoelaces around neck. Staff found patient in bathroom with shoelaces around neck. Staff removed [the shoelaces]. Reddened area noted around neck.

Traditionally, behavioral health facilities have focused on access control and surveillance technologies such as fences, locks, key controls, doors and windows, alarm systems, and closed-circuit television systems.¹ These strategies may be limited in their ability to address a vital issue to the behavioral health environment—the opportunity for patients to construct weapons from or otherwise harm themselves with objects found in their environment.¹

Risk Reduction Strategies

Environmental Design

Because reports submitted to PA-PSRS mainly involve self harm in the patient room, the strategies discussed in this article will focus on this setting. Patient rooms are especially vulnerable areas for patient harm because the extended periods of time that patients spend in their rooms provide ample opportunity for self harm.^{1,2} Where applicable to the strategies discussed below, relevant cases reported to PA-PSRS are presented. (For further education, PA-PSRS has developed an interactive illustration of the objects or structures in patients' rooms that have contributed to self harm, according to reports submitted to PA-PSRS. The illustration can be viewed online at <http://www.psa.state.pa.us>.)

Physical structure. Secure and permanently affix walls, ceilings, moldings, and floors to prevent concealment of harmful items such as razor blades, matches, and drugs.^{1,2} Coat walls, ceilings, and furniture with nontoxic substances in case patients attempt to ingest these materials.^{1,2} If permitted under fire code, install doors to allow opening in both directions. Recess all hinges, and install doorknobs with push/pull latches and handles pointing down; this installation may reduce the risk of patients using doors (e.g., doorknobs) for hanging.^{1,2} Recess fire sprinklers and light fixtures, and use tamper-resistant fixtures to prevent their use for hanging. Fasten heating and cooling

Visit the Patient Safety Authority Web site (<http://www.psa.state.pa.us>) to view an interactive graphic of the objects or structures in patients' rooms that have contributed to patient harm. The graphic (see below) is also available in a printer-friendly format.



To view the graphic, click on "[Advisories and Related Resources](#)" in the left-hand column of the Authority's home page. Then, click on "[Resources Associated with Patient Safety Articles](#)." The interactive graphic is located under the heading "Other Resources." Be sure to review the accompanying descriptive text for system compatibility and user instructions.

vents with security screws. Vents with small perforations and protective, fine-mesh coverings are preferable. Place unbreakable covers over lighting and exits signs to reduce patient access to harmful objects.^{1,2}

Attentive design of behavioral health facilities promotes patient safety by denying resourceful patients opportunities to harm themselves. The following PA-PSRS report demonstrates such a resourceful patient:

Patient reported she swallowed metal piece from heating vent in her room. Patient was transported to the ER. Objects were removed by scope.

Windows. Use insulated tempered glass panels at least 1-inch thick for exterior windows.² Use of sash control devices that limit opening windows to no more than 6 inches may reduce the risk of patients jumping out.^{3,4} Reinforce older windows with heavy-gauge stainless steel frame and screen fabric. If window treatments are used, use flame-retardant material with no cords.^{1,2}

The report below demonstrates the harm patients may sustain even when windows are reinforced with screening.

Diligence and Design in Behavioral Health Impact Patient Safety (Continued)

Patient was admitted under Section 302 and placed on low level suicide precautions including every 15-minute checks. Patient was found by physician on the deck outside his office having fallen from the window in his room. Patient was transported to trauma center having sustained multiple fractures requiring surgical intervention. The safety screen was bent, and the window was partially broken.

Glass. Use unbreakable glass or acrylic for mirrors and picture frames.^{1,2}

Patients have managed to harm themselves with both glass and acrylic, as noted in the PA-PSRS reports below.

Patient admitted from the intensive care unit following an overdose. Patient had constant one-on-one visual observation at the time of the event. Patient pushed past staff member and bolted down the hallway. The patient took a picture from the wall and broke the glass (the picture was thought to have been framed with Plexiglass™, as are all of the other pictures on the unit). Patient used a piece of glass to lacerate the left side of her throat, transecting the jugular vein. The code team was called. Pressure was applied to the neck, an intravenous line was started, and oxygen was applied. The patient remained alert and able to speak. The wound was packed with gauze, and the patient was taken to the operating room. The wound was repaired without complications.

Patient punched a picture on the wall, breaking acrylic glass. Patient had lacerations to left wrist that required sutures.

Electrical cords and outlets. Polycarbonate cover plates with tamper-resistant screws provide the best cover for electrical outlets.^{1,2}

The report below indicates patients may tamper with outlet covers and attempt to harm themselves.

Patient called staff to his room and stated, "I tried to kill myself today." He then showed staff that he had partially ripped off an outlet cover and totally removed another. He had used a piece of tinfoil to shock himself. No visible injury was noted.

Electrical cords and any other cords may be used for self harm. Preferably, limit the availability of cords in patient rooms. Secure any cords that must be used and limit the length to less than 12 inches. Cordless phones may be provided for patient use but may not be left unattended in patient rooms because they can be used as weapons.^{1,2}

Phones with cords present the same issues with cords that are discussed above and noted in the PA-PSRS report below.

The patient was found on the floor with a telephone cord wrapped tightly around neck. The patient was cyanotic and breathless. Cord was cut off and patient started to breathe. Patient remained unresponsive and then had a seizure.

Bathrooms. Wall-mounted toilets with plumbing through the back wall will limit patient access to supply piping, which may be used for self harm. Install recessed shower heads, faucets, and spigots. Towel bars, shower curtain rods, and lever handles are not permitted.⁷ Install breakaway rods and racks for showers, towel bars, and closets to limit opportunities for hanging.^{1,2}

PA-PSRS has received more than 30 reports indicating patients use bathroom appliances to harm themselves, including the following:

While in the bathroom showering, patient attempted to hang self by tying tube socks to pipes under sink. Patient did not respond to medical technician doing 15-minute checks. The patient was immediately untied.

Patient told staff she had swallowed screws that she removed from sink. Patient was transported to the ER, and screws were removed via scope.

Patient turned off water faucet in bathroom hard. It broke off, and it was used to puncture hand between thumb and index finger. Patient was sent to the ED for sutures.

Furniture and miscellaneous items. Sturdy wood furniture bolted to the floor will stand abuse and decrease opportunities to hide contraband. Preferably, any furniture would be difficult to disassemble and have curved instead of sharp edges. A desk chair is the only moveable furniture allowed in the room. If table lamps are used, firmly attaching them to the

Diligence and Design in Behavioral Health Impact Patient Safety (Continued)

surface may prevent patients from using the lamp as a weapon. Additionally, avoid using lightbulbs that are not “shatter-resistant.”^{1,2} Use of paper liners instead of plastic liners in trash cans^{1,2} may prevent patients from attempting suffocation. Keep medications out of patient rooms, and prevent overdose by only allowing staff to administer.⁵

For example, the following report of how a patient was injured on room furniture was reported to PA-PSRS:

Patient dismantled dresser in an attempt to barricade self in room. Patient received 2 lacerations on hand from broken dresser drawer, which required 10 stitches.

Performing assessments of the structures most commonly used by patients to self harm and/or attempt suicide may reduce harm to patients. An environmental surveillance tool can be used to document, identify, and eliminate potentially dangerous objects in the environment.^{3,4} A multidisciplinary team including nursing, quality management, engineering, and staff members certified as healthcare safety professionals may perform the assessment biannually. In addition, facilities may conduct daily walkthrough rounds of rooms, units, and common areas to eliminate potentially dangerous objects.^{4,5}

Staff Education/Training

Education focusing on environmental design and potentially dangerous objects in the behavioral health setting provided to staff may reduce harm to patients.³ Consider the following components for staff education:

- Educate all clinical staff about the hidden risks of the environment and the behavioral characteristics of the population.^{3,4,8}
- Educate nonclinical staff, too (e.g., house-keeping, dietary staff). The literature indicates cases in which patients have ingested unsecured cleaning supplies.³ Furthermore, PA-PSRS has received more than 20 reports in which patients have cut themselves with plastic silverware or glass dishes.
- Conduct annual competencies related to knowledge of potential hazards in the environment.⁴
- Provide adequate clinical staff to meet patient needs.^{3,4,8}

Patient Assessment

On admission to the behavioral health facility, performing a patient assessment may help to identify patients at risk for suicide and/or self harm.⁴ Consider the following components for patient assessment:

- Revise/implement risk assessment and re-assessment tools to identify patients at risk for inflicting harm to themselves or others.³⁻⁶
- On admission and thereafter, conduct an inventory of a patient’s personal items, including clothing.²
- Perform complete physical examinations on admission to identify contraband, and reassess patients at intervals determined by their individual risk assessment for self harm.⁵
- Review and revise as needed the policies and procedures for direct patient observation. The level of observation may vary from constant to random; base observation on individual assessment of the patient.⁵

Family Education

Educating the families and caregivers of behavioral health patients is an important aspect of care.⁸ Consider the following components for education:

- Communicate to families the details of any individualized patient care planning, patient safety issues, and available community resources.³⁻⁵
- Provide family, friends, and visitors with information related to environmental hazards and patient behaviors that may indicate the potential for harm to the patient and/or others.³
- Advise visitors to have staff review any items brought for patients.³

The behavioral health environment plays a significant, often unrecognized role in patient safety. Achieving balance between designing a risk-free environment while maintaining a therapeutic environment can be challenging, but the mitigation strategies presented here and vigilant attention to the physical environment in behavioral health facilities may reduce patient harm.⁸

Notes

1. ECRI Institute. Thwarting behavioral health violence through facility design. *Healthcare Hazard Management Monitor* 2004 Aug;17(12):1-5.

Diligence and Design in Behavioral Health Impact Patient Safety (Continued)

2. Sine DM, Hunt JM. Design guide for the built environment of behavioral health facilities: second edition—2007 [online]. 2007 Jun 28 [cited 2007 Aug 6]. Available from Internet: http://www.naphs.org/Teleconference/documents/BHdesignguideSECONDEDITION.FINAL.4.27.07_002.pdf.
3. Lieberman DZ, Resnik HL, Holder-Perkins V. *Suicide Life Threat Behav* 2004 Winter;34(4):448-53.
4. Dlugacz YD, Restifo A, Scanlon KA, et al. Safety strategies to prevent suicide in multiple health care environments. *Jt Comm J Qual Saf* 2003 Jun;29(6):267-78.
5. ECRI Institute. Preventing patient suicides. *Risk Management Reporter* 2007 Aug;26(4):1, 3-8.
6. Joint Commission. Inpatient suicides: recommendations for prevention. Sentinel Event Alert 1998 Nov 6 [cited 2007 Aug 6]. Available from Internet: http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_7.htm.
7. *Guidelines for design and construction of healthcare facilities*. Washington (DC): American Institute of Architects; 2006.
8. Reducing the risk of suicide: using environmental controls to help support suicide prevention efforts. *Environ Care News* 2006 Oct;9(10):4-5.

Three “Never Complications of Surgery” Are Hardly That

PA-PSRS has previously reported on three complications of surgery that should never be considered risks that the patient must accept when undergoing an operation: unintentionally leaving something behind (retained foreign body; see “Tips from PA Facilities: Enforcing the Time Out and Preventing Retained Foreign Bodies” in the June 2005 *PA-PSRS Patient Safety Advisory*), operating on the wrong site (wrong-site surgery; see “Doing the ‘Right’ Things to Correct Wrong-Site Surgery” in the June 2007 *Advisory*), and setting the patient on fire (surgical fire; see articles in the March 2007, December 2006, and September 2007 issues of the *Advisory*). During separate analyses of these three complications, PA-PSRS has determined the number of reports of each during the time periods of analysis for each project. Based on reports from the Pennsylvania Department of Health of 2,424,879 total operations in 2005 in Pennsylvania hospitals and ambulatory surgery centers,^{1,2} PA-PSRS analysts calculated the chances of a patient

experiencing a complication that should never be a risk that the patient must accept (see Table).

Although these “never complications of surgery” should never occur, more than 100 patients are currently anticipated to experience them every year. A reasonable goal is zero.

Notes

1. Pennsylvania Department of Health Bureau of Health Statistics and Research. Selected data from the annual hospital questionnaire reporting period July 1, 2004 through June 30, 2005 (Report 11-A): utilization of operating rooms in general acute care hospitals [online]. [cited 2007 Aug 6]. Available from Internet: <http://www.dsf.health.state.pa.us/health/lib/health/facilities/hosamb/2004-2005/REP11A.pdf>.
2. Pennsylvania Department of Health Bureau of Health Statistics and Research. Data from the annual ambulatory surgery center questionnaire reporting period July 1, 2004 through June 30, 2005 (report 1): utilization and services by facility and county [online]. [cited 2006 Aug 7]. Available from Internet: <http://www.dsf.health.state.pa.us/health/lib/health/facilities/hosamb/2004-2005/ASCREP120042005.pdf>.

Complication	Number of Reports during Time Period	Time Period	Number per Year	Operations per Event (assumes 2,424,878 operations/year)
Retained foreign bodies (within incision)	60	12 months	60	1 per 40,415 operations
Wrong-site surgery (partial and complete)*	116	30 months	46	1 per 52,260 operations
Surgical fires	83	36 months	28	1 per 87,646 operations
Any of the three			134	1 per 18,087 operations

* Wrong-site surgery information is derived from the following detailed, scientific study, which was authored by PA-PSRS staff: Clarke JR, Johnston J, Finley ED. Getting surgery right. *Ann Surg* 2007 Sep;246(3):395-405.

Table. Risk of Three “Never Complications of Surgery”

The Time for Transfer of Trauma Patients to Accredited Trauma Centers Can Impact Quality and Timeliness of Patient Care

Juliet Geiger, RN, MSN, Executive Director,
Pennsylvania Trauma Systems Foundation

PA-PSRS has received reports illustrating problems involving transfers to trauma centers, including at least one report suggesting that the emergency department of an acute care hospital did not have a working transfer agreement with any trauma center accredited by the Pennsylvania Trauma System Foundation. PA-PSRS invited Juliet Geiger, RN, MSN, to comment on this issue.

—John R. Clarke, MD, Editor

In 1985, Pennsylvania became the eighth state in the country to develop a trauma system. The goal of a trauma system is to reduce the burden of injury to individuals and society through “a group of related injury-oriented facilities, personnel, and organizational entities operating in an organized coordinated manner, typically within a defined geographic area.”¹ The spectrum of activities needed to achieve this goal covers all phases of care from the prevention of injury, to primary care within the hospital environment, to care in the rehabilitation setting.

In 2002, the U.S. Health Resources and Services Administration published a report titled “A 2002 National Assessment of State Trauma System Development, Emergency Medical Services Resources, and Disaster Readiness for Mass Casualty Events.”² In this publication, all states were reviewed according to criteria established by West et al.³ and later expanded upon by Bazzoli in 1995,⁴ which define the components of the ideal trauma system. These criteria are as follows:

1. Legal authority to designate trauma centers
2. Formal process for designating trauma centers
3. Use of American College of Surgeons (ACS) standards for trauma center designation
4. On-site verification of compliance with trauma center standards
5. Number of trauma centers limited based on community need
6. *Pre-hospital triage criteria allowing for bypass of non-designated hospitals* (emphasis added)
7. Processes to monitor trauma system outcomes

The above components recognize the key parts of a system that need to be in place, but the components vary in how they interconnect and function within a given state.

In Pennsylvania, the Pennsylvania Trauma Systems Foundation (PTSF) is the accrediting body for trauma centers. This accreditation process is accomplished through the development of standards for the operation of trauma centers in Pennsylvania, adopting, at minimum, the current guidelines for trauma centers as defined by ACS. Then, PTSF evaluates the Pennsylvania hospital that is applying for accreditation to determine if the applicant hospital meets the Standards for Trauma Center Accreditation.⁵

Oversight of prehospital emergency medical services (EMS) is under the auspices of the Pennsylvania Department of Health Bureau of Emergency Medical Services. The bureau deals with care of the trauma patient at the scene of the injury and prior to arrival to a hospital. The component of the West criteria requiring “pre-hospital triage criteria allowing for bypass of nondesignated hospitals” is also under the jurisdiction of the bureau.

Importance of Transferring Trauma Patients to Accredited Trauma Centers

As part of the statewide protocols developed by the Department of Health, EMS personnel are required to transport trauma patients to the appropriate facility based on an algorithm of care that ensures that only mild injuries are treated at community hospitals, and actual or potentially moderate to severe injuries are treated at accredited trauma centers.⁶ Research has proven that mortality rates are significantly lower when trauma patients are treated in trauma centers.⁷

Although algorithms are in place for EMS personnel to bypass community hospitals in favor of trauma centers for patients meeting selected criteria, often patients who arrive to the hospital with seemingly “mild” trauma (e.g., a single extremity fracture after a fall from standing position) are found to have more extensive injury upon diagnostic review than what was apparent upon initial assessment by the EMS provider in the field. This is particularly true when it comes to pediatric or geriatric patients. Both groups of patients require special diagnostic considerations due to cognition and physiology. Additionally, the elderly patient often presents with a cadre of coexisting medical conditions. A typical scenario encountered by a hospital emergency department is the elderly patient who falls, hits his or her head, and is taking Coumadin. Upon

The Time for Transfer of Trauma Patients to Accredited Trauma Centers Can Impact Quality and Timeliness of Patient Care (Continued)

admission, a computed tomography scan of the brain may be negative, but a later scan may show bleeding. Complicating the neurologic assessment are factors such as dementia and brain atrophy. For this reason, many trauma centers identify age greater than 65 coupled with use of Coumadin as an automatic indication for consultation with the trauma team. Likewise, multiple broken ribs in a young person may not be fatal, but the same injury pattern in an elderly patient with limited pulmonary reserves can lead to pneumonia and rapid cardiopulmonary deterioration when coupled with pre-existing coronary artery disease. The importance of quickly transferring these types of patients to a trauma center cannot be overemphasized (see the sidebar below).

In summary, community hospitals that establish transfer agreements with trauma centers can optimize care delivery of injured patients. Benefits to the patient from timely transfers to a trauma center are:

1. enhanced quality of care through a team approach to trauma care provided by

educated trauma care providers who are available 24 hours/day in an environment dedicated to placing trauma patients as a top priority; and

2. expeditious care including timely diagnosis and timely response by subspecialists, all of whom are monitored by PTSF through the trauma center accreditation process.

Benefits to the hospital are:

1. cost savings to the community hospital by assuring that patients with potentially complex injuries are stabilized and rapidly transferred to trauma centers where they will receive appropriate and timely diagnostic studies and therapeutic procedures provided by competent trauma care providers; and
2. decreased potential for technical errors in patient management due to lack of utilization of evidence based trauma protocols.

Examples from PA-PSRS Reports

Here is one example of a report submitted to PA-PSRS involving an elderly patient:

76 year-old female [emergency department (ED)] patient — diagnosis: Multiple trauma [patient] arrived in ED via ALS ambulance following trauma resulting from being dragged by car 30 feet and run over. Emergency medicine physician did not order blood work or radiology studies, stating “all that is necessary for transfer is a chest x-ray, Foley catheter, and NG tube.” Neighboring ED was called but refused to accept transfer. Further studies were then ordered.

The report suggests that the ED of an acute care hospital did not have a working transfer agreement with any Pennsylvania Trauma System Foundation trauma center. This is an example of not just a simple fall, but a patient at risk for multisystem injuries (based on mechanism of injury) who may have suffered a poor outcome through lack of laboratory studies being drawn to assess for signs of coagulopathy and internal bleeding. Furthermore, the absence of radiology films of the spine, chest, and pelvis would have placed this patient at risk for death or disability had there been potentially life-threatening conditions requiring stabilization prior to transfer. Had the hospital had a transfer agreement with a higher level trauma center, rapid

communication could have occurred, prompting completion of appropriate diagnostic studies, which could have been communicated to the receiving facility prior to transfer. Receipt of all of this information would have expedited transfer of the patient, reduced redundancy of diagnostic studies by the receiving facility, and also assisted the trauma center in preparing the proper personnel and resources to meet the demands of the patient upon admission.

Here is another example of the reports submitted to PA-PSRS that center around system delays, which could have been due to lack of an established relationship with an accredited trauma center:

21-year-old male ED patient given discharge instructions to go to a neighboring trauma facility for care/evaluation without facilitation of transfer process.

These delays can be reduced through written agreements whereby the receiving trauma center educates the sending facility about expectations for diagnostic screening prior to transfer and about the protocol for who to call when a trauma patient requires transport. Such agreements can save countless hours of personnel time to arrange the transfer, and, most importantly, expedite care of the patient and provide optimum treatment at a facility with an organized process of trauma care delivery.

The Time for Transfer of Trauma Patients to Accredited Trauma Centers Can Impact Quality and Timeliness of Patient Care (Continued)

Notes

1. American College of Surgeons (ACS) Committee on Trauma. *Resources for Optimal Care of the Injured Patient: 2006*. Chicago (IL): ACS; 2006.
2. U.S. Department of Health and Human Services, Health Resources and Services Administration, Trauma-EMS Systems Program. A 2002 national assessment of state trauma system development, emergency medical services resources, and disaster readiness for mass casualty events. 2003 Aug.
3. West JG, Williams MJ, Trunkey DD, et al. Trauma systems. Current status—future challenges. *JAMA* 1988 Jun 24;259(24):3597-600.
4. Bazzoli GJ, Madura KJ, Cooper GF, et al. Progress in the development of trauma systems in the United States. Results of a national survey. *JAMA* 1995 Feb 1;273(5):395-401.
5. Pennsylvania Trauma System Foundation. Standards for trauma center accreditation [online]. 2007 [cited 2007 Jul 10]. Available from Internet: <http://www.ptsf.org>.
6. Pennsylvania Department of Health Bureau of Emergency Medical Services. Pennsylvania statewide basic life support protocols [online]. 2006 Apr 10 [cited 2007 Jul 16]. Available from Internet: http://www.dsf.health.state.pa.us/health/lib/health/ems/bls_protocols_2004.pdf.
7. MacKenzie EJ, Rivara FP, Jurkovich GJ, et al. A national evaluation of the effect of trauma-center care on mortality. *N Engl J Med* 2006 Jan 26;354(4):366-78.

Profitability is Associated with Reporting Patient Safety Events

There is a small, but significant relationship between the number of reports per licensed bed that an acute care hospital made last year and its operating margin as reported by the Pennsylvania Health Care Cost Containment Council (PHC4). Among 168 acute care hospitals for which there was sufficient information to make comparisons, 3.7% of the variation in the operating margin could be accounted for by the number of reports per licensed bed. Although the correlation was small ($r=0.18$), it was highly significant statistically (probability less than 0.02 that it was random variation).

Hospitals with negative operating margins, according to the PHC4 report "Financial Analysis 2006, Volume One,"¹ were found by PA-PSRS analysts to have submitted an average of 3.42 reports per licensed bed to PA-PSRS. Hospitals with positive operative margins submitted an average of

5.24 reports per licensed bed. Even within the hospitals with positive operating margins, those above the median operating margin for profitable hospitals of 3.33% submitted more reports per licensed bed than those below (see Table).

For a theoretical 200-bed hospital, the average difference in reporting calculates to be 684 reports during the year for a hospital with a negative operating margin, 882 for a hospital with a moderate operating margin, and 1,217 for a hospital with a higher operating margin. The relationships between quality and profitability or quality and reporting remain untested.

Note

1. Pennsylvania Health Care Cost Containment Council. Financial analysis 2006, volume one: general acute hospitals [online]. 2007 Jun [cited 2007 Jul 16]. Available from Internet: http://www.phc4.org/reports/fin/06/docs/fin2006report_volumeone.pdf.

Operating Margin Reported by PHC4	Range of Operating Margin	Number of Hospitals	Average Number of Reports/Bed Submitted to PA-PSRS (2006)
Negative	-50.07% to -0.03%	55	3.42
Positive, up to the positive median	0.14% to 3.33%	57	4.41
Positive, above the positive median	3.42% to 22.69%	56	6.09

Table. Relationship between Hospital Operating Margins and PA-PSRS Reporting

Inadvertent Mix-Up of Morphine and Hydromorphone: A Potent Error

Morphine is the quintessential opioid agonist and the accepted standard against which other opioids are tested in controlled clinical trials.¹ However, because some patients cannot tolerate morphine or have conditions such as renal or hepatic impairment that may impact its use, another opioid may be needed as a replacement drug. Hydromorphone (Dilaudid®) is a common alternative to morphine for treating pain. When a patient requires an alternative to morphine, the analgesic equivalence between morphine and the alternative needs to be considered. The most common hospital-based source of medication errors involving potency is when a patient is switched from morphine to hydromorphone.² Hydromorphone by any route is significantly more potent than morphine, as indicated by the following:³

- Oral hydromorphone is approximately **four** times more potent than oral morphine.
— **For example, 7.5 mg hydromorphone per os (PO) = 30 mg morphine PO.**
- Parenteral hydromorphone is approximately **seven** times more potent than parenteral morphine.
— **For example, 1.5 mg hydromorphone intravenous (IV) = 10 mg morphine IV.**
- Parenteral hydromorphone is approximately **20** times more potent than oral morphine:
— **For example, 1.5 mg hydromorphone IV = 30 mg morphine PO.**

In addition, name similarities have led to inadvertent mix-ups between morphine and hydromorphone, or the mistaken belief that hydromorphone is the generic name for morphine.⁴ Analysis of wrong drug errors submitted to PA-PSRS shows that mix-ups between these two medications outnumber all other pairs of medications (see “Common Medication Pairs that Contribute to Wrong Drug Errors” on page 89 of this *Advisory*). When errors occur with these two medications and the same milligram dose is given (e.g., hydromorphone 5 mg IV given instead of morphine 5 mg IV), the potential for harm exists. In the previous example, 5 mg of parenteral hydromorphone is equivalent to 35 mg of parenteral morphine.

A few reports submitted to PA-PSRS involved breakdowns in the communication of drug orders, such as the following:

A doctor and nurse were at the patient's bedside. The doctor spoke about considering Dilaudid, but at the command post the doctor gave a verbal and written order for morphine.

The nurse stated that she did not hear the verbal order and Dilaudid had been given. The patient became lethargic and diaphoretic, and the rapid response team was called. Narcan was given and patient improved within a few minutes.

A patient's pre-op orders were continued along with the post-op orders which were written. The patient had been ordered Dilaudid IV pre-op and morphine IM post op. A nurse continued to give Dilaudid IV. The patient developed respiratory distress and was transferred to the telemetry unit.

Some of the errors reported to PA-PSRS, such as the following, occurred when the pharmacy department dispensed the wrong medication or replenished an automated dispensing cabinet (ADC) or unit stock with the wrong medication:

A patient was ordered morphine for pain. There was a possibility that the patient received Dilaudid instead of morphine. Morphine and Dilaudid were later found mixed in the morphine drawer in the ADC. No injury to patient.

The unit's ADC was restocked with morphine 4 mg injection instead of Dilaudid 4 mg injection. A patient received two doses of morphine instead of the ordered medication of Dilaudid.

Seventy-one percent of reports of mix-ups between morphine and hydromorphone indicate that the errors occurred when these medications were obtained from unit stock (i.e., ADCs, medication carts), prior to administration. Examples include the following:

During the 3-11 shift change report, the oncoming nurse was told that a patient was receiving morphine [patient-controlled analgesia (PCA)]. Upon checking the PCA settings, the patient asked why he was now on morphine, as he was getting no relief. The nurse checked orders and found that the patient should have been on Dilaudid PCA. The incorrect medication had been removed from the ADC and had been infusing for approximately five hours.

Dilaudid 4 mg was removed from narcotic drawer instead of morphine 4 mg. The nurse

See page 107 for self-assessment questions related to this article.

Inadvertent Mix-Up of Morphine and Hydromorphone: A Potent Error (Continued)

attempted to scan the drug but aborted the effort when the computer did not accept the scan and thought it was a malfunction. The patient received the medication but remained stable.

In the emergency room, a physician ordered Dilaudid for the patient. Upon discharge, the nurse removed the medication from the automated dispensing cabinet and unknowingly gave the patient morphine to take home, thinking it was Dilaudid. After completing a discrepancy check with Pyxis, the error was discovered. The patient was called at home, but the patient had already taken the medication. There were no complications per the patient.

Further analysis of these wrong drug reports involving either morphine or hydromorphone shows that:

- Of all wrong drug error reports that include morphine and/or hydromorphone, 36% involve a mix-up between those two drugs.
- Of wrong drug reports that involve these two drugs, 62% show morphine as the prescribed medication and hydromorphone given in error.
- The most common care areas where this mix-up occurred were medical/surgical units, medical/oncology units, emergency departments (EDs), and telemetry units.
- Elderly patients (patients 65 years and older) were involved in 34% of the reports.

Adverse events related to inadvertent mix-up of these two medications have occurred elsewhere. In a tragic event that took place in Canada, a 69-year-old patient was given 10 mg of hydromorphone IM instead of 10 mg of morphine.⁵ The patient presented to the ED with a chest injury sustained while horseback riding. Prior to discharge, the ED physician wrote an order for morphine 10 mg IM for pain, but hydromorphone was mistakenly selected from the narcotic drawer. Both hydromorphone and morphine were stocked in 1 mL, 10 mg/mL ampuls. Based on equianalgesic dose conversion charts, the patient, who was likely opiate-naïve, received an equivalent dose of about 60 to 70 mg of morphine. Shortly after the patient was discharged, the nurse discovered the error after a scheduled narcotic count showed a discrepancy between the two drugs. Hospital staff immediately tried

to contact the patient and finally located him in a rural hospital close to his home. The patient's condition had rapidly deteriorated until he arrested. Despite rescue efforts, the patient died.⁶

Another example includes an error in a hospital, where the darkness of the room during laser surgery (i.e., all lights were off except a spotlight) contributed to mix-ups between look-alike, prefilled syringes of morphine and hydromorphone.⁷ (See photos below of look-alike syringes.) In a third case, hydromorphone 4 mg cartridges were mixed in with similar looking morphine 4 mg cartridges in the floor stock narcotic cabinet. The hydromorphone was administered instead of morphine for postoperative pain control. Unfortunately, two hours later the patient was found dead.⁸

The Joint Commission has turned its attention to the confusion between these names and the potential harm that can occur, as is reflected in its National Patient Safety Goal 3C, which states that organizations, "identify and, at a minimum, annually review a list of look-alike/sound-alike drugs used in the organization, and take action to prevent errors involving the interchange of these drugs."⁹ The Joint Commission has included morphine and hydromorphone as a name pair that both acute care and ambulatory care sites should consider adding to their look-alike/sound-alike lists.

Safe Practices

Mix-ups between morphine and hydromorphone are the most common and potentially serious errors that can occur involving two high-alert drugs. This risk exists in almost every facility in Pennsylvania. Assume that this error *will* eventually happen in your facility, and consider the following steps to reduce the risk of patient harm.⁷

Limit access. Reduce stock amounts of hydromorphone wherever possible, and eliminate it from floor stock if usage is low. For example, some health systems where this type of error occurred removed all hydromorphone from every ED in the health region. If the drug is needed on patient care units, only the 2 mg/mL strength is available, except in palliative care units. The pharmacies in these health systems continue to stock hydromorphone for compounding PCA or continuous infusions.

Reduce options. If both drugs are available in patient care units, avoid stocking morphine and hydromorphone in the same strength. For example,

Inadvertent Mix-Up of Morphine and Hydromorphone: A Potent Error (Continued)



Figure. Look-Alike Morphine and Hydromorphone Syringes.

Images provided courtesy of ISMP.

since both drugs are available in 2 mg and 4 mg prefilled syringes, stock 2 mg of hydromorphone and 4 mg of morphine (but not vice versa, since 4 mg of hydromorphone could be an excessive dose). If the drugs are stored in an ADC, consider allowing access to morphine via an override function in emergencies, but require pharmacy order review before removing a first dose of hydromorphone. Also, be sure to store each medication in a separate, individual bin or drawer in the ADC or unit-stock to help prevent drug selection errors. In the pharmacy, segregate prefilled syringes and vials of these drugs, especially if they contain the same concentration.

Reduce “look-alike” potential. When possible, use tall man lettering to emphasize the lettering, like “HYDRO” or “PHONE” on pharmacy labels, auxiliary labels, medication administration records, pre-printed orders and drug listings on prescriber and pharmacy order entry screens or ADCs. Consider adding label reminders on hydromorphone indicating the brand name equivalent, “DILAUDID,” to help prevent confusion. Some ADCs may also offer the capability of asking “This is DILAUDID. Is that correct?” when nurses retrieve hydromorphone.¹⁰

Employ technology. Technological solutions (e.g., bar coding, automated dispensing technology that requires pharmacy order screening prior to dose retrieval) may reduce, but not eliminate, the risk of mix-ups.

Require redundancies. Require an independent double check before administering IV narcotic doses. Since nurses routinely obtain narcotics from floor stock, the typical pharmacist-nurse double check is not in place (as it is with patient-specific doses dispensed from the pharmacy). Some ADCs can be programmed to require a licensed “witness” when selected narcotics are removed, or when the override feature is used to access selected narcotics. Reminders can also appear on the screen.

Monitor patients. Implement policies that specify the scope, frequency, and duration of monitoring

that should occur before discharging patients who have just received a parenteral narcotic.

Educate staff. Provide safety information on the use of potent narcotics via newsletters and in-service meetings. Educate staff about the differences between hydromorphone and morphine, as some of the reported mix-ups have been due to the mistaken belief that hydromorphone is the generic name for morphine.

Educate patients. Prior to administration of a narcotic, repeat the name of the medication out loud to the patient as another source of confirmation.

Notes

- Dunbar PJ, Chapman CR, Buckley FP, et al. Clinical analgesic equivalence for morphine and hydromorphone with prolonged PCA. *Pain* 1996 Dec;68(2-3):265-70.
- Pain Task Force, Massachusetts General Hospital. Opioid potency and equianalgesia: critical facts [online]. 2005 Mar [cited 2007 Feb 2]. Available from Internet: <http://www.mgh.harvard.edu/PainRelief/Equianalgesia.pdf>.
- Approximate equianalgesic dosing of opioid analgesics in adults. In: Facts and Comparisons® 4.4.120 [database on CD-ROM]. St. Louis (MO): Wolters Kluwer Health, Inc.
- Institute for Safe Medication Practices. Safety issues with patient-controlled analgesia: part I—how errors occur. *ISMP Medication Safety Alert! Acute Care Edition*. 2003 Jul 10;(8)14:1-4.
- Institute for Safe Medication Practices. An omnipresent risk of morphine-hydromorphone mix-ups. *ISMP Canada Safety Bulletin*. 2004 Jun;4(6).
- Institute for Safe Medication Practices. Risk of deadly mix-up exists in most hospitals. *ISMP Medication Safety Alert! Acute Care Edition*. 2004 Jul 1;9(12):1-2.
- Institute for Safe Medication Practices. Cutting errors out of the operating room—part II. *ISMP Medication Safety Alert! Acute Care Edition*. 2002 Mar 20;(7)6.
- Confusion between opioid analgesics results in deaths [online]. USP Quality Review 1995 Feb [cited 2007 Feb 2]. Available from Internet: <http://www.usp.org/hqi/practitionerPrograms/newsletters/qualityReview/qr461995-02-01a.html>.
- Joint Commission. 2007 national patient safety FAQs [online]. [cited 2007 Jan 29.] Available from Internet: <http://www.jointcommission.org/NR/rdonlyres/C92AAB3F-A9BD-431C-8628-11DD2D1D53CC/0/LASA.pdf>.
- Institute for Safe Medication Practices. Safety issues with patient-controlled analgesia: part II—how to prevent errors. *ISMP Medication Safety Alert! Acute Care Edition*. 2003 Jul 24; 8(15):1-3.

Common Medication Pairs that Contribute to Wrong Drug Errors

There have been more than 13,000 reports submitted to PA-PSRS classified as “Medication Error, Wrong Drug.” Analysis of these reports found that 35.5% (4,617 reports) did not list the second drug involved in the event. Review of the remaining 64.5% (8,400 reports) determined that the most common pair of medications mentioned in these reports is morphine and hydromorphone (see page 86 of this *Advisory* for an article discussing this pair of medications). The most commonly cited drug in reports of wrong drug errors is OXYcodone with acetaminophen (Percocet®), which has been confused with HYDROcodone with acetaminophen (Vicodin®, Norco®), acetaminophen with codeine (Tylenol No. 3), and OXYcodone without acetaminophen. The accompanying table lists the 25 most commonly cited pairs of medications involved in wrong drug errors submitted to PA-PSRS.

There are many strategies organizations can implement that may help prevent medication errors due to confusion between drug names. As a first step, consider identifying the look-alike and sound-alike drug pairs that are most often involved in errors at your facility. Then, consider incorporating the following strategies to reduce the risk of errors with those medications:

- Separating products with look-alike names on storage shelves, computer screens, and on any printed prescriber or stock order forms.
- Building computer alerts notifying the prescriber, pharmacy, and nursing and affixing warning labels to products or storage areas as appropriate.
- Advising staff and patients about the potential for confusion.
- Using bold print to clearly distinguish letters which differ on product and storage bins labels with look-alike drug names. This strategy is commonly referred to as “tall man lettering” (e.g., chlorproMAZINE and chlorproPAMIDE).

PA-PSRS users can track medication errors associated with look-alike/sound-alike names. When entering medication error reports, Question 22, “System Factors Contributing to Medication Errors” allows users to indicate if drug name confusion played a role in medication errors during prescribing, preparation/dispensing, or administration.¹

More importantly, when entering wrong drug events into PA-PSRS, entering both drug names (i.e., the one that was prescribed and the one that was or could have been administered) will enable users to track the name pairs that are a problem in their organizations.

Note

1. Pennsylvania Patient Safety Reporting System. Medication errors linked to drug name confusion. *PA PSRS Patient Saf Advis* 2004 Dec;1(4):7-8.

Drug #1	Drug #2	Total Reports	Percent of Applicable Wrong Drug Errors (n=8400)
morphine	hydromorphone	295	3.5%
HYDROcodone w/acetaminophen	OXYcodone w/acetaminophen	199	2.4%
oxycodone	Oxycontin	188	2.2%
alprazolam	lorazepam	173	2.1%
acetaminophen w/codeine	OXYcodone w/acetaminophen	146	1.7%
OXYcodone	OXYcodone w/acetaminophen	108	1.3%
MS Contin	OxyContin	79	0.9%
Novolog Mix 70/30	Novolin 70/30	75	0.9%
morphine	meperidine	70	0.8%
propoxyphene w/acetaminophen	OXYcodone w/acetaminophen	63	0.8%
cefazolin	ceftriaxone	57	0.7%
clonazepam	clonidine	49	0.6%
clonazepam	lorazepam	46	0.5%
doPAMine	doBUTamine	41	0.5%
Solu-Cortef	Solu-Medrol	39	0.5%
Novolog	regular insulin	35	0.4%
hydromorphone	meperidine	35	0.4%
hydrOXYzine	hydrALAzine	35	0.4%
Humalog	Humulin-R	34	0.4%
Novolog	Novolin R	34	0.4%
glipiZIDE	glyBURIDE	34	0.4%
Humalog	regular insulin	32	0.4%
Vicodin	Vicodin ES	28	0.3%
diazepam	lorazepam	27	0.3%
ampicillin	cefazolin	26	0.3%
Total of Above		1948	23.1%

Table. Top 25 Medication Pairs Involved in Wrong Drug Errors Reported to PA-PSRS

Distribution of Event Types in ASFs versus Hospitals

PA-PSRS compared the distribution of event types in ambulatory surgical facilities (ASFs) relative to hospitals from June 2004 to May 2007. ASFs have proportionately more reports of the event types listed in the Table. Significance was determined by Chi-square (results yielding $p < 0.05$). ASF reports were proportionately more common in event types involving surgical or invasive procedures rather than in those involving medication errors, falls, or transfusions. Proportionately more events were reported in “other” (miscellaneous) categories by ASFs than by hospitals. On review, the analysts felt this phenomenon represented ASFs quickly defaulting to an “other” category rather than a disproportion of unusual events. ASFs may wish to make more effort in classifying an event in an existing event type category to get the most out of aggregate reports.

The most important specific category disproportionately represented by ASF reports is unplanned return

to the operating room (OR). In hospitals, Birkmeyer concluded that unplanned returns to the OR may be useful for monitoring quality and for identifying opportunities for quality improvement.¹ In the Netherlands, Kroon found that most unplanned returns to the OR were caused by errors in surgical technique (70%) compared to patients’ comorbidities (21%).²

Proportionately, more reports from ASFs involve surgical or invasive procedures. ASFs can use unplanned returns to the OR as cues for quality improvement. Using existing event types rather than defaulting to “other” categories may make aggregate reports more valuable.

Notes

1. Birkmeyer JD, Hamby LS, Birkmeyer CM, et al. Is unplanned return to the operating room a useful quality indicator in general surgery? *Arch Surg* 2001;136:405-11.
2. Kroon HM, Breslau PJ, Lardenoye JW. Can the incidence of unplanned reoperations be used as an indicator of quality of care in surgery? *Am J Med Qual* 2007;22:198-202.

Event Type	ASFs	Hospitals	Event Type	ASFs	Hospitals
<u>Adverse Drug Reaction</u> (not a medication error)			(continued)		
Skin reaction (rash, blistering, itching, hives)	141	4,320	<u>Complication of Procedure/ Treatment/Test</u>		
Other	79	4,076	Complication following surgery or invasive procedure		
<u>Equipment/Supplies/Devices</u>			Myocardial infarction	2	28
Equipment malfunction	82	3,048	Unplanned return to operating room	223	3,192
Medical device problem	26	634	Wound dehiscence	14	122
Equipment safety situation			Deep venous thrombosis	7	102
Failed test of standard procedures	2	30	Other	813	3,485
Broken item(s)	19	337	Anesthesia event		
Outdated items(s)	2	27	Myocardial infarction	1	9
Other	31	1,022	Aspiration	45	113
<u>Error Related to Procedure/ Treatment/Test</u>			Intubation trauma	9	333
Surgery/invasive procedure problem			Use of reversal agents	17	255
Break in sterile technique	16	719	Other	114	1,148
Consent missing/inadequate	91	2,993	Emergency department (ED)		
Foreign body in patient	11	423	Unplanned return to ED in 48 hours requiring admission	27	1,048
Preparation inadequate/wrong	45	1,165	Nosocomial infection		
Procedure cancelled or not performed	463	3,144	Wound or surgical site infection	66	2,456
Procedure delayed	41	2,264	Complication following spinal manipulative therapy	3	28
Procedure not completed	53	469	Other	677	4,990
Unintended laceration or puncture	89	1,239	<u>Skin Integrity</u>		
Wrong procedure	9	89	Burn (electrical, chemical, thermal)	31	778
Wrong patient	5	113	Rash/hives	13	467
Wrong site	13	118	Abrasion	64	3,356
Wrong side (left vs. right)	29	234	<u>Other/Miscellaneous</u>		
Other	127	3,008	Electric shock to patient	1	7
			Other	1,819	32,396
			All Reports (No Difference)	6,483	507,394

Table. Reports Submitted to PA-PSRS from Ambulatory Surgical Facilities and Hospitals

Obstructive Sleep Apnea May Block the Path to a Positive Postoperative Outcome

Obstructive sleep apnea (OSA) is a common sleep disorder characterized by recurrent episodes of complete and partial airway collapse during sleep, resulting in apnea or hypoapnea.¹ Apnea is defined as a complete cessation of breathing during sleep that lasts more than 10 seconds.² Hypoapnea is diminished airflow and oxygen desaturation that occurs for 3 to 10 seconds.² The adverse effects of OSA include oxyhemoglobin desaturation, fluctuations in blood pressure and heart rate, increased sympathetic activity, cortical arousal, and sleep fragmentation.¹ OSA affects an estimated 2 to 4% of the U.S. adult population.³ A prospective sleep cohort study conducted by the Medical College of Wisconsin suggests approximately 4% of women and 9% of men in the United States (ages 40 to 65 years) have moderate OSA.⁴

Problem

Approximately 80 to 90% of OSA patients are undiagnosed.^{2,4} Some reasons may include practitioners' inability to recognize sleep-related symptoms and lack of time and resources to perform the standard test, a polysomnogram, to diagnose OSA.⁵ Identifying these patients during the perioperative period may help reduce complications.⁵ The inherent problems of airway management during administration of general anesthesia and the large patient population with undiagnosed OSA increases the risk of developing respiratory and cardiopulmonary complications postoperatively, with reintubation and cardiac events identified as the most serious complications.^{6,7}

Anesthesia providers may not be aware of the comorbidities and risk factors associated with OSA. Practitioners need to consider risks factors for OSA and the perioperative management of potential problems in each patient.⁶ Although there is no consensus regarding optimal perioperative management of patients with OSA, there are techniques that may minimize complications.⁶ Therefore, identification of patients at risk, appropriate preoperative assessment, intraoperative management, and postoperative care are critical elements in optimizing patient care and safety.

PA-PSRS has received more than 250 reports since June 2004 in which OSA is specified as a contributing factor. Approximately 20% of reports were classified as Serious Events associated with patient harm, including three deaths. The reports included medical and surgical patients in both ambulatory and acute care facilities. Sleep apnea was present in the medical history in the majority of reports. Examples of events reported as incidents include the

following: extended length of stay in the postanesthesia care unit (PACU), postoperative reintubation, transfer to a higher level of care, postoperative transfer from ambulatory care centers to acute care for further treatment, falls without serious injury, need for reversal agents following narcotic administration, and increased hospital length of stay. These findings reflect similar complications cited in the literature and noted above. Examples reported to PA-PSRS include the following:

Patient was status post shoulder arthroscopy with rotator cuff repair. Patient was found to have undiagnosed sleep apnea. Oxygen saturation was unable to be maintained above 90%, and the patient was snoring. Anesthesia and surgeon determined the need for transfer and monitoring and respiratory care at hospital overnight.

Patient had cardiorespiratory arrest the night of surgery for gastric bypass. The patient was evaluated, and it was determined patient had severe sleep apnea. The patient was transferred to the [intensive care unit (ICU)].

A middle-aged patient was originally admitted with a septic joint post total knee replacement. He was obese and had a past medical history of diabetes, hypertension, obstructive sleep apnea, and hypercholesterolemia. He had been having respiratory problems with one failed attempt at intubation in OR to drain knee wound. The patient was admitted to a monitored unit. He had a respiratory arrest and was successfully intubated and transferred to the ICU. During the ICU stay, on the evening shift, he extubated himself while staff rotated the patient on a specialty bed. He was unable to be reintubated. An emergent tracheostomy was done, but the resuscitation was unsuccessful.

This article presents the pathophysiology, etiology, risk factors, signs and symptoms, diagnosis, and treatment modalities for OSA. Additionally, strategies are discussed to improve the perioperative care of patients with suspected OSA to reduce the risk of adverse outcomes. These strategies can be applied to both inpatients and outpatients receiving sedation, analgesia, or anesthesia for diagnostic or therapeutic procedures and/or surgery.

See page 107 for self-assessment questions related to this article.

Obstructive Sleep Apnea May Block the Path to a Positive Postoperative Outcome (Continued)

Pathophysiology

OSA is caused by repetitive upper airway obstruction during sleep as a result of narrowing of the respiratory passages. In obese patients, there is peripharyngeal infiltration of fat and/or increased size of the soft palate and tongue. Some patients have airway obstruction because of a receding jaw that does not allow sufficient room for the tongue. These anatomical abnormalities decrease the cross-sectional area of the upper airway. Decreased airway muscle tone during sleep and the pull of gravity in the supine position further decrease airway size and impede air flow during respiration. Initially, the obstruction is partial, but as tissues collapse and the patient rolls over onto his or her back during sleep, the airway may become completely obstructed. These obstructions lead to partial arousals from sleep as the patient struggles to breathe. These arousals often go unrecognized by the individual and may occur hundreds of times throughout the night. The muscle tone of the tongue and airway tissue increases with each arousal, but soon after the patient falls back to sleep, these muscles relax and cause partial or complete airway obstruction. The cycle continues throughout sleep.⁸

Sites of Airway Obstruction in Sleep Apnea

Airway obstruction may occur in the nasopharynx, or pharynx, and hypopharynx. There is controversy regarding the contributing factors of nasal polyps and septal deviation in airway obstruction. The most common site for obstruction is the oropharynx. Redundant peripharyngeal tissue reduces the size of the posterior airway and leads to obstruction. An elongated soft palate and enlarged uvula may further compromise the airway. The base of the tongue is a common site of hypopharyngeal obstruction, as seen in a patient with a small receding jaw. Occasionally, obstruction may be caused by an enlarged tongue, with the base of the tongue impinging on the airway just above the glottis.⁸ Additionally, OSA may be caused by less common medical problems, such as hypothyroidism, acromegaly, renal failure, post-polio syndrome, and restrictive lung disease from scoliosis.⁸

Risk Factors

Obesity is the most common risk factor associated with OSA.⁷ Family history of OSA also places an individual at greater risk.⁴ The prevalence of OSA increases with age, with a higher incidence in persons 65 years old and older.¹

Craniofacial and upper-airway structures, such as the following, may impact the occurrence of OSA: a short, thick neck circumference (i.e., greater than 17 inches for men and greater than 16 inches for

women); a large tongue; a small or receding chin; and an enlarged or elongated palate.^{5,7,9}

OSA Characteristics

The patient with OSA may present with a variety of nighttime and daytime symptoms, including the following:

- Nighttime symptoms:^{4,8}
 - Loud snoring
 - Frequent awakening
 - Gasping and choking
 - Breathing pauses (apneas)
- Daytime symptoms:^{4,8}
 - Sleepiness
 - Fatigue, irritability
 - Deficits in attention and memory

Diagnosis

The “gold standard” diagnostic test is an attended, all-night sleep study or polysomnogram.^{3-5,8} During polysomnography, several physiologic variables are recorded while the patient sleeps, including brain electrical activity, eye movements, chin and leg activity, airflow, respiratory effort (i.e., chest and abdominal movement), oxygen saturation, and cardiac rhythm.^{5,8,10} The test should be performed for at least six hours to assure valid results.¹⁰

The U.S. Food and Drug Administration has approved a few devices for home diagnosis of OSA. Several home testing devices are available, and the instrumentation ranges from simple nocturnal oximetry to multichannel systems that monitor many of the same parameters as polysomnography. Home studies are less expensive and more convenient for patients. However, the role of home evaluation devices remains a matter of debate. A comprehensive review conducted jointly by the American Academy of Sleep Medicine (AASM), American College of Chest Physicians, and American Thoracic Society concluded there was insufficient evidence to support the use of home devices to confirm or rule out OSA.⁵

Treatment of OSA

Treatment includes medical and surgical approaches. There is currently no successful pharmacological treatment for OSA.¹¹ Continuous positive airway pressure (CPAP) is the preferred treatment for most patients with OSA.³ AASM recommends CPAP treatment based primarily on the respiratory disturbance index (RDI), which is defined as the total number of apneas and hypoapneas per hour of sleep.¹² Some laboratories use an RDI of 20 episodes per hour as

Obstructive Sleep Apnea May Block the Path to a Positive Postoperative Outcome (Continued)

the threshold for initiating CPAP treatment. Treatment may also be considered in patients with a relatively low RDI who have significant symptoms and other comorbidities.^{5,12} CPAP is most successful in patients with severe disease because they have prompt reversal of their symptoms.⁸

Risk Reduction Strategies

Preoperative Evaluation

In many facilities, the preoperative screening process focuses on the diagnosis of heart and lung disease with little attention to breathing disorders like OSA.¹³ A critical element in reducing the risk of surgical complications for OSA patients is the initial preoperative screening evaluation.

The preoperative evaluation includes a review of the medical history and a physical examination.¹⁴ The anesthesia provider's review of the patient's medical record focuses on any previous airway difficulty with anesthetics, identifying comorbidities associated with OSA such as hypertension, right heart failure, pulmonary hypertension, diabetes, and arrhythmias.⁷ In addition, consider the results of any sleep studies, if available.¹⁴ The physical examination includes an evaluation of the airway, nasopharyngeal characteristics, neck circumference, tonsil size, and tongue volume.¹⁴

The following clinical signs and symptoms may be indicative of OSA:^{5,13,14}

- Body mass index greater than 35 kg/m²
- Neck circumference in excess of 17 inches for men or 16 inches for women
- Craniofacial abnormalities affecting the airway
- Anatomical nasal obstruction
- Tonsils nearly touching or touching in the midline
- Inability to visualize the soft palate

During the patient and/or family interview, use of a screening tool aimed at identifying patients with undiagnosed OSA would seem reasonable, although no such tool has been validated for use in the preoperative setting.⁵ (A sample screening tool is available online and can be adapted for use during preoperative evaluation at your facility; see the sidebar on page 96.) In the absence of a sleep

study, a presumptive diagnosis of OSA may be made based on past medical history, physical assessment, and clinical symptoms identified during the interview process or by a screening tool.¹⁴ If OSA is suspected, the anesthesiologist and the surgeon should jointly decide whether to treat the patient as though he or she has OSA.^{14,15}

To assure optimal outcomes, anesthesia providers may wish to consider the following: severity of OSA disease, invasiveness of the procedure, and the requirements for postoperative analgesics.¹⁴ Another consideration for OSA patients is whether surgery is performed on an in- or outpatient basis.¹⁴ Determining factors include facial anatomical abnormalities, comorbidities, type of surgery, type of anesthesia, need for postoperative opioids, patient age, outpatient facility capabilities, and discharge planning.¹³⁻¹⁵

Patients with documented or suspected OSA may be candidates for outpatient surgery, as identified by the American Society of Anesthesiologists (ASA) Task Force on Perioperative Management of Obstructive Sleep Apnea,¹⁴ if they

- have OSA that does not require CPAP,
- will undergo a minimally invasive procedure,
- will only be administered a local anesthetic, and
- have a limited need for narcotic analgesia.¹³

Patients may be candidates for inpatient care, as identified by the ASA task force,¹⁴ if they

- have OSA requiring use of CPAP at home,
- will undergo an abdominal or other major surgery,
- will be administered general anesthesia, or
- they are anticipated to need a significant amount of pain medication.¹⁵

The patient and his/her family should be informed of the potential complications associated with suspected OSA and involved in decisions regarding when and where to perform surgery. A preoperative screening tool may help avoid cancellations, as demonstrated in the following report submitted to PA-PSRS.

Obstructive Sleep Apnea May Block the Path to a Positive Postoperative Outcome (Continued)

The patient was admitted to preop [holding area]. Oxygen saturation at rest was 92% and 89% with activity. Patient had a probable history of sleep apnea. The case was cancelled. Recommendation was issued to reschedule patient as an inpatient and follow-up for 24 hours post surgery. The patient was discharged to home.

Intraoperative Care

Once the decision to proceed with the procedure or surgery is determined, the anesthesia care provider designs an intraoperative plan of care to reduce the risk of complications for patients with known or suspected OSA. Intraoperative concerns include airway management, choice of anesthetic, patient monitoring, and use of sedatives and opioids.^{13,14}

Airway management considerations include the use of CPAP or noninvasive positive pressure ventilation (NIPPV) in the perioperative period to lessen upper airway edema.^{6,14} Patients with OSA are at increased risk for difficult mask ventilation and difficult tracheal intubation.⁷ Techniques for optimal intubation include the following:

- Placing patient in the sniffing position (i.e., head extension with cervical flexion introduced)¹⁶
- Inserting an oropharyngeal airway to hold the base of the tongue out of the airway for mask ventilation⁶
- Using a fiberoptic bronchoscope and other airway rescue devices⁶

OSA patients are especially susceptible to the respiratory depressant and airway effects of sedatives, opioids, and inhaled anesthetics.¹⁴ Avoiding the use of sedative and opioid medications in the intra- and postoperative period may reduce complications.¹⁷ In the event sedatives or opioids are administered, reduce the dose and titrate the drug slowly.¹⁸ The following report demonstrates how sedatives negatively affected a patient's respiratory status.

The patient had large tonsils in addition to sleep apnea. Versed dosage was ordered by the anesthesiologist. It was noted that child was large for age. Correct dosage was given. After 45 minutes, the patient experienced obstructive breathing. O₂ saturation was 60. O₂ was given per nasal cannula, an IV was started, and the patient was given

reversal agent (Romazicon® times two doses). The operation proceeded.

Consider the type of anesthesia in relation to the surgical procedure.¹⁷ Anesthesiologists may consider alternatives to general anesthesia with OSA patients; for example, administration of a local anesthetic or peripheral nerve blocks for superficial procedures and administration of spinal or epidural anesthesia for peripheral and intra-abdominal surgery.¹⁴

Intraoperative patient monitoring should focus on airway management and include the following:¹⁴

- Respiratory rate
- Oxygen saturation
- Capnography (i.e., measurement of carbon dioxide [CO₂])

Postoperative Care

The most important interventions to increase patient safety and reduce complications occur during the postoperative period.¹⁹ The most critical time is the first 24 hours.^{6,14} However, deaths from complications have occurred beyond 24 hours, and patients may be at risk for 3 to 5 days post procedure.²⁰ Postoperative risk reduction strategies begin in the PACU; for example, monitoring patients for obstructed airways so that early detection leads to prompt treatment.¹⁸ Other risk reduction strategies include the following:

- Positioning the patient in a lateral or semi upright position—not supine¹⁴
- Extubating the patient when he or she is fully awake^{14,21}
- Attaching CPAP or NIPPV after extubation, especially for a patient who has undergone major abdominal surgery⁷
- Observing the patient for periods of apnea while he or she is sleeping⁷
- Monitoring the patient's pulse oximetry every 15 minutes for at least 3 times on room air⁷
- Obtaining an arterial blood gas (ABG) for periods of apnea and or pulse oximetry less than 90%^{7,14}

Obstructive Sleep Apnea May Block the Path to a Positive Postoperative Outcome (Continued)

The importance of close observation in the PACU is demonstrated in the following PA-PSRS report:

Patient did not report significant history of sleep apnea prior to surgery, although retrospective review indicated reference [to sleep apnea] in the notes of a previous admission. Review of body systems through history and physical, nursing admission assessment, and preoperative anesthesia assessment did not identify any history of respiratory problems. After 45 minutes in PACU, the anesthesiologist assessed the patient and determined the patient was stable. The anesthesiologist left the facility. Later, the PACU nurse assessed there was a change in condition including reduced level of consciousness and shallow respirations. Although on-call resident was not available, the physician on site responded. Anesthesiologist was notified of change in condition and he returned to hospital. The patient required a jaw lift, ventilation with Ambu bag, and administration of Narcan®.

PACU. The patient's clinical course in PACU can guide practitioners in determining the optimal care area for the patient's recovery. Patients with apneic periods and pulse oximetry less than 90% on room air with associated arterial blood gases indicating CO₂ retention should remain in PACU for further monitoring or be transferred to the intensive ICU for closer monitoring.¹⁴ Other factors to consider in determining the appropriate care area include past medical history and the amount and type of analgesia the patient may require.⁷ The availability of emergency airway equipment dictates the standard of care regardless of the care area to which the patient is admitted.¹⁷ The safe transportation of the postoperative OSA patient includes consideration of proper patient position (see above), administration of oxygen, and continuous monitoring of pulse oximetry. The handoff communication includes patient history; surgical procedure performed; and summary of PACU care, including airway management and medications administered during the intra- and postoperative periods.^{6,7}

After PACU and nursing care. This is a critical period because of the lingering effects of general anesthesia and sedative/opioid analgesics on the upper airway.^{18,20} Complications may include hypertension, cardiac dysrhythmias, oxygen desaturation, airway obstruction, and reintubation.¹⁵ Consider the use of standardized order sets aimed at pain

control, airway management, and early detection and prevention, such as the following:

- Properly positioning the patient (i.e., lateral, semi-upright)⁷
- If the patient is on CPAP or NIPPV at home, continuing until discharge⁷
- Administering supplemental oxygen to maintain pulse oximetry above 90%⁷
- Maintaining continuous pulse oximetry with alarm system at central nurses station⁷
- Frequent monitoring of vital signs, especially respiratory rate and pattern^{7,17,22}
- If periods of apnea or desaturation are observed, notifying the attending and obtaining arterial blood gas⁷
- Providing regional anesthesia for pain control⁷
- Avoiding benzodiazepines due to effects minor tranquilizers may have on respirations^{7,15}
- Treating with nonsteriodals whenever possible^{7,15}
- Preferably, administering opioids via epidural or regional catheter instead of intravenous or intramuscular routes⁷
- Monitoring patients who have been administered narcotics^{7,15}

The following reports demonstrate the importance of monitoring patients with OSA that have been administered narcotics and sedatives as well as considering closer monitoring of these patients in ICU setting.

Patient developed respiratory failure felt to be secondary to narcotics (OxyContin) and underlying lung disease and/or obstructive sleep apnea. The patient required bipap for respiratory support. The patient was transferred to the medical intensive care unit for observation.

Patient was admitted for umbilical hernia repair. Medical clearance was obtained from primary care practitioner, but referral was made for sleep apnea evaluation. Patient

Obstructive Sleep Apnea May Block the Path to a Positive Postoperative Outcome (Continued)

had uneventful procedure, and following short stay in PACU, went to care area on O₂ via nasal cannula at 4 p.m. Patient was morbidly obese; consequently, pulse oximetry was ordered. Patient on patient-controlled analgesia pump 1 mg with 8 minute lockout with good pain control. Saturations were 91 to 94%. Short periods of O₂ desaturation were noted late evening. Respiratory therapy consulted and O₂ was increased to 60% face tent. The patient frequently removed the tent. Supplemental O₂ was added in the next hour. Physician was not notified of this change. Nurse received new admission two hours later at which time the patient's pulse oximetry alarm sounded. Patient was found unresponsive. Patient had removed all O₂ and no pulse or respiration was observed. The [code] blue team followed the advanced cardiac life support protocol. Patient was difficult to intubate, then vomited and aspirated. The patient went into PEA and cardiac standstill. Code was called. Postmortem is pending.

In summary, patients with known or suspected OSA are at increased risk for anesthetic and sedative complications, including life-threatening cardiorespiratory complications.²² A standardized approach to the management of these patients may reduce harm. The first step involves incorporating a screening tool into the preoperative period to identify patients with OSA. Finally, implement strategies to provide safe, quality care in the intra- and postoperative periods.

Notes

1. Young T, Skatrud J, Peppard PE. Risk factors for obstructive sleep apnea in adults. *JAMA* 2004 Apr; 291(16):2013-6.
2. den Herder C, Schmeck J, Appelboom DJ, et al. Risks of general anesthesia in people with obstructive sleep apnea. *BMJ* 2004 Oct 23;329(23): 955-9.
3. Piccirillo JF, Duntley S, Schotland H. Obstructive sleep apnea. *JAMA* 2000 Sep;284(12):1492-4.
4. Stierer T, Punjabi NM. Demographics and diagnosis of obstructive sleep apnea. *Anesthesiol Clin North America*. 2005 Sep;23(3):405-20.
5. Mendez JL, Olson EJ. Even "mild" OSAHS can have a significant impact. Obstructive sleep apnea syndrome, part 1: Identifying the problem. *J Respir Dis* 2006 Apr;27(4):144-52.
6. Meoli AL, Rosen CI, Kristo D, et al. Upper airway management of the adult patient with obstructive sleep apnea in the perioperative period—avoiding complications. *Sleep* 2003 Dec 15;26(8):1060-5.
7. Finkel K, Saager L, Becker C, et al. The silent perioperative pandemic. *Sleep Review*. 2006 Jul-Aug [cited 2007 Jul 3]. Available

Visit the Patient Safety Authority Web site (<http://www.psa.state.pa.us>) to view or download the "Obstructive Sleep Apnea Preoperative Screening Tool," which can be adapted for use during preoperative evaluation at your facility. Click on "Advisories and Related Resources" in the left-hand column of the Authority's home page. Then, click on "Resources Associated with Patient Safety Articles."

from Internet: http://www.sleepreviewmag.com/issues/articles/2006-07_09.asp.

8. Victor LD. Obstructive sleep apnea. *American Family Physician*. 1999 Nov 15 [cited 2007 Jul 3]. Available from Internet: <http://www.aafp.org/afp/991115ap/2279.html>.
9. Kaw R, Golish J, Ghamande S, et al. Incremental risk of obstructive sleep apnea on cardiac surgical outcomes. *J Cardiovasc Surg* 2006 Dec;47(6):683-9.
10. Loube D, Gay PC, Strohl KP, et al. Indications for positive airway pressure treatment of adult obstructive sleep apnea patients. *Chest* 1999 Nov;115(3):863-6.
11. Silverberg DS, Iaina A, Oksenberg A. Treating obstructive sleep apnea improves essential hypertension and quality of life. *American Family Physicians*. 2002 Jan 15 [cited 2007 Jul 3]. Available from Internet: <http://www.aafp.org/afp/20020115/229.html>.
12. Couch ME, Senior B. Nonsurgical and surgical treatments for sleep apnea. *Anesthesiol Clin North America* 2005 Sep;23(3):525-34, vii.
13. Kaw R, Michota F, Jaffer A, et al. Unrecognized sleep apnea in the surgical patient: implications for the perioperative setting. *Chest* 2006 Jan;129(1):198-205.
14. Gross JB, Bachenberg KL, Benumof JL. Practice guidelines for the perioperative management of patients with obstructive sleep apnea: a report by the American Society of Anesthesiologists Task Force on Perioperative Management of patients with obstructive sleep apnea. *Anesthesiology* 2006 May;104(5):1081-93.
15. Kaw R, Golish J. Obstructive sleep apnea: what to do in the surgical patient? IMPACT consults. Proceedings of the 2nd Annual Cleveland Clinic Perioperative Medicine Summit. *Cleve Clin J Med* 2006 Sep;73 Electronic Suppl 1:S15-7.
16. Takenaka I, Aoyama K, Iwagaki T, et al. The sniffing position provides greater occipito-atlanto-axial angulation than simple head extension: a radiological study. *Can J Anesth* 2007 Feb;54(2):129-33.
17. Okwuone CO, Po W, Swick JT, et al. Obstructive sleep apnea—implications for procedural sedation. *J Radiol Nurs* 2006;25(1):2-6.
18. Moos DD, Cuddeford JD. Implications of obstructive sleep apnea syndrome for the perianesthesia nurse. *J Perianesth Nurs*. 2006 Apr;21(2):103-15.
19. Lickteig C, Grigg P. Risks of OSA and anesthesia. *Sleep Review*. 2003 Jan-Feb [cited 2007 Jul 3]. Available from Internet: http://www.sleepreviewmag.com/issues/articles/2003-01_02.asp.
20. Pang KP. Identifying patients who need close monitoring during and after upper airway surgery for obstructive sleep apnea. *J Laryngol Otol* 2006 Aug;120(8):655-60.
21. Benumof JL. Obesity, sleep apnea, the airway and anesthesia. *Curr Opin Anaesthesiol* 2004 Feb;17(1):21-30.
22. Paje DT, Kremer MJ. The perioperative implications of obstructive sleep apnea. *Orthop Nurs* 2006 Sep-Oct;25(5):291-7.

IV Infiltration: Be Alarmed Even When Your Infusion Pump Isn't

Between June 2004 and August 2007, PA-PSRS received 10 reports of events involving fluid infiltration or extravasation in patients during intravenous (IV) therapy via infusion pumps that specifically mentioned the infusion pumps' occlusion alarms. Five of the reports indicated that the infusion pumps *did not* alarm for the infiltration or extravasation, and five reports indicated that the pumps *did* alarm during the infusion therapy. The 10 PA-PSRS reports, as described below, indicate that some clinicians may misunderstand the role of occlusion alarms of infusion pumps.

The terms infiltration and extravasation are often used interchangeably; however, they do have different meanings. The Infusion Nurses Society (INS) defines infiltration as the inadvertent administration of a *nonvesicant* solution into surrounding tissue, instead of into the intended vascular pathway.¹ INS defines extravasation as the inadvertent administration of a *vesicant* solution into surrounding tissue, instead of into the intended vascular pathway.¹ A vesicant is an agent that has the potential to cause blistering or tissue necrosis.² Common vesicants include chemotherapy/antineoplastic medications, certain vasodilators and vasopressors, parenteral nutrition, certain antibiotics, and certain electrolyte solutions.³ For more information on extravasation and vesicant solutions, see the article "Extravasation of Radiologic Contrast" in the September 2004 issue of the *PA-PSRS Patient Safety Advisory*.

PA-PSRS Reports

The 10 PA-PSRS reports on IV infiltration and extravasation are described below:

Intravenous antibiotic infused via a heparin well that had recently been inserted into patient's left hand. Upon routine check of the patient, her left hand was swollen, and the heparin lock was infiltrated with half the dose of antibiotic having been infused. The [brand omitted] pump did not alarm for elevated pressure.

Patient's left forearm IV (dopamine) infiltrated. The machine never alarmed. Infiltration was found only when checking site.

IV started at right antecubital site at 12:05 a.m. with 20-gauge catheter. IV access with excellent blood return and running on gravity. IV placed on the [brand omitted] pump on minimum setting for 30 minutes. Setting was changed to moderate. IV site assessed at

1 a.m., and there were no signs of infiltration. IV site assessed at 2 a.m., and some soft tissue edema was noted. IV access was discontinued and dressing applied. IV pump did not alarm due to occlusion, and when IV access was determined to be no longer patent, the pump was indicating there was no occlusion. IV pump was removed from service.

The pump did not alarm for occlusion. The IV site infiltrated. The [physician] was aware. A warm compress was applied.

Found right arm edematous from IV infiltration; pump never alarmed.

Dopamine 400 mg/250 cc D5W at 5 mcg/kg/min running through 22 g in left wrist, found Dopamine just beginning to infiltrate when the [brand omitted] pump began alarming. IV was removed, and site was infused with Regitine as per protocol.

During transfusion of packed red cells, pump alarmed occlusion. Staff found site infiltrated. Infusion discontinued and warm compress applied.

Patient admitted and requiring IV dopamine. When nurse answered alarm from IV pump, it was noted that the patient's IV site in the left AC was infiltrated. Catheter removed intact and Regitine used at site. Site was edematous.

IV infusing with vancomycin at 100 cc/hr via IV in left bicep. Bicep became infiltrated. Patient used call bell to notify nurse when the [brand omitted] pump alarmed. Patient complained of discomfort. Vancomycin infusing for 60 minutes. Infusion stopped; heparin lock removed. Warm compresses applied. IV team called to place new HL. Old IV site in left bicep was reddened and tender, slightly firmness to palpation. Heat pad ordered.

Patient arrived from another hospital's ER with IV infusing with heparin. Staff noted infiltration, and IV catheter was kinked. Patient stated the IV pump had been alarming throughout the night, and it was just reset by the staff. Patient requested this be reported.

See page 107 for self-assessment questions related to this article.

IV Infiltration: Be Alarmed Even When Your Infusion Pump Isn't (Continued)

Patient also had heparin drip started at about 9 p.m. and did not have partial thromboplastin line monitored per protocol.

FDA IV Infiltration Reports

A search of the U.S. Food and Drug Administration's (FDA's) Manufacturer and User Facility Device Experience (MAUDE) database using the search terms "infiltration" and "infusion pump" revealed 28 reports between 1992 and 2006 describing patients who experienced fluid infiltrations during intravenous infusion therapy. Some of the MAUDE reports indicated that the infusion pumps' occlusion alarm did not activate to alert staff of an infiltration condition. Many of the reports also included statements from the implicated infusion pump manufacturers indicating that the respective infusion pumps do incorporate downstream occlusion detection circuitry, but that they are not capable of detecting infiltration conditions.

The Misconception of Infusion Pump Occlusion Alarms

Occlusion alarms on infusion pumps *do not* detect or prevent infiltration or extravasation. Infusion pumps are equipped with downstream occlusion (pressure) sensor circuitry used to detect elevated pressures in the IV administration set between the infusion pump mechanism and the patient. When the sensor circuitry detects an elevated pressure that equals the pump's preset occlusion alarm limit (e.g., 10 psi), the infusion pump will initiate an audible and a visual alarm and stop the IV flow.

Infiltration and extravasation pressures are typically much lower than pumps' downstream occlusion alarm limit settings and therefore will not trigger the occlusion alarm. Setting an infusion pump's maximum downstream occlusion alarm limit to a very low value (greater sensitivity) would still not reliably detect infiltration or extravasation pressures but would, instead, create nuisance alarm situations, which would only inconvenience the patient and caregiver. In some cases, an infusion pump may alarm for a downstream occlusion during an infiltration or extravasation; however, the occlusion condition would most likely be for reasons other than infiltration or extravasation (e.g., kinked IV tubing between the pump mechanism and the patient, a blocked IV port site).

Infusion pumps play an ancillary role in infiltration or extravasation events, and the belief that the pumps themselves produce the infiltration or extravasation is inaccurate.⁴ Infiltration or extravasation may be caused by mechanical means, such as the needle puncturing the vein wall or the needle dislodging from the implanted port, obstructed blood flow,

obstructed fluid flow, or an inflammatory reaction (e.g., chemical irritation from medications).⁵

Identifying Infiltration

Relying on an infusion pump's downstream occlusion alarm to identify an infiltration condition is not good practice. To avoid infiltrations or reduce their likelihood, monitor the IV sites of patients receiving infusion therapy via an infusion pump as frequently as possible to ensure that the catheter or needle has not dislodged. Being aware of the signs and symptoms of infiltration is also a good risk reduction strategy. INS has published an infiltration scale that can be used to document an infiltration condition. According to INS, infiltrations are graded according to the most severe presenting indicator and extravasations should always be rated as Grade 4, as follows:¹

Grade	Clinical Criteria
0	No symptoms
1	Skin blanched Edema less than 1 inch in any direction Cool to touch With or without pain
2	Skin blanched Edema 1 to 6 inches in any direction Cool to touch With or without pain
3	Skin blanched, translucent Gross edema greater than 6 inches in any direction Cool to touch Mild to moderate pain Possible numbness
4	Skin blanched, translucent Skin tight, leaking Skin discolored, bruised, swollen Gross edema greater than 6 inches in any direction Deep pitting tissue edema Circulatory impairment Moderate to severe pain Infiltration of any amount of blood product, irritant, or vesicant

Reprinted with permission from the Infusion Nurses Society, Norwood, Massachusetts.

It is important to stop the infusion therapy (i.e., infusion pump) immediately when infiltration or extravasation is first observed, and treatment is based on the severity of the infiltration.¹ Treatment options and the clinical aspects of infiltration or extravasation are beyond the scope of this article; for more information on infiltration or extravasation, see the references listed below in the "Notes" section.

IV Infiltration: Be Alarmed Even When Your Infusion Pump Isn't (Continued)

Notes

1. Infusion Nurses Society. Infusion nursing standards of practice. *J Infus Nurs* 2006 Jan/Feb;29(1S):S59-62.
2. Brown KA, Esper P, Kelleher LO, et al., eds. Chemotherapy and biotherapy: guidelines and recommendations for practice. Pittsburgh (PA): Oncology Nursing Society;2001.

3. Hadaway LC. Preventing and managing peripheral extravasation. *Nursing* 2004 May;34(5):66-7.
4. ECRI Institute. Infiltration during infusion therapy. *Health Devices* 1998 Jan;27(1):39.
5. Hadaway LC. I.V. infiltration: not just a peripheral problem. *Nursing* 2002 Aug;32(8):36-42.

Preventing Adverse Events Related to Chest Tube Insertion

A chest tube insertion tutorial program for physicians, particularly surgical and emergency department residents, is available from the U.S. Agency for Healthcare Research and Quality (AHRQ). The 11-minute DVD, "Problems and Prevention: Chest Tube Insertion," discusses four major sources of adverse and fatal outcomes for patients and clinicians: breaks in sterile technique, inadequate anesthesia, incorrect insertion technique, and inadequate self-protection by clinicians. After using video clips of chest tube insertion procedures to illustrate these four problems, the program then discusses correct procedures and preventive measures; for example, remembering the mnemonic UWET (i.e., Universal precautions, Wider skin prep, Extensive draping, and Tray positioning) to help prevent breaks in sterile technique.¹

PA-PSRS Reports

More than 1,100 reports have been submitted to PA-PSRS that mention chest tube insertion or placement. Most of these reports indicate chest tube insertion in response to a patient medical condition (e.g., pneumothorax). At least two reports of deaths were associated with problems or complications of chest tube placement, such as the following:

Patient was undergoing a chest tube insertion by a CT surgeon. Difficulty was encountered, and a massive hemorrhage resulted. Patient experienced a cardiac arrest and transferred to intensive care unit, where she later died.

The patient went to the operating room for repair of a diaphragmatic tear following a motor vehicle accident. There was cardiac injury during insertion of the chest tube, and, ultimately, the patient died. The patient's thoracic internal organs were out of place due to the injury received in the accident. There was a pericardial tear and the heart was out of alignment, as was the stomach, which had pushed up into the lung area. The heart and stomach were injured during the placement of the chest tubes due to this misalignment, causing massive bleeding. The insults to the organs were repaired, but the heart ceased functioning, and numerous attempts to resuscitate were unsuccessful.

Examples of the sources of adverse and fatal outcomes discussed in the DVD also can be found in reports submitted to PA-PSRS, although most examples pertain to incorrect

insertion technique. Some problems with technique that the DVD program focuses on include avoiding intercostal neurovascular damage, avoiding lacerations of the lung, and avoiding damage to other organs or structures.¹ Examples in reports to PA-PSRS include those above and the following:

Injured stomach from chest tube (perforation).

Physician performed chest tube insertion. Approximately 15 minutes later, physician noted bright red blood draining into pleurovac. Patient taken to operating room for exploratory thoracotomy and wedge resection of right upper lobe. Upon closure, small arterial bleeder noted within layer of muscle. No further bleeding noted within chest.

During its focus on insertion technique, the DVD program also discusses appropriate suturing to avoid leaks by closing the skin around the entry point and suturing the tube into position.¹ Outcomes that may be related to suturing are apparent in multiple reports to PA-PSRS, such as the following examples:

On admission assessment from operating room, bubbling observed in chest tube collection system. The original chest tube was inserted at another hospital. Upon further assessment, drain holes from chest tube exposed and sutures not intact. Chest tube discontinued and new chest tube inserted by trauma surgeon.

Patient was pulled up in bed. Chest tube not secured properly. Chest tube was found on bed.

Obtaining the DVD

"Problems and Prevention: Chest Tube Insertion" was developed by the Charles "McC." Mathius, Jr., National Study Center for Trauma and Emergency Medical Systems at the University of Maryland School of Medicine and funded by an AHRQ grant. More information is available from AHRQ at http://www.qualitytools.ahrq.gov/summary/summary.aspx?doc_id=9928.

Note

1. Charles "McC." Mathius, Jr., National Study Center for Trauma and Emergency Medical Systems, University of Maryland School of Medicine. Problems and prevention: chest tube insertion [DVD]. AHRQ Pub No. 06-0069-DVD. Rockville (MD): 2006 Sep.

Should Patients be Accompanied When Discharged from Ambulatory Surgery?

A Pennsylvania healthcare facility asked PA-PSRS to address the issue of whether or not ambulatory surgery patients must have escorts who can accompany them home following the procedure. While some clinicians in the facility felt it was acceptable to let patients take a taxi or public transportation following discharge, others believed this was unsafe.

Recovery Phases

Recovery from anesthesia has three phases:

1. Early: The period occurring from discontinuation of anesthetic agents to resumption of protective reflexes and motor function.
2. Intermediate: The period when the patient meets discharge criteria.
3. Later: The period when the patient returns to a preoperative physiological state.^{1,2}

Effects of Anesthesia

While patients are discharged home when they fulfill discharge criteria, ambulatory surgery patients may not regain their preoperative physiological state at discharge. Patients in clinical studies demonstrate significant cognitive and psychomotor impairment after various types of anesthesia (general, regional, and monitored anesthesia care).¹

For example, 20 patients who underwent left knee arthroscopic ambulatory surgery with general anesthesia were compared with a matched control group of 20 health subjects.³ Both groups underwent the following evaluation preoperatively and at 2 and 24 hours postoperatively: driving simulation performance; electroencephalographic (EEG) verified parameters of sleepiness; and subject assessment of sleepiness, alertness, fatigue, and pain. Compared to healthy individuals, patients showed impaired driving skills and lower alertness levels preoperatively and at two hours postoperatively. Sleepiness, alertness, and driving performance were worse at two hours after surgery. However, testing indicated that the patients were safe to drive 24 hours after general anesthesia.

In another study,^{4,5} 103 outpatients were surveyed via telephone the day after an endoscopic procedure. A substantial number of patients experienced a postoperative problem; see Table for complete results.

While groggy, patients may injure themselves or others.⁶ They also may be unable to obtain help if a postsurgical complication arises.⁶ Patients who drive

Problem	Percentage (n = 103)
Could not remember instructions given by the physician	94%
Could not remember instructions given by the nurse	67%
Stated they could not have managed without a caregiver	31%
Did not feel like him/herself by the morning after the procedure	29%
Experienced pain/discomfort since leaving ambulatory surgery	24%
Experienced dizziness or fell since the procedure	12%
Indicated they were disoriented the first few hours at home after the procedure	9%
Reported nausea and vomiting	7%

Table. Postoperative Problems Experienced by Outpatients.

Sources: Gall S, Bull J. Clinical risk: discharging patients with no-one at home. *Gastroenterol Nurs* 2004 May/June;27(3):111-4; Bull J, Gall S. Safely home: safety issues surrounding the discharge of day patients post endoscopy. *J. GENCA* 2004 Jan;13(4):8-9.

after receiving sedation or narcotics have been compared to people who drive while under the influence of alcohol.⁶

PA-PSRS reports also reveal some of the adverse outcomes patients experience following discharge from ambulatory surgical facilities (ASFs).⁷

Regulations/Guidelines/Standards

State regulatory bodies, accrediting organizations, and professional medical and nursing societies specify that ambulatory surgery patients have a responsible person accompany them home because of significant cognitive and psychomotor impairment after anesthesia and sedation.⁶

Regulations

The Pennsylvania Code for ASFs requires that preoperative care shall include providing patients or responsible persons written instructions that include the following:

Upon discharge of a patient who has received sedation or general anesthesia, a

Should Patients be Accompanied When Discharged from Ambulatory Surgery? (Continued)

responsible person shall be available to escort the patient home. With respect to patients who receive local or regional anesthesia, a medical decision shall be made regarding whether these patients require a responsible person to escort them home. [28 Pa. Code §555.22(c)(5)]

The postoperative care standards include the following:

Patients shall be discharged in the company of a responsible person if one is deemed necessary under §555.22(c)(5). [28 Pa. Code §555.24(e)]

These regulations do not define “responsible person.”

Medicare’s Conditions of Participation for ambulatory surgery centers indicate that all patients are discharged in the company of a responsible adult, except those exempted by the attending physician.⁸

Accrediting Organizations

The Joint Commission standards indicate that patients who have received sedation or anesthesia are discharged in the company of a designated, responsible adult.⁶ The Accreditation Association for Ambulatory Health Care (AAAHC) specifies that patients are discharged in the company of a responsible adult when they have received general anesthesia, regional anesthesia, or either moderate or deep sedation/analgesia.⁶

Professional Societies

The American Society of Anesthesiologists’ (ASA) Practice Guidelines for Postanesthetic Care⁹ indicate that the following should be mandatory for all patients who have just received general anesthesia, regional anesthesia, or moderate or deep sedation: “As part of a recovery room discharge protocol, all patients should be required to have a responsible individual accompany them home,” to increase patient comfort and satisfaction and to reduce adverse outcomes.

Moreover, the 2003 ASA Guidelines for Ambulatory Anesthesia and Surgery recommend, in part, that patients who receive other than unsupplemented local anesthesia must be discharged with a responsible adult.⁶

The American Society of PeriAnesthesia Nurses 2004 Standards of Perianesthesia Nursing Practice specify discharge criteria that include:

- verifying arrangements for safe transportation home and
- reinforcing discharge planning with the patient and family or accompanying responsible adult.⁶

The Australia and New Zealand College of Anaesthetists 2000 Recommendations for Day Surgery^{4,5} require that a responsible person transport the patient home in a suitable vehicle (a train or bus is not usually deemed suitable). The responsible person should stay with the patient at least overnight following discharge from ambulatory surgery.

Responsible Person

To be deemed a responsible person, such a person must be physically and mentally able to make decisions for the patient’s welfare if necessary. Moreover, the responsible person must understand the requirements for postanesthetic care and intend to comply with these requirements, especially concerning public safety.^{4,5}

A taxi driver is not considered a responsible person for a sedated patient. While a taxi driver may get the patient to the patient’s home address, someone needs to be available to get the patient into the house, such as assisting a patient on crutches to navigate the steps.⁸

Role of Responsible Persons

Responsible persons can ensure that the patient arrives home safely and assist the patient with postoperative complications such as nausea, vomiting, dizziness, and pain.² They can also request medical assistance in the event of an emergency.² Another role of a responsible person may be reflected in the Association of periOperative Registered Nurses (AORN) Guidance Statement: Postoperative Patient Care in the Ambulatory Surgery Setting: “Discharge instructions should be reviewed with the patient and a responsible adult before discharge.”¹⁰

Effectiveness of Responsible Persons

The literature is largely silent about whether a responsible person accompanying the patient home results in fewer adverse outcomes. One small prospective study at one tertiary care institution compared outcomes of 55 patients who had no responsible person with a matched control group of patients with a responsible person.² The study did not find a statistically significant difference in

Should Patients be Accompanied When Discharged from Ambulatory Surgery? (Continued)

outcomes such as emergency visits, readmission to the hospital within 30 days, or rates of unanticipated admission. Larger multicenter studies are required to further determine whether responsible persons are beneficial to patients discharged from ASFs.²

Risk Reduction Strategies

Risk reduction strategies begin well in advance of the ambulatory surgical procedure, with pre-procedure planning and intensive education.^{4,5} Safe discharge planning involves a comprehensive pre-operative assessment, effective communication between the physician's office, the ASF, the patient and family/responsible person, and strong patient/family/responsible person education.^{11,12}

In the physician's office when surgery is first discussed, the physician can inform the patient that a responsible person is required to take the patient home upon discharge.^{6,8} Such discussions can be documented on a form that becomes part of the patient's medical record.⁶ This information can also be restated during preoperative registration and upon arrival to the ASF.⁸ This requirement can also be reinforced on the physician's and the ASF's Web site,⁶ as well as specifying this requirement in written preoperative instructions and/or in a patient brochure given to the patient.⁸

During calls the day before the procedure, the patient can be reminded that a responsible person will be required. At that time, any potential problems complying with this requirement can be identified,⁸ so that alternative arrangements can be made.⁴ Patients can be educated about what to expect after surgery, and that health insurance will not pay for an overnight hospital stay after the procedure.^{11,12} Patients can be referred to social services and community resources for transportation assistance.^{11,12} Some ASFs actually obtain the name and telephone number of the responsible person when surgery is scheduled.⁶ Other facilities require that the responsible person be present before the procedure and stay at the ASF during the procedure. If the responsible person cannot stay, the ASF obtains a telephone or pager number and calls the responsible person as soon as the patient reaches the recovery area.⁸ If the patient arrives at the ASF without arrangements for a responsible person, some facilities postpone or cancel the surgery.^{4,6,8,11,13}

Planning in advance for challenging scenarios that might arise will help ASFs approach transportation

and responsible person problems in a consistent manner. Consider the following strategies:

- Conduct a staff meeting and develop action plans to ensure safe discharge for all patients.⁸
- Compile a list of resources to call upon when transportation problems arise, such as community and church volunteer groups, van services, homeless shelters, and patient medical escort services.^{6,8}
- Some hospitals offer a "hotel bed" where patients can pay a fee to stay in a hospital setting overnight without nursing care but with easy access to emergency assistance.⁶ Or, nursing homes or assisted living facilities may provide a supervised environment for such patients on a temporary basis.⁶
- Offer home health visits^{4,5} or hire an agency nursing assistant to help allow the patient to go home safely.⁶
- If medically feasible, consider performing minor procedures with local or no anesthesia⁶ if transportation or a responsible person is not available to the patient.

A Creative Example

A medical center in Pittsburgh¹⁴ has arranged to pay a local ambulance company to take patients home. The ambulance staff are trained healthcare professionals and usually provide transportation in a four-wheel drive vehicle. This arrangement has been used on those few occasions when a patient has no one to escort them home, but a caretaker is available at their house to provide assistance.

Taxis

Most ASFs do not use taxis because the driver is not considered a responsible adult in relation to a patient who has undergone sedation or anesthesia.⁶ However, when no other alternative exists, some facilities allow the patient to remain for additional hours at the ASF to allow the patient to recover more fully.⁶ If a taxi must be used to transport a patient home, it is prudent to call the home to make sure someone is at the house to meet the taxi.⁸

Against Medical Advice (AMA)

Some patients state at the time of admission that someone will be picking them up, but no escort arrives at the time of discharge. If a patient insists on driving home, the patient is technically not being

Should Patients be Accompanied When Discharged from Ambulatory Surgery?(Continued)

discharged, but is leaving against medical advice.¹³ If the patient is impaired by drugs, the ASF should encourage the patient to remain until more fully recovered.⁸ Inform the patient that medical insurance may not pay for the procedure when patients leave AMA.⁶ Try to convince the patient that he/she is responsible for the safety of others, not just his/her own. Discuss the potential harm to innocent people if he/she drives under the influence of sedation/anesthesia.⁶ Strongly advise the patient against this highly unsafe course of conduct.¹³

However, ASFs cannot keep sedated patients against their will, as this may constitute false imprisonment.⁶ Healthcare workers cannot physically restrain the patient or keep his clothes or car keys.¹³ If patients insist upon leaving without an escort, facilities can call the patient's home to confirm that the patient arrives safely and try to contact someone else at home who can assist the patient during the postoperative period.⁶ Facilities also can warn such patients that they will notify the police if they choose to drive; if the patient does drive, the facility can inform police of a potentially impaired driver on the road.^{6,8}

While ASFs have a responsibility to ensure that a patient is discharged appropriately, the ASF does not have control of the patient's actions once the patient leaves the ASF.⁸ At the time of admission, healthcare workers may rely on a patient's statement that someone will be picking them up at discharge.¹³ The ASF has no responsibility to screen escorts ahead of time.⁸

Conclusion

Patient safety is enhanced when the ASFs accomplish the following:

- Implement a written protocol regarding escorts which incorporates state regulations, accreditation standards, and professional organization guidelines,^{6,8} including
 - under what circumstances is an escort required;
 - when no escort, no surgery applies;¹³
 - actions for unforeseen circumstances;
 - a definition of responsible person;^{6,8} and
 - what constitutes a safe discharge.

- Educate healthcare workers regarding this protocol.^{6,8}
- Monitor compliance with the protocol.⁸
- Preoperatively, thoroughly instruct patients about why escorts are required.⁸
- Provide patients with preoperative instructions/brochure indicating that an escort is required postoperatively.⁸
- Ensure that staff follow the protocol to the best extent possible and acts reasonable in unforeseen circumstances.⁶
- Thoroughly document patient assessments and staff interventions⁶ to ensure that the patient has a caregiver until the patient is able to care for him/herself.⁶

Notes

1. Awad IT, Chung F. Factors affecting recovery and discharge following ambulatory surgery. *Can J Anesth* 2006 Sep;53(9):858-72.
2. Chung F, Imasogie N, Ho J, et al. Frequency and implications of ambulatory surgery without a patient escort. *Can J Anesth* 2005 Dec;52(10):1022-6.
3. Chung F, Kayumov L, Sinclair DR. What is the driving performance of ambulatory surgical patients after general anesthesia? *Anesthesiology* 2005 Nov;103(5):951-6.
4. Gall S, Bull J. Clinical risk: discharging patients with no-one at home. *Gastroenterol Nurs* 2004 May/Jun;27(3):111-4.
5. Bull J, Gall S. Safely home: safety issues surrounding the discharge of day patients post endoscopy. *J. GENCA* 2004 Jan;13(4):8-9.
6. Flowers L. Ambulatory surgery centers: tips for enforcing patient escort policies. *OR Manager* 2006 Jul;22(7):25-7.
7. Pennsylvania Patient Safety Reporting System. Unanticipated care after discharge from ambulatory surgical facilities. *PA PSRS Patient Saf Advis* 2005 Dec;2(4):1,4-6.
8. Mathias JM. Ambulatory surgery centers: what's ASC's obligation for escorts? *OR Manager* 2004 Mar;20(3):29-31,34.
9. American Society of Anesthesiologists. Practice guidelines for postanesthetic care. *Anesthesiology* 2002 Mar;96(3):742-52.
10. Association of periOperative Registered Nurses (AORN). AORN guidance statement: postoperative patient care in the ambulatory setting. *Standards, recommended practices, and guidelines*. Denver (CO): AORN 2005.
11. Flowers L. Ambulatory surgery centers are your elderly patients safe to go home? *OR Manager* 2005 Dec;21(12):21,23,25.
12. Burden N. Discharge planning for the elderly ambulatory surgical patient. *J PeriAnesth Nurs* 2004 Dec;19(6):401-5.
13. No designated driver: court refuses to place liability burden on discharge nurses. *Legal Eagle Eye News! Nurs Prof* 2005 May;13(5):1.
14. Medical center offers rides home to day surgery patients. *Quality Improvement Report* 2007 May;2(5):9.

Deaths Following Ambulatory Surgery

The Centers for Medicare & Medicaid Services (CMS) are revising their criteria for services that can be performed in ambulatory surgical facilities (ASFs).¹ This prompted us to look at PA-PSRS reports of death following ambulatory surgical facility procedures. We found the following 10 reports:

2004

Patient A: An elderly patient had a colonoscopy for rectal bleeding. The procedure was complicated by a perforation of the colon. The patient was transferred to a hospital, underwent surgical correction, and died following postoperative complications.

Patient B: An elderly patient had a cardiopulmonary arrest while receiving postoperative discharge instructions after an unspecified procedure. The patient was resuscitated and transferred to a hospital, but died there.

2005

Patient C: An elderly patient had an upper gastrointestinal (GI) endoscopy with dilation. Several days later, the patient had upper GI bleeding, was admitted to the hospital and appropriately treated, but died.

Patient D: An elderly patient had an uneventful screening colonoscopy and was discharged in stable condition. The patient was found dead at home the next day. The cause of death was listed as “natural causes.”

Patient E: A young adult vomited during an upper GI endoscopy, aspirated the emesis, was intubated, was transferred to a hospital, and subsequently died.

Patient F: A middle-aged patient had a cardiopulmonary arrest during a retrobulbar block for eye surgery. The patient was intubated, transferred to a hospital in unstable condition, and died.

Patient G: A young adult had an apparently routine tonsillectomy. The patient was found unresponsive later that day at home; resuscitation efforts were not successful. The autopsy showed no gross pathology.

2006

Patient H: An elderly patient had uneventful eye surgery. The patient died at home later that day after complaining of not feeling well.

Patient I: An elderly patient had a respiratory arrest at the end of a procedure. The patient was intubated, transferred to a hospital, and subsequently died.

Patient J: A middle-aged patient had respiratory distress during the recovery period after a procedure. The patient required re-intubation, but progressed to cardiac arrest. The patient was transferred to a hospital in unstable condition and died.

We note that it is not the procedure itself that is the emergency, but the complication. In this cohort, the common factors that were identifiable were either pre-existing co-morbid medical conditions that produced cardiopulmonary arrest or problems with ventilation. These experiences underscore the importance of ASFs having the capacity to respond to predictable emergency conditions. In addition to the obvious—cardiopulmonary arrest, problems managing the airway, dysrhythmias, and bleeding—air embolus and malignant hyperthermia are more unusual problems that could theoretically occur in the ASF setting. As previously noted, the capacity of ASFs to respond to emergencies includes established transfer agreements with hospitals.²

Notes

1. Centers for Medicare & Medicaid Services. 42 CFR parts 410, 414, et al. Medicare: hospital outpatient prospective payment system and CY 2007 payment rates; proposed rule. *Fed Regist* 2006 Aug 23;71(163):49636-46.

2. Pennsylvania Patient Safety Reporting System. Expecting the unexpected: ambulatory surgical facilities and unanticipated care. *PA PSRS Patient Saf Advis* 2005 Sep;2(3):6-8.

The Big Picture

**Janet Johnston, RN, MSN, JD, Patient Safety Analyst
Pennsylvania Patient Safety Reporting System**

Jan Johnston was the first nurse analyst hired for PA-PSRS. She is a registered nurse with a Master of Science in Nursing. She also has a law degree. Prior to joining PA-PSRS, she was the risk manager of a hospital system in New Jersey. She has reviewed tens of thousands of the reports submitted to PA-PSRS and written more than 30 articles for the Advisories. She has provided tremendous expertise and insight to the PA-PSRS team. She and her husband are retiring and moving to their vacation spot in Vermont. The PA-PSRS team is very appreciative of her dedication and contributions to patient safety in Pennsylvania. Prior to her departure, we asked Jan to give us her general impression of patient safety in Pennsylvania. The PA-PSRS team will miss her wisdom and wishes her a well-deserved retirement looking out her big picture window over the autumn leaves of Vermont.

—John R. Clarke, MD, Editor

As a clinical analyst over the past three years, I have had the privilege of reviewing thousands of Serious Events and Incidents submitted to PA-PSRS since its inception in June 2004. It has been quite an exciting experience seeing the program grow to a database containing nearly 600,000 reports.

Upon my retirement, I'd like to share one concept about these adverse events and near misses — a very common thread that runs through many of these reports. It has to do with what I call "The Big Picture." It seems that many medical errors may occur because in performing individual health-related tasks we may not see how these tasks contribute to the patient's condition as a whole. It's sort of like having a bunch of jigsaw pieces in a box before we put them together to reveal a beautiful landscape. Each piece separately does not reveal the whole. And without each puzzle piece, the picture is not complete — we're missing something. In healthcare, each task is very important to the patient's care. However, if we do one task without seeing how it relates to the other tasks ordered for a patient, we may miss something vital, compromising the patient's safety.

Here are some PA-PSRS reports that, I believe, highlight this point.

A diabetic patient was NPO after midnight as ordered for a diagnostic test the next

day. The patient received insulin as ordered the next morning, went for the diagnostic test, and became hypoglycemic, requiring administration of D50.

An 80-year-old patient was ordered intravenous (IV) fluids at 250 cc/hr. This order was fulfilled for three days, at which time the patient was diagnosed with congestive heart failure.

An NPO patient received no medications by any route for three days.

A child who had a documented allergy to dairy products received a tube feeding of 100% whey as part of a protein tolerance test for renal function. The child sustained a life-threatening anaphylactic reaction.

A patient was on an Integrelin drip [blood thinner] after a cardiac catheterization. Overnight, the patient developed hemoptysis, and blood continuously oozed from the groin insertion site. The nurse documented detailed assessment notes and frequently monitored the patient. The nurse notified the resident. There were no new or revisions in orders. The next morning, the cardiologist saw the patient, stopped the Integrelin infusion, and ordered a sandbag on the groin after the Angio-Seal™ was discontinued.

Healthcare workers do not come to work intending to do a bad job. However, there are times when there is so much to do for so many patients that we become task oriented — writing orders or following orders without always considering whether such interventions are really appropriate in the context of the individual patient's diagnosis, co-morbidities, and condition. Our clinical director, Dr. John Clarke, has called the process of putting the pieces together sense making, or situational awareness. This process could also be called holistic thinking, or "the big picture." What systems or process breakdowns might have occurred to cause the errors specified above?

- Why was the NPO patient's insulin order not adjusted to prevent hypoglycemia?



Jan Johnston, RN, MSN, JD

The Big Picture (Continued)

- Did it make sense for an elderly patient to have such a large amount of IV fluids for several days?
- Does it make sense that a hospitalized patient receive no medications for several days?
- Why was the dairy allergy not linked to the ingredients of the tube feeding that was ordered and administered?
- Why would Integrelin (a blood thinner) be administered to a patient who was actively bleeding?

Adding systems and processes that incorporate a holistic perspective for each patient, rather than the tunnel vision of performing specific tasks, might enhance patient safety. Is there a way to formalize or standardize the process of seeing the big picture for each patient during the following situations:

- With every new order/set of orders?
- At change-of-shift report?

- Whenever handoff communication occurs?
- During multidisciplinary patient rounds?
- During development and revisions of patient care plans and/or the medication administration record?
- Whenever a patient's level of care changes?

I am providing this food for thought in hopes of promoting dialogue. Maybe you have additional ideas about this subject. If so, please share them with the Patient Safety Authority through the PA-PSRS Help Desk at 866-316-1070 or support_papsrs@state.pa.us so we can publish them in the *PA-PSRS Patient Safety Advisory*.

I am so proud of all the facilities, staff, and Patient Safety Officers who have made PA-PSRS a reality and such a success. Keep up the good work! I know Pennsylvania will continue to be in the forefront of patient safety, as a model for the United States and around the world.

Self-Assessment Questions

The following questions about selected *PA-PSRS Patient Safety Advisory* articles may be useful for internal education and assessment. You may use the following examples or come up with your own.

Inadvertent Mix-Up of Morphine and Hydromorphone: A Potent Error

- The approximate equianalgesic dose of oral hydromorphone is which one of the following?
 - One-tenth the dose of oral morphine
 - One-fourth the dose of oral morphine
 - Equal to the dose of oral morphine
 - Twice the dose of oral morphine
 - Ten times the dose of oral morphine
- The approximate equianalgesic dose of parenteral hydromorphone is which one of the following?
 - One-tenth the dose of parenteral morphine
 - One-fourth the dose of parenteral morphine
 - Equal to the dose of parenteral morphine
 - Twice the dose of parenteral morphine
 - Seven times the dose of parenteral morphine
- Conditions that may contribute to harm from mix-ups between morphine and hydromorphone include all EXCEPT which one of the following?
 - The more potent morphine is given instead of hydromorphone
 - The location of care areas (e.g., the emergency department)
 - The similarity in the names of the medications
 - Breakdown in the communication of drug orders
- Which of the following steps would not help to reduce the risk of patient harm with the use of morphine and hydromorphone?
 - Reducing the number of available concentrations of both drugs
 - Allowing unlimited stock of these medications
 - Using tall man lettering to differentiate hydromorphone from morphine
 - Learning about the differences between both medications

Obstructive Sleep Apnea May Block the Path to a Positive Postoperative Outcome

- Which one of the following indicates clinical symptoms of obstructive sleep apnea (OSA)?
 - Muscle cramps and twitching
 - Decreased libido
 - Frequent awakening associated with gasping and choking
 - Diaphoresis, frequent urination
- To identify OSA during preoperative evaluations of surgical patients, it is important for anesthesia providers to obtain patient information including all EXCEPT which one of the following?
 - Previous difficulties with anesthesia
 - Large neck circumference, body mass index greater than 35kg/m², and nasopharyngeal characteristics
 - Loud, excessive snoring, daytime fatigue, and irritability
 - Swallow test and electroencephalogram results

- Intraoperative treatment for the patient with suspected OSA may include which one of the following?
 - Insertion of an oropharyngeal airway, use of fiber optic intubation
 - Use of sedatives in the preoperative period
 - Bolus administration of large doses of sedatives and opioids
 - Use of general anesthesia for all procedures
- Patients with OSA require more time in the postanesthesia care unit to assess and maintain airway stability.
 - True
 - False
- Which one of the following risk reduction strategies applies to the postoperative OSA patient?
 - Extubating early
 - Positioning the patient in a lateral or semi upright position
 - Obtaining blood gas
 - Monitoring vital signs and pulse oximetry every four hours

IV Infiltration: Be Alarmed Even When Your Infusion Pump Isn't

- The difference between infiltration and extravasation is which one of the following?
 - Nonexistent; the terms are interchangeable.
 - Extravasations are larger, involving all the fluid.
 - Extravasations are reserved for infiltration of agents that can cause local tissue necrosis.
 - Extravasations are infiltrations caused by pressure injectors.
- Infusion pump occlusion alarms do not detect or prevent infiltration or extravasation conditions.
 - True
 - False
- Infiltration may be caused by mechanical means, such as the needle puncturing the vein wall or the needle dislodging from the implanted port, obstructed blood flow, obstructed fluid flow, or an inflammatory reaction (e.g., chemical irritation from medications).
 - True
 - False
- According to Infusion Nurses Society's infiltration scale, grade 2 clinical criteria for assessing infiltration includes all EXCEPT which one of the following?
 - Skin blanched
 - Edema 1 to 6 inches in any direction
 - Cool to touch
 - Possible numbness
 - With or without pain

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



An Independent Agency of the Commonwealth of Pennsylvania

The Patient Safety Authority is an independent state agency created by Act 13 of 2002, the Medical Care Availability and Reduction of Error (“Mcare”) Act. Consistent with Act 13, ECRI Institute, as contractor for the PA-PSRS program, is issuing this publication to advise medical facilities of immediate changes that can be instituted to reduce Serious Events and Incidents. For more information about the PA-PSRS program or the Patient Safety Authority, see the Authority’s Web site at www.psa.state.pa.us.



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



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