PA PSRS
Pennsylvania Patient Safety Reporting System

Patient Safety Advisory

Produced by ECRI under contract to the Patient Safety Authority

Vol. 1, No. 3—Sept. 2004

Patient Safety Authority Update

PA-PSRS continues to receive recognition as an innovative approach to promoting patient safety and reducing medical errors. In its September 2004 issue, *Healthcare Informatics*, a monthly magazine, website and weekly newsletter published by The McGraw-Hill Companies, named Dr. Robert Muscalus, Pennsylvania's Physician General and Chair of the Authority's Board of Directors, as one of nine IT Healthcare Innovators for 2004 who "creatively utilize technologies to improve the quality and safety of patient care." More information about the award is available on the Authority website at www.psa.state.pa.us.

While numerous facilities have expressed favorable comments about their ability to access PA-PSRS and utilize the system's analytical tools, the Authority has stressed that PA-PSRS is a dynamic system that will undergo periodic system improvements and enhancements. To help assure that PA-PSRS effectively meets your needs, the Authority is developing a survey tool to solicit feedback from all facility-users. You can expect to receive a copy of the survey later this fall. We value your input; please take time to complete and return the survey when you receive it.

In a similar vein, numerous facilities have inquired about the possibility of developing a so-called "interface" between their existing internal reporting systems and PA-PSRS. During facility training sessions, Authority staff promised to look at the feasibility of developing an "interface" and to determining how, if at all, the Authority might facilitate this process. Now that PA-PSRS is up-and-running, the Authority has begun to assess this matter. We will be seeking input from many facilities and will keep you posted as this feasibility study moves forward.

Extravasation of Radiologic Contrast

Extravasation of radiologic contrast media accounts for a substantial proportion of reports submitted to PA-PSRS. Intravenous complications account for approximately 5% of all reports submitted to PA-PSRS. Complications related to administration of radiologic contrast media account for approximately 11% of these IV complications.

Occurrences related to radiologic contrast administration are reported to PA-PSRS as either infiltrations or extravasations. Over half of the contrast administration issues are categorized as infiltrations. The terms "infiltration" and "extravasation" seem to be used interchangeably as they relate to contrast media. However, there is an important difference between these terms.

The Infusion Nurses Society (INS) defines an infiltration as the inadvertent administration of a *nonvesicant* solution into surrounding tissue, instead of into the intended vascular pathway. Extravasation is 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] Radiologic contrast media are considered to be vesicant solutions.

Though chemotherapy/antineo-plastic medications are well-known vesicants, other vesicant solutions include certain vasodilators and vasopressors, parenteral nutrition, certain antibiotics, and certain electrolyte solutions.[3] See the inset article "Common and Lesser Known Vesicants" for a detailed list.

Vesicant solutions are capable of causing significant injury to patients. Such injuries depend upon such factors as: the type of vesicant, amount and concentration infused, and the length of time the drug remains in the tissue. Once extravasation occurs, damage can continue over a long period of time,

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

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Extravasation of Radiologic Contrast (Continued)

involving skin, nerves, connective tissue, and joints.[4-6] Consequences of extravasation may include infection, loss of function, necrotic ulcers, disfigurement, reflex sympathetic dystrophy, surgical debridement/plastic surgery, skin grafting, amputation, and skin sloughing.[2-4,6] Severe extravasation injuries associated with contrast media include: skin ulceration, necrosis, hypoasthesias, marked deformity of the extremity involved, weakness, pain, decreased range of motion, flexion contractures, difficulty performing activities of daily living, and surgical debridement including skin graft procedures.[5]

Approximately 3% of PA-PSRS reports relating to contrast occurrences categorized as infiltrations or extravasations were Serious Events with harm scores of E or F. In one case, the "hold" button of the power injector used to administer a vesicant did not function. A clinician had to shut off the main power to the injector to stop the injection. Thereafter, the patient was admitted to the hospital for three days for treatment of the extravasation site. In another case, a patient developed compartment syndrome, resulting in an operative procedure.

Risk factors for contrast extravasation and subsequent severe injuries include the following.[5,7] [Table 1 indicates how some risk factors are reflected in PA-PSRS.] Patients with major extravasation injury tend to be under 11 or over 70 years of age. Approximately half of the contrast extravasation events reported to PA-PSRS occurred in patients within those age ranges. Greater morbidity from extravasations occurs when the dorsum of the hand, the foot or the ankle are used to inject contrast media. Patients with arterial insufficiency, compromised venous/lymphatic drainage, venous thrombosis, altered perfusion in the extremity injected are at increased risk for contrast extravasation. Health problems reflecting abnormal circulation/perfusion may include: atherosclerotic peripheral vascular disease, diabetic vascular disease, connective tissue disease, Raynaud phenomenon, regional node dissection, prior radiation therapy to limb injected. Also considered at increased risk are non-communicative/unconscious patients, severely debilitated/chronically ill patients, and those with significant weight loss or extensive metastatic disease. Severe damage to extravascular tissue is more likely to occur when large volumes of contrast media are extravasated.[5] While serious extravasation injuries are more likely with ionic contrast[8], the clinical literature also contains case reports of significant extravasation injury associated with nonionic contrast.[9,10]

Table 1. Presence of Risk Factors in PA-PSRS Reports Categorized as Contrast Extravasation or Infiltration

Selected Risk Factors	Reports Citing Risk Factor (%)	Comments
Age: <11 or >70	48%	
IV Site: dorsum of hand, foot, ankle	11%	39% site was arm or upper extremity 50% site not documented
Large volume contrast extravasated	9% 100-150 cc 14% 21-80 cc	29% 1-20 cc 48% volume not documented
Use of Ionic Contrast	Unknown	16% documented nonionic contrast 84% contrast type not documented
Use of power injector	9% documented	One report indicated hand injection. Remaining reports did not specify mode of delivery or indicated some form of the word "inject."

COMMON AND LESSER-KNOWN VESICANTS

CHEMOTHERAPY DRUGS – VESICANTS

Vinca Alkaloids
Vinblastine sulfate (Velban)
Vincristine sulfate (Oncovin)
Vindesine (Eldisine)
Vinorelbine (Navelbine)

Alkylating Agents
Cisplatin (Platinol)
Dacarbazine-Dric-Dome
Mechlorethamine HC. – Mustargen
Nitrogen mustard

Anthracyclines/Antitumor Antibiotics
Dactinomycin (Actinomycin D)
Daunorybicin HCl (Cerubidine)
Doxorubicin HCl (Adriamycin)
Mitomycin (Mutamycin)
Mitomycin C
Epirubicin HCl (Ellence)
Idarubicin (Idamycin)
Esorubicin
Mitoxantrone, Novantrone

Other
Paclitaxel (Taxol)
Carmustine
Pliamycin
Streptozocin
Amsacrine
Mithramycin
Mustine
Melphalan

LESSER-KNOWN VESICANTS

Hyperosmolar Agents
Calcium chloride
Calcium and Calcium-containing compounds
Calcium gluconate 10%
Glucose/dextrose in concentrations ≥10%
Hypertonic saline ≥10%
Magnesium sulfate
Mannitol 10% and 20%
Parenteral nutrition/hyperalimentation
High concentrations of potassium chloride
High concentrations of sodium bicarbonate
Radiographic contrast media
Solutions with pH <5.0 or >9.0 or osmolarity >500mOsm/L

Vascular Regulators
Dopamine
Epinephrine
Norepinephrine bitartrate (Levophed, Levarterenol)
Norepinephrine
Metaraminol bitartrate (Aramine)
Phenylephrine
Dobutamine
Dopamine
Vasopressin

Antibiotics
Vancomycin
Nafcillin
Doxycycline
Piperacillin
Zosyn (Piperacillin/Tazabactam)

Miscellaneous
Amphotericin B
Phenytoin (Dilantin)
Promethazine (Phenergan)
Diazapam (Valium)
Doxapram
Lorazepram
Thiopental

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The use of certain equipment may also increase the risk of contrast extravasation.[4,5] Extravasation is more likely when a tourniquet is used but not released during injection. Administering contrast via indwelling intravenous lines in place longer than 20 hours also increases extravasation risk. Extravasations are more likely to occur through metal needles than through plastic catheters. Multiple attempts at intravenous access at the same site or through different sites in the same vein also increase extravasation risk. Finally, the risk of extravasation of contrast media is greater when using an automated power injection device, compared to hand injection or drip infusion.

To treat contrast extravation, the clinical literature suggests elevation of the extremity to disperse the contrast for quicker absorption[2,3,5,8,11,12] and contrast aspiration using the needle through which the extravasation occurred.[7,8] There appears to be some

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Extravasation of Radiologic Contrast (Continued)

difference of opinion in the literature concerning the issue of skin temperature pertaining to treatment of contrast media extravasation. One resource indicates the use of warm compresses,[13] while another indicates that cold or warm packs are appropriate to apply to the extravasated area.[11] Most of the clinical literature indicates that application of cold significantly reduces skin toxicity in the event of a contrast extravasation.[2-6,8,14-17] Most reports of contrast extravasation submitted to PA-PSRS (65%) do not specify a treatment regimen. Ice or cold compresses are specified in 25% of the reports, while 11% indicate hot compresses. Elevation is indicated in 10% of the reports. Warm, then cold compresses were documented in one report.

A formal policy/protocol concerning the administration of contrast media may be a helpful first step in reducing the incidence of contrast extravasation.[5,7] Currently some facilities may address extravasation protocols within their policies on the use of chemotherapy agents. However, these policies may not be accessible or perceived as applicable when extravasation of a non-antineoplastic agent occurs.[14]

Some elements to consider in an extravasation prevention/treatment program include: education and training required to administer contrast;[15,11] identification of patients with selected risk factors; interventions based on volume of extravasation and type of contrast;[5,8,11] and observation, follow-up, and availability of extravasation response/antidote kits.[2,5]

In terms of tracking cases of extravasation, elements to consider documenting include:[5,15]

- Description of symptoms
- Interventions
- Date/time orders received from physician
- Date/time nursing unit notified
- Date/time of discovery
- Time of vesicant administration
- Time elapsed since onset of extravasation
- Vein location
- Type, gauge, and size of catheter
- Type of media administered
- Amount of contrast infused
- Mode (e.g., power injector, hand injection)
- Patient complaints
- Clinical signs (e.g., estimated size/extent of extravasation)
- Image of extravasation site for medical record
- Patient education/instructions

Cohan, et al.,[5] and the Oncology Nursing Society[2] describe the use of an extravasation form to capture the above information. Such forms can be placed in the medical record or outpatient notes and can be used to collect data as part of a quality management/performance improvement program. Collection of such data will help to identify trends that may be useful in educational programs and policy or protocol revisions, as indicated.[11,16,19]

Reports submitted to PA-PSRS suggest that several facilities provide an instruction sheet to patients who have a contrast extravasation. Some injuries from extravasation may not become apparent for several days (sometimes after a patient has been discharged). Instruction sheets may be helpful for reminding patients about what types of symptoms to report.

The following selected resources may be useful in developing or evaluating extravasation protocols.

Resources

American College of Radiology. ACR practice guideline for the use of intravascular contrast media (Res 5.1). 2001. Available from Internet: http://www.acr.org/departments/stand_accred/standards/pdf/iv_contrast_media.pdf.

Infusion Nurses Society (INS) [Web site]. Norwood (MA): INS. Available from Internet: http://www.ins1.org.

Lynn Hadaway Associates [Web site]. Milner (GA): Lynn Hadaway Associates, Inc. Available from Internet: http://hadawayassociates.com.

League of Intravenous Therapy Education (LITE) [Web site]. White Oak (PA): LITE. Available from Internet: http://www.lite.org.

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Resources (Continued)

National Extravasation Information Service (NEIS) [Web site]. Birmingham (United Kingdom): NEIS. Available from Internet: http://www.extravasation.org.uk/home.html.

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Focus on High-Alert Medications

While all medications have a level of risk if used incorrectly, a small number of medications bear a heightened risk of significant patient harm when they are used in error. These drugs are commonly referred to as "high-alert" medications. Though mistakes may or may not be more common with these drugs, the consequences of errors with these medications are more devastating to patients.

Approximately one in four medication error reports submitted to PA-PSRS involves a high-alert medication.

A 1998 Institute for Safe Medication Practices (ISMP) study revealed that 11% of all serious medication errors involve insulin misadministration, and another 8.9% involved heparin.[1] In addition, the summary information from the MedMarx[SM] 2002 report found that the top seven medications involved in events involving harm (comparable to Harm Score Categories E thru I in PA-PSRS) are high-alert medications including insulin, morphine, heparin, intravenous concentrated potassium chloride, warfarin, hydromorphone, and fentanyl.[2] These medications along with meperidine, intravenous chemotherapy, and neuromuscular blocking agents are among those considered high-alert medications.

Among medication error reports submitted to PA-PSRS, approximately one out of four reports involve high-alert medications. Of those reports:

- 44% involved pain management medications including morphine, hydromorphone (DILAUDID®), meperidine (DEMEROL®) and fentanyl.
- 14.2% involved heparin.
- 16.3% involved insulin products.
- 9.4% involved warfarin (COUMADIN®).

Sixty-five percent of Serious Events involving medications involved high-alert medications. Examples of medication errors involving high alert medications include:

- A patient receiving an infusion of fentanyl for pain control was ordered a 50 mcg bolus dose, but received 50 mLs.
- Insulin was administered to the wrong patient based on blood sugar levels of another patient.
- Two reports concerned patients receiving concentrated epinephrine 1:1,000 undiluted intravenously.
- An intravenous heparin infusion was programmed to run at 150 mL/hr (the rate for the patient's antibiotic) rather than the ordered rate of 10 mL/hr.

A list of common high-alert medications is available as a drop down box when entering reports into PA-PSRS at question 23. In addition, a complete list is available from ISMP (www.ismp.org/MSAarticles/highalert.htm) as well as in the PA-PSRS Training Manual and Users' Guide in Appendix B, page 87.

Additionally, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) includes in their 2004 National Patient Safety Goals that organizations "improve the safety of using high-alert medications" by removing concentrated electrolytes (including, but not limited to, potassium chloride, potassium phosphate, and sodium chloride >0.9%) from patient care units and standardizing and limiting the number of drug concentrations available in the organization.[3]

Strategies to safeguard the medication use process for high-alert medications may include limiting access to these medications; using auxiliary labels and automated alerts; standardizing the ordering, preparation, and administration of these products; and employing automated or independent double checks when necessary.

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Use of Checklists in Complex Environments

A recent report submitted to PA-PSRS concerned a patient whose physician changed a central venous catheter with the patient in the head-up position. The patient suffered an air embolus—a known hazard of open venous access above the heart while in the head-up position. For this reason, such procedures are performed with the patient supine. What seems like an error of commission (changing the catheter with the patient in the head-up position) was more likely an error of omission (missing the essential step of putting the patient in the head-down position).

Reminders are an essential part of monitoring activities in complex environments. The aviation industry, which is frequently cited as a safety-related model for healthcare, recognizes the importance of reminders and incorporates them into crew resource management programs in two ways: through the use of checklists and through encouragement to speak up when observing mistakes.

Table 2 briefly presents the findings of a brief literature search for studies involving clinical experiences using checklists.

Table 2. Studies of Checklists to Promote Safety in the Healthcare Setting

Study	Clinical Setting	Checklist Elements	Results
VA Ann Arbor Healthcare System[1]	ICU	Compliance with safety standards, performed twice daily	Staff could articulate how the program made the ICU a safer environment
Ludwig-Maximilians University, Munich[2]	Neurosurgery	Essential details in neurosurgical procedures	Limited reduction of adverse events
Spectrum Health, Grand Rapids[3]	Preoperative services	Comparison of procedure data to physician's orders	Team members are compliant
Queen Elizabeth II Jubilee Hospital, Brisbane[4]	Anesthesia	Preoperative visit and equipment check	It is argued that the chart improves patient safety
Princess Margaret Hospital, Toronto[5]	Anesthesia	Procedural guidelines and monitoring equipment for the safe use of daily anesthesia	Successful treatment of one uncooperative (autistic) patient for radiotherapy
Addenbrooke's NHS Trust Hospital, Cambridge[6]	Nursing Development Unit	Evidence-based management of urinary catheters	Changes in practice
ISMP[7]	Cancer chemotherapy	Anti-neoplastic drug ordering	Can help avoid errors
British Society of Gastroenterology[8]	Endoscopy	Identification of adverse risk factors	May be aided by the use of a checklist
University of British Columbia, Vancouver[9]	Prenatal care	Implementing clinical practice guidelines for prenatal care	Most respondents thought the checklist very useful
Princess Alexandra Hospital Brisbane[10]	Division of General Practice	Multidisciplinary quality improvement program including checklists for the care of patients with acute coronary syndromes and congestive heart failure	Statistically significant improvement in risk-adjusted 6 and 12-month mortality rates for patients with CHF
Johns Hopkins University[11]	ICU	Best practice for patients with mechanical ventilation	Adherence to four best practice processes increased significantly from 30% to 96%

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Use of Checklists in Complex Environments (Continued)

Objective demonstration of improvement is sparse. A review of patient safety practices commissioned by the Agency for Healthcare Research and Quality (AHRQ) includes several safe practices on the topic of inserting central lines alone, including the use of maximum sterile barriers during insertion, the use of antibiotic-impregnated catheters, and the use of real-time ultrasound guidance to localize the vein.[12] The use of checklists to confirm that each step has been done is a "line of defense" against the imperfection of human memory. Elements of a checklist aimed at preventing the type of event described above might include: verifying patient consent, placing patient in the head-down position, establishing a complete sterile barrier, adequate skin preparation, adequate local anesthesia, localization of vein, correct size/type of catheter, and others.

The AHRQ review did look specifically at pre-anesthesia checklists. Though the available information was limited, the studies reviewed failed to find significant differences in rates of problem identification when these checklists were used. Barriers to effective use include the need for training in the use of the checklists and the heterogeneity of the devices used. Research questions focus on effective methods of implementation, which are related to the sensitivity and specificity of the checklist elements in detecting problems, the effort involved (including redundancy), the yield, and other factors of usability.

Institutions might either want to share their experiences with checklists or think about gaining some experience trying to use checklists to avoid mental lapses, while considering the factors cited above.

A less obvious component of this report is that another healthcare provider had to be helping the physician. Was this assistant aware of the potential complication of air embolus when manipulating a central venous catheter? Did they notice, but were afraid to speak up? Being afraid to speak up is not uncommon. If institutions were to identify this failure as a root cause, interventions might be considered to help change the culture to one of safety in which speaking up about safety concerns would be expected.

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Electrosurgical Units and the Risk of Surgical Fires

Most surgical fires involve electrosurgery and begin when the electrosurgical unit (ESU) is activated in oxygen-enriched environments. Severe burns and death are associated with these types of fires, which are often preventable. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) includes reduction of surgical fires among their 2005 Patient Safety Goals for ambulatory care and office-based surgery.[1]

PA-PSRS has received two reports of OR fires. In one case, a facial fire occurred involving the ESU active electrode in an oxygen-enriched environment. In the second case, inadvertent activation of the ESU ignited bone cement being used in an orthopedic procedure. Most OR fires occur during use of electrosurgery or electrocautery (i.e., hot wire) devices.

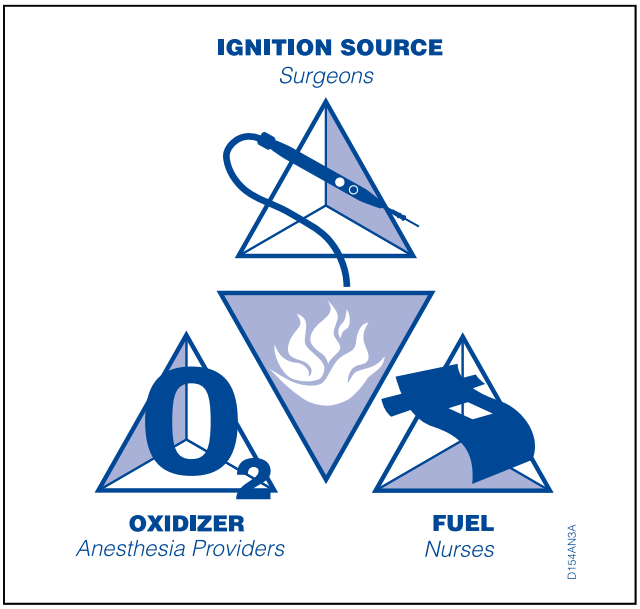
A number of other reports have been submitted by both hospitals and ambulatory surgical centers describing ESU-related electrical burns in the area of the face, neck, chest, and abdomen. While electrical burns, including "alternate site" burns, represent a fundamentally different mechanism of injury from surgical fires, both are known hazards of ESU use.

Fires require three elements (see Figure 1):

- An ignition source, such as an ESU active electrode.
- Oxidizers, such as oxygen, room air, N2O, or medical compressed air.
- Fuel, such as hair, surgical drapes, face masks, tracheal tubes, and other materials. Materials that don't readily ignite and burn in room air (21% O2) will easily burn when the atmosphere is slightly enriched. For example, polyvinylchloride endotracheal tubes burn in 26% O2, and body hair will ignite in a flash fire and burn rapidly in oxygen-enriched atmospheres greater than approximately 50%.

Because oxygen is "heavier" than air, it collects in unexpected places, such as under surgical drapes in the head and neck area. It sometimes wells up through the drape fenestration into the surgical site. Fires in oxygen-enriched environments are easier to ignite, burn hotter and spread faster than fires do in normal air. A further complication in the OR that increases the likelihood of a fire is that different people may be managing different aspects of the elements that must come together to cause a fire. For example, surgeons may handle the ignition source, anesthesiologists may deliver the oxidizers, and nurses may handle the fuels such as OR materials and flammable skin prepping agents. Communication among OR team members about specific fire risks is vital to reducing the risk of fire.

Figure 1. The Components of OR Fires.



Source: ECRI. Reprinted with permission.

Manufacturers have tried to make equipment and surgical drapes safer but there simply is no clear engineering solution to the surgical fire problem. For example, there are two ways to activate the ESU, using the hand piece or the foot switch. Inadvertent activation has been reported with both methods in the clinical literature.

Clinicians address this problem by putting the ESU pencil in a holster when it is not in active use. Mayo stands are used for laparoscopic active electrodes, as they are too big for holsters. These preventive measures rely on trained staff to keep the patient and clinical personnel safe. If the ESU is inadvertently activated, it will often cause a burn and may cause a very serious fire. Both of those unfortunate circumstances are often preventable when a holster is consistently used.

In regard to drapes, it is a common misconception that fire-retardant drapes are available. They are not. This is primarily because the technology for making a fabric that will be fire-retardant in very high oxygen concentrations does not yet exist.

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Electrosurgical Units and the Risk of Surgical Fires (Continued)

Practices that may help to reduce the risk of surgical fires include:

- Educating all members of the surgical team regarding the surgical fire hazard.
- Controlling potential ignition sources.
- Managing fuels, such as flammable surgical skin prep solutions.
- Minimizing the potential for medical gases to collect under surgical drapes.

The following resources may help you learn more about this important subject.

Print Resources

De Richemond A and Bruley ME. Head and neck surgical fires. Chapter 37. In: Eisele DW, ed. *Complications in head and neck surgery*. St. Louis (MO): Mosby; 1992;492-508.

ECRI. Fire safety poster [online]. Available from Internet: http://www.mdsr.ecri.org.

ECRI. A clinician's guide to surgical fires: How they occur, how to prevent them, how to put them out [guidance article]. *Health Devices* 2003;32(1):5-24. Summary available from Internet: http://www.guideline.gov/summary/summary.aspx?doc_id=3688&nbr=2914&string=fire.

Flowers J. Code red in the OR—implementing an OR fire drill. *AORN J* 2004 Apr;79(4):797-805.

Joint Commission on Accreditation of Healthcare Organizations. 2005 ambulatory care national patient safety goals [online]. Available from Internet: http://www.jcaho.org/accredited+organizations/patient+safety/05+npsg/05_npsg_amb.htm.

Joint Commission on Accreditation of Healthcare Organizations. Preventing surgical fires [online]. *Sentinel Event Alert* 2003 Jun 24;29. Available from Internet: http://www.jcaho.org/about+us/news+letters/sentinel+event+alert/sea_29.htm.

National Fire Protection Agency. NFPA 99: standard for health care facilities. 2002.

National Fire Protection Agency. NFPA 115: recommended practice on laser fire protection. 1999.

Valley Lab Hotline News. OR fires! Minimizing the risk [online]. Available from Internet: http://www.valleylab.com/displaynews.cfm?articlepageid=221&pageid=221&menu=education&old=124.

Educational Videos

Association of periOperative Registered Nurses (AORN). Fire Safety in the Perioperative Setting [video]. Denver (CO).

Medfilms. Operating room fire [video]. Tucson (AZ).

Molnlycke Health Care. Fire safety in the OR: A triad of prevention [video]. Goteborg (Sweden).

Notes

1. Joint Commission on Accreditation of Healthcare Organizations. National patient safety goals for 2004 and 2005 [online]. [Cited 2004 Aug 11.] Available from Internet: http://www.jcaho.org/accredited+organizations/patient+safety/05+npsg/05_npsg_amb.htm.

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Risk of Overdose from Multiple Transdermal Patches

The number of medications and the ways in which they can be administered have expanded dramatically over the years. One such advance has been the development of transdermal patch delivery systems. These medication-containing patches release active ingredients so that they can be absorbed through the skin to elicit their desired effect. Examples of medications available in this dosage form include nicotine (several manufacturers), scopolamine (TRANSDERM-SCOP®), lidocaine (LIDODERM®), clonidine (CATAPRESS®), nitroglycerin (e.g., NITRO-DUR®) and fentanyl (DURAGESIC®). While the use of these products can make drug administration more convenient and increase compliance, the use of transdermal patches is not without risk.

Errors associated with the use of transdermal patches, like all medication errors, are comprised of many factors. One factor involved in errors associated with transdermal patches is the variability in the frequency of application. Another is that practitioners and patients often do not realize that a significant amount of medication resides in the patch even after their intended period of application has expired. For example, a DURAGESIC® 50 mcg/hour patch contains 5 mg or 5,000 mcg of medication.[1] At a delivery rate of 50 mcg/hour for the recommended duration of application of 3 days, 1,400 mcg of fentanyl would remain in the patch after 72 hours. This means that approximately 28% of the total content of the drug would remain after 3 days of placement.

Medication error reports submitted to PA-PSRS and reports from national databases include many stories of practitioners applying patches to the patient's skin without removing the old patch, which continues to deliver medication. The products involved include all those mentioned above. However, errors associated with the use of fentanyl (DURAGESIC®) patches pose the greatest risk of harm.

Fentanyl is considered a high alert medication in PA-PSRS, which means that, while not necessarily more prone to medication errors, if an error does occur, there is a greater risk of patient harm or death. DURAGESIC® patches are intended to be replaced every 72 hours. However, PA-PSRS has received several reports of multiple fentanyl patches being found on patients. In one case, an elderly woman was ordered DURAGESIC® 75 mcg/hour. The day after administration of a new patch the patient experienced mental status changes. Upon examining the patient, two patches were found affixed to her back. The "outdated" patch was removed, and the patient's vital signs returned to normal and her mental status improved throughout the day.

Other examples of related reports submitted to PA-PSRS include:

- An elderly man was ordered DURAGESIC® 50 mcg/hour. Upon transfer to the floor from a critical care unit it was noted that two DURAGESIC® 50 mcg/hour patches were on the patient.
- An elderly woman was ordered DURAGESIC® 50 mcg/hour. While being washed, two DURAGESIC® 50 mcg/hour patches were found affixed to the patient. One patch was dated, but the second had no date or time noted.

There are a number of strategies that may help decrease the risk of error associated with the use of transdermal patches, such as:

- Treating the removal of patches just as if it were its own order. For example, on the medication administration record (MAR), listing the details of the patch removal.[2] Also, the exact time a patch is removed and applied and the location to which a patch is applied can be charted.
- In facilities with computerized MARs, programming this information into the pharmacy computer system so these entries automatically appear on the MAR.
- Adding a prompt to intake and pre-op assessment forms to check if the patient is wearing any patches.
- Educating all practitioners regarding transdermal delivery of medications, including information about the need to check for and remove current patches the patient may have and the fact that a significant amount of medication remains in the patch after the recommended application time.
- Educating patients on the proper use of patches, emphasizing the need to remove the old patch prior to applying a new patch.[3]

Notes

1. Duragesic® (Fentanyl Transdermal System) US Prescribing Information, Janssen Pharmaceuticals, 2003.

2. Lee M and Phillips J. Transdermal patches: high risk for error? *Drug Topics* 2002 Apr 1;54-5. Available from Internet: http://www.fda.gov/cder/drug/MedErrors/transdermal.pdf.

3. ISMP Medication Safety Alert![online] 18 Apr 2001;(6)8. Available from Internet: http://www.ismp.org/MSAarticles/Calendar/pr01.html#Apr18,2001.

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Two Takes on the "Time Out"

The practice of holding a "time out"—pausing for final verification of a patient's identity, procedure, and operative site—has been widely cited as one strategy to prevent wrong patient, wrong site, and wrong procedure errors in surgery and other invasive interventions. The time out can be a useful defense against these types of errors, as illustrated in several reports submitted to PA-PSRS in which time outs highlighted potential patient identification problems. These reports represent success stories for the time out practice.

Other reports we have received document problems in implementation that may limit the theoretical benefits of this safety practice. However, these stories, too, hold lessons that may help other facilities promote and execute this practice more effectively.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) includes the use of a time out immediately prior to surgeries and "other invasive procedures that expose patients to harm" in its Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™. [Ed. Note: The JCAHO Universal Protocol was previously addressed in the June 2004 *PA-PSRS Patient Safety Advisory*, under the headline "Patient Safety News."] This protocol, which became mandatory for all JCAHO-accredited facilities on July 1, 2004, requires that the time out:

> [B]e conducted in the location where the procedure will be done, just before starting the procedure. It must involve the entire operative team, use active communication, be briefly documented…and must, at the least, include:
>
> - Correct patient identity
> - Correct site and side
> - Agreement on the procedure to be done
> - Correct patient position
> - Availability of correct implants and any special equipment or special requirements
>
> The organization should have processes and systems in place for reconciling differences in staff responses during the "time out."[1]

JCAHO is not the only organization to advocate the use of the time out practice. The American College of Surgeons (ACS) suggests that members of the surgical team conduct a final verification process to ensure that the patient, procedure, and site are correctly identified. Further, ACS suggests that all activities be halted until verification is accurate.[2] The Association of periOperative Registered Nurses (AORN) also advocates the time out procedure in its position statement on correct-site surgery.[3] VHA, a national alliance of not-for-profit hospitals and health systems, incorporates the time out practice in its safety program "7 Absolutes to Avoid Surgical Site Errors."[4]

The Success Stories

Case #1: An elderly patient undergoing repair of a hip fracture was prepped for a *right*-sided procedure, consistent with the consent, history and physical, and a consultation report. During the time out, the surgical team determined [*method unspecified*] that the patient had a *left* hip fracture, which was then confirmed by x-ray. The procedure was performed on the correct side.

Case #2: Prior to performing an angiography, the team conducted a time out and found an unspecified error on the patient's wrist band. A nurse familiar with the patient was called to the radiology department to positively identify the patient. A new, corrected wrist band was placed on the patient before the procedure began.

Case #3: An adolescent patient was brought to interventional radiology for a lumbar puncture. During a time out, the team discovered that the birth date on the patient's wrist band was incorrect. The procedure was halted while the correct birth date was confirmed with the patient's parents. The error was corrected and a new wrist band applied prior to beginning the procedure.

These reports are "success stories" because the healthcare providers seem to have executed the time out procedure very well. The time out in the first case clearly prevented a wrong-side surgery. In neither case 2 nor 3 had they been about to perform a procedure on the wrong patient; the only aspect of the verification process noted as problematic is the wrist band. Yet, in both cases the clinical team took the safe course in halting the procedure until all information used in the verification process was in agreement.

It is also interesting to note that the facility in the third case performed a time out before a lumbar puncture, which is not universally viewed as an in-

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vasive procedure. While the time out is typically performed prior to surgeries and other invasive procedures to prevent patient identification errors, these are not the only clinical situations where patient identification is a problem. For example, during one month, PA-PSRS received twice as many reports involving the wrong patient, side, site, or procedure in relation to radiology/imaging as in relation to surgeries/invasive procedures.

One might ask why something as common as wrist band errors would bring to a halt procedures where all other sources of verification—including presumably the members of the clinical teams themselves—were in agreement. While on its face this question seems reasonable, consider the counter-argument. How many opportunities would there have been to check these patients' identities before they reached the sites of their procedures? How many times must someone have failed to look at their wrist bands, or looked but failed to notice the errors, or noticed the errors but failed to correct them? The fact that these errors were not caught earlier during medication administration and/or diagnostic testing appropriately made these clinical teams confirm their patients' identities and correct the errors.

A number of other reports recount the time out procedure successfully identifying errors or omissions in documentation used in the verification process, failure to obtain or document consent, and failure to mark the operative site.

Tips for Performing the "Time Out"

- Performing immediately before the procedure begins
- Performing in the same location where the procedure will be performed
- Performing with the patient and clinical team in the same positions as during the procedure
- Performing after marking the operative site
- Involving all members of the clinical team
- Using active communication (i.e., not assuming silence means assent)
- Using all available documentation (e.g., patient wrist band, history and physical, OR schedule, patient consent, results of imaging or other diagnostic studies)
- Holding the procedure until all forms of verification are in agreement
- Documenting the results of the time out, including how any discrepancies were resolved

Sources: JCAHO[5, 6] and ECRI

The Cautionary Tales

Case #1: A patient presented for cystoscopy and replacement of a stent in the *left* ureter. The OR team completed a final time out before beginning the procedure. During the procedure, an unspecified feature of the patient's anatomy caused the surgeon to assume the patient's consent (and presumably other documentation) had been in error, and she inserted the stent in the *right* ureter. With the patient in recovery, the surgeon contacted her office and confirmed that the *left* had been the correct side. The patient was brought back to the OR, the stent placed earlier was removed, and a stent was placed correctly in the left ureter.

The problem in implementing the time out procedure in this case is that the surgeon ignored the results of the time out, which presumably ended with all members of the surgical team concurring with the available documentation that this was a left-sided procedure. When the surgeon encountered contradictory evidence about the correct side for this procedure in the form of some anatomical feature of the patient, she weighed the evidence of the pre-operative documentation and the surgical team's time out against the evidence provided by the patient's anatomy. Presumably, the latter evidence seemed the more compelling at the time, and the procedure proceeded incorrectly.

During a time out, if any single element of the verification process is inconsistent with the others, some clinical teams will halt the procedure until the error is corrected. Though the time out had been completed and the procedure was in progress when the surgeon encountered the contradictory evidence, it may have been possible for the surgeon to pause long enough to contact her office from the OR during the procedure rather than after it. Further, the fact that the surgeon implicitly discounted the evidence reviewed during the time out may indicate that documentation errors are so frequent that clinicians are predisposed to doubt their veracity.

Case #2: A 45-year-old female patient presented for surgery for release of "trigger thumb." Prior to conducting a time out, the surgeon made an incision at the site for a carpal tunnel release. Another clinician alerted the surgeon to the error. After suturing the incorrect incision, the team stopped to perform a time out, and then proceeded to perform the scheduled operation.

Clearly, the problem in implementing the time out in this case is that the surgeon made an incision *before* performing the time out. It is not clear whether this was a lapse or an intentional violation. The systems lesson in this case is less about the technical details of the time out than it is about teamwork and

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Two Takes on the "Time Out" (Continued)

a culture of safety. If the surgeon was impatient and skipped the time out intentionally, this sends a message to the rest of the OR team that safety measures are unimportant and can be ignored.

However, if this was an unintentional lapse, the team might consider whether a change in group dynamics surrounding the time out might decrease the probability of omitting it. For example, if it is not clear who is responsible for calling the time out, *no one* may feel responsible. On the other hand, if the surgeon feels that he or she alone bears all the responsibility for patient identification, he/she may feel that "it's their call" whether to ignore verification-related safety practices.

We cannot leave this case, of course, without noting that another member of the team did stop the surgeon when witnessing the wrong incision. A fundamental attribute of a culture of safety is the recognition that safety is everyone's responsibility. In another facility or in another surgical team, that same clinician may have felt too intimidated to correct the surgeon's mistake.

Notes

1. Joint Commission on Accreditation of Healthcare Organizations. Universal protocol for the prevention of wrong site, wrong procedure, and wrong patient surgery [online]. 2003 Jul 18 [Cited 16 Aug 2004]. Available from Internet: http://www.jcaho.org/accredited+organizations/patient+safety/universal+protocol/wss_universal+protocol.htm.

2. American College of Surgeons. Statement on ensuring correct patient, correct site, and correct procedure surgery. *Bull Am Coll Surg* 2002 Dec;87(12).

3. Association of periOperative Registered Nurses. AORN position statement on correct site surgery [position statement]. 2003 Feb [Cited 2004 Aug 16]. Available from Internet: http://www.aorn.org/about/positions/correctsite.htm.

4. Mathias JM. VHA's program to curb wrong-site surgery. *OR Manager* 2002 Mar;18(3):7-9.

5. Joint Commission on Accreditation of Healthcare Organizations. Guidelines for implementing the universal protocol for the prevention of wrong site, wrong procedure, and wrong patient surgery [online]. 2003 Jul 18 [Cited 2004 Aug 16]. Available from Internet: http://www.jcaho.org/accredited+organizations/patient+safety/universal+protocol/up+guidelines.pdf.

6. Joint Commission on Accreditation of Healthcare Organizations. Frequently asked questions about the universal protocol for preventing wrong site, wrong procedure, wrong person surgery [online]. 2003 Jul 18 [Cited 2004 Aug 16]. Available from Internet: http://www.jcaho.org/accredited+organizations/patient+safety/universal+protocol/faq_up.htm.

Bed Exit Alarms to Reduce Fall Risk

Bed exit alarms warn caregivers when patients leave or attempt to leave their beds. While they can be an important component of a fall prevention program, they are not always used effectively. This article highlights the main considerations regarding bed exit alarms to help the clinical community get the most out of this technology.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) cites bed exit alarms as both part of effective risk reduction strategies and as one of the root causes of problems when they malfunction or are misused.[1] Both situations are reflected in the reports submitted to PA-PSRS. In just the short period since mandatory reporting began in June 2004 through early August, PA-PSRS received over 145 reports of falls where bed exit alarms were in use, 20 of which were Serious Events.

The principle behind bed exit alarms is that they warn caregivers, and in some cases patients themselves, when a patient leaves or attempts to leave the bed. They are not restraints and do not prevent falls by themselves.

Here are some things they can do:

- Warn the caregiver that the patient has changed position and is about to leave the bed. This may give the caregiver enough time to enter the room and assist the patient.
- Warn the caregiver that the patient has already left the bed. This may give the caregiver enough time to intercept the patient before a fall or at least to respond more promptly if the patient has already fallen.
- Warn the patient that they are "doing something that they shouldn't." In some cases the sound of the alarm may remind the patient to call for assistance and prompt them to sit back in bed.

Bed alarms are made in many forms. A common form is a pressure-sensitive pad that is placed be-

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neath the patient, usually in the shoulder area or in the area of the buttocks. The pad is attached to a control unit that is generally mounted on the bed or the wall. Placing the pad beneath the buttocks reduces the incidence of nuisance alarms for some patients but may provide the caregiver less "lead time" in responding to activated alarms. Other forms of bed alarms include:

- Cords and garment clips consist of a control unit mounted on the bed or the wall and a cord that is attached to the patient's clothing. The alarm is activated when the patient exits the bed and detaches the cord from the control unit.
- Patient-worn alarms are attached directly to the patient (for example, by means of a leg cuff) and are activated by changes in the patient's position.
- Floor mats are pressure-sensitive mats placed alongside the bed.
- Bedside infrared beam detectors are typically set up next to the bed or on the wall to send a beam over the top or alongside the bed. They are activated when the patient breaks the beam.

The control units for these devices vary in the features they offer, including latching and non-latching alarms, alarm delay and standby features to temporarily disable the alarm. Some of the units can also activate the nurse call system.

Some keys to properly using bed alarms may include:

- Knowing what your bed exit alarm is and how it works.
- Using the right type of alarm for your patient. Many reports describe patients removing alarms clipped to their garments or otherwise deliberately deactivating their alarm. Also, remember that some patients with hearing deficits may not hear their own alarms.
- Understanding that bed exit alarms may improve the timeliness of your response to a situation but do not prevent falls by themselves.
- Following your protocols for assessing the risk of patient falls and considering the use of bed exit alarms as part of an overall fall reduction program.

Resources

Agostini JF, Baker DI, Bogardus ST. Prevention of falls in hospitalized and institutionalized older people. Chapter 26. In: *Making health care safer: a critical analysis of patient safety practices*. Evidence report/technology assessment no. 43. Rockville (MD): Agency for Healthcare Research and Quality; 2001 Jul. AHRQ 01-E058.

ECRI. Bed-exit alarms a component (but only a component) of fall prevention. *Health Devices* 2004 May;33(5):157-168.

ECRI. Bed-exit alarms evaluation [in press]. *Health Devices* 2004 Sep;33(9).

Department of Veterans Affairs, National Center for Patient Safety. Tips on fall prevention [online]. 2002 Mar 29 [Cited 2004 Apr 23]. Available from Internet: http://www.patientsafety.gov/falls.html.

Notes

1. Joint Commission on Accreditation of Healthcare Organizations. *Sentinel Event Alert* [online] 2000 Jul 14;14. Available from Internet: http://www.jcaho.org/about+us/news+letters/sentinel+event+alert/sea_14.htm.

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Web Resources for Fall Prevention Programs

Premier Safety Institute Web Site

The Premier Safety Institute has developed a series of Web-based modules on a variety of patient safety topics, including fall prevention. This site:

- Provides patient assessment instruments and classification scales.
- Identifies the formulae from the clinical literature most commonly used in monitoring rates of patient falls.
- Offers a variety of materials that may be useful in developing or implementing a fall prevention program at your facility, including resources for patients.

To access this Web site, visit http://www.premierinc.com and select "Patient Safety Institute" on the left-hand menu.

Southern California EPC Report on Fall Prevention in the Medicare Population

The Centers for Medicare and Medicaid Services (CMS), as part of its Healthy Aging Project, commissioned the Southern California Evidence-Based Practice Center (EPC) to produce a systematic review of the evidence surrounding fall prevention interventions in the Medicare population. Among the interventions investigated in this report are:

- Exercise (both physiotherapy and non-physiotherapeutic activity).
- Multifactorial falls risk assessment and management programs that include at least: a fall risk assessment, a medical evaluation, and one or more follow-up interventions.
- Educational interventions.
- Assistive devices.
- Medication/medication review.
- Environmental modifications.
- Staff/Organization-related interventions.

The full report is available online at http://www.cms.hhs.gov/healthyaging/fallspi.asp.

National Guideline Clearinghouse™ (NGC™) Web Site

The NGC is a Web-based resource, funded by the Agency for Healthcare Research and Quality, for summaries and comparisons of evidence-based clinical practice guidelines on numerous topics. The Web site is available at http://www.guideline.gov. The NGC database contains summaries of six guidelines on fall risk assessment and prevention, outlined in Table 3 below. To locate these guideline summaries, visit the NGC Web site and simply type "falls" into the search box from the home page.

Table 3. Guideline Summaries Available at NGC on Fall Prevention

NGC Citation	Guideline Objectives
Guidelines for the prevention of falls in people over 65. Barts and the London, Queen Mary's School of Medicine and Dentistry. 2000 Oct 21. 5 pages. NGC:001798	To translate trial evidence about prevention of falls into recommendations that can be implemented in different settings, with the aim of reducing the rate of falls and injurious falls in people over 65.
Fall prevention for older adults. University of Iowa Gerontological Nursing Interventions Research Center, Research Dissemination Core. 1996 (revised 2004 Feb). 60 pages. NGC:003480	To reduce the number of falls among elderly patients. To reduce injuries sustained during falls.
Prevention of fall injuries in the older adult. Registered Nurses Association of Ontario. 2000 Jan. 57 pages. NGC:002938	To present nursing best practice guidelines for the prevention of falls and fall injuries in the older adult. To increase all nurses' confidence, knowledge, skills and abilities in the identification of adults at risk of falling and to define interventions for prevention of falling.
Guideline for the prevention of falls in older persons. American Academy of Orthopedic Surgeons, American Geriatrics Society, British Geriatrics Society. 2001 May. 9 pages. NGC:002199	To assist health care professionals in their assessment of fall risk. To assist health care professionals in their management of older patients who are at risk of falling and those who have fallen.
Preventing falls in acute care. The John A. Hartford Foundation Institute for Geriatric Nursing. 2003. 32 pages. NGC:002736	To provide nurses in the acute care setting with an easy and effective way to implement a falls prevention program and raise the level of care provided to older patients in the acute care setting.
Falls and fall risk. American Medical Directors Association. 2003. 16 pages. NGC:003521	To improve the quality of care delivered to patients in long-term care facilities who have a recent history of falls or who are at risk of falling. To guide care decisions and to define roles and responsibilities of appropriate care staff.

Source: Agency for Healthcare Research and Quality, National Guideline Clearinghouse

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PA-PSRS User Experience

Several recent callers to the PA-PSRS Help Desk asked how they could use the PA-PSRS Web site to track the incidence of specific types of events in their facilities. One caller was specifically interested in tracking labeling problems for lab specimens. This article briefly outlines one approach to monitoring the occurrence of different event types.

You can generate a list of all reports your facility has submitted that match a certain event type (or set of event types) by using the search feature in the PA-PSRS system. To do so, take the following steps:

1. While logged in under the role of the Patient Safety Officer (i.e., not the Facility System Manager), from the PA-PSRS main screen select "Analytical Data Tools," then click on "Search Submitted Event Reports." This will open a new window displaying the search interface screen.

2. Enter a date range for your search. For example, to limit your results to reports of events that occurred during the month of August, you would enter: From: 08/01/2004 To: 08/31/2004

3. At the bottom of the search screen, click the link "Add/Change Event Type Criteria" at Item 9. This will open a new window that allows you to pick one or more event types.

4. In the new window that opens, place your cursor over the link that reads "Point Here for Event Type." This will generate the menu for the Event Type taxonomy, similar to the menu you see at Question 8 when submitting a new report to PA-PSRS.

5. Choose the Event Types you want to monitor. For example, if you were monitoring specimen labeling problems in your laboratory, you might choose the following Event Type codes:

   - E.2.j, Error related to procedure/treatment/test; Laboratory test problem; Mislabeled specimen

   - E.2.k, Error related to procedure/treatment/test; Laboratory test problem; Specimen label incomplete/missing

6. Click the "Add" button after each Event Type code you wish to include.

7. When you have added all the event types of interest, click "Add These Criteria" at the bottom of the screen. This will add these Event Type codes as a parameter in your search and return you to the search interface screen.

8. Click the "Generate Report" button. This will create the list of reports that meet your search criteria.

Once this list is generated, you can sort the reports by clicking on the table headings in each column. To change your sort from ascending to descending order, click on the up or down arrows beneath each column heading. If you have used more than one Event Type code in your search, you may want to sort them by Event Type, but you could also sort them by Harm Score, Date, or any other column.

When doing searches for reports of particular Event Types, you may choose a code at any level of the Event Type taxonomy. For example, you could search for any of the following:

- All reports of "E. Errors related to procedure/treatment/test."

- All reports of "E.2. Errors related to procedure/treatment/test; Laboratory test problem."

- All reports of "E.2.j. Errors related to procedure/treatment/test; Laboratory test problem; Mislabeled specimen."

If you are primarily interested only in the total number of reports of different Event Types, this information appears in the search results screen on the left-hand side, just above the table of reports. For example, you might see, "Showing 1-10 of 50 Total Reports." This tells you that there were 50 reports of the Event Types you selected over the time period you entered.

Do you have a topic you would like to see addressed in a future Advisory? Do you have any success stories to share about how the PA-PSRS system has helped you to monitor patient safety concerns in your own facility? Let us know by sending us an e-mail at support_papsrs@state.pa.us. We look forward to hearing from you.

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PA-PSRS Program Notes

New Resources Available

In response to requests from Pennsylvania health-care facilities, the Patient Safety Authority recently released the presentations used during the state-wide training sessions. The presentations are available via the PA-PSRS system under a new menu item in the blue task bar called "Resources." The presentations are provided in Microsoft PowerPoint® format. The Training Manual and Users' Guide is also available under the Resources item. To view the Training Manual and Users' Guide, please make sure you have Adobe Reader® software (for viewing PDF files) installed on your computer.

How to Report Crimes or Intentionally Unsafe Acts

Under PA-PSRS, all crimes and intentionally unsafe acts are reported as Infrastructure Failures. Even if a facility is reporting an unsubstantiated allegation of a crime (e.g., reported abuse), this is not reported as either a Serious Event or Incident. Most of the Event Type codes relating to crimes appear under Event Type Code V, "Criminal/Potentially Criminal or Illegal Activity." Refer to Appendix B in the Training Manual for the complete list of Event Type Codes. If you are not able to find a code that seems applicable, consider reporting it under Event Type Code X, "Other (Infrastructure Failure)."

Request for Information about Fall Precautions

A gap in many reports of falls relates to the use of different types of fall precautions or protocols. Fall precautions and protocols are addressed in Item H under the "Fall Event Details Questions" (see the Training Manual and Users' Guide, Appendix A, page 91). Items I and J address two types of fall precautions: restraints and sitters.

Many reports of falls—even in patients identified as at high risk and with fall precautions in place—fail to identify the *type* of fall precautions being used. Other reports of these types of events simply provide a generic descriptor such as "high risk."

Examples of fall precautions include:

- Identifying high risk patients via stickers or other visible insignia on patients' charts, wristbands, armbands, and name/room number plaques.
- Increasing monitoring frequency.
- Assigning patients to rooms close to nurses' stations.
- Placing mattresses on the floor.
- Using bed exit alarms.
- Using 1:1 observation/sitters.
- Using physical restraints (e.g., bed siderails, "lap buddies," geri chairs, waist belts, Posey vests, and others).

Providing this information may make it possible to identify patterns in the use of specific fall precautions that have patient safety implications.

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Patient Safety News

Pennsylvania Hospital Wins National Patient Safety Award

The National Quality Forum (NQF) and the Joint Commission on Accreditation of Healthcare Facilities (JCAHO) have announced that the University of Pittsburgh Medical Center (UPMC)—McKeesport (Allegheny County) has won a 2004 John M. Eisenberg Patient Safety and Quality Award in the category of "Innovation in Patient Safety and Quality at a Local or Organization Level." This prestigious award recognizes UPMC—McKeesport for the facility's work in developing personalized patient safety self-instruction materials to facilitate resolution of problems related to falls and nosocomial infections through organizational culture change.

Last year, Abington Memorial Hospital (Montgomery County) won a 2003 Eisenberg Award for system innovation recognizing the facility's creation of "The Virtual Anticoagulation Clinic," and Lehigh Valley Hospital and Health Network (Lehigh County) received a 2003 Eisenberg Award for the facility's advocacy in reducing preventable adverse events.

Study Finds Limited Evidence on Medical Error Disclosure

A recently published systematic review found that though there is considerable support for disclosure of medical errors among both physicians and the public, the evidence suggests many such occurrences are not disclosed. This review synthesized evidence from 17 studies, the majority of which were based on questionnaires or other modes of self-report. The authors conclude that most studies conducted to date have focused on the decision whether or not to disclose errors to patients and that more research is needed on disclosure processes, the consequences of disclosure, and the relationships between them. Mazor KM, Simon SR, Gurwitz JH. Communication with patients about medical errors: a review of the literature. *Arch Intern Med* 2004;164:1690-7.

A Success Story of Culture Change

Authors from the Missouri Baptist Medical Center (MBMC) recently published the results of a more than three-year effort to change their hospital's punitive culture to a "just and fair" culture by implementing a number of patient safety-related practices. A series of focus groups found that staff members were reluctant to report safety problems because the reporting systems were time-consuming and intimidating, they did not believe it was appropriate to report "near misses," and because they feared negative consequences from reporting.

MBMC embarked on a multifaceted patient safety program that included executive leadership commitment, structural changes in the organization, redesign of the reporting system, adoption of tools to aid event investigation and prevention, and a feedback/communication component. Elements of the program cited as critical success factors were "highly visible behavior" by senior management to demonstrate their commitment to safety and the recruitment of "safety champions" among the medical staff and other front-line employees to lead specific initiatives. Other program elements included the creation of a new Patient Safety Specialist position to coordinate all related initiatives and the inclusion of patients as partners in helping to ensure safe care.

The authors measured the success of the program using outcomes derived from monthly employee surveys as well as through measures of the volume of events reported. For example, the number of events reported per 1,000 patient days more than tripled between the pre- and post-intervention periods. Use of a safety "hotline" increased even more dramatically over the study period, and the proportion of callers who felt comfortable enough to identify themselves doubled. Cohen MM, Kimmel NL, Benage MK, et al. Implementing a hospitalwide patient safety program for cultural change. *Jt Comm J Qual Saf* 2004 Aug;30(8):424-31.

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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, as contractor for the PA-PSRS program, is issuing this newsletter 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 website at www.psa.state.pa.us.

ECRI is an independent, nonprofit health services research agency dedicated to improving the safety, efficacy and cost-effectiveness of healthcare. ECRI's focus is healthcare technology, healthcare risk and quality management and healthcare environmental management. ECRI provides information services and technical assistance to more than 5,000 hospitals, healthcare organizations, ministries of health, government and planning agencies, and other organizations worldwide.

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.

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