PA PSRS
Pennsylvania Patient Safety Reporting System

# Patient Safety Advisory

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## Patient Safety Authority Update

This month marks the one year anniversary of the PA-PSRS system, a significant milestone in patient safety for Pennsylvania's healthcare providers and patients alike.

While we will have received more than 150,000 reports by the time this *Advisory* goes to print, numbers alone are not the measure of PA-PSRS's success. That measure is the result of how facilities use PA-PSRS and how they respond to Act 13's other patient safety requirements.

In a recent conversation, the vice president for medical affairs at a hospital in Central Pennsylvania spoke enthusiastically about how Act 13 and the PA-PSRS reporting system raised patient safety to the forefront within his facility. He described how they considered patient safety in designing a new wing and how mandatory reporting has enhanced communications between different segments of the staff. PA-PSRS, he recounted, has increased physician awareness of process issues and is encouraging nurses to speak out more freely. In summary, he concluded that PA-PSRS has both focused his organization's attention on patient safety and actually increased patient safety within his facility.

These are not isolated comments. In a recent news story carried in publications targeted to the physician community, several hospital executives cited examples where PA-PSRS has facilitated clinical improvements and other positive outcomes within their organizations. For example, a critical access hospital streamlined its patient transfer process based on the results of a root cause analysis conducted after a PA-PSRS report submission. A large academic medical center reported making changes within its operating rooms as a

*(Continued on page 2)*

## Clostridium Difficile: A Sometimes Fatal Complication of Antibiotic Use

**"C. diff": What Is It?**

Technically, *Clostridium difficile* (C. diff) is a bacteria in the Clostridia family, which also includes C. perfringens (gas gangrene), C. tetani (tetanus), and C. botulinum (botulism). The Clostridia bacteria are spore-forming anaerobic gram positive bacilli which are particularly virulent because of the toxins they produce.

Clinically, "C. diff" refers to an overgrowth of C. difficile in the colon which can manifest as diarrhea, sometimes profound, colitis, or toxic megacolon, sometimes complicated by dehydration, colonic perforation, and/or death. The overgrowth of C. diff in the colon usually results from alterations in the normal colonic flora associated with use of antibiotics.

**A Serious Problem Reported to PA-PSRS**

C. diff is documented in almost half the reports submitted to PA-PSRS under the Event Type code "Nosocomial infection: antibiotic-associated diarrhea." However, of greatest concern is the number of reports involving patient deaths in which C. diff is mentioned as a major contributing factor. PA-PSRS has received 15 such reports to date. Diagnoses include sepsis/septic shock, toxic megacolon, colitis, diarrhea, and abdominal pain. Most patients in these reports (86%) were age 70 or older.

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## Patient Safety Authority Update (Continued)

result of a recent *Patient Safety Advisory* article. And a community hospital attributed a reduction in medication errors to use of the PA-PSRS analytical tools, singling out the usefulness of being required to answer questions related to so-called "contributing factors" on the PA-PSRS reporting form.

While each of the above-cited facilities focuses on different aspects of PA-PSRS, their examples validate the system's usefulness and the benefits of a mandatory reporting system based on a culture of learning. This issue of the *Patient Safety Advisory*, the eighth since we initiated publication last year, is an integral component of the Authority's commitment to promote patient safety by sharing knowledge and best practices. As one hospital executive noted, *Advisory* articles are inherently practical because they are derived from actual events in Pennsylvania institutions, whereas many academic articles about patient safety have little immediate clinical relevance.

We hope that you are finding PA-PSRS beneficial in enhancing patient safety efforts and promoting a culture of safety within your facility. We encourage you to share your experiences with us so we, in turn, can share them with others.

Alan B. K. Rabinowitz
Administrator
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## Clostridium Difficile: A Sometimes Fatal Complication of Antibiotic Use (Continued)

Several reports indicate that patients treated with antibiotics prophylactically for an elective surgical procedure developed symptoms of C. diff infection in the community after discharge. They failed to return to the healthcare system until their disease had progressed significantly. From the patient's perspective, the relatively routine nature of the surgery in several cases (e.g., knee replacement, repair of a hip or ankle fracture, hysterectomy) may have obscured the connection between the gastrointestinal symptoms of C. diff infection and their recent treatment.

The following reports submitted to PA-PSRS illustrate this point.

> *A 72-year-old patient came to the ED complaining of a near syncopal episode. He had been discharged two weeks before, after being treated for community-acquired pneumonia. He was taking an antibiotic upon discharge and finished the full course of medication at home. The patient also complained of diarrhea, nausea, and abdominal discomfort over the previous week. The patient arrived, in fact, in septic shock. Fecal testing was positive for C. diff. Despite aggressive intervention, the patient died of C. diff sepsis within 16 hours of returning to the ED.*

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## Clostridium Difficile: A Sometimes Fatal Complication of Antibiotic Use (Continued)

*An 87-year-old patient was discharged to a rehabilitation facility after repair of a hip fracture and receipt of antibiotic therapy. Eighteen days later, the patient returned to the hospital in septic shock associated with C. diff. The patient died the day she returned to the hospital despite aggressive intervention.*

**The Bottom Line**

The message for the healthcare community is to avoid complacency about the risk of C. diff infection and to help patients to understand when they need to return to the healthcare system for additional treatment, especially for diarrhea complicating antibiotic use. The risks of surgical complications may overshadow the risks of prophylactic antibiotics not only in the minds of patients and their families but also among healthcare workers.

**C. Diff Infections**

While much attention has been focused on such hospital-acquired infections as MRSA (Methicillin-resistant Staphylococcus aureus) and VRE (Vancomycin-resistant enterococcus), C. diff has become a growing concern. C. diff-associated diseases cause significant morbidity and mortality. Patients with C. diff-associated diarrhea (CDAD) have hospital stays that are, on average, 3.6 days longer, and each patient results in additional hospital costs of an average of $3,669.[1] A conservative estimate of the cost of this disease in the US is over $1 billion annually.[1]

In its spore form, C.diff can withstand drying and heat, and is resistant to many disinfectants. The spores can survive up to five months in the environment.[2,3] It can be transmitted from person-to-person, as well as by persons touching objects contaminated with the organism.[3] In the healthcare environment, C. diff has been cultured in rooms of infected individuals up to 40 days post discharge. Objects from which C. diff has been cultured include: scales, call buttons, telephones, floors, bedpans, toilets/commodes, bed frames, bathing tubs, and electronic thermometers.[2-4] It has also been cultured from healthcare workers' shoes, fingernails and fingertips, as well as the underside of rings.[2,3]

For the organism to cause disease, C. diff must be in the gastrointestinal system. Then, there must be a change in the normal colonic flora to allow the organism to grow and flourish. Finally, the C. diff must produce toxins.[2] The organism produces two toxins. Toxin A is an enterotoxin that causes excretion of large amounts of fluid from the bowel. Toxin B is cytotoxic, attacking and disintegrating cells of the intestines. In addition, C. diff produces tissue-degradative enzymes.[3,5] These processes elicit a profound inflammatory response within the colon that can result in a spectrum of diseases.

**Spectrum of Disease**

At one end of the spectrum, C. diff can reside in the gut asymptomatically.[2,3] Many patients colonized with C. diff do not develop clinical signs of the disease.[6,7] This organism can be isolated in up to 3% of healthy adults in the general population and from 50% to 80% of healthy newborns and infants.[2,3]

C. diff also causes simple antibiotic-associated diarrhea.[2,3] C. diff is a leading cause of nosocomial diarrhea in the US,[8] accounting for nearly 20% of antibiotic-associated diarrhea.[9,10] While there is evidence of community-acquired C.diff-related diarrhea, it is rare;[2] only about 20,000 cases are diagnosed in the outpatient setting annually.[3] The diarrhea is watery and may contain mucus.

More serious manifestations of infection are colitis and pseudomembranous colitis.[2,3,6] In addition to diarrhea, there may be loss of appetite, nausea, and abdominal tenderness or pain.[3,7] C. diff is responsible for 50-70% of antibiotic-related colitis.[10]

Approximately 1-3% of patients with C. diff infection develop fulminant colitis.[11] Symptoms include severe diarrhea, marked leukocytosis, high fever, chills, and severe lower quadrant or diffuse abdominal pain.[11] The colon may become so compromised that a paralytic ileus may develop,[2] in which case diarrhea is absent,[2,11] and constipation may be apparent.[12,13] Abdominal distension may develop.[11]

Toxic megacolon may ensue;[11] this is a life-threatening complication of colitis with an acute dilatation of all or a substantial portion of the colon to a diameter larger than 6 cm. It is associated with systemic toxicity.[14] Surgery is required in 65-71% of these cases.[14]The literature indicates that subtotal colectomy is the procedure of choice to reduce mortality.[14] Colonic perforation can occur,[6,11] and the protein-losing enteropathy can lead to hypoalbuminemia and ascites.[2,11]

Death is also a reported complication of C. diff infection.[3,6] Mortality associated with active C. diff infections is 0.6% for those with pseudomembranous colitis and 57% in patients requiring colectomy for toxic megacolon. The mortality rate for fulminant C. diff colitis is also high. This may be due to a failure to diagnose this disease in its early, more subtle stages, particularly if diarrhea is not present and

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## Clostridium Difficile: A Sometimes Fatal Complication of Antibiotic Use (Continued)

abdominal findings are unclear.[11] Overall, studies have reported mortality rates associated with CDAD ranging from 0.6%[9] to 3%.[1]

### Concern

The incidence and severity of C. diff infection and related diseases appears to be increasing in developed countries, such as the US, UK, and Canada, probably due to increased use of broad-spectrum antibiotics, such as third-generation cephalosporins, during the past 20 years.[6]

A Canadian study describing cases of CDAD in one institution over a 13-year period found that incidence increased from 35.6 per 100,000 population in 1991 to 156.3 per 100,000 in 2003. In the patients aged 65 years or older, the rate increased from 102.0 to 866.5 during the same period. Complicated cases of C. diff infection increased from 7.1% to 18.2%. The proportion of patients who died within 30 days after diagnosis of C. diff infection increased from 4.7% to 13.8%.[15]

A study in the US Pacific Northwest describing a single institution's 20-year experience with C. diff colitis found that the number of cases rose by more than 30% when comparing the first and last 10-year periods. The mortality rate increased from 3.5% to 15.3%.[16]

A study conducted in Pennsylvania indicated that incidence of fulminant C. diff colitis increased from 0% in 1990 to 3.2% in 2000.[17] Another study in a Pennsylvania teaching hospital[18] found an increase in the incidence of nosocomial C. diff from 2.7 to 6.8 cases per 1,000 discharges from 1999 to 2000-01. Further, 0.15 cases per 1,000 discharges of severe C. diff-related disease in 1999 rose to 0.60 in 2000-01. Some severe cases resulted in colectomy and death.

Recent case studies and anecdotal reports indicate that the course of C. diff-related disease may be changing. There appears to be a trend of more debilitating disease from this infection, higher mortality rates, and an increased need for operative treatment[16]—from an organism that has previously been considered relatively innocuous and responsive to treatment.[17]

### Risk Factors

Once C. diff becomes resident in the gastrointestinal tract, the predominant risk factor for developing disease is treatment with antibiotics, particularly broad-spectrum antibiotics.[2,6-8,10,16,19] Though disease may occur in the absence of a history of antibiotic therapy,[2] the use of the following antibiotics are most frequently associated with the development of C. diff-associated disease: cephalosporins, penicillins (ampicillin and amoxicillin), and clindamycin.[3,7,16] More recently, there have been reports of fluoroquinolone-associated CDAD,[6,8,18] including ciprofloxacin[8] and levofloxacin.[18] Antibiotic use, whether for prophylaxis or treatment, is a more important risk factor for C. diff-related disease and potentially poor outcomes than horizontal transmission via exposure to contaminated surfaces.[16]

Other general factors that determine whether C. diff-related disease develops include the type and timing of antibiotic exposure, the virulence of the strain of C. diff, and susceptibility or immune status of the patient.[3]

A multitude of patient factors may place patients at higher risk for C. diff-associated disease, increased mortality and morbidity, and recurrent infection. These include: advanced age;[2,6-8,19] severity of comorbid conditions;[2,19] renal disease;[2,6,12,13] cancer;[2] diabetes mellitus;[16] diseases that compromise the immune system;[7,16] patients in intensive care units;[2,19] and patients with a low serum albumin.[19] In these situations, patients' ability to mount an immune response against the bacteria is compromised.[8]

Hospitalization is a risk factor. Studies indicate that from 13-31% of inpatients are colonized with C. diff if hospitalized more than one week, and 56% of these develop CDAD.[1,3] Those hospitalized more than four weeks may have a rate of acquisition of 50%.[3]

Gastrointestinal surgery is associated with increased risk of C. diff-associated disease. Procedures include: recent gastrointestinal (GI)/bowel surgery or manipulation of the GI tract;[7] non-surgical GI procedures;[19] presence of nasogastric tube/tube feedings.[2,19]

Patients with C. diff colitis and a markedly elevated leukocyte could have a poor prognosis and higher mortality rate than those without a leukemoid reaction.[20]

In the northern hemisphere during winter, CDAD outbreaks are more likely.

### Treatment

The following interventions can be implemented once a C. diff-associated disease is diagnosed:

- Discontinuing the offending antibiotic.[2-4]

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## Clostridium Difficile: A Sometimes Fatal Complication of Antibiotic Use (Continued)

- Administering another antibiotic only if continued antimicrobial therapy is needed and using antimicrobics that are less frequently associated with the C.diff-associated disease.[3]
- Providing supportive measures to correct fluid loss and electrolyte imbalances.[3]
- Implementing enteric isolation precautions for infected patients.[3]
- Treating the infection with vancomycin, metronidazole, or bacitracin as first line therapy.[1-3] Treatment is more likely to be successful if administered orally for 10 days.[4] However, use of vancomycin continues to be restricted because of the risk of developing vancomycin-resistant enterococcus. Ordinarily, oral vancomycin is reserved for patients with metronidazole intolerance. Metronidazole continues to be the drug of choice for CDAD.[3]
- If a patient receiving metronidazole therapy develops a white blood cell count greater than 20,000 cells/mm$^3$ and/or an elevated creatinine level, it may be an indication of more severe C. diff-related outcomes. Based on limited observational data, vancomycin treatment may be indicated in such cases.[15,21,22] Large, prospective, randomized controlled trials are needed, however, to confirm the effectiveness of such a change in therapy.
- In patients with refractory or recurrent C. diff colitis, a recently published uncontrolled study of 103 patients indicated that the rate of successful treatment was about the same whether prolonged metronidazole therapy or vancomycin was used.[23]
- Avoiding peristaltic agents[3] and antidiarrheal/antiperistaltic agents. Antidiarrheal agents such as loperamide may delay clearance of C. diff toxins from the patient's colon and may predispose the patient to toxic megacolon.[4,7]

Healthcare workers can provide supportive care; observe and document bowel habits and changes; document the characteristics of bowel movements; and educate patients/relatives about infection control procedures, such as handwashing and wearing of gloves and gowns if directly involved with the patient's incontinence care or toileting needs.[2] Several other approaches to the management and prevention of C. diff are being studied, as well, such as drugs (tinidazole or nitazoxanide), immunotherapy, vaccine, and probiotics (*Lactobacillus species* or *Saccharomyces boulardii)*.[1,4,23]

**Prevention**

Several interventions can help prevent C. diff transmission in the healthcare environment.

Handwashing

The Centers for Disease Control and Prevention (CDC) guidelines for hand hygiene in healthcare

### Emerging Strain of Clostridium Difficile

On April 11, 2005, at the annual meeting of the Society for Healthcare Epidemiology of America, infectious disease experts presented information concerning a new, highly toxic, strain of *Clostridium difficile*. This emerging strain is associated not only with severe diarrhea and colitis, but also colectomy and death.

The strain contains a mutation on a gene that regulates production of toxins A and B and which also may produce an additional toxin. The strain produces a higher level of toxin than most other strains, and it is also resistant to fluoroquinolones.

Since 2001, this strain has been identified in outbreaks in at least seven US hospitals in six states, as well as in Sherbrooke and Montreal in Quebec, Canada.

The hospital in Sherbrooke has substantially reduced the use of antibiotics known to be associated with C. diff infection. This was followed by a 33-50% reduction in C. diff-associated disease.

In May 2005, a Pennsylvania facility submitted a report to PA-PSRS indicating that the CDC had confirmed a genetically altered virulent strain of C. diff in a patient's specimen. A 30-year-old patient with multiple trauma received antibiotics, then developed a C. diff infection, which was treated with Flagyl. However, the patient developed pseudomembranous colitis and required an emergent total colectomy. Fortunately, the patient survived.

Sources

Canadian Press. Quebec C. difficile strain has high toxin levels. [online]. 2005 Apr 11 [cited 2005 May 16]. Available from Internet: http://www.ctv.ca/servlet/ArticleNews/story/CTVnews/1113222804128_6/?hub-Health

Acambis. Emerging strain of common bacteria Clostridium difficile is highly toxic. [online]. 2005 Apr 11 [cited 2005 May 16]. Available from Internet: http://www.acambis.com/documents/sites/1/News_releases/SHEA_release.pdf

International Society for Infectious Diseases. Researchers report emergence of epidemic strain of C. difficile. Archive number 20041004.2735. [online]. 2004 Oct 3 [cited 2005 May 16]. Available from Internet: http://www.promedmail.org/pls/askus/f?p=2400:1001:491458::NO::F2400_P1001_BACK_PAGE,F2400_P1001_PUB_MAIL_ID:1000,26867

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## Clostridium Difficile: A Sometimes Fatal Complication of Antibiotic Use (Continued)

settings[21] contains information concerning: handwashing and hand antisepsis, hand hygiene technique, surgical hand antisepsis, selection of hand hygiene agents, and skin care. These guidelines include information that can be applied to preventing transmission of C. diff by healthcare workers. C. diff spores have been shown to be present on clinicians' hands, which may become contaminated through contact with infected fixtures, equipment, and patients and may then be instruments of contamination themselves.[2]

No agent used in antiseptic handwash or antiseptic hand-rub preparations is reliably sporicidal against C. diff (chlorhexidine, hexachlorophene, iodophors, alcohols, PCMX, triclosan). Spores may be physically removed from contaminated hand surfaces by washing hands vigorously with either non-antimicrobial or antimicrobial soap and water.[21]

While gloves are worn when caring for patients with C. diff diarrhea, after glove removal, hands are washed with a non-antimicrobial or an antimicrobial soap and water, or are disinfected with an alcohol-based hand rub. During outbreaks of C. diff-related infections, washing with soap and water after removing gloves is prudent, as frequent use of alcohol-based hand rubs may dry the skin, making it more vulnerable to breakdown.[21]

Handwashing also reduces contamination by the vegetative state of C. diff. Technique is important, however, if this decontamination process is to be effective in preventing transmission. Such techniques are described in Figure 1.[2,3,7,21]

The Veterans Administration's National Center for Patient Safety has recently recommended that when C. diff is suspected, caregivers' hands hygiene includes increasing glove use to protect hands from contamination and handwashing with soap and water for decontamination.[25]

When using soap and water:

- First, wet the hands with water
- Apply the manufacturer-recommended amount of the product to the hands
- Rub hands together vigorously at least 15 seconds
- Cover all fingers and surfaces of the hands
- Rinse hands thoroughly with water
- Dry completely with a disposable towel
- Turn off the faucet with the towel
- Avoid using hot water because repeated exposure to hot water may increase the risk of dermatitis

When decontaminating with an alcohol-based hand rub:

- Apply the product to the palm of one hand
- Rub hands together
- Cover all hand and finger surfaces until the hands are dry
- Follow the manufacturer's recommendations regarding the volume of the product to use

Figure 1. Handwashing Techniques

Isolation

- Instituting contact and enteric precautions[3,26] until the patient has formed stools—ideally for 48 hours after diarrhea ceases.[2]
- Placing the patient in a private room with private toilet[6,24] or placing patients with C. diff-associated disease in the same room (cohorting).[26]
- Using disposable equipment and dedicating reusable equipment solely for that patient.[7,26]

Personal Protective Equipment

- Wearing gloves when entering patients' rooms and when providing care to a patient with C. diff-associated disease.[3,26]
- Wearing gowns when there is a possibility that the clinician's clothing might become soiled while caring for the patient.[7,26]
- If the patient is experiencing explosive CDAD, using goggles might be prudent during incontinence care.

Cleaning/Disinfection

Thorough cleaning of surfaces, equipment, reusable devices, and the hospital environment prevents C. diff transmission, acquisition, infection, and reinfection.[7,26] For example:

- After cleaning surfaces and reusable devices according to label instructions, using an EPA-registered hypochlorite-based disinfectant,[3,6,24] alkaline gluteraldehyde, or ethylene oxide.[3]
- Generic sources of hypochlorite, such as household chlorine bleach, may be diluted and used as labeled.[26]
- Cleaning with a hypochlorite disinfectant has been found to be more effective than using a neutral detergent to decrease the incidence of C. diff contamination.[6]

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## Clostridium Difficile: A Sometimes Fatal Complication of Antibiotic Use (Continued)

- Carefully cleaning/disinfecting environmental surfaces and items that are likely to be contaminated with fecal material and/or that are frequently touched.[7,26]
- Following manufacturer instructions for disinfection of endoscopes and other devices.[26]
- Alcohol-based disinfectants are not effective against C. diff and are therefore inappropriate for disinfection of environmental surfaces.[26]

Prudent Antibiotic Use

Some healthcare facilities have changed antibiotic policies to limit use of broad spectrum antibiotics associated with C. diff infection.[2] The restriction of fluoroquinolone use among inpatients has been shown to decrease CDAD rates.[8] In one study, a formulary restriction of clindamycin was associated with a decrease in the incidence of CDAD.[27] Restricting the use of fluoroquinolones, however, needs to be balanced with the drug's advantages such as efficacy of oral administration and convenient dosing.[8]

Several hospitals in the UK have implemented antibiotic policies in which later-generation cephalosporins have been replaced with narrow-spectrum penicillins, fluoroquinolones, clarithromycin, pipericillin-tazobactam, metronidazole, trimethoprim, and/or aminoglycosides. Diseases treated were pneumonias, severe sepsis/septic shock, urinary tract infections, H. influenzae. The number of CDAD cases decreased significantly after the implementation of such policies.[6,28,29]

Education

An important factor in encouraging the prevention of C. diff transmission is education.[8] Healthcare workers can receive information about the disease, its epidemiology, methods of preventing transmission, handwashing techniques, personal protective equipment, cleaning/disinfection, as well as the potential for severe sequelae from C. diff infection.

Healthcare workers can also teach patients, family members, and visitors about effective handwashing techniques, as well as use of personal protective equipment if family is to become involved in incontinence care/toileting of an infected patient.[2,7] The CDC has fact sheets for healthcare providers and the general public that describe the disease and how to prevent transmission.[24,30]

Both patients and healthcare workers also can develop awareness that if a patient with current or recent antibiotic use develops diarrhea or abdominal symptoms, it may be indicative of C. diff-associated disease with the potential for serious, life-threatening ramifications.[11]

While antibiotic use precedes almost all cases of C. diff-associated disease, [11] the onset of such diseases may occur during or several weeks after therapy.[3] C. diff-associated diseases are no longer exclusively hospital-acquired infections,[2] and symptoms do not necessarily begin during a hospital stay. Inpatient hospital stays continue to grow shorter, pre- and post- operative/procedure antibiotic therapy is conducted outside of the healthcare facility. The number of procedures conducted in ambulatory surgery centers continues to rise. Fluoroquinolones are prescribed for patients in the community because they can be taken orally.

All of these factors contribute to the likelihood of patients experiencing initial symptoms of C. diff-associated disease in a community setting. At least half of the C. diff-associated deaths reported to PA-PSRS indicated that the onset of diarrhea occurred outside the acute hospital setting.

Patients, family members, referring physicians, and healthcare workers in all settings can benefit from recognition that antibiotic use has the potential of causing substantial morbidity and even mortality. If the index of suspicion is raised about this link, medical intervention for evaluation and early treatment of C. diff-associated diseases may be sought in a more timely manner, thus helping to prevent serious negative outcomes.

### Notes

1. Kyne L, Hamel MB, Polavaram R, et al. Health care costs and mortality associated with nosocomial diarrhea due to Clostridium difficile. *CID* 2002 Feb 1;34:346-53.

2. Jenkins L. The prevention of Clostridium difficile associated diarrhea in hospital. *Nurs Times* 2004 Jun 29-Jul 6;100(26):56-7,59.

3. Hurley BW, Nguyen CC. The spectrum of pseudomembranous enterocolitis and antibiotic-associated diarrhea. *Arch Intern Med* 2002 Oct 28;162(19):2177-84.

4. Gerding DN, Johnson S, Peterson LR, et al. Clostridium difficile-associated diarrhea and colitis. *Infect Control Hosp Epidemiol* 1995;16:459-77.

5. Naaber P, Mikelsaar M. Interactions between Lactobacilli and antibiotic-associated diarrhea. *Advances in Applied Microbiology* 2004;54:231-60.

6. Riley TV. Nosocomial diarrhea due to Clostridium difficile. *Curr Opin Infect Dis* 2004 Aug;17(4):323-7.

7. McConnell EA. Prevent the spread of Clostridium difficile. *Nursing* 2002;32(8):24-5.

8. McCuster ME, Harris AD, Perencevich E, et al. Fluoroquinolone use and Clostridium difficile-associated diarrhea. Emerging Infectious Diseases [online]. 2003 Jun [cited 2004 Dec 15].

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## Clostridium Difficile: A Sometimes Fatal Complication of Antibiotic Use (Continued)

Available from Internet: http://www.cdc.gov/ncidod/EID/vol9no6/02-0385.htm.

9. Miller MA, Hyland M, Ofner-Agostini M, et al. Morbidity, mortality, and healthcare burden of nosocomial Clostridium difficile-associated diarrhea in Canadian hospitals. *Infect Control Hosp Epidemiol* 2002 Mar;23(3):137-40.

10. Koehler R, Mone M, Kimball E, et al. Clostridium difficile pericarditis complicating pseudomembranous colitis in a trauma patient. *J Trauma* 2003 Oct;55(4):771-3.

11. Longo WE, Mazuski JE, Virgo KS, et al. Outcome after colectomy for Clostridium difficile colitis. *Dis Colon Rectum* 2004 Oct;47(10:1620-6.

12. Kovithavongs T. Clostridium difficile colitis associated with chronic renal failure. *Nephrol Dial Transplant* 1999;14:2256-7.

13. Cunney RJ, Magee C, McNamara E, et al. Clostridium difficile colitis associated with chronic renal failure. *Nephrol Dial Transplant* 1998;13:2842-6. [Abstract]

14. Dobson G, Hickey C, Trinder J. Clostridium difficile colitis causing toxic megacolon, severe sepsis and multiple organ dysfunction syndrome. *Intensive Care Med* 2003;29:1030.

15. Pepin J, Valiquette L, Alary ME, et al. Clostridium difficile-associated diarrhea in a region of Quebec from 1991 to 2003: a changing pattern of disease severity. *CMAJ* 2004 Aug 31;171 (5):466-72.

16. Morris AM, Jobe BA, Stoney M, et al. Clostridium difficile colitis. *Arch Surg* 2002 Oct;137:1096-100.

17. Dallal RM, Harbrecht BG, Boujoukas AJ, et al. Fulminant Clostridium difficile: an underappreciated and increasing cause of death and complications. *Ann Surg* 2002 Mar; 235(3):363-72.

18. Muto CA, Pokrywka M, Shutt K, et als. A large outbreak of Clostridium difficile-associated disease with an unexpected proportion of deaths and colectomies at a teaching hospital following increase fluoroquinolone use. *Infection Control and Hospital Epidemiology* 2005 Mar;26(3):273-80.

19. Eckel F, Huber W, Weiss W, et al. Recurrent pseudomembranous colitis as a cause of recurrent severe sepsis. *Z Gastroenterol* 2002 Apr;40(4):255-8.

20. Marinella MA, Burdette SD, Bedimo R, et al. Leukemoid reactions complicating colitis due to Clostridium difficile. *South Med J* 2004 Oct;97(10):959-63.

21. Gerding DN. Metronidazole for Clostridium difficle-associated disease: is it ok for mom? *Clin Infect Dis* 2005 Jun 1;40:1598-1600.

22. Pepin J, Alary M-E, Valiquette L, et al. Increasing risk of relapse after treatment of Clostridium difficle colitis in Quebec, Canada. *Clin Infect Dis* 2005 Jun 1;40:1591-7.

23. Musher DM, Aslam S, Logan S, et al. Relatively poor outcome after treatment of Clostridium difficile colitis with metronidazole. *Clin Infect Dis* 2005 Jun 1;40:1586-90.

24. Centers for Disease Control and Prevention (CDC). Guideline for hand hygiene in health-care settings. *MMWR* 2002 Oct 25;51(RR-16):1-48.

25. Eldridge N, Danko L. Hand hygiene and diarrheal diseases in healthcare settings. Topics in Patient Safety 2005 May/Jun;5 (3):2.

26. Centers for Disease Control and Prevention. Clostridium difficile: information for health care providers [online]. 2004 Sep 23 [cited 2005 Feb 3]. Available from Internet: http://www.cdc.gov/ncdod/hip/gastro/ClostridiumDifficileHCP.htm.

27. Climo MW, Israel DS, Wong ES, et al. Hospital-wide restriction of clindamycin: effect on the incidence of Clostridium difficile-associated diarrhea and cost. *Ann Int Med* 1998;128:989-95.

28. McNulty C, Logan M, Donald IP, et al. Successful control of Clostridium difficile infection in an elderly care unit through use of a restrictive antibiotic policy. *J Antimicrob Chemother* 1997 Nov;40(5):707-11.

29. O'Connor KA, Kingston M, O'Donovan M, et al. Antibiotic prescribing policy and Clostridium difficile diarrhea. *QJM* 2004 Jul;97(7):423-9.

30. Centers for Disease Control and Prevention. Clostridium difficile: general information [online]. 2004 Aug 10 [cited 2005 Feb 3]. Available from Internet: http://www.cdc.gov/ncidod/hip/gastro/ClostridiumDificileGEN.htm.

### PA-PSRS Pointers: Avoiding Betadine Burns

PA-PSRS has received a dozen reports of patients sustaining Betadine® burns in the OR. Skin irritation and severe skin reactions may occur when wet, unevaporated solution comes in prolonged contact with the skin.

This may occur following preoperative preparation of a patient. The Betadine solution "pools" beneath the patient, in intertriginous creases, or around the drapes during the surgical procedure. A chemical contact dermatitis may result from a combination of the chemical, heat, and pressure.

To reduce this risk, the following pointers are suggested:

1. During the surgical preparation process, tucking disposable, absorbent pads beneath the patient to absorb excess Betadine solution.
2. Not supersaturating the applicators, so that excess solution does not run off the area bring prepped.
3. Removing the absorbent pads prior to draping the patient.
4. Following manufacturer's instructions for proper topical application of Betadine solution to the skin/mucous membranes.

Sources

1. Purdue Frederick. Answers to most frequently asked questions about Betadine Microbicides [online]. [cited 2005 Jun 27]. Available from Internet: http://woundcare.org/newsvol2n2/ar1.htm.

2. Physicians Desk Reference. PDR drug information for Betadine solution [online]. 2004 [cited 2005 Jun 27]. Available from Internet: http://www.drugs.com/PDR/Betadine_Solution.html.

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# The Five Rights: Not the Gold Standard for Safe Medication Practices

Beginning in nursing school, every nurse learns about the "Five Rights" of medication administration: the right patient, drug, time, dose, and route. Unfortunately, adherence to the Five Rights is sometimes regarded as the gold standard for safe medication practices. Yet many errors, including lethal ones, have occurred in situations in which nurses firmly believed they had verified each of the Five Rights.

The Five Rights focus on individual performance rather than the reliability and safety of systems. While the Five Rights are essential goals, they do not address the human factors and system-based causes of errors. Therefore, they do not stand alone in the effort to prevent medication errors.

Further, the Five Rights offer little procedural guidance on how to meet these goals. For example, how does a nurse check the right dose of a newer medication if the drug reference texts on the unit are several years old or if a pharmacist is not readily available? How does a nurse providing care in a psychiatric facility's outpatient clinic identify the right patient if name bracelets are not used? Without adequate systems in place to help nurses achieve the goals of the Five Rights, errors can and do happen.

The Five Rights focus on individual performance, whereas safe medication practices require a combination of multidisciplinary efforts and reliable systems. Thus, despite nurses' best efforts, the use of error-prone abbreviations, ambiguous drug labels, lack of effective double checks, inadequate staffing patterns, poorly designed medical devices, illegible handwritten orders, and many other system issues can contribute to a practitioner's inability to accurately verify the Five Rights.

The Five Rights do not take into account the significant role human factors play in errors. The term "human factors" refers to the study of the interrelationships between humans, the tools they use, and the environments in which they work. For example, nurses who select the wrong medication with a label or package similar to the correct drug may honestly think that they read the label to verify the right drug correctly; however, they did not see it correctly. Human factors researchers call this confirmation bias.[1]

As we gain experience, we develop images in our minds of the items we work with every day. When we go to select a familiar item, we are sometimes unable to see evidence that indicates the wrong product has been selected. Instead, we see only what we intend to find, especially if enough characteristics match the image in our mind. This kind of human factors variable, among many others, can contribute to errors when our minds make corrections for what our eyes are seeing.

While the Five Rights may represent a standard clinicians try to live up to, they are not the most practical tools for preventing medication errors. PA-PSRS has received over 220 medication error reports in which "failure to follow the Five Rights" was indicated as the cause of the error, or in which the recommendation for system improvement was for the nurse to be more careful in adhering to the Five Rights. The number of reports grows to over 1,100 if one includes reports that state the recommendation for error reduction is to educate and counsel the practitioner to be more careful.

Focusing on these "solutions" makes it easier for individual performance to be the target of remediation and correction without targeting the systems problems. Managers may correct nurses for not following the Five Rights without recognizing and addressing the human factors and system-based causes of errors. Licensing bodies may follow suit, perpetuating the myth that the Five Rights are the only things needed to prevent errors.

Instead of focusing on those closest to the error, consider the alternative model of shared accountability, in which we translate our concern for patient safety into effective system-based solutions.[2] True improvement in the safety of healthcare will not occur without investigating beyond the Five Rights for the system-based causes of errors and implementing more effective types of error reduction strategies (see Table 1).

Items at the top of the list in Table 1, such as forcing functions and computerization, are more powerful strategies because they focus on systems. The tools in the middle attempt to fix the system, yet rely in some part on human vigilance and memory. Items at the bottom, such as education, rely on individual performance and will likely be ineffective when used alone.


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## The Five Rights: Not the Gold Standard for Safe Medication Practices (Continued)

| Error Reduction Strategy | |
|---|---|
| Forcing functions and constraints | High Leverage |
| Automation and computerization | ↓ |
| Standardization and protocols | |
| Checklists and double check systems | |
| Rules and policies | |
| Education / Information | Low Leverage |

**Table 1. Rank Order of Error Reduction Strategies.**[3] Source: ISMP. Reprinted with permission.

### Notes

1. ISMP. Medication Safety Alert! Acute Care Edition. 7 Apr 1999;(4)7.

2. ISMP. Medication Safety Alert! Community/Ambulatory Care Edition. Apr 2005;(4)4.

3. ISMP. Medication Safety Alert! Acute Care Edition. 2 June 1999;(4)11.

### PA-PSRS Pointers: Watch Out for That Dermabond

PA-PSRS has received four reports of patients' eyelids being inadvertently glued shut while Dermabond® was applied to facial lacerations. The following simple pointers are suggested to help prevent such occurrences:

- Placing dry gauze over the eyes when working in that area.
- Positioning the wound so that any excess adhesive will not "run off" to sensitive areas of the face and head.
- Initially crushing and inverting the Dermabond vial away from the patient.
- Gently squeezing the vial until a drop forms at the applicator tip, so that when squeezing is stopped, the adhesive will be drawn back into the vial.
- Applying the adhesive with gentle, brushing strokes.
- Avoiding the practice of dripping the adhesive from the end of the vial onto the patient.
- Wiping away excessive adhesive immediately with a dry gauze pad. The adhesive becomes too hardened to wipe away in about 10 seconds.

In the event that a patient's eyelids do become glued shut, ophthalmic antibiotic ointment on the eyelids will usually break down the adhesive in one to two days.

#### Source

Bruns TB, Worthington JM. Using tissue adhesive for wound repair: a practical guide to Dermabond. American Family Physician [online]. 2005 Mar 1 [cited 2005 Apr 1]. Available from Internet: http://www.aafp.org/afp/20000301/1383.html.

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## A Different Mindset: One Facility's Experience with the Anonymous Report Process

The law that established PA-PSRS (Act 13 of 2002, or "Mcare") contains a provision that allows a healthcare worker to anonymously report a Serious Event directly to the Patient Safety Authority if they know the event has been reported internally according to their facility's Patient Safety Plan and if they believe the event has not been reported to PA-PSRS.

Anonymous Reports offer a learning opportunity for the facility involved and for other facilities as well. That is the case with an Anonymous Report submitted in November 2004. Following its receipt, the Patient Safety Authority conducted a review involving a site visit to the facility and issued a report of its findings to the Authority Board of Directors. This report was accepted by the Board with a recommendation that the facility's handling of the event be published in the *PA-PSRS Patient Safety Advisory* as a case study. The case study is informative because the facility's management of the reporting process in this case—like the Serious Event itself—contained an error, system weaknesses, a root cause analysis, and corrective action.

Eight weeks prior to the filing of an Anonymous Report, a patient died following injury to the heart from the placement of a chest tube. This event was reported by several healthcare workers through the facility's internal patient safety system. From the perspective of the individual who submitted the Anonymous Report, it was not evident that any action had been taken. Upon receiving the Anonymous Report, the Authority contacted the facility and confirmed that the event had occurred, that it had been reported to the facility's Patient Safety Officer, and that the facility had not yet reported it to PA-PSRS. The facility volunteered that it had initiated an investigation of the event immediately upon receiving the initial reports through its internal reporting process.

As required, the facility provided a definitive response to the Anonymous Report within the 30 days stipulated by Act 13. Their letter stated that they had completed their internal investigation, determined that the event was reportable as a Serious Event, and had just submitted the report through PA-PSRS.

The Authority determined that it would conduct its own review of the case. The review team visited the facility, reviewed relevant records, and had a joint interview with the facility's Patient Safety Officer, risk manager, involved clinical service chief, vice-president for medical affairs, and legal counsel, among others.

It was clear to all involved that the event should have been reported to PA-PSRS in a more timely manner as a Serious Event. Of note, the attending physician reported the event to the patient's family and the service director at the time of the occurrence. At the completion of its own internal investigation, the facility also followed up with the family.

The Authority's review team reached the same conclusions as the facility's internal investigation. This critique of the delay in reporting is presented on the premise that other facilities may find themselves vulnerable to the same weaknesses:

- The first problem was that the decision whether to report the occurrence to PA-PSRS was referred to an individual who had the misperception that a Serious Event, involving patient harm as the result of medical care, also had to involve a medical error. This misperception was ultimately corrected by education from the facility's counsel, who clarified that *the definition of a Serious Event requires that the patient harm is the result of patient care. It does not require that the harm be the result of an error in delivering the care.*

- The second problem, identified astutely by the facility, was that it failed to recognize that *patient safety reporting, for learning from aggregated confidential reports, is independent of the peer review process.* Indeed, the facility was not ignoring the event, but was rather methodically investigating a concern that the event was part of a pattern of behavior by the involved healthcare provider. The delay in reporting to PA-PSRS was caused by the comprehensive, methodical review that ultimately resulted in the individual relinquishing some clinical privileges.

- The third problem, also identified by the facility, was *the lack of a tracking mechanism for potential reports requiring investigation*. The internal investigation was delayed not only by the desire for peer review, but also by vacations and illnesses of critical decision makers.

- The fourth problem, also recognized by the facility, was that *the decision about whether*

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## A Different Mindset: One Facility's Experience with the Anonymous Report Process (Continued)

*The facility staff indicated that the process of analyzing the delay in reporting had been a learning experience.*

*the event was reportable was the responsibility of a single individual,* without sufficient input from others involved in the patient safety, peer review, and risk management processes.

Stimulated by the letter from the Authority about the Anonymous Report, the facility conducted a root cause analysis of the breakdown in timely reporting. It recognized in retrospect that it should have reported the event to PA-PSRS at the time it confirmed that the patient sustained the injury from the clinical care.

The facility staff indicated that the process of analyzing the delay in reporting had been a learning experience. They developed an action plan to correct these deficiencies.

The opinion of the Authority's review team was that there was no intent to hide or minimize the event. The facility likely would have reported it as a Serious Event eventually, if for no other reason than to help justify the peer review action taken. Based on the facility's record of reporting, the delay in confirming this specific occurrence as a Serious Event appeared not to be part of a pattern to minimize reporting. The facility had wisely conducted a root cause analysis on its perceived failure to report a Serious Event in a timely fashion and changed its Patient Safety Plan to correct the problems.

The site visit team independently came to the same conclusions, and the Patient Safety Authority Board concurred with the lessons learned:

- The definition of a Serious Event requires that the patient harm is the result of clinical care, but does not require that the harm be the result of *an error* in delivering the care.
- Patient safety reporting, for learning from aggregated confidential reports, is independent of the peer review process.
- A tracking mechanism for potential reports requiring investigation may identify impending delays.
- Decisions about potentially reportable events should be known and reviewed by appropriate team members in the patient safety, peer review, and risk management processes.

### Setting Your Own "Standards" of Care

The PA-PSRS staff is planning a review of the use of standardization to improve patient safety. Standardization has been proposed to decrease variability, increase reliability, and make deviation from best practice more obvious to detect. We are interested in collecting and sharing "success stories" and "lessons learned" from Pennsylvania healthcare facilities.

Examples might include limiting the makes/models of a medical device throughout your facility, standardizing drug protocols, "pre-flight" checklists, protocols for variable dose medications, and others.

If your facility has had a good—or bad—experience standardizing a particular process of care that you would like to share with your colleagues, please contact us at (866) 316-1070 or via email at Support_papsrs@state.pa.us. We look forward to the opportunity to share your experiences as part of this review.


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# Risk of Fire from Alcohol-Based Solutions

While flammable liquid germicides (alcohol and alcohol-based solutions) are good antimicrobial agents, their misuse can present a significant fire hazard. These solutions have been used for many years in surgical preparation to prevent infections to patients and are now being used throughout healthcare facilities in the form of hand sanitizers or "hand rubs".

**Alcohol-Based Skin Prep Solutions**

A report submitted to PA-PSRS described a patient receiving a second-degree burn and singed hair from the use of an alcohol prep solution during electrosurgery. Another report described a patient's hair catching fire; though the report did not indicate that an alcohol or alcohol-based prep solution was used, hair catching fire can be indicative of the hair containing alcohol. Although electrosurgery was the ignition source in the two reported events, surgical fires or burns can occur with any ignition source (e.g., electrosurgical unit, electrocautery unit, laser, fiberoptic light source).

A search of the U.S. Food and Drug Administration's Manufacturer and User Device Experience (MAUDE) database, using the keywords "alcohol AND burn" and "alcohol AND fire" revealed 10 out of 41 reports specifically associating the use of alcohol or alcohol-based solutions with surgical fires or patient burns. The remaining reports were unrelated to prep solutions and surgical fires or burns or lacked information to make an association.

Controversy currently exists over the use of flammable liquid germicides during electrosurgery or electrocautery procedures. Several Authorities Having Jurisdiction* (AHJ), such as the state of Nebraska (state fire marshals, government health and human services departments) and Centers for Medicare and Medicaid Services (CMS), have interpreted National Fire Protection Association Standards for Healthcare Facilities (2005) as permitting the use of only nonflammable germicides in anesthetizing locations.

The NFPA 99 standard section 13.4.1.2.2[1] states:

> 13.4.1.2.2.1 Medicaments, including those dispersed as aerosols, shall be permitted to be used in anesthetizing locations for germicidal purposes….
>
> 13.4.1.2.2.2 Liquid germicides used in anesthetizing locations, whenever the use of cautery or electrosurgery is contemplated, shall be nonflammable.
>
> 13.4.1.2.2.3 Whenever flammable aerosols are employed, sufficient time shall be allowed to elapse between deposition and application of drapes to permit complete evaporation and dissipation of any flammable vehicle remaining.

The controversy arises due to the inconsistencies between flammable aerosols and liquids among the three subsections. Literal interpretation of the sections suggests that the use of flammable aerosols is permitted in anesthetizing locations and that the use of flammable liquids is not. However, the contention is that, since it is the ignition of flammable vapors from the aerosols or liquids that occurs, the interpretation should include the permitted use of both forms of germicides, provided the germicide is properly used and applied to the patient's skin.

The American Society for Healthcare Engineering (ASHE) of the American Hospital Association has proposed a tentative interim amendment (TIA)[2] to NFPA (NFPA 99) to amend and expand the language to section 13.4.1.2.2. The amendment would include permitting the use of flammable germicide solutions during surgical procedures involving ignition sources such as electrosurgery and electrocautery, with emphasis on the proper use and application of the germicide solutions. We will continue to follow this issue as the controversy develops or the resolution to the controversy develops.

A combination of two factors involving alcohol or alcohol-based prep solutions can lead to fire or burns:[3-5]

- If improperly applied, the solution may wick into the patient's hair and linens or pool on the patient's skin, which can prolong the solution's drying time.
- If the patient is draped before the solution is completely dry, the alcohol vapors can become trapped under the surgical drapes and channeled to the surgical site.

If these conditions occur, a heat source used at the surgical site could ignite the alcohol vapors, resulting in a fire and/or burn. Many clinicians are unaware of the risk of surgical fires or burns associated with the use, or misuse, of alcohol and alco-

*Authority Having Jurisdiction* is a term defined by NFPA to describe federal, state, local, or regional agencies—typically government—concerned with public safety, such as the fire marshal or health department.

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## Risk of Fire from Alcohol-Based Solutions (Continued)

hol-based prep solutions. Practices that may help to reduce this risk include:

- Purchasing skin prep solutions that provide clear and explicit instructions and warnings.
- Ensuring that the prep solution does not soak into hair or linens. Sterile towels can be placed to absorb drips and runs during application, and can then be removed prior to draping the patient.
- Prior to draping, ensuring that the prep solution is completely dry. This may take a few minutes or more depending on the amount and location of the solution. Inspecting the prepped area before draping. Some solutions change appearance when dry (e.g., change from shiny to matte).
- During surgery, being aware of any sudden flash of heat. Such a flash is indicative of an alcohol fire. If a fire is suspected, immediately search for any flaming or smoldering materials, and remove and extinguish them.
- Following prep solutions suppliers' recommended instructions for use.
- In-service about the proper use and risks of using alcohol and alcohol-based prep solutions could be provided to all surgical staff including nurses, surgeons, and anesthesia providers.

### Alcohol-Based Hand Rub Sanitizing Solutions

In January 2003, CMS published a Final Rule in the *Federal Register*, Fire Safety Requirements for Certain Health Care Facilities (68 FR 1374),[7] which included requirements for prohibiting "the placement of accelerants, including alcohol-based hand rub dispensers (ABHR), in egress corridors," but allowing their placement in patient rooms and other areas.

The concern with the hand rub sanitizers is the potential risk of fire from the released vapor from the alcohol-based ingredient of the dispenser. However, on March 25, 2005, CMS amended this Final Rule[6] to allow placing hand rub dispensers in egress corridors. Placing hand rub dispensers in egress corridors is based on certain conditions specified in the amendment. The amendment to the Final Rule became effective on May 24, 2005. Factors influencing the decision to amend the Final Rule are that the dispensers contain a relatively small amount of alcohol-based gel (alcohol-based gel is the most common form of hand rub sanitizers), the dispensers do not release alcohol vapors, and the risk of fire is low when the dispensers are properly installed and used.

### Notes

1. National Fire Protection Association (NFPA) Standard for Healthcare Facilities. NFPA 99. Quincy (MA):2005.

2. ASHE Proposes Amendment to NFPA 99 For Safe Usage Of Alcohol Based Surgical Prep Solutions, suggests hospitals cited by CMS consider requesting a waiver. American Society for Healthcare Engineering of the American Hospital Association (ASHE) [online] [cited 2005 May 17]. Available from Internet: http://www.ashe.org/ashe/codes/nfpa/nfpa099_proposeamend_absp.html.

3. ECRI. A Clinician's Guide to Surgical Fires: How They Occur, How to Prevent Them, and How to Put Them Out [Guidance Article]. *Health Devices* 2003;32(1):5-24.

4. ECRI. Improper Use of Alcohol-Based Skin Preps Can Cause Surgical Fires. [Hazard Report]. *Health Devices* 2003;32 (11):441-3.

5. ECRI. Fire Hazard Created by the Misuse of DuraPrep Solution [Hazard Report]. *Health Devices* 1998;27(11):400-2.

6. CMS Issues Interim Final Rule Allowing Alcohol-based Hand Rub Dispensers in Egress Corridors. ASHE Regulatory Advisory. American Society for Healthcare Engineering of the American Hospital Association [online] [cited 2005 May 17]. Available from Internet: http://www.ashe.org/ashe/codes/handrub/pdfs/regadv_abhr_interimfinalrule_rev2_050325.pdf.

7. 42 CFR Parts 403, 416, 418, 460, 482, 483, 485 Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities; Amendment [online]. *Fed Reg* 2005 Mar;70(57):15229-39. [cited 2005 May 17]. Available from Internet:http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/pdf/05-5919.pdf.

## New Video Highlights Patient's Role in Patient Safety

A new campaign—5 Steps to Safer Health Care—offers patients and providers information on the role patients can play to help avoid errors related to prescription medicines, laboratory tests, procedures, and surgery.

The campaign is a collaborative effort of the Agency for Healthcare Research and Quality (AHRQ), the American Medical Association (AMA) and the American Hospital Association (AHA).

Posters and fact sheets from the campaign are available at AHRQ's Web site: www.ahrq.gov/consumer/5steps.htm. A Spanish language version is also available.

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# Poor Labeling of Respiratory Therapy Medications Can Impact Patient Safety

PA-PSRS has received a number of reports in which the look-alike nature packaging made of low-density polyethylene (LDPE) may have contributed to actual or potential medication errors. In a recent report, the packaging similarities of albuterol and ipratropium led to these products being stored in the same storage bin. As a result, a patient may have received ipratropium instead of the intended albuterol treatment.

In another case, pharmacy mistakenly dispensed Atrovent® instead of albuterol during a cart fill. Fortunately, a nurse discovered the mix-up and returned the medication to the pharmacy before the patient received the incorrect drug. In response to this occurrence, the facility now labels their nebulizer medication storage bins with auxiliary labels to alert practitioners about the similarities of the products.

Practitioners have reported concerns for almost a decade with manufacturers' labeling of unit-dose respiratory therapy medications (as well as flush solutions, ophthalmic preparations and injectable products) packaged in LDPE containers. In fact, the Food and Drug Administration (FDA) has received more than 100 error reports through the USP-ISMP Medication Errors Reporting Program (MERP) and the FDA MedWatch program that cite poor legibility of these products as a major concern.[1]

Figure 1. Various Respiratory Medications. Image provided courtesy of ISMP.

Figure 2. "Clearly" a Problem. From top to bottom: albuterol sulfate, Xopenex (levalbuterol HCl), ipratropium bromide. Image provided courtesy of ISMP.

Many inhalation products intended for use by nebulization are packaged in LDPE containers, such as:

- Albuterol (Proventil®)
- Ipratropium (Atrovent®)
- Albuterol-ipratropium combinations (Duoneb®)
- Levalbuterol (Xopenex®)
- Cromolyn (Intal®)
- Budesonide (Pulmicort Respulse®)

These medications are generally marketed in boxes that contain foil pouches, each pouch holding multiple unit-dose LDPE containers. However, many of these LDPE containers have little difference in shape or color (see Figure 1). Even worse, the LDPE containers have the drug name, concentration, lot number, and expiration date embossed into the plastic using transparent, raised letters, making it virtually impossible to read (see Figure 2). Some of these products are also available in multiple dosage strengths, but poorly visible labels make it hard to differentiate them.

The embossing method of labeling is used because FDA no longer permits paper labels or ink printing on these containers.[2] LDPE is permeable to the volatile chemicals used in label adhesives, paper, and ink. In fact, FDA analytical surveys of commercially available LDPE packaged products have shown that 29 of 37 samples tested positive for volatile chemicals. The presumed source of the volatile chemicals was the packaging and labeling materials used, such as adhesives, inks, and sol-

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## Poor Labeling of Respiratory Therapy Medications Can Impact Patient Safety (Continued)

vents.[3] It stands to reason that this contamination could have potentially harmful effects in patients with asthma, chronic bronchitis, cystic fibrosis, and emphysema.[4]

A "solution" some facilities and practitioners have considered or implemented to more easily identify these medications is to use marking pens on individual containers to color code or mark a letter indicating the drug name or to affix labels to them. However, it seems reasonable that the ink from a marker and volatiles from the label adhesives could migrate through the LDPE, just as inks and adhesives used by manufacturers do. Therefore, these practices are discouraged.

Until the FDA and the manufacturers solve this labeling problem, consider the following measures to help prevent errors with these products:[5,6]

- Identifying which products packaged in LDPE are used in your facility.
- Whenever possible, ensuring that LDPE containers are stored in their original outer packaging, as this often provides clearer labeling. Keep in mind that many of these medications are packaged in foil pouches to reduce exposure to light and potential contaminants. Manufacturers of such products recommend storing unopened containers in the protective foil pouch until ready to use. Also, most manufacturers recommend that containers removed from the foil pouch be used within one week.
- Avoiding the practice of storing individual LDPE containers together in a single location, since many products look alike and could be inadvertently mixed together.
- If the medications cannot be stored in their original packaging, asking pharmacy to dispense all LDPE containers in clearly labeled plastic bags (consider light-resistant bags for photo-sensitive products).
- Avoiding the practice of affixing labels to or writing on individual LDPE containers to minimize contamination.
- Considering products that are commercially available as individual foil over-wrapped unit-dose containers (see Figure 3).

Figure 3. An Example of an Individually Foil Wrapped Unit-Dose Vial. Image provided courtesy of ISMP.

- Counseling patients and caregivers on the proper use and storage of these medications, including the potential for misidentification and the need to store these products in their original, clearly labeled packaging.

For additional information, refer to the Meeting Documents from the FDA Drug Safety and Risk Management Advisory Committee from May 5, 2004. They are available online at http://www.fda.gov/ohrms/dockets/ac/cder04.html#DrugSafetyRiskMgmt.

### Notes

1. Cohen MR. FDA tackles poor labeling on plastic containers. *Hosp Pharm*. Jul 2004;(39)7:620-1.

2. Cohen MR. Poor readability of low-density polyethylene plastic ampul labels. *Hosp Pharm*. Apr 2004;(39)4:310.

3. Sullivan E. Permeability of LDPE vials: a clinical perspective. Presented at: Meeting of the FDA Drug Safety and Risk Management Advisory Committee. 5 May 2004; Rockville, MD.

4. ISMP. Medication Safety Alert! Acute Care Edition. 20 May 2004;(9)10.

5. ISMP. Nurse Advise-Err. Dec 2004;(2)12.

6. ISMP. Medication Safety Alert! Community/Ambulatory Care Edition. Jul 2004;(3)7.

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# Tips from PA Facilities: Enforcing the Time Out and Preventing Retained Foreign Bodies

On occasion, reports submitted to PA-PSRS include the results of the facility's root cause analysis (RCA) and systems-level solutions for addressing a patient safety issue. In rare instances, the solution to a problem presents itself immediately, and the facility shares this information with PA-PSRS in their original report. More often, though, these "pearls" are submitted in amended reports after a thorough investigation and, in some cases, an RCA.

When facilities share their experience through PA-PSRS, Patient Safety Officers, clinicians, and other healthcare workers can make a difference not only in their own organizations but in healthcare facilities across the Commonwealth. With respect for your contributions and efforts to find innovative solutions, we are happy to share these "lessons learned" with your colleagues throughout Pennsylvania.

**Surgical Prep Redesign to Enforce the Time Out**
Reports submitted to PA-PSRS of both actual and "near miss" wrong patient, wrong site, and wrong procedure surgeries suggest that the practice of the time out before surgery has become widespread. However, several reports indicate that the surgeon sometimes begins the procedure before the time out is performed.

In one such case, the surgeon started operating on the wrong hand prior to the time out. An amendment to the facility's original PA-PSRS report indicates that the facility changed their pre-surgery process to minimize the potential for the procedure to begin without a time out: *The surgical blade is not attached to the scalpel handle until after the time out is performed.*

This same suggestion surfaced in a similar report from another facility that reported a near miss indicating that not all staff members were informed of a new policy requiring the time out to precede the placement of the blade in the scalpel handle.

Notice that this simple suggestion doesn't add any steps to the process. It doesn't require any new technology, increase costs, or cause a delay in the procedure. Simply reordering the existing steps provides an additional safety barrier between the patient and the inevitable human error.

This solution is a good example of a "forcing function." The Agency for Healthcare Research and Quality (AHRQ) Patient Safety Network (PSNet), defines a forcing function as "an aspect of a design that prevents a target action from being performed or allows its performance only if another specific action is performed first."[1] An example cited by PSNet is the elimination of concentrated potassium from floor stock medication cabinets. Forcing functions take different shapes such as "lockins" which prevent exiting until safe; "lockouts" prevent access until conditions are acceptable and; "interlocks" which require a specific order of events or sequencing.[2]

Other common examples of forcing functions include:

- CPOE systems that require blood glucose monitoring when insulin is administered or stop an insulin drip (with physician notification) when an NPO order is entered.[3,4]
- Medical gas cylinders are accessed by a specific pattern of holes with matching pins from the appropriate regulator. This "Pin Index System" helps ensure that the patient doesn't get nitrous oxide rather than oxygen by preventing the user from getting the lines crossed.[2]

A "procedural forcing function" is weaker than a mechanical or physical one, as it relies on a process where human actions are interdependent and thus lacks the mechanics of a failsafe design. Procedural changes fall into this category.[2] The practice of not attaching the handle and scalpel until the time out is performed is an example of a procedural forcing function. Other examples include the pre-surgery time out itself and blood product verification by two people.[2]

**The Surgical Towel as Retained Foreign Body**
Numerous reports have been submitted to PA-PSRS of discrepancies related to instrument, sharp and sponge counts. Frequently, these case reports indicate that a radiograph was used to confirm the absence of a retained foreign body. Most instruments and sharps are radiopaque. Objects introduced into the body that are not, such as sponges, have radiopaque markers to facilitate identification on a radiograph.

A recent case submitted to PA-PSRS reported identification and removal of a surgical towel left from a procedure that occurred two years earlier. Sterile surgical towels are draped around the wound to minimize contact with the skin. Because they are not intended for use within the wound, they

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## Tips from PA Facilities: Enforcing the Time Out and Preventing Retained Instruments (Continued)

typically do not have radiopaque markers as surgical sponges do. However, occasionally towels are dislodged or are used to cover the wound during intra-operative radiographs or to cover organs, displaced onto the operating surface to facilitate exposure, in order to decrease evaporation from their moist surfaces and prevent desiccation.

The facility reporting this occurrence to PA-PSRS responded to this hazard by changing to radiopaque towels and by taking the following actions to help prevent recurrence:

- Using radiopaque towels when towels will be placed in a body cavity
- Including towels used in open wounds as part of routine sponge/instrument counts.

The Association of PeriOperative Registered Nurses (AORN) supports this approach: "If a towel is used for packing, the scrub person must inform the circulating nurse, who must add the towel to the count sheet. The closing count includes verification that the towel has been removed. A better alternative is to use commercially available towels that have x-ray detectable strips and are designed specifically for packing."[5]

The Veterans Administration's National Center for Patient Safety also suggests that, "Without exception, all sponges and towels should have radiopaque markers."[6]

These actions may help to prevent surgical towels from becoming retained foreign bodies:

- Incorporating the AORN standards into surgical policies and procedures.
- Using commercially available towels with radiopaque detectable strips designed specifically for packing.[5]
- Independent inspection or exploration of the operative field by the surgeon either routinely[7,8] or following procedures that are known for risk of retention of a foreign body, such as emergent cases, those cases with unplanned changes in procedure, and when the patient has a high body-mass index.[9]

### Notes

1. Patient Safety Net: Glossary. Agency for Healthcare Research and Quality [online]. [Cited 2005 Apr 22.] Available from Internet: http://psnet.ahrq.gov/glossary.aspx.

2. Gaba DM. Thin air. Web M&M: Morbidity and Mortality Rounds on the Web [online]. Agency for Healthcare Research and Quality. 2004 Oct [Cited 2005 Apr 22.] Available from Internet: http://webmm.ahrq.gov/case.aspx?caseID=76.

3. Cucina R. The forgotten med. Web M&M: Morbidity and Mortality Rounds on the Web [online]. Agency for Healthcare Research and Quality. 2005 Apr [Cited 2005 Apr 22.] Available from Internet: http://webmm.ahrq.gov/case.aspx?caseid=93.

4. Rubin HR, Fajtova VT. Too tight control. Web M&M: Morbidity and Mortality Rounds on the Web [online]. Agency for Healthcare Research and Quality. 2004 May [Cited 2005 Apr 22.] Available from Internet: http://webmm.ahrq.gov/case.aspx?caseID=60.

5. Petersen C. AORN journal: September 2001 clinical issues. AORN [online]. 2001 Sep 1 [Cited 2005 Apr 27.] Available from Internet: http://www.aorn.org/journal/2001/sepci.htm.

6. Samples C, Dunn E. Reducing the vulnerability of retained surgical sponges. NCPS TIPS (National Center for Patient Safety), Sep/Oct 2004.

7. Kaiser CW, Friedman S, Spurling KP, et al. The retained surgical sponge. Ann Surg. 1996;224:79-84.

8. Hyslop JW, Maul KI. Natural history of the retained surgical sponge. South Med J. 1982;75:657-60.

9. Gawande AA, Studdert DM, Orav JE, et al. Risk factors for retained instruments and sponges after surgery. NEJM 2003 Jan;16(348):229-35.

## Spotted Again: Insulin/TB Syringe Confusion

In an October 28, 2004, Supplementary Advisory (Vol. 1, Sup. 1), we reported mix-ups between insulin and tuberculin (TB) syringes leading to insulin overdoses. PA-PSRS has received a recent report in which 50 units of Humalog was mistakenly administered instead of the ordered dose of 5 units because a TB syringe was used by mistake. As a result, the patient's blood glucose level to dropped to 50 mg/dL.

Strategies that may help limit the potential for this confusion include: storing insulin syringes separately from all other syringes and evaluating whether TB syringes are needed in patient care areas. See the December 2004 Advisory (Vol. 1, Sup. 4) for strategies from other Pennsylvania facilities.

The Advisories are available at www.psa.state.pa.us. Click on "Advisories" in the left-hand menu.

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# Forgotten But Not Gone: Tourniquets Left on Patients

Since the implementation of PA-PSRS a year ago, Pennsylvania healthcare facilities have submitted more than 125 reports of tourniquets being left on patients' extremities.

While few of the reports submitted to PA-PSRS were considered Serious Events, this problem has the potential to cause significant circulatory, neurological, vascular, and muscular damage. Certain laboratory test results, such as complete blood counts or potassium levels, may be altered if a blood specimen is drawn from an extremity on which a tourniquet is placed for a prolonged period.[1] Inappropriate care/treatment of the patient may be the consequence.

The longer a tourniquet is left in place, the greater the chance of significant injury. In only 5% of the reports submitted to PA-PSRS was the tourniquet discovered within a half hour of application. Two-thirds were left on patients for up to two hours. The remaining third were left in place from two to 18 hours.

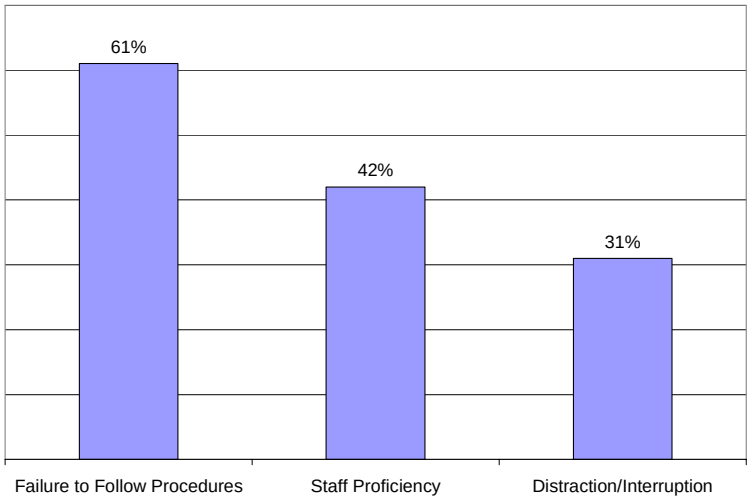


Figure 1. Factors Cited in Reports of Forgotten Tourniquets. Among those reports citing any contributing factors, the percentage of reports citing these factors is shown. The most commonly cited factors suggest a narrow focus on the individual healthcare worker, rather than a broader focus on more systematic solutions.

Many of the reports indicate that the cause of the error was related to failure to follow procedures or individual clinicians' proficiency. However, multiple reports were submitted by more than 60 hospitals, suggesting that this is a systemic problem that could benefit from system-wide solutions.

**How Does It Happen?**

In approximately half of the reports, the tourniquet was being used in conjunction with starting an IV line, while in the other half it was used for drawing a blood specimen for laboratory tests.

Of the 36 reports that identified any contributing factors, 61% cite staff failure to follow procedures, 42% cite staff proficiency, and 31% cite distractions and interruptions (see Figure 1). Other contributing factors cited in the reports included: inexperienced staff, communication problems between providers, change of service, cross-coverage situation, lack of patient compliance, and lack of patient understanding.

The majority of facilities' recommendations for improvement involved individual counseling, discussion, or education, and referral to the department perceived as causing the occurrence. At least 17% of reports indicated that no system improvement issues were identified.

Seven reports indicated an Eindhoven Causal Code, six of which involved human behavior: external, coordination, intervention, and rules based-monitoring. One report indicated a Causal Code of patient-related factor. Another report cited patient observation procedures as a root cause according to the Joint Commission Root Cause Analysis (RCA) taxonomy.

Despite this focus on the individual, environmental and task-related factors contributed to many of these occurrences. Several reports indicated that the presence of the tourniquet was hidden. For example, a tan-colored tourniquet may blend in with light skin tones, making it difficult to see. In ORs/Special Procedure areas, a surgical drape may cover an extremity in which an IV was started and a tourniquet was inadvertently left in place. In a critical care area, a tourniquet was discovered under an automatic blood pressure cuff. In a morbidly obese patient, a tourniquet may sink into fatty tissue/skin folds and may not be visible once applied. In a few cases, IVs appeared to run well even though the tourniquet had not been released, suggesting that successful infusion is not an indication that all is well.

**Harm**

While 98% of these reports were submitted as Incidents (indicating no harm), 48% of these Incidents did indicate a symptom related to prolonged tourniquet use. The predominant symptoms documented were redness and indentation at the tourniquet site.

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## Forgotten But Not Gone: Tourniquets Left on Patients (Continued)

Other symptoms documented were: pain or discomfort; extremity edema; extremity temperature change; extremity color change (pale, blue, gray, purple, dusky); numbness/tingling/burning sensation; skin tears; IV infiltrations; and delayed capillary refill.

Two reports were categorized as Serious Events. In one case, the harm was IV infiltration. In the other, the patient was transferred to a higher level of care for evaluation after a tourniquet was left on for 18 hours. Fortunately, compartment syndrome and thrombosis were ultimately ruled out.

**Interventions**

Interventions in response to the assessment involved: monitoring the extremity; notifying the physician; examination by the physician; notifying other departments viewed as causing the occurrence (ED, Lab, IV team); and notifying the patient's family.

The following types of patient care were reported: movement of the extremity, application of warm compresses or ice, and elevating the extremity. Skin integrity-related interventions involved consultation with the wound care team, application of skin cream, and application of occlusive dressing. In one case a venous Doppler study was documented as ordered. In another, the patient was transferred to a higher level of care for evaluation.

**Who Leaves/Discovers Tourniquets**

Of the 28% of the reports that indicated the category of healthcare worker who left the tourniquet in place, a variety of personnel are described including nurses, student nurses, laboratory technicians/phlebotomists, nursing assistants, anesthesiologists, IV teams, and blood teams. Only one report documented that the person who applied the tourniquet discovered it in place thereafter. Myriad personnel discovered tourniquets left in place by others.

In 19% of these reports, the tourniquet was discovered after the patient was transferred to another department for care. While more than half of these occurrences originated on medical/surgical units (30%), Emergency Departments (14%), and inpatient/ambulatory surgical services departments (14%), few departments were immune to this risk. Occurrences were also reported from numerous other units and settings. In addition, at least three patients arrived from other facilities with tourniquets in place.

Patients at the extremes of age may be particularly vulnerable to this type of error, possibly due to inability to recognize or communicate the problem to healthcare workers. Sixty percent of patients involved in these cases were 70 years of age or older, and several were less than two years old. Only 5% of the reports indicated that a patient/family member identified the presence of the tourniquet. Some reports indicated that the patient's condition may have caused the patient to be unaware of/unable to feel the tourniquet (i.e., the patient was asleep/anesthetized or had a cognitive or neurological impairment). Patients may be unable to communicate verbally the presence of a tourniquet (e.g., infants, patients with expressive aphasia or advanced dementia). If other equipment or supplies mask the tourniquet, the patient may be unaware of its presence. Some patients may think that the tourniquet is left on for a therapeutic purpose.

*One Pennsylvania facility recognized that tourniquets' color might contribute to their being left on patients. The facility changed its tourniquets from tan to royal blue, increasing the visual contrast with all skin tones.*

**Risk Reduction Strategies**

While most reports focused upon the individual healthcare worker/department perceived as causing the occurrence, at least one Pennsylvania facility recognized that color might contribute to tourniquets being left on patients. In an effort to make their tourniquets more visible, the facility changed the color of its tourniquets from tan to royal blue, increasing their visual contrast with all skin tones.

Root Cause Analysis teams within the Veterans Administration identified the following strategies in a recent review[2] of over 90 occurrences of tourniquets being left behind:

- Loosening tourniquets during any interruption in the blood draw process, when blood begins to flow into a vacuum tube or after the IV catheter is advanced, or before needle withdrawal.
- Documenting procedures only after completing them (including tourniquet removal).
- Double-checking that a tourniquet has been removed prior to leaving a patient's room and documenting the procedure completion.
- Having two healthcare workers sign the IV flow sheet to verify tourniquet removal after IV insertion.

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## Forgotten But Not Gone: Tourniquets Left on Patients (Continued)

- Controlling/reconciling the number of tourniquets used via checklists. Having a second healthcare worker verify that the number of tourniquets and IV kits used are equal/accounted for.
- When entering and leaving a unit, the phlebotomist reconciling a list of patients for venipunctures with the number of tourniquets in the venipuncture tray.
- For ambulatory patients, considering a separate location on the unit for specimen/blood draws. This may reduce distractions or interruptions.
- Standardizing blood draw/IV start schedules across departments so they do not coincide with periods of increased activity.
- Using consistent, proficient personnel to perform blood draws.
- Heightening awareness of healthcare workers to the problem and consequences of leaving a tourniquet on too long.
- Rolling up gown sleeves (rather than pushing sleeves up) to enhance tourniquet visibility. Placing the tourniquet over a sleeve may also promote visibility and enhance patient comfort by preventing pinching and tears of friable skin.
- Raising the bed height to view the patient's extremity fully.
- If blood flow does not stop quickly, checking for tourniquet placement.
- When clinically appropriate, limiting blood draws or IV starts until experienced IV team/phlebotomy staff are available.

Other strategies to consider include:

- Heightening awareness that a tourniquet may still be in place, even if an IV is running well.
- Using long tourniquets so the ends of applied tourniquets are more visible.
- Being aware of patient nonverbal cues. Patient agitation/fussiness may be a symptom of discomfort associated with prolonged tourniquet use.
- Routinely incorporating into patient assessments an evaluation for the presence of tourniquets (even in verbal, oriented patients).
- Involving the patient/family in the care by instructing/developing a brochure[3,4] concerning phlebotomy/IV starts including:
  - The concept that a tourniquet is usually left on for a few minutes.
  - To tell healthcare workers if a tourniquet remains on for a longer period.
  - That laboratory test results may be altered if a specimen is drawn from an extremity on which a tourniquet is applied for longer than 2-3 minutes.

A combination of strategies going across healthcare disciplines and departments, as well as patient involvement, may help to address the systems-related issues involved with forgotten tourniquets.

### Notes

1. ECRI. Leaving tourniquets on too long may have severe consequences. *Health Devices Alerts*. Accession Number S0072 [online]. 2005 May 6 [cited 2005 May 10].

2. Samples C. When tourniquets are left behind. *TIPS Topics in Patient Safety*. VA National Center for Patient Safety. 2005 Mar/Apr;5(2):2-3.

3. How can I decrease my discomfort when getting a blood sample drawn. MMSupport.net [online]. [cited 2005 May 10]. Available from Internet: http://web.mmsupport.net/content/view/17/25/.

4. Greenwich Hospital. Patient information sheet. Intravenous catheter [online] 2004 Aug [2005 May 17]. Available from Internet: http://www.greenhosp.org/greenwich/pe_pdf/iv_catheter.pdf.

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# PA-PSRS Data Brief

## Unintended Lacerations or Punctures During Surgery

A review of a sample of reports submitted to PA-PSRS involving unintended lacerations or punctures during surgery found that 78% of the reports described injuries to the colon (mostly during colonoscopy), the bladder (mostly during hysterectomy), or the uterus (mostly during hysteroscopy).

The accompanying table shows the relative distribution of these reports by location of injury and the procedure being performed.

| Procedure \ Site of Injury | Colon | Bladder | Uterus | Small Bowel | Ureter | Esophagus | Vagina | Bile Duct | Rectum | Other | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Colonoscopy | 23% | | | 1% | | | | | 1% | 2% | 27% |
| Hysterectomy | 1% | 14% | | | 2% | | 1% | | 1% | | 19% |
| Hysteroscopy | | | 8% | | | | | | | 1% | 9% |
| Laparoscopy | 5% | | 1% | 1% | 1% | | | | | 1% | 8% |
| Laparoscopic Tubal Ligation | 1% | | 3% | | | | 1% | | | | 5% |
| Cholecystectomy | 1% | | | 1% | | | | 2% | | 1% | 5% |
| Laparotomy | 2% | 1% | 1% | | | | | | | | 4% |
| Hernia | 2% | 2% | | | | | | | | | 4% |
| Endo/Gastroscopy | | | | | | 3% | | | | 1% | 4% |
| Myomectomy | | 1% | 1% | | | | 1% | | | | 3% |
| Cesarean Section | | 3% | | | | | | | | | 3% |
| Bladder Suspension | | 2% | | | 1% | | | | | | 3% |
| Cholecystectomy | 3% | | | | | | | | | | 3% |
| Herniorraphy | | 3% | | | | | | | | | 3% |
| Other | 1% | 1% | 1% | 1% | | | | | | | 4% |
| Total | 38% | 26% | 14% | 4% | 4% | 3% | 3% | 2% | 2% | 5% | 100% |

Notes: Includes reports: 1) submitted to PA-PSRS from June through December 2004, 2) which were coded as Event Type E.1.m, Error Related to Procedure/Treatment/Test; Surgery/Invasive Procedure Problem; Unintended Laceration or Puncture, 3) and where the procedure being performed was identified. N=111. Row and column totals are subject to rounding error.


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## PCA by Proxy—An Overdose of Care

Patient-controlled analgesia (PCA) has considerable potential to improve pain management for patients, allowing them to self-administer more frequent but smaller doses of analgesia. When used as intended, PCA actually reduces the risk of over-sedation, which is an unintended consequence of the more traditional method of nurse-administered analgesia in larger, less frequent doses. In fact, with PCA, patients often develop a synergism with the device and can quickly learn how to manage their pain while avoiding undue mental clouding.

Several safety features exist with PCA to make sure patients do not receive too much analgesia. These include a lockout interval that specifies the minimum amount of time between each dose, and a maximum allowable amount that may be administered during a set time interval.

Another "built-in" safety feature that is often overlooked is that the device is intended for *patient* use. A sedated patient will not press the button to deliver more opiate, thus avoiding toxicity. However, family members and health professionals have administered doses for the patient, by proxy, hoping to keep them comfortable. This well-intentioned effort has resulted in cases of over-sedation, respiratory depression, and even death.[1]

PA-PSRS has received a number of reports where family members activated the PCA bolus. In one such report, a patient received morphine PCA at 1 mg/hr with a 1.5 mg patient-administered bolus every eight minutes as needed. When the attending physician from the Pain Service entered the patient's room, he witnessed the patient's boyfriend pushing the PCA button for the patient. The patient was placed on a monitor, and it was noted that her oxygen saturation had dropped to 40%. Her PCA was stopped, and she was placed on 100% oxygen until her oxygen saturation improved.

PA-PSRS has also received reports of *nurse*-controlled analgesia. Nurse-controlled analgesia may be used in critical care settings if patient selection protocols have been established and assessment tools are in place to guide the level of pain and sedation.

However, another report stated that during the changing of a patient's linens, the patient experienced severe sternal pain. When the patient was asked what was wrong, he verbally expressed that he was in pain. When asked if he was using his PCA button, the patient responded "What button?" Further investigation by the organization revealed that the patient had been given pain medication throughout the night, but the nurse had been pushing the button. The patient had not received any education on pain control before the initiation of PCA therapy.

Similar cases have been reported to other patient safety reporting systems. For example, the USP-ISMP Medication Errors Reporting Program (MERP), received a report involving nurse-controlled analgesia in which a 72-year-old woman, following cancer surgery, was prescribed PCA with a 2 mg morphine loading dose and 1 mg every 10 minutes as needed (6 mg maximum per hour). Initially, the patient was restless and agitated in the post-anesthesia care unit, but she remained obtunded after surgery. Despite the patient's inability to verbalize pain, nurses pushed the PCA button and delivered frequent doses of morphine over the next 48 hours. Subsequently, the patient suffered a cardio-respiratory arrest and seizure, leading to hypoxic encephalopathy. She died several months later without ever regaining consciousness.[2]

In this case, the patient was most likely not a good candidate for PCA, and adequate assessment tools were not used to guide nurse-controlled analgesia. This patient was at risk for morphine toxicity because she was obtunded, obese, and had compromised lung capacity. Though vital signs were recorded periodically (oxygen saturation monitoring was not used), nurses did not recognize the signs of morphine toxicity and continued to administer the analgesic despite serious hypotension and very shallow respirations.[2]

Based on 15 reports of PCA error by proxy submitted to the U.S. Pharmacopeia (USP) medication error databases—12 cases were attributed to family members, two to a nurse, and one to a pharmacist.[3] Based on this information, the Joint Commission on Accreditation of Healthcare Organizations has recently issued a Sentinel Event Alert, which is being distributed to more than 8,500 accredited hospitals, critical access hospitals and home-care organizations across the country, on errors related to patient-controlled analgesia by proxy.[3]

To help reduce the risk of overdoses with PCA, consider the following steps:

- **Establishing selection criteria** for PCA and nurse-controlled analgesia. While PCA is used for a wide range of patients to

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## PCA by Proxy—An Overdose of Care (Continued)

safely manage pain (not agitation or restlessness), some patients are unsuitable candidates due to level of consciousness, psychological reasons, or limited intellectual capacity. Consider:
  - The types of patients who may be suitable for nurse-controlled analgesia.
  - Risk factors (age, weight, preexisting conditions, concomitant medications, etc.) that might necessitate increased monitoring.
  - Periodic reassessment of the appropriateness of therapy at regular intervals.[4]

- **Developing protocols and standardized order sets** to guide the selection of drugs, dosing, lockout periods, and infusion devices. Consider:
  - Avoiding use of meperidine (due to the risk of neurotoxicity), and if hydromorphone is used, ensuring proper dosing based on narcotic equivalents.
  - Prohibiting use of other analgesics while PCA is being administered.

- **Increasing patient monitoring**. Opiates, even at therapeutic doses, can suppress respiration, heart rate, and blood pressure, so the need for monitoring and observation cannot be overemphasized. This can be more important during the first 24 hours and at night since the effects of opiate analgesics on intellectual functioning are not entirely predictable, and nocturnal hypoxia can be a serious side effect. Monitoring parameters might include regular clinician assessment of vital signs, alertness, pulse oximetry or capnography, and patient self-reported pain using a consistent pain scale. If support staff takes vital signs, a timely clinician's review is important. If continuous pulse oximetry or capnography is not available for all patients, using it for those with heightened risk of toxicity and when nurse-controlled analgesia is employed may be wise.

- **Requiring two clinicians to independently double check** patient identification and PCA device dose settings prior to use (and each pump refill) to detect possible errors.

- **Educating patients and families** about the proper use of PCA before initiation. Starting this education during the preoperative testing visit may improve patient understanding and recall. Warning family members and visitors about the danger of PCA by proxy may also help to prevent this type of error.[5]

- **Educating staff about proper use of PCA**. One strategy is to encourage clinicians to critically think about the cumulative dose that the patient could receive if the maximum dose limits were given. Ensuring that staff receives adequate training on all pumps that are used to deliver analgesics is also important.

### Notes

1. ISMP. Medication Safety Alert! 10 Jul 2003; (8), 14.
2. ISMP. Medication Safety Alert! 29 May 2002; (7), 11.
3. Joint Commission on Accreditation of Health Care Organizations. Sentinel event alert: patient controlled analgesia by proxy [online]. 20 Dec 2004; (33). [Cited 2005 Feb 21.] Available from Internet: http://www.jcaho.org/about+us/news+letters/sentinel+event+alert/sea_33.htm.
4. ISMP. Nurse Advise-ERR™. Feb 2005; (3), 2.
5. ISMP. Medication Safety Alert! 24 Jul 2003; (8), 15.

## PA Facilities Receive HealthGrades Patient Safety Award

Ten Pennsylvania hospitals received the HealthGrades Distinguished Hospital Award for Patient Safety™. They are:

- Evangelical Community Hospital (Lewisburg)
- Good Samaritan Hospital (Lebanon)
- Hamot Medical Center (Erie)
- Lancaster General Hospital (Lancaster)
- Main Line Hospital Bryn Mawr Campus (Bryn Mawr)
- Mercy Hospital (Scranton)
- Northwest Medical Center UPMC (Franklin)
- St. Clair Memorial Hospital (Pittsburgh)
- UPMC St. Margaret (Pittsburgh)
- York Hospital (York)

These facilities were among 135 hospitals nationwide that were ranked by HealthGrades as being in the top 10% of hospitals nationally based on an analysis of Medicare data using 13 Patient Safety Indicators developed by the Agency for Healthcare Research and Quality (AHRQ).

For more information, visit www.healthgrades.com.

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# Skin Integrity Issues Associated with Pulse Oximetry

Pulse oximeters, devices which estimate the oxygen saturation of arterial blood, have been in wide use since the 1980's[1] because this modality is non-invasive, convenient to use, and often portable.[2] In 1986, the American Society of Anesthesiologists endorsed pulse oximeters as a standard of care whenever anesthesia was used.[1] Initially, pulse oximeters were used in the Operating Room by anesthesiologists and nurse anesthetists, or by respiratory care practitioners in critical care settings.[3]

Over the past 15 years, however, use of pulse oximetry has expanded to a variety of settings including: monitoring patients during ambulance transport; spot-checking on general medical-surgical units and in outpatient areas/centers; during sleep studies; while exercise testing; home monitoring of infants at risk for sudden infant death syndrome or patients receiving respiratory therapy treatments; and in dental offices during anesthesia.[1]

Because they are non-invasive, pulse oximeters are considered a safe medical technology.[4] While the sensor emits a small amount of heat into the skin, testing indicates that the sensors are considered safe up to a temperature of 43°C on well perfused skin for up to 8 hours.[5]

However, reports submitted to PA-PSRS indicate that patients have sustained injuries from this modality. There have been at least eight occurrences of skin integrity problems including: cuts/ lacerations, skin discoloration, blanched pressure areas/necrosis, induration, burns, and blisters.

While, to date, the injuries reported to PSRS appear to be minor, the clinical literature indicates that irreparable injury may occur during pulse oximetry in both infants and adults. Some case reports of pulse oximetry-related injuries in the literature include:

- Full thickness burn of an adult's distal phalanx that required amputation and skin grafting.[6]
- Thermal burns of an adult post-CABG patient with poor circulatory perfusion.[7]
- Third degree burn on the anterior and posterior aspects of a finger, requiring debridement and full-thickness skin grafting.[8]
- A neonate developed second degree burns of a finger and third degree of an ear where a pulse oximeter sensor had been placed.[9]
- A premature infant sustained burns to the dorsum of a foot, leading to gangrene and loss of 4 toes.[2]

**Mechanisms of Injury**

Equipment

Injuries may occur due to problems/malfunctions of the device.[10] The wiring of sensors and pulse oximeter monitors from different manufacturers may be incompatible.[1] In older equipment, this incompatibility may not be readily apparent because the sensor cable from one manufacturer may easily fit into an oximeter unit from another manufacturer. However, the incompatibility may overheat the sensor, causing burns when the sensor is applied to the skin.[2,9,11-13] Design changes in the connections of newer sensors and oximeter base units often prevent the connection of incompatible equipment.

Sensor overheating can also occur due to short circuits between wires in the sensor lead.[14] If insulation over the light-emitting diode (LED) portion of the sensor is damaged or missing, the sensor's electrical components may contact the patient's skin. An electrochemical burn at the site may result, caused by low-voltage direct-current tissue electrolysis.[15] Further, the protective cover over the LED may become damaged, allowing the sensor to overheat.[2,4,14] These problems are more likely with repeated use of a disposable one-patient sensor.[14] Skin injury has also been reported associated with pressure from a fold that may develop in the inner surface of a flexible pulse oximetry sensor.[16]

Patient Condition

The condition of the patient may contribute to the risk of pulse oximetry injury. Decreased blood flow to the area where the sensor is applied (usually a distal extremity) increases the risk of burn injury. The heat generated by the LED may not be dissipated from the site because of inadequate blood flow. Therefore, temperature increases in the area, and the area is in contact with the heat over a length of time. Shock, hypothermia, and ischemia of the extremity used for monitoring could all result in this type of injury.[5]

The thinness of the patient's skin increases the risk of more severe injury.[5] Toes and fingers, where sensors are usually placed, may have thinner skin than other areas of the body.[5] Infants (particularly premature infants) and the advanced elderly have delicate, more friable/fragile skin and may also have poor peripheral perfusion. Compression of the skin by the sensor may further decrease blood flow, reducing the body's ability to dissipate sensor-

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## Skin Integrity Issues Associated with Pulse Oximetry (Continued)

generated heat.[2] Among oximetry-related skin injury reports submitted to PA-PSRS, 50% were aged 3 months or younger, 25% were aged 13 to 24 months, and the remaining 25% were over age 80.

Persons at higher risk for severe skin injuries are those unable to communicate or perceive noxious stimuli such as skin heating: persons with insensate limbs, communication impairments, altered mental status; infants; unconscious/obtunded patients; and those under general anesthesia or local anesthesia to the area where the sensor is applied.[6]

Technique

Decreased blood flow can occur by mechanical means, such as the pressure exerted by wrapping or taping the sensor around the finger/toe.[12] This may result in a tourniquet-like effect.[5] The duration of skin contact with the sensor increases the risk of skin discoloration and burn injury.[5] For example, in a case reported in the literature, ultraviolet tanning of an infant's foot occurred after a sensor was on the same site for five days.[17]

Diagnostic/Treatment Modalities

Severe burns associated with pulse oximetry have occurred in patients undergoing Magnetic Resonance Imaging (MRI).[1,6] Most healthcare workers are aware of such contraindications to MRI as metallic aneurysm clips, cardiac pacemakers, and intraocular metal fragments. However, the potential for thermal or electrical burns associated with electrical monitoring devices may be less well known.[6]

During MRI, electrical currents are induced in all conductive materials exposed to the radio-frequency and gradient magnetic fields used during imaging.[18] The current generated in such conductive materials can produce enough heat to cause a burn.[1,8] The potential for burns is greater if monitor cables are looped or if cables are in direct contact/ taped to the skin.[8,18]

A review of the Food and Drug Administration's Manufacturer and User Facility Device Experience (MAUDE) database reveals a recent report pertaining to the use of a dye for a clinical purpose. A patient admitted to undergo parathyroidectomy for adenoma received 65 ml of IV methylene blue. A pulse oximeter sensor was attached to the fingertip. Surgery lasted 1.5 hours, followed by 2 hours' recovery. On the eighth post-operative day in the physician's office, the surgeon noted a healing circular brown blister on the patient's finger where the pulse

### Limitations of Pulse Oximetry

A 1994 study of what nurses and doctors in medical surgical units understood about pulse oximetry found that 97% did not know how pulse oximetry worked or what factors affected the readings.[1] Today, pulse oximetry use has expanded and is no longer used in only ORs and ICUs. The following limitations of pulse oximetry may be overlooked in common situations.

Patient Factors

The accuracy of pulse oximetry measurements requires normal hemoglobin. Abnormal hemoglobins, such as methemoglobin or carboxyhemoglobin, may cause great inaccuracies in pulse oximetry measurements of oxygen saturation.[2,3] For example, carbon monoxide has a stronger affinity for hemoglobin than oxygen, and pulse oximetry cannot differentiate between oxygen and carbon monoxide combined with hemoglobin. Therefore, patients with carbon monoxide poisoning, smoke inhalation, or cigarette smoking may have inaccurately increased $SaO_2$ readings that reflect the sum of oxyhemoglobin and carboxyhemoglobin saturations.[3] Such patients may be suffering from hypoxemia (lack of oxygen in the blood) without producing abnormal readings on pulse oximetry.[2]

Pulse oximetry does not measure the actual content of oxygen in the blood. Pulse oximetry estimates the percent of oxygenated hemoglobin present in the total of reduced and oxygenated hemoglobin. Therefore, a patient with anemia or polycythemia will have less oxygen content than a person with normal hemoglobin levels, even though their pulse oximetry measurements of oxygen saturation may be comparable.[2] Severe forms of anemia (hemoglobin less then 5mg/dL) prevent accurate pulse oximetry measurement.[2-4]

Although pulse oximetry may reflect oxygenation of the blood, it does not evaluate the patient's ability to ventilate. Partial pressure of carbon dioxide ($pCO_2$) is an appropriate measurement of ventilation.[2] Pulse oximeters also do not measure pH, which assesses acid-base status.[3]

Pulse oximetry does not evaluate whether oxygen present in the blood is available for use at the tissue or cellular level. Conditions such as acidemia, hyperthermia, or hypercapnea (increased $pCO_2$) decrease oxygen affinity, making oxygen more available to the cells. In contrast, in situations of increased oxygen affinity, such as alkalosis, hypothermia, or hypocapnea (decreased $pCO_2$) oxyhemoglobin is less able to release the oxygen molecules at the tissue level.[2]

Pulse oximeter oxygen saturation measurements are based on pulsating arterial blood. If the arterial pulse is not stronger than the surrounding venous blood/tissue, the oximeter cannot accurately reflect arterial oxygenation. Causes of low perfusion include hypothermia, hypotension, vasoconstrictive drug therapy, low cardiac output, and peripheral vascular disease.[2-4]

*(Continued on next page)*

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## Skin Integrity Issues Associated with Pulse Oximetry (Continued)

oximeter sensor had been applied. The biomedical department did extensive testing on the equipment but could not find a source for this problem.[19]

Methylene blue can profoundly affect $SpO_2$ because of its ability to absorb light emitted from the pulse oximeter sensor LED.[20] Combined with poor perfusion, this might contribute to heat build-up at the sensor site, increasing the risk for burn.

Photodynamic therapy can also increase the risk of pulse oximeter-related injury. This therapy is used to treat cancers by combining the effects of a photosensitizing drug activated by visible light.[10,21] The photosensitized drug is retained in greater concentrations in malignant tissue than in normal tissue.[21] This modality is increasingly becoming an adjunctive cancer treatment because it is minimally invasive, with low morbidity, and high efficacy.[21] Cancers treated by this method include those of the bladder, lung, gynecologic system, abdomen, brain, head, neck, gastrointestinal system, and skin.[10,21]

However, the photosensitized drug remains in the skin for 6 to 8 weeks.[10,21] As a result, the patient must be protected from bright light.[21] A photosensitizing drug such as Photofrin may be activated by the red light emitted by the pulse oximeter sensor.[21] One case in the clinical literature indicated that a second degree burn of the index finger and subsequent loss of the finger nail occurred. A pulse oximeter was in use during photodynamic therapy, and the sensor was on the finger for three hours.[10]

### Prevention/Risk Reduction

Several interventions can help to reduce the potential for pulse oximeter-associated injury.

Equipment

- Standardizing the makes and models available throughout the organization.
- If a facility uses oximeters and sensors from more than one company, checking the equipment to determine whether incompatibilities can occur—both mechanical and/or functional.[9]
- Not connecting pulse oximetry sensors and machines from different manufacturers—even when their electrical connectors are mechanically compatible—unless manufacturers' manuals/packaging instructions indicate that this is safe.[9]

### Limitations of Pulse Oximetry (Continued)

*(Continued from previous page)*

External Factors

External factors that can affect the accuracy of pulse oximetry include:

- Lighting (e.g., surgical lights, bilirubin lights, infrared radiant warmers).[3] Patient movement/motion artifacts.
- Non-pulsatile substances that absorb light: (e.g., nail polish, false nails, dried blood, heavy skin pigmentation/tattoos).
- Intravascular compounds that absorb light at the same wavelengths as hemoglobin (e.g., dyes like methylene blue, indocyanine green, or indigo carmine).[2-4]

Electrosurgical units (ESUs) can interfere with pulse oximetry by generating high-frequency currents which can radiate to the oximeter sensor. Some models freeze the $SpO_2$ display during ESU activation, which may lead clinicians to mistakenly rely on an inaccurate measurement of oxygen saturation. There have also been reports of the magnetic field of Magnetic Resonance Imaging systems affecting pulse oximeter circuitry and performance. Pulse oximetry is ineffective/inaccurate if intravenous infusions, blood pressure cuffs, or tourniquets are used on the same extremity.[3]

The most common reasons for inaccurate pulse oximetry readings are: movement, loss of pulse signal, and disconnection between the sensor and the patient.[4] Other issues affecting the accuracy of pulse oximetry measurements include: failing to use a sensor that is appropriate to the age of the patient; placing a transmittance sensor on a flat body surface, or a reflectance sensor on a digit; or securing the sensor too loosely or too tightly on the body.[5]

Pulse oximetry is a useful tool to monitor a patient's condition, but pulse oximetry measurements don't substitute for a full, direct, and comprehensive patient assessment. Education concerning indications, proper use, and limits of this technology can help to ensure accurate interpretation of pulse oximetry readings and prevent life-threatening or even fatal mistakes.

#### Notes

1. Stoneham MD, Saville GM, Wilson IH. Knowledge about pulse oximetry among medical and nursing staff. *Lancet* 1994 Nov 12;344(8933):1339-42.

2. ECRI. Pulse oximetry – more than meets the eye. *HRC Risk Analysis* 1997 Jul;4(Critical Care 6):1-6.

3. ECRI. Oximeters, pulse. *Healthcare Product Comparison System* 2004 Mar:1-64.

4. Sobel DB. Burning of a neonate due to a pulse oximeter: arterial saturation monitoring. *Pediatrics* 1992 Jan;89(1):154-5.

5. WelchAllyn. Spot vital signs.420 series. operator's manual. Appendix A-$Sp0_2$ sensors [online] 2000 [cited 2005 Jun 2]. Available from Internet: http://www.qmc.nhs.uk/Divisions/Diagnostics/MESU/Documents/Welch%20Allyn%20Spot%20420%20Monitor.pdf.

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## Skin Integrity Issues Associated with Pulse Oximetry (Continued)

- Ensuring that warning labels about incompatibilities are on sensor cables and pulse oximetry units.[22]
- Inspecting sensors and wires for cracks/breaks in insulation, and exposed electrical connections/wires, before application and each time the site is changed.[5,12,14]
- Reusing disposable one-patient-use pulse oximeter sensors only in accordance with manufacturers' recommendations.[14,15]
- Investigating any instance of freezing of the pulse oximetry monitor display, which can indicate short circuits in the sensor cable wiring.[14]
- Not allowing damaged sensors with exposed electrical connections to come in contact with the patient.[15]
- Removing from service and clearly labeling damaged sensor/cable/oximeters and sending them to biomedical engineering staff for evaluation.[15]
- Assessing the patient population served by the healthcare facility and using pulse oximetry equipment that effectively addresses those patients' needs.
- If appropriate, considering newer pulse oximetry technologies that might reduce the risk of skin integrity problems. For example, some newer models include flat reflectance sensors that can be used on more central body locations when poor peripheral perfusion is an issue.[1]
- Securing equipment so that it will not fall on patients.

Patient Condition

- Changing the sensor site more frequently (such as hourly), especially in conditions of decreased skin perfusion[14] or for unconscious patients,[23] critically ill premature infants,[2] and ICU patients.

Technique

- Frequently changing the sensor site to avoid prolonged skin contact,[12,14] at least every 2-4 hours.[7,14,17]
- Not wrapping flexible sensors tightly around the end of the finger/toe; avoiding wrapping sensors with elastic adhesive tape.[17]
- Assessing sensor sites frequently—at least whenever the site is changed.[10,14,17]

MRI

- Using only specially trained personnel to institute precautions and monitor pulse oximeter apparatus during MRI.[6,8]
- Ensuring that oximeter leads contact the patient at only one point,[6,8] as far away as possible from the imaging site.[18,23]
- Positioning cables from monitoring devices coming into contact with the patient so that no conductive loops are formed.[8,18,23]
- Keeping dry any skin surfaces coming in contact with leads.[6]
- Immediate removal of monitoring equipment that malfunctions during MRI.[6,8]
- Removing unused, clinically unnecessary sensors, cables, and surface coils from the MRI system/bore of the magnet/area.[18,23]
- Instructing patients to call out if they experience heat/discomfort.[23]
- Installing intercoms to check on patients frequently during procedures.[23]
- Frequently inspecting oximetry sites of insensate/unconscious patients.[23]
- Placing insulation (e.g., a blanket) between wires or cables and the patient's skin.[18,23]
- When possible, selecting monitoring equipment with electrically non-conducting paths or high-resistance paths, if clinically appropriate.[6,23] Some pulse oximeters use non-conductive fiberoptic cables that will not cause radio-frequency burns.[1]
- Considering MRI-compatible alternatives to pulse oximeters to evaluate respiratory function (such as end-tidal $CO_2$ or capnometers), which may use non-conductive tubing.[8,23]
- Using all devices according to the manufacturer's instructions.[23]

Photosensitized Drugs/IV Dyes

- Including a question in the history and physical that explicitly addresses these interventions in patients who may receive pulse oximetry.
- If pulse oximetry is clinically required, moving the sensor frequently to prevent prolonged contact with one area of the skin.

Education

- Educating staff to ensure that they understand the following: purpose, limitations (See Sidebar), proper use/protocols, maintenance/inspection, dangers/risk reduction strategies.[3]
- Developing criteria concerning what categories of healthcare providers can use pulse oximetry.[3]
- Having available written materials, including

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## Skin Integrity Issues Associated with Pulse Oximetry (Continued)

manufacturer's operating manuals, for healthcare worker reference.[3]

- Instructing staff to follow manufacturer directions/protocols concerning site assessment, changing sensor locations, and equipment inspection.[15]
- Heightening awareness about pulse oximetry and skin integrity problems.[15]
- Developing pre- and post-training tests, and using competency skills checklists to confirm knowledge and affirm safe practice pertaining to use, reading, and interpretation of pulse oximeters.[3]
- Ensuring that new employees and independent contractors receive orientation to the proper use of pulse oximetry.[3]
- Reinforcing to clinicians that oxygen saturation as determined by pulse oximetry is not necessarily equal to arterial blood oxygen saturation.[3] (See Sidebar)
- Emphasizing that pulse oximetry is not a substitute for direct assessment of the patient.[3]
- Warning staff not to use a damaged sensor or cable.[15]

General

- Developing and implementing clinical protocols concerning the use of pulse oximetry equipment.[15]
- Investigating problems related to the use/misuse of pulse oximetry and taking appropriate action.[3]
- Tracking/analysis of such problems to identify opportunities for improvement.[3]
- Reporting such occurrences to the Patient Safety Officer and/or others who may determine whether further reporting is indicated[15] (e.g., Administration, PA-PSRS, FDA).
- Remaining current concerning regulatory standards for the use of pulse oximetry.[3]

### Notes


1. ECRI. Oximeters, pulse. *Healthcare Product Comparison System* 2004 Mar:1-64.

2. Lin C-W, Wang H-Z, Hsieh K-S. Pulse oximeter-associated toe injuries in a premature neonate: a case report. *Chin Med J (Taipei)* 1999;62:914-6.

3. ECRI. Pulse oximetry – more than meets the eye. *HRC Risk Analysis* 1997 Jul;4(Critical Care 6):1-6.

4. Sobel DB. Burning of a neonate due to a pulse oximeter: arterial saturation monitoring. *Pediatrics* 1992 Jan;89(1):154-5.

5. Greenhalgh DG, Lawless MB, Ches BB, et al. Temperature threshold for burn injury: an oximeter safety study. *J Burn Care Rehabil* 2004 Sep-Oct;25(5):411-5.

6. Brown TR, Goldstein B, Little J. Severe burns resulting from magnetic resonance imaging with cardiopulmonary monitoring. *Am J Phys Med Rehabil* 1993;72:166-167.

7. Bannister J, Scott DHT. Thermal injury associated with pulse oximetry. *Anesthesia* 1988 May;43(5):424-5.

8. Shellock FG, Slimp GL. Severe burns of the finger caused by using a pulse oximeter during MR Imaging. *AJR* 1989 Nov;153 (5):1105.

9. Murphy KG, Secunda JA, Rockoff MA. Severe burns from a pulse oximeter. *Anesthesiology* 1990 Aug;73(2):350-2.

10. Radu A, Zellweger M, Grosjean P, et al. Pulse oximeter as a cause of skin burn during photodynamic therapy. *Endoscopy* 1999;31(9):831-3.

11. Baker GL, Mani M. Infant monitoring resulting in burns – tissue damage: literature review and case report. *J Burn Care Rehabil* 1993 Jan-Feb;14(1):113-9.

12. Pandey CK, Rani AR, Srivastava K, et al. Thermal injury with pulse oximeter probe in hypothermic patient. Pulse oximeter probe burn in hypothermia. *Canadian Journal of Anesthesia* 1999 Sep;46(9):908-9.

13. Kohjiro M, Koga L, Komori M, et al. A case report of a burn produced by the probe of a pulse oximeter. *Masui* 1992 Dec;41 (12):1991-3.

14. Mills GH, Ralph SJ. Burns due to pulse oximetry. *Anaesthesia* 1992 Mar;47(32):276-7.

15. ECRI. Exposed connections in pulse oximeter sensors can cause electrochemical burns [hazard report]. *Health Devices* 2001 Dec;30(12):456-7.

16. Bethune DW, Baliga N. Skin injury with a pulse oximeter. *Br J Anaesth* 1992 Dec;69(6):665.

17. Miyasaka K, Ohata J. Burn, erosion, and "sun" tan with the use of pulse oximetry in infants. *Anesthesiology* 1987 Dec;67 (6):1008-9.

18. Bashein G, Syrovy G. Burns associated with pulse oximetry during magnetic resonance imaging. *Anesthesiology* 1991 Aug;75(2):382-3.

19. Manufacturer and User Facility Device Experience (MAUDE) [database online]. Rockville (MD): Food and Drug Administration (FDA); Accession number 529658. Report date 2004 Apr 1. [cited 2004 Oct 21]. Available from ECRI, Plymouth Meeting, PA.

20. Kessler RM, Eide T, Humayun B, et al. Spurious pulse oximeter desaturation with methylene blue injection. *Anesthesiology* 1986 Oct;65(4):435-6.

21. Farber NE, McNeely J, Rosner D. Skin burn associated with pulse oximetry during perioperative photodynamic therapy. *Anesthesiology* 1996 Apr;84(4):983-5.

22. Willingham MD. A warning in the use of pulse oximeters: I. *Anesthesiology* 1990 Aug;73(2):358.

23. ECRI. Thermal injuries and patient monitoring during MRI studies. *Health Devices* 1991 Sep;20(9):262-3.


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## Complexity of Insulin Therapy

A 1998 Institute for Safe Medication Practices (ISMP) study found that 11% of serious medication errors involve insulin misadministration.[1] With the rising prevalence of diabetes in recent years has come a corresponding increase in the use of insulin. Though it is often the most effective treatment for this chronic disease, data derived from scientific research and adverse event reporting systems such as PA-PSRS show that errors related to insulin are frequent and often cause significant patient harm. In fact, nearly 16% of all medication errors classified as Serious Events in PA-PSRS involved the use of insulin.

*Nearly 16% of medication errors classified as Serious Events in PA-PSRS involved insulin.*

Insulin therapy has always required thoughtful management; however, over the last decade, the release of new insulin formulations, insulin delivery devices, and blood glucose monitors has made this process increasingly complex.[2] There are now close to a dozen different types of insulins manufactured by several companies, many with names or packages that look or sound alike.[3]

It should not be surprising that 12.8% of the medication error reports involving insulin have been classified as "wrong drug" errors. For instance, organizations have reported errors related to confusion between **LENTE** (insulin zinc suspension) and **LANTUS** (insulin, glargine) and **HUMULIN** (insulin, human) and **HUMALOG**. Figure 1 lists insulin product names that Pennsylvania facilities have reported as being confused with one another.

Figure 1. Examples of Insulin Products Reported to PA-PSRS as "Wrong Drug" Errors.

Humalog – Humulin R
Humulin N – Humulin R
Humulin R – Humulin 70/30
Humulin 70/30 – Humalog 75/25
Humalog 75/25 – Humalog
Lente Insulin – Lantus
Novolog – Novolog Mix 70/30
Novolog Mix 70/30 – Humulin 70/30
Novolin 70/30 – Novolog Mix 70/30

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

*The physician ordered Humalog 72 units sq every A.M. and 48 units sq every P.M. After giving the A.M. dose, the nurse realized the type of insulin ordered was not the same as the patient's home insulin type of Humulin 70/30. The physician was contacted, an IV of D5W was started, and accuchecks were monitored. The patient did not require any further treatment.*

*Patient ordered Novolog 70/30 insulin. Nurse pulled Novolin 70/30 instead. No Novolog was available in floor stock.*

Insulin mix-ups also occur among premixed products containing both rapid and intermediate acting insulin. These "mix" products are available in varying combination strengths (e.g., **HUMULIN 50/50** or **70/30**, **HUMALOG MIX 75/25, NOVOLOG MIX 70/30, NOVOLIN 70/30**). As a result, several errors have been reported in which clinicians forgot to include the strength or transcribed the order incorrectly.

Another cause of many insulin-related errors is the use of error-prone abbreviations when communicating prescription information. As mentioned in a previous *Advisory*, the abbreviation "U" to indicate "units" contributes to many errors when it is misread as a zero (0) or the number four (4).[4] Examples of medication error reports submitted to PA-PSRS in which the use of "U" for unit, many of which contributed to a 10-fold or greater overdose, include:

*The pharmacist misread the order and added 80 units of regular insulin in the TPN* [total parenteral nutrition] *solution when the order was for 8 units of regular insulin.*

*Order for Humulin R insulin 70 units twice daily. Patient stated that this was more than she usually took at home. Order was clarified with physician to be 7 units.*

*100 units of regular insulin were given IM* [intramuscular injection]. *MD ordered 10 units of regular insulin.*

*Patient received 44 units of insulin instead of 4 units of insulin. The MAR* [medication administration record] *was misread by the nurse administering the medication.*

*Physician wrote an order for insulin 5 units. The handwriting could be interpreted as 54 units. The nurse caught and corrected the error prior to administration.*

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## Complexity of Insulin Therapy (Continued)

It is not uncommon for patients to receive widely varying insulin doses or to receive more than one type of insulin concurrently. Confusion among several different insulin products and failure to discontinue previous insulin when switching to a new product may go unnoticed until patient harm occurs. ISMP has received several reports through the USP/ISMP Medication Error Reporting Program (MERP) where patients were hospitalized after taking both Humalog and regular insulin, or Lantus along with twice daily NPH insulin.[2]

### Potential Solutions

The examples above, and many others that have been reported to PA-PSRS, leave no doubt that insulin is a "high alert" drug that is prescribed, dispensed, and administered via error-prone processes and to patients who often are at risk for an adverse outcome if an error occurs. With such complexity, it is not surprising that errors with insulin are frequent and characteristically harmful to patients. As such, this high alert medication warrants special handling.

The following strategies may help to reduce the incidence of insulin-related errors:

- **Obtaining an accurate history** of insulin therapy from patients upon admission and following up with questions to detect possible confusion between the many look- and sound-alike insulin products. Whenever possible, encourage patients or families to bring in the insulin for validation.
- **Communicating prescriptions clearly** using the entire product name and writing out the word "units." (Overdoses have occurred when the abbreviation "U" has been misinterpreted as a "0" [zero] or a "4.")
- **Discouraging the use of verbal orders**. If they are used, reading back the spelling of the product name to avoid confusion with sound-alike insulin products. Considering the patient's usual times for meals and specifying a clear relationship between insulin administration and the meals.
- **Storing insulin safely**. In the refrigerator, segregating vials (e.g., with storage bins) that may have look-alike names or packaging, or using other means (e.g., stickers, labels, enhancement with pen or marker) to call attention to important information that could be missed.
- **Building alerts into pharmacy and prescriber order entry systems to warn about the potential for error.** For example, using bold print or upper case lettering in order entry screens to clearly differentiate drug names that are similar and dangerous if confused (e.g., HumALOG vs. HumULIN, NovoLOG vs NovoLIN). In addition, emphasizing the word "Mix" along with the name of the insulin product mixture (e.g., Novolog **Mix** 70/30).
- **Performing an independent double check** of all doses before dispensing and administering insulin. Building the double check into daily work processes so it can be accomplished without disruption. In pharmacies, the original order could be compared with both the product to be dispensed and the computer-generated label before reaching the patient.
- **Providing staff with ongoing education** about insulin products, delivery devices, and monitoring devices. Consider providing staff with a chart that lists all insulin products used in your organization. Include: generic and brand names; onset, peak, and duration of action; time of administration in relationship to meals; and special precautions (e.g., measuring the proper dose, mixing instructions, more frequent patient glucose monitoring). Posting the charts in areas where insulin is prescribed, stored, and administered.

Don't assume that there are no problems with insulin therapy in your organization. Periodic auditing of orders for episodes of misuse of the abbreviation "u" in prescriptions, the frequency of verbal insulin orders, and other poor prescribing habits, could help identify errors "waiting to happen." Even if these problems are not obvious in your facility today, every facility can proactively anticipate and address problems with insulin use by discussing insulin errors that have happened in other facilities and incorporating the risk reduction strategies presented above.

### Notes

1. Cohen MR, et al. Survey of hospital systems and common serious medication errors. *J Healthc Risk Manag.* 1998;18(1):16-27.

2. ISMP. Medication Safety Alert! Acute Care Edition. 17 Apr 2002;(7)8.

3. ISMP. Medication Safety Alert! Community/Ambulatory Care Edition. Jan 2004;(3)1.

4. Pennsylvania Patient Safety Reporting System. Abbreviations: A shortcut to medication errors. *PA-PSRS Patient Safety Advisory*. Mar 2005;2(1):19-20.

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PATIENT SAFETY AUTHORITY

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.

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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.

ISMP

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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