



Pennsylvania Patient Safety Reporting System

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PATIENT SAFETY ADVISORY

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PATIENT SAFETY AUTHORITY

All Pennsylvania-licensed hospitals, ambulatory surgical facilities and birthing centers are now submitting reports through the new Pennsylvania Patient Safety Reporting System (PA-PSRS). As of June 28, more than 400 healthcare facilities are subject to Act 13's mandatory reporting requirements, making Pennsylvania the first state in the country to require the reporting of both actual events (called "Serious Events" in the Act) and near-misses (called "Incidents").

During facility training sessions prior to the introduction of mandatory reporting, we received considerable feedback related to PA-PSRS and the training sessions themselves. Overall comments were very positive, and patient safety officers participating in the training expressed high expectations for the system's utility. In a recent editorial, the *Philadelphia Inquirer* noted that Pennsylvania's new patient safety initiatives, including PA-PSRS, "are seen as among the most progressive in the nation."

As of June 28, more than 400 healthcare facilities are subject to Act 13's mandatory reporting requirements.

While PA-PSRS program staff will receive, tabulate and analyze reports to identify trends and suggest improvements to enhance patient safety, we encourage individual facilities to take full advantage of the system's analytic tools as well. These software programs allow you to generate reports specific to your own facilities, and we are confident that you and other managers can use these reports for your own internal quality improvement and patient safety activities.

We want to hear back from you about how PA-PSRS is enhancing your patient safety focus and how you are integrating a "culture of safety" into your institution's protocols. We also want to hear your suggestions for system improvements. Please keep in touch through the PA-PSRS website.

HIDDEN SOURCES OF LATEX IN HEALTHCARE PRODUCTS

Over the past decade, considerable scientific and clinical information has been acquired and strategies have been implemented to reduce allergic reactions to latex in healthcare settings. Despite this effort, however, reports submitted in the PA-PSRS system indicate that latex exposure and allergic reactions continue. The following examples were reported to PA-PSRS:

- A condom catheter was placed on a patient with a documented latex allergy. The patient developed dermatitis.
- A surgeon used latex gloves while performing an invasive procedure on a patient with a documented latex allergy. During recovery, the patient became short of breath, and oxygen saturation decreased. The patient was treated until symptoms resolved.

Patients with latex allergy may experience reactions ranging from minor rashes to anaphylaxis.¹ The more exposures a latex-sensitive patient experiences, the more severe their reactions may become.²

Now that latex allergy protocols are implemented in the healthcare community, the new frontier may be to assure that such interventions are updated, effective, and fully implemented by the staff. Latex is extremely common in healthcare and consumer products. Approximately 40,000 products contain natural latex rubber proteins.³ Approximately 2,000 of these products are used in healthcare settings.⁴ Identifying which products contain latex and which are latex-free can be a tremendous challenge.

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Hidden Sources of Latex (Continued)

To prevent latex sensitization in high-risk groups or to prevent serious allergic reactions in those sensitized to latex, the most effective method is avoidance of contact with latex-containing materials.⁵ It is important that healthcare providers recognize that some products may contain latex and that appropriate alternatives may be available. In addition, updated information about latex-containing products can be integrated into patient education programs.

This article presents selected information from the clinical literature about latex-containing products that may be less well-known. The information is not comprehensive, but is designed to pique interest and spark further inquiry, as protocols and staff/patient education programs are reviewed and updated.

Since September 1998, the Food and Drug Administration (FDA) has required labeling of the presence of latex on all medical equipment that may come in contact with humans, as well as latex packaging materials that come in contact with the product.⁶ While the labeling requirement is helpful, there may be many products currently in use that were manufactured prior to the implementation of this labeling requirement. For example, providers may use latex-containing personal stethoscopes or reflex hammers that were acquired many years ago. In addition, the ruling does not include pharmaceuticals or items not regulated by the FDA. Also, individual components within a larger package may not be labeled.⁷

The following products may contain latex:

Hospital supplies: blood pressure cuffs; tubex syringes; ECG wires; pulse oximeters and cables; vascular compression stockings; ready-to-use enemas; Ace bandages; spacers for multi-dose inhalers; adhesive tapes; tourniquets; CPR mannequins; condom catheters; wheelchair cushions; oxygen masks/cannulas; incentive deep breathing exercisers; fitted hospital bed sheets; IV injection ports/tubing; disposable syringes with rubber plungers; ostomy pouches and straps; disposable incontinence pads; washable underpads; latex-stoppered multidose vials; nasogastric tubes (silastic-covered latex); certain dressings.

Personal protective equipment: goggles; masks; gloves; respirators.

Operating room: drapes with adhesive strips; bouffant caps and shoe protectors; surgical wound drains; instrument mats; mesh; electrode grounding pads; anesthesia machine reservoir bags; anesthesia masks; body positioning/holder devices; fiberoptic/video scopes; eye shields; laparoscopy insufflation hoses; needle counting systems; rubber breathing circuits and ventilation bellows; teeth protectors/bite blocks; bronchoscopy components (T-piece, saline injector, suction tubing).

Critical care/Emergency Departments: Ambu bags; endotracheal tubes; cervical spine collars; Swan-Ganz catheters.

Physical Therapy: exercise bands and balls; crutch pads (axillary and arm grips); cold/hot packs.

Medical Imaging: rubber aprons; positioning blocks; head straps.

Dietary: latex gloves (may contaminate food served to patients and employees).⁸

USE OF MULTIDOSE MEDICATION VIALS AND LATEX ALLERGY

One latex avoidance strategy suggested in the literature relates to multidose vials. It was thought that the solution in such vials contained latex allergen from the stopper, or that the allergen could enter the needle used to puncture the vial stopper. It has been suggested that multidose vials with latex stoppers be replaced with glass ampules or latex-free vials.¹ Another proposed strategy was to remove latex stoppers from multidose vials to draw up medications, rather than puncturing the stopper with a needle in order to obtain the medication.²

A review of the literature, however, indicates that the risk of latex exposure from the use of multidose vials with latex stoppers is not clear.³ The level of latex allergen in such vials has been determined to be extremely low. In one study, the amount of latex protein found in medication vials was not detectable when the rubber stopper was punctured up to 40 times.⁴ Also, studies have indicated that there was no difference in measurable allergen of the solution when puncturing rubber stopper, compared to when latex stoppers were removed.⁵

The Johns Hopkins Hospital, which uses multidose vials widely, indicates the following in its Interdisciplinary Clinical Practice Manual: "When drawing up medication, it is not necessary to remove the stopper from the vial. Multidose vials should only be punctured once and then discarded, unless using the Clave multidose vial adaptor. Use IV tubing sets with synthetic ports to eliminate allergen exposure."⁶

Isolated cases, however, continue to be reported of allergic reactions associated with use of multidose vials.⁷ Coring may occur with repetitive puncturing of a stopper on a multidose vial. This may result in microscopic rubber particles that may contaminate the medication or be injected into subcutaneous tissue.⁸

It is, therefore, incumbent upon each healthcare institution to decide whether and/or how to use multidose vials in the care of the latex-sensitive patient. In determining such a policy, institutions may wish to balance the potential for latex exposure by withdrawing a medication through a latex-stoppered vial with other considerations, including the patient's degree of latex hypersensitivity and the potential for errors in dosage, dilution, contamination, and waste.⁹

Notes

1. Latex Sensitivity. ECRI Healthcare Risk Control 1996 Jan; Environmental Issues 18:1. Also AORN Latex Guideline. AORN Journal 2004 Mar; 79(3):653-672.
2. Davis BR. Perioperative Care of Patients with Latex Allergy. AORN Journal 2000; 72:47-54.
3. Senst BL, Johnson RA. Latex Allergy. Am J Health Syst Pharm 1997; 54:1071-5.
4. Yunginer et al. Latex Allergen Contents of Medical and Consumer Rubber Products. Journal of Allergy Clinical Immunology 1993; 91:241.
5. Thomsen DF, Burke TG. Lack of Latex Allergen Contamination of Solutions Withdrawn from Vials with Natural Rubber Stoppers. Am J Health Syst Pharm 2000; 57:44-7. Also Yunginger JW, Jones RT, Fransway AF, Kelso JM, Warner MA, Hunt LW. Extractable Latex Allergens and Proteins in Disposable Medical Gloves and Other Rubber Products. J Allergy Clin Immunology 1994; 93:836-42.
6. Brown RH, Hamilton, RG, McAllister MA. How Health Care Organizations Can Establish and Conduct a Program for a Latex-Safe Environment. Joint Commission Journal on Quality and Safety 2003; 29(3): 113-123.
7. Vassallo SA, Thurston TA, Kim SH, Todres ID. Allergic Reaction to Latex from Stopper of a Medication Vial. Anesth Analg 1995; 80:1057-8.
8. Primeau MN, Adkinson NJ, Hamilton RG. Natural Rubber Pharmaceutical Vial Closures Release Latex Allergens That Produce Skin Reactions. Journal of Allergy and Clinical Immunology 2001 Jun; 107:958-962. Also Asakura T, Seino H, Noxaki S, Abe R. Occurrence of Coring in Insulin Vials and Possibility of Rubber Piece Contamination by Self-Injection. Journal of the Pharmaceutical Society of Japan 2001 Jun; 121 (6): 459-463.
9. Senst BL, Johnson RA. Latex Allergy. Am J Health Syst Pharm 1997; 54: 1071-1075.

Hidden Sources of Latex (Continued)

A review of the clinical literature identifies common elements in protocols related to the latex allergic patient:

- Coordination by a multidisciplinary committee/task force.
- Assessment/identification of those at risk.
- Communication among staff about the allergy.
- Strategies to eliminate/minimize latex exposure.
- Maintaining lists of latex-containing and latex-free products, using brand names.
- Latex-free carts/kits.

Hidden Sources of Latex (Continued)

- Latex-safe procedures for specific patient care areas/departments.
- Ongoing education programs for healthcare providers and patients/families.
- Identification of symptoms and being prepared to provide interventions.
- Reviewing/monitoring data concerning latex reactions to assess program effectiveness and to take corrective actions.⁹

Several resources compile and communicate information about latex allergy to both healthcare providers and patients. Many are accessible on the Internet. Such information can be invaluable when updating protocols and educational programs.

Available Resources

- Mitchell N. Latex Allergy: accessing information of the Internet. *J Emerg Nurs.* 1007; 23:51-52.
- American College of Allergy, Asthma, and Immunology. www.allergy.mcg.edu/physicians/ltxhome.html.
- American Latex Allergy Association, ALERT. www.latexallergyresources.org
- National Institutes for Occupational Safety and Health. www.cdc.gov/NIOSH/latexalt.html
- Nurses World, Latex Free Information. www.nursesworld.com/latex.htm
- Pryor JP, Vonfricken K, Seibel R, Kauder DR, Schwab CW. Anaphylactic Shock from a Latex Allergy in a Patient with Spinal Trauma. *Journal of Trauma Injury, Infection, and Critical Care* 2001 May; 50(5): 927-930.
- Latex Allergy News. CETRA Latex-Free Information Services. www.latexallergyhelp.com
- Spina Bifida Association of America. www.sbaa.org
- Latex Allergy Links. www.latexallergylinks.org
- Thurlow KL. Latex Allergies: Management and Clinical Responsibilities. *Home Healthcare Nurse* 2001 Jun; 19(6):369-371.
- Safety and Health Topics: Latex Allergy. U.S. Department of Labor, Occupational Safety & Health Administration. www.osha.gov/SLTC/latexallergy/index.html
- Holmes SA. Looking Out for Latex. *Science and Children* 1999 Feb; 21-25, 52-53.
- Binkley HM, Schroyer T, Catalano J. Latex Allergies: A Review of Recognition, Evaluation, Management, Prevention, Education, and Alternative Product Use. *Journal of Athletic Training* 2003; 38(2):133-140.

Notes

1. Sussman GL, Beezhold DH, Liss G. Latex Allergy: Historical Perspective. *Methods* 2002 May; 27(1):3-9. Also Leby DA, Leynadier F. Latex Allergy: Review of Recent Advances. *Current Allergy Reports* 2001; 1:32-38. Also Sussman G, Gold M. Guidelines for the Management of Latex Allergies and Safe Latex Use in Healthcare Facilities. *American College of Allergy, Asthma & Immunology* 1996 Aug. alergymcg.edu/physicians/latex.html. Also Patriarca G, Nucera E, Buonomo A, Roncallo C, DePasquale T, Polastrini E, Schiavino D. New Insights on Latex Allergy Diagnosis and Treatment. *J Investig Allerg Clin Immunol* 2002; 12(3):169-176.

USE OF X-RAYS FOR INCORRECT NEEDLE COUNTS

PA-PSRS received a report of an incorrect needle count during surgery in which a missing 7-0 suture needle could not be located. After searching the patient, the operating table, floor, and waste receptacles with a needle magnet and failing to locate the needle, the surgeon declined an x-ray of the surgical site, stating that the needle was too small to be visualized on an x-ray.

The clinical literature provides conflicting evidence for when x-rays may be useful in locating lost surgical needles.

During the test phase from November 2003 through April 2004, involving 22 volunteer facilities, PA-PSRS received reports of occurrences in which needle, sponge, and equipment counts were incorrect, incomplete or not performed. Problems with needle counts were the most commonly reported (50%), followed by equipment (22%) and sponge (15%) counts. All occurrences of incorrect needle counts were reported as Incidents, and the majority (78%) were coded as Harm Score D—an event requiring monitoring to confirm that it resulted in no harm and/or required intervention to prevent harm. Sixty-four percent of reports of incorrect needle counts indicated that an x-ray was performed to search for potentially retained needles.

The clinical literature provides conflicting evidence for when x-rays may be useful in locating lost surgical needles. A 2001 study found that suture needles as small as 8-0 could be visualized on x-ray with unassisted eyesight.¹ However, the results of a more extensive follow-up study² conflict with these earlier findings. In a 2003 Australian study, the smallest needle that could be visualized by a majority of observ-

Hidden Sources of Latex (Continued)

Notes (Continued)

- Charous BL. The Puzzle of Latex Allergy: Some Answers, Still More Questions. *Ann Allergy* 1994; 73(4):277-281. Also ECRI. Addressing Latex Allergy in Healthcare. *ECRI. The Risk Management Reporter* 1997 Oct. p.13. Also Lenehan GP. Latex Allergy: Separating Fact from Fiction. *Nursing* 2004 Feb; Suppl 12-18. Also U.S. Department of Labor. Occupational Safety and Health Administration 4/12/99. Technical Information Bulletin: Potential for Allergy to Natural Rubber Latex Gloves and Other Natural Rubber Products. Also Muller BA. Minimizing Latex Exposure and Allergy. *Postgraduate Medicine* 2003 Apr; 113(4):91-97.
- Gritter M. Latex Allergy. *Lippincotts Primary Care Practice* 1997 1(2):142-151. Also Johnson G. Avoiding Latex Allergy. *Nursing Standard* 13(31):12,21,49-56.
- Dyck RJ. Historical Development of Latex Allergy. *AORN Journal* 2000 Jul; 72:27-29, 32-33, 35-40.
- Poley GE, Slater JE. Latex Allergy. *J Allergy Clin Immunol* 2000; 105:1054-1062.
- Jeziarski M. Creating a Latex-safe environment: Riddle Memorial Hospital's Response to Protect Patients and Employees. *J Emerg Nurs* 1997; 23: 191-198. Also AORN Latex Guideline. *AORN Journal* 2004 Mar; 79(3): 653-672.
- Elliott BA. Latex Allergy: The Perspective from the Surgical Suite. *J Allergy Clin Immunol* 2002 Aug; 110 (2Suppl):117-120
- Latex in the Hospital Environment. Spina Bifida Association of America. 2003 Summer. www.sbaa.org. Also Tidwall J. About Latex Allergy. allergies.about.com/cs/latex/a/aa080999_p.htm. Also Binkley HM, Schroyer T, Catalfano J. Latex Allergies: A Review of Recognition, Evaluation, Management, Prevention, Education, and Alternative Product Use. *Journal of Athletic Training* 2003; 38(2):138-140. Also Hees A, von Hintzenstern J, Peters KP, et al. Allergic and Irritant Reactions to Rubber Gloves in Medical Health Services: Spectrum, Diagnostic Approach, and Therapy. *J Am Acad Dermatol* 1991; 26(3 pt 2): 831-839. Also Young MA, Myers M, McCulloch LD, et al. Latex Allergy: A Guideline for Perioperative Nurses. *AORN Journal* 1992; 56(3):488-502. Also Latex Allergy News. CETRA Latex-Free Information Services. www.latexallergyhelp.com. Also Schumann L, Buhr V. Screening Patients for Latex Allergies. *J Am Acad Nurse Pract* 2000 Sep; 12(9):380-385. Also Adkins D. Latex Products in the Hospital Environment. *J of Emergency Nursing* 1997; 23(2):135-138. Also Hamman CP, Rodgers PA, Sullivan K. Management of Dental Patients With Allergies to Natural Rubber Latex. *Gen Dent* 2002 Nov-Dec; 50(6):526-536. Also Brehler R, Kutting B. Natural Rubber Latex Allergy. *Archives of Internal Medicine* 2001 Apr; 161(8):1057-1064. Also Kramper MA. Latex Allergy: A Nursing Update. *ORL Head Neck Nurs* 2000 Summer; 18(3):7-11. Also Engelken GJ. Heighten Your Response to Latex Allergy. *JAAPA* 1999 Aug; 12(8):53-65. Also Guidelines for Preventing Sensitivity and Allergic Reactions to Natural Rubber Latex in the Workplace. Society of Gastroenterology Nurses and Associates. Revised 2004. www.SGNA.org.
- ECRI. Sample Policies and Procedures: Latex Sensitivity in Patients and Healthcare Workers. *Healthcare Risk Control. Environmental Issues* 18.2. 1998 Nov; 3:1-27. Also Stenst BL, Johnson RA. Latex Allergy. *American Journal of Health Systems Pharmacy* 1997 May; 54(9):1071-1075. Also Gehring LL, Ring P. Latex Allergy: Creating a Safe Environment. *Dermatol Nurs* 2000 Jun; 12(3):197-201. Also Jennings LM. Latex Allergy: Another Real Y2K Issue. *Rehabilitation Nursing* 1999 Jul-Aug; 24(4):140, 142.

Use of X-Rays for Incorrect Needle Counts (Continued)

ers on at least one of three different films was 17 mm (corresponding to a 5-0 suture size), and only 13% of observers were able to find a 13 mm needle (6-0 suture size).

The authors of the 2003 study felt that x-rays for missing needles smaller than 13 mm (6-0 suture size) would expose patients to unnecessary radiation for a very small chance of locating retained needles. Participants in this study (which focused on the thoracoabdominal cavity) chose department x-ray (51%) as the preferred mode for detecting retained needles, followed by a mobile image intensifier (39%), and a portable x-ray machine (7%). Departmental radiography is not feasible in the OR, however, where a mobile image intensifier may be the best method.

Some healthcare facilities have developed formal policies or procedures for how clinicians respond to cases of incorrect counts following surgery—in particular when x-rays are used to search for potentially retained needles. Barrow, the author of the 2001 study, states that hospital staff reported decreased anxiety over when to order such imaging after a formal policy was developed and implemented.

Notes

1. Barrow CJ. Use of x-ray in the presence of an incorrect needle count. *AORN J* 2001 Jul;74(1):80-1.
2. Macilquham MD, Riley RG, Grossberg P. Identifying lost surgical needles using radiographic techniques. *AORN J* 2003 Jul;78(1):73-8.

PROBLEMS RELATED TO INFORMED CONSENT

The duty of healthcare providers to provide comprehensive information to patients regarding the material risks, benefits, side effects, and alternatives to surgical and some medical procedures is firmly established and well known among the members of the healthcare community. Act 13 of 2002, which established the Patient Safety Authority, also details the procedures for which informed consent is required (see Section 504). Yet, confusion still remains over what constitutes proper disclosure to patients and when this information must be disclosed.

During the test phase of PA-PSRS, we reviewed a sample of reports of inadequate or missing informed consent. Contrary to what one might expect, less than one-third of the reports indicated emergency situations or other circumstances where obtaining consent might be particularly difficult.

After excluding these emergency or otherwise problematic cases, the most commonly reported problem involved cases where patients received several procedures during the same episode of care and consented to some procedures but not others. For example, a patient who had consented to cystoscopy, possible transurethral resection of the prostate, and possible biopsy also underwent placement of bilateral ureteral catheters to which he had not consented.

A second type of problem occurs during a procedure when a need for additional, unconsented procedures becomes apparent and consent cannot be readily obtained—such as during surgery when a patient is already anesthetized. In one case reported to PA-PSRS, a patient who had consented only to a total vaginal hysterectomy also had a fallopian tube and ovary removed that were adhered to the uterus. Another report concerned a patient who had consented to a ventral hernia repair but also had a loose tooth removed due to risk of aspiration while under anesthesia. The surgery team obtained a dental consult before deciding to remove the tooth, but there was no consent for the tooth extraction.

Several reports address cases in which patients received a procedure different from that to which they consented. In one case, a patient underwent insertion of a different brand of catheter for hemodialysis access than that to which he had consented. In another case, a patient consented to placement of a left-side catheter but received bilateral catheters.

Problems Related to Informed Consent (Continued)

In limited circumstances, a physician may be justified in carrying out a different procedure from that which the patient authorized. However, these usually are medical emergencies and unanticipated events (such as during surgery) that necessitate immediate action to avoid endangering the life or health of the patient.¹

While Pennsylvania law regarding informed consent is unique in many respects, and literature addressing a physician's obligations under other states' laws may be inapplicable, the accompanying resources may be useful in reviewing or revising policies and procedures or in staff or patient education related to informed consent.

Available Resources

Consent to HIV-related test, Pa. Stat. Ann. Purdon 2002; tit. 35, § 7605

Informed consent for treatment of breast disease, Pa. Stat. Ann. Purdon 2002; tit. 35, §§ 5641-5642

Minor's consent to medical, dental and health services, Pa. Stat. Ann. Purdon 2002; tit. 35, §§ 10101-10105

American Academy of Pediatrics—141 Northwest Point Blvd, PO Box 927, Elk Grove Village, IL 60009-0927, Phone (847) 228-5005, Fax (847) 228-5097, Web site www.aap.org, E-mail kids-docs@aap.org.

Consent by proxy for nonurgent pediatric care, Committee on Medical Liability Pediatrics 2003 Nov; 112(5):1186-95

Consent for emergency medical services for children and adolescents 1993 (revised 2003), Committee on Pediatric Emergency Medicine Pediatrics 2003 Mar; 111(3):703-6

American Association of Nurse Anesthetists—222 S Prospect Ave, Park Ridge, IL 60068-4001, Phone (847) 692-7050, Fax (847) 692-6968, Web site www.aana.com, E-mail info@aana.com.

Informed consent in anesthesia, 1991; Catalog: 1012 Price: \$ 5.00

American Cancer Society—1599 Clifton Rd NE, Atlanta, GA 30329, Phone (404) 320-3333 (404) 329-7608 (Publications) (800) 227-2345, Web site www.cancer.org.

Informed consent, Price: N/C

American College of Radiology—1891 Preston White Dr, Reston, VA 20191, Phone (703) 648-8900, Fax (703) 648-9176, Web site www.acr.org, E-mail info@acr.org.

Informed consent, 1987 (renewed 1997); Price: N/C single copy; \$100.00/set

ACR practice guideline on informed consent for image-guided procedures, 2001; Price: Book \$160.00; CD \$40.00

American College of Surgeons—633 N Saint Clair St, 27th Floor, Chicago, IL 60611-3211, Phone (312) 202-5000, Fax (312) 202-5001, Web site www.facs.org, E-mail postmaster@facs.org.

Statement on principles underlying perioperative responsibility, Bull Am Coll Surg 1996 Sep; 81(9):39-40 Catalog: ST-25 Price: N/C

Problems Related to Informed Consent (Continued)

American Medical Association—515 North State St, Chicago, IL 60610, Phone (312) 464-5000 (800) 621-8335, Fax (312) 464-5600, Web site www.ama-assn.org.

Informed consent, 1981; Price: N/C

Substitution of surgeon without patient's knowledge or consent, revised 1994; Price: N/C

American Psychiatric Association—1000 Wilson Blvd, Suite 1825, Arlington, VA 22209-3901, Phone (703) 907-7322 (800) 368-5777, Fax (703) 907-1091, Web site www.psych.org, E-mail apa@psych.org.

Consent to voluntary hospitalization, 1992; Price: N/C

American Society for Aesthetic Plastic Surgery—36 W 44th St, Suite 630, New York, NY 10036, Phone (212) 921-0500, Fax (212) 921-0011, Web site www.surgery.org, E-mail media@surgery.org.

Informed consent, 1998 Aug.

American Society for Gastrointestinal Endoscopy—13 Elm St, Manchester, MA 01944, Phone (630) 573-0600, Fax (630) 573-0691, Web site www.asge.org, E-mail info@asgeoffice.org.

Informed consent for gastrointestinal endoscopy, *Gastrointest Endosc* 1988 May-Jun; 34(3 Suppl):26S-27S; Price: N/C

American Society for Reproductive Medicine—1209 Montgomery Hwy, Birmingham, AL 35216-2809, Phone (205) 978-5000, Fax (205) 978-5005, Web site www.asrm.org, E-mail asrm@asrm.org.

Elements to be considered in obtaining informed consent for ART, 1998 Jan.

AVSC International—440 Ninth Ave, New York, NY 10001, Phone (212) 561-8000, Fax (212) 561-8067, Web site www.avsc.org, E-mail info@avsc.org.

Informed consent and voluntary sterilization: An implementation guide for program managers, 1988; Catalog: IC-01 Price: \$ 5.00

Notes

1. Rozovsky F. Consent to treatment: a practical guide. 2nd ed. Boston: Little, Brown, and Co., 1990 (with annual supplementation).

PATIENT IDENTIFICATION

Ensuring positive identification of patients is a challenge in all healthcare settings. Sometimes patient misidentification can be a causative factor in many events involving medication administration, invasive procedures, transfusions, injections of contrast media, phlebotomy, pathology specimen preparation, and provision of emergency medical services. The potential for errors of patient identification may be greatest in acute care hospitals, where a wide range of interventions are delivered in various locations by numerous staff who work in shifts.

The true extent of harm to patients caused by misidentification is unknown. The Joint Commission on the Accreditation of Healthcare Organization's (JCAHO) national sentinel event database contains 30 reports over an eight-year period of invasive procedures performed on the wrong patient.¹ New York State's mandatory reporting system has reports of 27 patients who underwent invasive procedures intended for another patient.² U.S. Pharmacopeia's MedMARxSM system received reports of 8,196 medication errors involving the wrong patient in 2002, 1.4% of which involved harm.³

Patient Identification (Continued)

Preliminary reports from the 22 healthcare facilities participating in the test phase of PA-PSRS indicate that Pennsylvania facilities are not immune from the risks of patient misidentification. Between November 2003 and April 2004, PA-PSRS received a number of reports in which patient identification was or may have been a contributing factor (see Table 1). While nearly all of these reports were Incidents as defined in Act 13, in which no harm came to the patient, the volume of reports demonstrates that patient identification can be a significant issue.

Wrist bands are not a panacea for the risk of mis-identification.

An analysis of major blood transfusion errors reported to the Food and Drug Administration (FDA) over a ten-year period from 1976 to 1985 revealed that 10 patient deaths occurred in situations in which the actual and intended recipients bore the same last name and that five deaths occurred involving patients who shared the same room.⁴ These contributing factors have also been cited in patient misidentification reports submitted to PA-PSRS.

Table 1. Levels of Harm Associated with Reports Potentially Involving Patient Identification Problems (November 2003-April 2004)

Level of Harm	Percentage of Total
Incident: Unsafe Conditions (PA-PSRS Harm Score A)	7%
Incident: No Harm (PA-PSRS Harm Scores B1-D)	90%
Serious Event: Temporary Harm (PA-PSRS Harm Scores E-F)	1%
Serious Event: Significant Harm (PA-PSRS Harm Scores G-I)	1%

In one case reported to PA-PSRS, a patient received medications intended for another patient with the same first name. The report indicated that medications were administered in part based on patient first names. While the patients' charts were marked with "same name alert" stickers, the practitioner administering the drugs may not have checked the charts, and the report indicates they may also have failed to check the patient's wrist band. In an effort to prevent this type of error, many facilities use two unique patient identifiers (e.g., name, telephone number, birth date, social security number), particularly before high-risk interventions such as administering medications or blood products or before performing surgery.

Wrist bands are a common medium for unique identifiers, and Pennsylvania regulation requires the use of a patient identification band or other visible means of identification on individuals at the time of admission to a hospital (PA Code 28, Section 105.15). Wrist bands are not a panacea for the risk of misidentification, however. The College of American Pathologists (CAP) reported⁵ on several studies it conducted between 1991 and 2000 to identify wrist band errors. In these studies (which focused on the hospital setting), mean error rates ranged from approximately 2.4% to 8.4%.

Practices to enhance patient identification reported by the best and most improved performers in recent CAP studies include:

- Placing new wrist bands on patients immediately following removal of a band during a procedure.
- Having a written protocol for identifying patients at the time of phlebotomy.

Patient Identification (Continued)

- Forbidding phlebotomists from drawing blood from patients with wrist band errors.
- Educating staff members who use wrist bands and defining a process to immediately fix a wrist band error.

Healthcare facilities use a variety of system elements to correctly identify patients and to catch identification errors when they occur, and clinicians play a crucial role in that system. Each interaction with a patient is an opportunity to verify correct identification and to serve as a system safeguard when identification errors are present.

Notes

1. Croteau R. (Executive Director, Strategic Initiatives. Joint Commission on the Accreditation of Healthcare Organizations). Personal communication with ECRI 2003 Mar 17.
2. Chassin M, Becher EC. The wrong patient. *Ann Intern Med* 2002 Jun 4;136(11):826-33.
3. Hicks RW, Cousins DD, Williams RL. Summary of information submitted to MedMARxSM in the year 2002. The Quest for Quality. Rockville (MD): USP Center for the Advancement of Patient Safety; 2003.
4. Sazama K. Reports of 355 transfusion-associated deaths: 1976 through 1985. *Transfusion* 1990 Sep;30(7):583-90.
5. Howanitz PJ, Renner SW, Walsh MK. Continuous wristband monitoring over 2 years decreases identification errors: a College of American Pathologists Q-Tracks study. *Arch Pathol Lab Med* 2002 Jul;126(7):809-15.

PA-PSRS PROGRAM NOTES

How to Code Reports of Elopements

Several facilities have expressed confusion about how to code reports of elopements. At the PA-PSRS training sessions, Department of Health representatives stated that elopements from the emergency department (ED) waiting area do not need to be reported through PA-PSRS. However, the Department does want to be notified of inpatient elopements as well as elopements from the ED in cases where the patient eloped from the treatment area.

When submitting reports through PA-PSRS, inpatient elopements should be reported as Infrastructure Failures under Event Type code T.4: Administration, Inpatient Elopement/AWOL. Elopements from an ED treatment area should be reported under Event Type code X.1: Other Infrastructure Failure.

For more information about the Department's guidance on reporting elopements, go to www.health.state.pa.us/facility. You do not need a password. Just click on the green arrow and locate the message dated January 14, 2003.

Reporting Occurrences from Other Facilities

Several facilities have contacted the PA-PSRS Help Desk to ask when they should report Serious Events or Incidents that occurred at another health-care facility. This issue might arise, for example, in relation to a patient transferred from another facility with pre-existing pressure ulcers. Ideally, both facilities would report such an occurrence and document the details of the case in the narrative section of their reports.

A related issue arises when one facility contracts for services (e.g., lab work) from another facility and a serious event or incident occurs related to the contracted facility's services. Who should report these occurrences? Assuming both facilities are subject to Act 13 requirements, both facilities could submit a report through PA-PSRS.

Any PA-PSRS participating facility that identifies a Serious Event or Incident should submit a report, regardless of whether the patient was under their direct care at the time the event occurred. The focus in PA-PSRS is not on numbers, *per se*, but on the opportunity to learn from the facts surrounding an event so steps can be taken to prevent a recurrence.

PATIENT SAFETY NEWS

Patient Safety in Pediatrics

According to a study¹ funded by the Agency for Healthcare Research and Quality (AHRQ), children in hospitals often experience adverse patient safety events—such as medical injuries or errors—in the course of their care. Those in vulnerable populations, such as children under one-year of age, are at highest risk. By diligently reporting and using the analytical tools in PA-PSRS, you can keep track of these types of events to determine if you need to take steps to improve patient safety for this age group or others. For more information on the AHRQ study, go to www.ahrq.gov.

Notes

1. Miller MR, Zhan C. Pediatric patient safety in hospitals: a national picture in 2000. *Pediatrics*. 2004 Jun;113(6):1741-6.

Preventing Wrong-Site Surgery

A new JCAHO rule called the “Universal Protocol for Preventing Wrong Site Surgery, Wrong Procedure and Wrong Person Surgery” goes into effect on July 1, 2004. The Protocol relates to patient and procedure identification, site marking, and “time-out” prior to the start of a surgical or invasive procedure. Although only JCAHO-accredited organizations are subject to the requirement, other facilities should be familiar with this important patient safety protocol. For more information on the new Universal Protocol, visit the website of the Joint Commission on Accreditation of Healthcare Organizations at www.jcaho.org.



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, 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 health care. ECRI’s focus is health care technology, health care risk and quality management and health care environmental management.

ECRI provides information services and technical assistance to more than 5,000 hospitals, health care organizations, ministries of health, government and planning agencies, and other organizations worldwide.