PA PSRS
Pennsylvania Patient Safety Reporting System

Patient Safety Advisory

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Remain Steadfast in Patient Safety Efforts

This issue of the *Patient Safety Advisory* marks three full years of publication. Since releasing the first quarterly issue in March 2004, the Authority has published 12 quarterly and 4 Supplementary *Advisories*, containing more than 100 individual articles based on actual adverse events and near-misses reported through the PA-PSRS system.

The *Advisory* has grown in quality with each successive issue, and Dr. John Clarke, PA-PSRS clinical director and *Advisory* editor, can be justifiably proud of the final product and the research conducted by the team of PA-PSRS clinical analysts.

But the measure of the *Advisory*'s success is in whether, and how much, it generates discussion, promotes change and improves patient outcomes in Pennsylvania's healthcare facilities. That's been our ongoing mantra over the past three years: translating the clinical guidance included in each *Advisory* article into actionable programs to improve patient care.

Since PA-PSRS was implemented, I've observed that many, if not most, submitted reports involve uncomplicated situations. These reports are not the result of sophisticated, complex or high-tech activities but simple systems failures such as problems associated with hygiene, communication, hand-offs, patient identity or procedure verification. Many events involve a problem that has long been identified and whose solutions are well known. Many relate to National Patient Safety Goals or are

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Bone Cement Implantation Syndrome

PA-PSRS has received reports of six intraoperative cardiac arrests in patients—five resulting in death—associated with hip arthroplasties using bone cement to implant prostheses. While hip surgery is a common procedure among the elderly and generally considered safe and effective, mortality most often occurs postoperatively, usually from cardiopulmonary causes such as myocardial infarction or pulmonary emboli.[1]

Intraoperative deaths during hip arthroplasty occur less frequently but are almost exclusively associated with cementing of the femoral prosthesis.[1,2] Although cardiac arrest and death are the most catastrophic symptoms associated with cemented arthroplasty, bone cement implantation syndrome (BCIS) is a well-recognized complex of sudden physiologic changes that occur within minutes of the use of methyl methacrylate cement to secure a prosthetic component into the femur.[1-4] The cardiopulmonary complications of BCIS can be reduced through modern cementing techniques, appropriate anesthesia interventions, and adequate patient preparation, as well as avoiding the use of cement altogether.

This article presents the traditional and current opinions about the theories and causes of BCIS. In addition, this article includes information from the clinical literature on risk factors, risk reduction strategies and treatment.

BCIS: Past and Present

Intraoperative cardiorespiratory changes during total hip arthroplasties have been reported since cemented components were introduced in 1961.[5,6] Theories about the cause of BCIS include the following:

Direct effect of exothermic reaction of cement temperature[7-9]

Air or gas embolism caused by polymerization of methyl methacrylate monomer[7,8,10]

Hypersensitivity/anaphylactic reaction to the acrylic monomer[7,9]

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Remain Steadfast in Patient Safety Efforts (Continued)

included on the list of the National Quality Forum's "never events." Unfortunately, systems are not yet in place throughout the industry to prevent repeated occurrences of even these commonly recognized problems.

Take, for example, reports of wrong medication, wrong dose, or administration to the wrong patient. A recent report from the Institute of Medicine, *Preventing Medication Errors*, estimated that a startling 1.5 million Americans are injured annually by medication errors.[1] Not surprisingly, one of the report's most basic recommendations was the computerization of prescription order systems.

This is not a new concept, yet it is commonly acknowledged that healthcare providers have been slow to adopt electronic medication systems. Even so, I was taken aback by a story in my small-town newspaper that demonstrated just how slow the health industry has been.

In a news article about the annual Shippensburg Community Fair, an old-fashioned eight-day event in rural Cumberland County, the reporter described the baked goods competition, where judges consider a multitude of factors (i.e., flavor, lightness, consistency, texture, crumb and general appearance) for a variety of cakes, cookies and pies submitted by people assigned to several categories (i.e., by age and gender).[2] The judges have to take these many variables into account in selecting a winner. However, this year, the husband of the baked goods committee chairwoman developed a bar-coded computer system to track submissions, record the scores, and tabulate the results.

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Remain Steadfast in Patient Safety Efforts (Continued)

While healthcare is obviously a more complex endeavor than a pie contest, we should all ask ourselves if a computer system can be developed and implemented for a pie contest, why wouldn't we invest in one for something as critical as our healthcare system?

I am not singling out computerized prescription order entry systems as much as I am encouraging the healthcare industry to hasten the implementation of proven protocols and interventions, whether electronic or otherwise, that are known to mitigate patient harm and improve patient outcomes, the kinds of clinical guidance contained in the *Patient Safety Advisory*.

After three years of publishing the *Advisory*, we continue to ask how you are utilizing PA-PSRS resources, whether *Advisory* articles or embedded analytical tools, to improve patient care in your organization. And we continue to invite you to submit accounts of your experiences. That is, after all, the point of PA-PSRS. As we have often said, we want to share the lessons you have learned and best practices you have adopted so other providers and managers can benefit from your patient safety success stories.

In closing, let me note that this is my final column for this publication. In mid-November, I submitted my resignation to the Board, effective at the end of the year. Looking back over the past four years, I value the opportunity to have worked with you, in many cases personally. This agency's success and the national recognition we have earned is due in large measure to the commitment of Pennsylvania's healthcare community to improving patient safety and engaging in a common vision of quality improvement. I will follow your progress with keen interest.

Notes

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Alan B.K. Rabinowitz
Administrator
Patient Safety Authority

Rabinowitz Resigns; Board Names Interim Administrator

Alan B.K. Rabinowitz has submitted his resignation as administrator of the Patient Safety Authority, effective December 29, 2006.

Rabinowitz was named the Authority's first administrator in November 2002. Under his tenure, the Authority developed and implemented the Pennsylvania Patient Safety Reporting System (PA-PSRS), a mandatory, statewide data collection and analysis system, and initiated publication of the *Patient Safety Advisory*, a clinical journal related to quality care and patient safety that is distributed around the country. Over the past four years, the Authority has garnered national recognition and recently won a prestigious 2006 John Eisenberg Award for advancing patient safety and quality, given jointly by the National Quality Forum and the Joint Commission on Accreditation of Healthcare Organizations.

Prior to being appointed administrator, Rabinowitz spent more than seven years as chief of staff in the Pennsylvania Department of Health. He previously worked in the private sector, and from 1979 to 1987, was on the personal staff of former Gov. Dick Thornburgh. In resigning from the Authority, Rabinowitz will retire from Commonwealth service.

The Authority's Board of Directors is conducting a search to find a successor. They have named Michael Doering, current PA-PSRS project manager at the Authority, as interim administrator.

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Bone Cement Implantation Syndrome (Continued)

Reflex bradycardia[7]

Increase in intramedullary pressure resulting from the introduction of hot acrylic cement (This increase could force marrow and fat into the circulation, producing pulmonary emboli.)[7-9]

Fat and debris from the femoral shaft embolize from the femoral canal during cement and implant insertion[3]

Toxic effects of the monomer (These effects may enhance the depressant cardiovascular effect of volatile halogenated anesthetic agents.)[7]

Toxic cardiovascular effects of methyl methacrylate monomer or additives (These substances may produce hypotension when absorbed into the circulatory system.)[6-9]

Increased amount of monomer absorbed by the large and well vascularized femoral shaft[7,9]

Small amounts of toxic, unreacted methyl methacrylate monomer absorbed rapidly into the circulation[9,11]

Embolic showers that occur during cement pressurization (Experimental studies using transesophageal echocardiography [TEE] indicate that these showers are directly correlated with changes in pulmonary parameters.)[3]

At one time, methyl methacrylate toxicity was considered the major cause of hemodynamic instability during arthroplasty surgery.[5,11] However, this hypothesis has not been confirmed by animal studies. More than 30 times the level of methyl methacrylate ordinarily used in human arthroplasty must be used to produce significant changes in cardiopulmonary parameters.[5,11,12] While absorbed monomer temporarily lowers blood pressure after insertion of bone cement, there is little evidence indicating that monomer causes severe systemic reactions.[13] No correlation has been found between blood pressure changes and monomer concentration.[5] Moreover, using a dog model, Orsini et al.[5,11] determined that similar cardiopulmonary changes occur when using either bone cement or inert bone wax, producing high intramedullary pressures that force bone marrow into the circulation at the time of cement and prosthesis insertion.[5,11] Methyl methacrylate monomer is no longer considered the cause of cardiopulmonary dysfunction during procedures using cemented components.[5]

BCIS is now considered to be caused by the hemodynamic effects of medullary fat embolism, rather than the toxic effects of the cement itself.[2,14] Cementing prior to prosthesis insertion causes sealing and pressurization of the femoral canal when the prosthesis is inserted. This leads to high intramedullary pressure, forcing medullary fat into the vasculature. This embolic load produces acute pulmonary hypertension that can lead to right ventricular dysfunction, ischemia, hypotension, and even sudden death.[1,11,14-16] The severity of these symptoms does not correlate with the amount of methyl methacrylate used.[16] Moreover, this syndrome occurs in the absence of methyl methacrylate use.[16] Non-cemented arthroplasty produces lower intramedullary pressures, fewer emboli, and much less hemodynamic disturbance.[2] TEE has shown that embolization of fat and marrow contents occurs with the insertion of both cemented and uncemented implants.[1,12] However, the emboli associated with cement are of greater number, size, and duration.[1]

Trends in Prosthesis Fixation

While fixation of femoral prostheses with cement remains popular, cementless stem fixation has become more durable and clinically effective over the past two decades.[17] A review of 10,299 primary total hip arthroplasties in the North American Hip and Knee Registry revealed that cement use for stem fixation declined from 66.2% of the procedures in 1995 to 38.6% in 2001 ($p < 0.001$). Patients with good bone quality are considered good candidates for uncemented implants, particularly those with thick cortices and small medullary canals.[18]

Symptoms

An elderly female presented via ambulance following a fall at home. She was diagnosed as having a fracture of the left femoral neck. The patient was medically cleared for

Visit the Patient Safety Authority Web site (http://www.psa.state.pa.us) to view or download "Risk Factors and Reduction Strategies for Bone Cement Implantation Syndrome (BCIS)," a pocket guide based on this article.

Click on "Advisories and Related Resources" in the left-hand column of the Authority's home page. Then, click on "Resources Associated with Patient Safety Articles."

Physicians may receive continuing medical education (CME) credits related to this article through a partnership with the Pennsylvania Medical Society. See page 35 for details.

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Bone Cement Implantation Syndrome (Continued)

surgery based upon physical examination, normal lab work, and a normal electrocardiogram. An urgent left hemiarthroplasty was performed under spinal anesthesia. Intraoperatively, after cementing of the prosthesis, the patient developed hypotension, bradycardia, and cardiac arrest. The surgical field was covered, and the patient was placed in supine position for cardiopulmonary resuscitation. The patient did not respond to resuscitative measures, and she expired.

The preceding account from a report submitted to PA-PSRS is an example of the onset of some BCIS symptoms in a patient. A more complete list of characteristics of BCIS includes the following:

- Systemic, life-threatening hypotension[2,4,5,14,19,20]
- Pulmonary hypertension[2,11,14,19,20]
- Increased central venous pressure[20]
- Pulmonary edema[11]
- Bronchoconstriction[11]
- Anoxia/hypoxemia[1,5,11,14,19,20]
- $P_{ET}CO_2$ decrease[4]
- Cardiac dysrhythmia/arrhythmias[1,4,11]
- Cardiogenic shock[1]
- Cardiac arrest[1,4,5,11,20]
- Sudden death[4,5,20]
- Fat/marrow emboli[2,11,20]
- Hypothermia[11]
- Thrombocytopenia[11]

Incidence

For patients undergoing total hip arthroplasty with cemented implants, cardiopulmonary changes have contributed to intraoperative mortality ranging from 0.02% to 6.6% of the cases.[5,21] Parvizi et al.[1] reviewed 38,488 hip arthroplasties in 29,431 patients in an institution's registry and found that the incidence of sudden intraoperative death during any kind of arthroplasty was 0.06%. For patients undergoing arthroplasty as a result of a fracture, however, intraoperative mortality increased to 0.18%. Those with fractures who received cemented arthroplasties had intraoperative mortality rates as high as 0.2% to 4.3%.[1]

Studies using TEE during hip arthroplasty indicate that intracranial and pulmonary emboli occur in from 0.5% to 2% of patients. Moreover, TEE revealed that emboli occur in most patients undergoing femoral medullary reaming and hip hemiarthroplasty.[22] This suggests that embolic events during hip arthroplasty (even subclinical occurrence) are more common than generally recognized.[22]

Pathophysiology

Clinical and laboratory studies of cement implantation syndrome indicate the underlying cause of the systemic hypotension and sudden cardiac failure is right ventricular failure secondary to increased pulmonary artery pressure (PAP).[2] Serious embolization increases the PAP and pulmonary vascular resistance (PVR), causing the thin-walled right ventricle to dilate so that the intraventricular septum shifts to the left.[12] These changes decrease left ventricular compliance, reducing left ventricular filling and cardiac output.[23] The resulting hypotension decreases coronary perfusion pressure. As right ventricular end-diastolic pressure increases, right coronary flow decreases, producing low systemic blood pressure and creating ischemia to the right ventricle.[2,23] This process produces a vicious cycle of right ventricular depression, failure, and death.[23] Such changes can occur within minutes of inserting a cemented prosthesis.[2] Overall, there is a markedly decreased stroke volume of

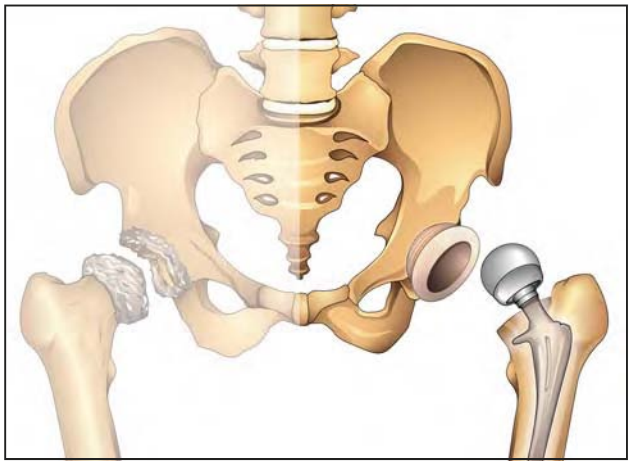

Figure 1. Diseased Right Hip and Total Arthroplasty Left Hip with Acetabular and Femoral Prostheses

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Bone Cement Implantation Syndrome (Continued)

the heart accompanied by increased right ventricular area and decreased left ventricular area.[12]

Embolization is enhanced when tissue thromboplastin from the bone marrow, forced into the veins of the proximal femur during prosthetic insertion, activates a clotting cascade, lesions of the venous endothelium, and thrombogenesis.[24]

Risk Factors

Patient Factors

Elderly patients with underlying cardiovascular disease who are undergoing cemented arthroplasty for repair of a fracture are at greatest risk for developing BCIS.[1] Advanced age has been associated with a higher mortality rate.[1,11,25] Severe osteoporosis may place a patient at higher risk also because osteoporotic bones have enlarged porous cavities and vascular spaces, which may allow marrow contents to enter the venous system more easily.[1,11] Intertrochanteric or pathologic fractures are a risk factor.[1,2] This may be due to the many co-morbid conditions associated with fractures that may increase mortality risk, compared to those patients undergoing elective hip replacement. Moreover, medical optimization may not occur in many fracture cases because of the urgency of surgical repair, increasing the potential for intraoperative mortality. Those with fractures have greater blood loss preoperatively and intraoperatively, contributing to hypovolemia and hypotension.[1] Pathologic fractures may be a risk factor because of pressurization of abnormal vessels in cancerous bone.[2]

Severe underlying cardiovascular disease makes some patients unable to tolerate the pathophysiologic effects associated with the cementing and embolic process.[1,11,24] Patients are susceptible to cardiac ischemia if their preoperative cardiopulmonary reserve is limited by pre-existing pulmonary hypertension, right ventricular dysfunction, or coronary artery disease.[2,23,24]

The pulmonary shunt values of healthy patients or those with mild systemic disease (ASA Class 1 or 2) who sustain embolic events can be re-established uneventfully at the end of the procedure. But, in those with severe systemic disease (ASA Class 3 or 4), pulmonary shunt values are likely to remain abnormally high even postoperatively, increasing the risk of morbidity.[24] The severity of the patient's pulmonary hypertension in response to embolization is associated not only with the extent of embolization and pre-existing cardiovascular status, but also with the compliance of the pulmonary vasculature and activity of humoral reflex mechanisms.[11,12]

Patients with fixed heart rates cannot compensate when stroke volume decreases.[12] Therefore, patients with pacemakers or those receiving a sympathetic blockade caused by epidural anesthesia are at increased risk for this syndrome.[12]

Patients who are hypotensive or who have inadequate volume replacement [25] pre- or intraoperatively are less able to tolerate further ischemic changes associated with this syndrome.

Femoral tumors or cancer place a patient at risk because of potential alterations in the femoral vascular architecture that may increase the risk of marrow embolization.[11]

Patients with large femoral canals (21 mm or more) are at risk for hypotension when cement is inserted into the femoral canal because of an increased vascular surface and a greater amount of embolizable intramedullary contents.[25] Males are more likely to have larger femoral canals than women.[25]

Severe outcomes from emboli may be more likely in those with a patent foramen ovale (25% of the population), which allows emboli to pass to the right heart (bypassing the lungs) and into the arterial system to the brain.[19]

Patients who are hemodynamically unstable at the time of cementing and prosthesis insertion are more likely to develop this syndrome.[2]

Technique

Technical aspects of the procedure can increase embolic load.[2] For example, long stem femoral components are associated with higher risk.[2,11,19] Revision surgery may increase the risk of cement-related hypotension as much as four times.[2,19] Yet, one study indicated that a previously undisturbed femoral canal may place the patient at higher risk.[11] Patients receiving volatile general anesthesia during arthroplasty procedures may be at greater risk for BCIS than those receiving spinal anesthesia.[25]

The risks of intraoperative death during cemented hip arthroplasty are well known.[19-21] In the study by Parvizi et al.[1] mentioned previously, involving a review of over 38,000 total joint arthroplasties, 23 intraoperative deaths occurred, all during cemented hip arthroplasty procedures ($p<0.001$). The cardiovascular collapse of all but three of these patients occurred during the process of cementing. However, in one year, no intraoperative deaths occurred in more than 12,500 patients who had a non-cemented procedure.

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Bone Cement Implantation Syndrome (Continued)

The same pattern was evident in a survey of trauma centers in Wales. In one year, 15 intraoperative deaths during hemiarthroplasty occurred in 847 patients having a cemented prosthesis. In the same year, no intraoperative deaths occurred in 328 patients having non-cemented prostheses.[20]

The major factor in emboli development is increased intramedullary pressure from mechanical compression in the femoral canal, which in turn is produced by the bone cement and insertion of the prosthesis stem.[24] The process of cementing produces a transient but significant decline in cardiac output and reduction in stroke volume.[26]

In a 72-patient prospective randomized clinical trial, the controls received bone cement mixed conventionally, while the experimental group received bone cement mixed in a vacuum. All patients received hemodynamic and transesophageal echocardiography during cemented hip arthroplasty procedures. The incidence of severe cardiac complications and death was significantly reduced in those receiving bone cement mixed in a vacuum.[10]

Risk Reduction Strategies

Surgeons and anesthesiologists can provide major patient safety interventions to reduce the risk of BCIS, including the following:

Patient Assessment

- During preoperative and preanesthetic assessments, identify risk factors, particularly the patient's cardiopulmonary reserve, and use this information to choose the prosthesis, surgical procedure, and techniques most likely to avoid cardiopulmonary complications.[1,2,23,27]
- If medically feasible, defer surgery until the patient's medical and cardiovascular status can be maximized.[1]

Anesthetic Techniques

- Maintaining normovolemia,[23] particularly at the time of cementing and prosthesis insertion.[1,2,19]
- Increasing inspired oxygen concentration by administering 100% oxygen during the procedure.[19,23]
- When using general anesthesia, decreasing the concentration of volatile agent prior to prosthesis insertion.[2,23]
- Utilizing invasive hemodynamic monitoring when pre-existing cardiopulmonary problems exist and during cementing.[1,19,23]
- Providing drug administration through a CVP catheter to provide access to the central circulation, improve coronary perfusion, and maintain cardiac output.[2]

Surgical Techniques

-Patient Condition

- In the presence of pre-existing cardiopulmonary dysfunction, avoiding bilateral hip replacements with cemented prostheses[23] and using non-cemented prostheses may prevent cardiovascular instability.[1,19,20,23]
- During the procedure, if the patient's mean arterial pressure decreases by 20 to 30% below baseline during canal reaming or plugging, changing the technique from cemented to uncemented prosthesis to minimize embolic load.[1,19]

-Lavage

- Conducting thorough, pulsatile, high pressure, high-volume lavage and brushing and drying of the intramedullary canal of the femoral shaft to remove tissue prior to cement insertion reduces disturbances in pulmonary function and prevents microembolization of marrow contents and the embolic response, thereby reducing the risk of fat embolism and minimizing circulatory changes.[1,3,11,15,19,23,27]

-Venting Hole

- For long-stem prostheses, using a venting hole in the distal femur reduces distal trapping of debris and reduces pressurization by creating intramedullary drainage.[1,3,5,11,15,19,21] However, drilling a venting hole may reduce the prosthesis stability or increase the risk of fracture.[2]

-Cement Restrictor/Plug

- Using a cement restrictor may cause less physiological disturbance.[17] The restrictor may help compartmentalize marrow, fat, debris, and blood, reducing the risk of BCIS,[3,28] particularly if combined with other methods to reduce intramedullary pressures (e.g., a venting hole). However, for some high-risk patients, the surgeon may wish to avoid increased femoral pressurization that might occur with the sole use of a restrictor.[1]

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Bone Cement Implantation Syndrome (Continued)

Methyl Methacrylate

Methyl methacrylate (MME) is commonly found in healthcare facilities in surgical bone cement. It is a volatile, colorless liquid that has a strong, sharp, distinctive odor. It is an irritant to eyes, skin, mucous membranes, and the respiratory system. Occupational health risks from MME are mainly associated with breathing the vapors and handling the bone cement; however, it also poses explosion and fire risks (see below). MME remains in use because it forms a strong, hard polymer that bonds tightly to many other substances. It can ensure a secure fixation of an implant to bone.

MME presents a fire hazard. When exposed to an ignition source (e.g., a Bovie), it can produce acetylene, which is an extremely flammable gas. Above the flash point (50°F), MME vapor-air mixtures can be explosive. Vapors are heavier than air and may flow to a distant ignition source and flash back.

Before working with MME, refer to the its Material Safety Data Sheet to learn of its properties, hazards, health effects, as well as requirements for storage and handling and measures for first aid, fire fighting, accidental release, exposure controls, and personal protection. Also, implement safe practices related to labeling of containers holding MME and its components, to ensure that this product is used as intended in the operative setting.

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-Cement Preparation

- Before insertion, working the cement to remove volatile vasodilator compounds.[23]
- Mixing bone cement in a vacuum.[10]
- Using low viscosity cement to reduce intramedullary canal pressures.[21]

-Insertion

- Using a cement gun to apply the cement under sustained low pressure, thus avoiding excessive cement pressurization.[1,11,19] The retrograde cement gun technique provides more even pressure distribution and less pressure of residual debris than finger packing of cement[7] and is less likely to negatively impact physiological parameters.[3,21]
- Slowly introducing the prosthesis stem into the cemented femoral canal reduces pressurization, as well.[19] Implant insertion produces maximum pressure, not cement insertion.[3]
- Some surgeons have used vacuum along the linea aspera to drain the proximal femur to reduce high intramedullary pressure during cement and prosthesis insertion, thus reducing migration of bone marrow and fat into the venous system.[24]

Parvizi et al. reported that many of these risk reduction strategies reduced the overall mortality rate more than 3.5 times from the first study period (1969 to 1988) to the second study period after these changes were implemented (1988 to 1997) ($p<0.05$).[1] This suggests that intraoperative death associated with hip arthroplasties can be reduced by interventions related to patient assessment, patient selection, intraoperative fixation techniques, and improved monitoring and anesthesia management,[1] including an immediate resuscitation protocol based on the pathophysiology of right ventricular failure.[2]

Treatment

BCIS may be reversible with prompt basic life support, combined with treatment to maintain both coronary perfusion pressure and right heart function.[14] An anesthesiologist ordinarily manages this intervention of supporting the cardiovascular system, treating right heart failure, administering 100% oxygen, and maintaining aggressive volume support. Quick initiation of hemodynamic monitoring is helpful in light of the potential for severe pulmonary hypertension and impaired cardiac output. Early placement of a pulmonary artery catheter allows use of pulmonary vasodilators, in addition to assessment of positive end-expiratory pressure levels in extreme circumstances.[11] When cement is first introduced into the femoral shaft and for about ten minutes thereafter, the anesthesiologist must be cautious about conducting anesthesia until the patient's arterial blood pressure spontaneously returns to its initial level.[9]

When symptoms of BCIS occur, the anesthesiologist can administer fluid volumes to augment right ventricular preload. When CVP monitoring indicates large increases in central venous pressure, the anesthesiologist can cease fluid loading.[23] Direct-acting vasopressors, such as phenylephrine or norepinephrine, can be titrated to restore adequate aortic

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Bone Cement Implantation Syndrome (Continued)

perfusion. This process combats right ventricular ischemia and improves right ventricular function.

To improve contractility and ventricular function, anesthesia can administer inotropes, such as dobutamine, provided there is adequate right ventricular perfusion pressure to meet the increased oxygen demand caused by these agents.[23] Isoproterenol can be beneficial if the patient has adequate perfusion pressure, even though it causes vasodilation. If perfusion pressure is inadequate, isoproterenol can cause further hypotension and deterioration in the patient's condition.[23]

The above interventions to restore right ventricular function must be initiated immediately when symptoms of embolization occur (e.g., reduced SaO_2, reduced $P_{ET}CO_2$, tachycardia, bradycardia).[23]

If this syndrome does not result in sudden cardiac death, it may persist for several hours.[15] BCIS is a time-limited process.[2] Both human and animal studies indicate that pulmonary artery pressures normalize within 24 hours.[2] Healthy hearts can recover within minutes, even from large embolic loads associated with cemented implantation. BCIS is reversible even in elderly, critically ill patients, if their hemodynamic stability is maintained by supportive therapy.[2] Therefore, it is essential to immediately identify BCIS and institute aggressive measures in the operating room that address the right ventricular ischemia and failure.[2,23]

The ability to tolerate embolic load is related to the heart's ability to maintain adequate right ventricular output during increased pulmonary vascular resistance.[12] A key factor in maintaining cardiac output during and after embolization is the ability to increase the heart rate in the presence of decreased stroke volume.[12]

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Perforations of the Colon during Colonoscopy

The Patient Safety Authority has been tasked under the Mcare law to improve patient safety across the Commonwealth. One of our efforts to improve patient safety will be a focused review and suggestions for reducing the risk of a serious perioperative complication: perforation following colonoscopy.

During the first year of reporting, PA-PSRS received 125 reports of perforations of the colon during colonoscopy and another 27 reports in which the diagnosis was uncertain or the situation was otherwise unclear. These results indicate that between 125 to 152 perforations were reported as complications of colonoscopies during the first full year of reporting to PA-PSRS. The morbidity and cost of this complication is high. A colon perforation requires an emergency laparotomy for repair of the colon, sometimes with a colostomy. An additional consideration is that many of the patients who suffered this complication were reasonably healthy people who intended to undergo a diagnostic screening test.

According to PHC4, 322,867 colonoscopies (ICD9 = 45.23 or 45.25) were done in hospitals and ambulatory surgical facilities (ASFs) in Pennsylvania during that same period. Therefore, the rate of reported colon perforations that complicated colonoscopies was between 0.039% and 0.047%, or 1 out of every 2,583 to 2,124 colonoscopies.

We checked the possibility that duplicate reports of the same event were reported both by the instigating ASF and the receiving hospital; we found no duplications of age, gender, and date. Also, we know that perforations may occur in doctors' offices and not be reported by the hospitals because they did not occur in a defined medical facility. Additionally, there may be under-reporting of events. However, most (83%) perforations are being reported as Serious Events, despite being "anticipated" as the most important complication of colonoscopy (i.e., discussed with patients during the consent process and on the mind of colonoscopists during procedures.

The rate of colon perforations during colonoscopies reported in PA-PSRS (0.039-0.047%) is low compared to the rates reported in the literature. For example, the Mayo Clinic in Scottsdale, Arizona, reported a perforation rate of 0.19%;[1] a university teaching hospital in Canada reported a rate of 0.13%;[2] and the Lehigh Valley Hospital reported a rate of 0.08%,[3] as did the Mayo Clinic in Rochester, Minnesota.[4] However, the *number* of perforations in the PA-PSRS database is high. For instance, of the literature that we reviewed, the largest number of perforations was 77, which occurred in a random sample of 5% of Medicare beneficiaries 65 years old or older in the Surveillance, Epidemiology, and End Results (SEER) program.[5]

Many patient and procedural factors have been proposed as risk factors for perforation of the colon during colonoscopy. Patient factors include pathology,[6] intra-abdominal adhesions,[6] and age,[5] among others. Procedure factors include the mechanics of advancing the colonoscope,[6] air insufflation,[6] and the method of biopsy,[6] again just to mention a few. Some of these risk factors can be controlled by the provider and some cannot. In theory, the risk of perforation of the colon during colonoscopy can be reduced by

1. identifying patient and procedural factors that could be modified to reduce the risk of perforation,

2. informing providers about these controllable risk factors, and

3. helping facilities implement programs to systematically control those risk factors during colonoscopies to minimize the risk of perforation.

Because of the number of reports and the morbidity of colon perforations, the Pennsylvania Patient Safety Authority Board of Directors has decided to undertake a focused objective cooperative analysis of perforations during colonoscopy as a special safety improvement project. The initial objective of this special initiative is to reduce the number of perforations during colonoscopies to at least less than 60 within a single year.

Facilities will notice this initiative in the following three areas and are encouraged to volunteer their commitment and full participation in this special safety improvement project:

1. The PA-PSRS team is looking for physicians and nurses of all specialties who do colonoscopy and who are interested in volunteering to provide their expertise and experience to this project.

2. PA-PSRS will be soliciting detailed information from facilities in follow-up to reports of perforations during colonoscopies. Hopefully,

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Perforations of the Colon during Colonoscopy (Continued)

facilities will understand the importance of gathering in-depth information on this complication; the burden will be small for any single facility, and the benefit large when the experience of the entire state is aggregated.

3. In order to understand which patient and procedure factors are not only commonly found with perforations, but more commonly found with perforations than with safe, uncomplicated procedures, it will be necessary to collect similar information on an equivalent-sized set of safely done procedures. The PA-PSRS team is looking for volunteer providers and facilities to provide this comparable information in order to identify the risk factors for perforation.

Armed with this information, the Authority will be able to identify controllable risk factors for perforation during colonoscopy, develop an educational program to inform Pennsylvania providers about these controllable risk factors, and assist them in developing system improvements to eliminate avoidable risks of perforation during colonoscopy.

To assist in this program, the PA-PSRS team will recruit an advisory panel. Members of the panel will represent various specialties and geographic areas. The advisory panel will help the PA-PSRS team develop a list of relevant questions, critique the analysis, advise the team on the development of an educational program, and suggest system improvements to create an effective risk-reduction program.

We will begin this special safety improvement program in January 2007.

If you are a provider or represent a facility that does colonoscopy, we need your help. If you would like to volunteer to participate in this special program, please contact:

John Clarke, M.D., Clinical Director
Pennsylvania Patient Safety Reporting System
via email at: jclarke@ecri.org

Notes

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Oxygen–Enriched Environments Increase the Fire Risk from Alcohol-Based Hand Sanitizers

Ignition of alcohol-based hand sanitizers in oxygen-enriched environments in healthcare facilities can lead to serious fires, according to a hazard report published in the October 2006 issue of ECRI's *Health Devices*.

The hazard report discussed a reported event in which a nurse in a neonatal intensive care unit was rubbing sanitizer into her hands as she approached an oxygen/air proportioner to change a setting. An investigation into the event concluded that the nurse's movements created a static electric charge that discharged to the grounded proportioner when she reached for the device's control knob.

Because the three requisite components of a fire were in place—an ignition source (i.e., the electrostatic discharge), a fuel (i.e., the hand sanitizer), and oxygen (i.e., present in the room air and in the oxygen-enriched environment surrounding the proportioner)—a fire ignited the sanitizer on the nurse's hand and on the control knob. The nurse's hand was burned; however, nearby clinicians were able to disconnect the device and extinguish the flames before additional injuries occurred or the fire spread. In the presence of normal oxygen concentration in the room air, the electrostatic discharge may have only ignited the sanitizer on the nurse's hand, but because of the oxygen-enriched environment surrounding the control knob, the knob also caught fire.

Suggestions from the hazard report for users of alcohol-based hand sanitizer include the following:

- Alerting users to this potential problem.
- Directing users to ensure that sanitizer fully evaporates from their hands before they touch devices, bed linens, or patients.

Source: ECRI. Fire risk from alcohol-based hand sanitizers worsens in oxygen-enriched environments. *Health Devices* 2006 Oct;35(10):390.

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Purple Glove Syndrome

Patrick J. McDonnell, PharmD, Associate Professor of Clinical Pharmacy, Temple University School of Pharmacy, Philadelphia, Pennsylvania

PA-PSRS has received several reports regarding "purple glove syndrome," an adverse drug reaction related to intravenous administration of phenytoin (DILANTIN). To address this topic, PA-PSRS invited Patrick J. McDonnell, PharmD, to submit this article. Dr. McDonnell specializes in drug safety and adverse drug reactions and has lectured and written extensively on these issues.

—John R. Clarke, M.D., Editor

An 82-year-old female with a history of seizure was unable to continue oral therapy of phenytoin due to new onset of seizure activity, so she was prescribed phenytoin 100 mg IV q8h. The phenytoin was infused via a #22-gauge catheter in her right hand, and when the nurse left the room, the patient dislodged the phenytoin infusion. The patient's right hand was cool with a purple mottling spreading from the IV site. Her attending physician was notified, and warm compresses with elevation were applied to the area. Plastic surgery was consulted, and Doppler studies revealed adequate perfusion. The patient was diagnosed with "purple glove syndrome" from phenytoin. Within three days, symptoms appeared to be improving with decreased edema of the right hand and less mottling. No necrosis was noted.

Phenytoin (**DILANTIN**), a broad spectrum anticonvulsant, has been widely administered parenterally for the treatment of seizures for more than 40 years. It is used as a first-line therapy for status epilepticus. Intravenous (IV) phenytoin is employed in emergency departments and neurological units for patients with active seizure disorders or who are unable to receive oral medication.

Adverse reactions to phenytoin are not uncommon in regards to phenytoin toxicity, due to phenytoin's narrow therapeutic index and pharmacokinetics; however, the adverse drug reaction known as purple glove syndrome (PGS) (see the PA-PSRS case report above), seems to be related exclusively to the IV administration of phenytoin.

PGS gets its name from the characteristic bluish discoloration of the skin, accompanied by pain and edema distal to the site of intravenous administration of phenytoin. Generally, PGS occurs in three stages:[1,4]

1. A pale blue or dark purple discoloration appears around the intravenous insertion site 2 to 12 hours after the administration of the drug.
2. Progression occurs during the next 12 to 16 hours as developing edema and continued discoloration spread around all sides of the fingers, hand and forearm, hence the term "purple glove."
3. Healing is the last stage as the discoloration recedes, starting from the periphery and moving toward the original site of injury. The majority of reported cases resolve without incident, but a few cases resulting in necrosis have been reported.

The mechanism for PGS is not totally understood but seems to be related to the reaction of the interstitial tissue to extravasation of the highly alkaline pH of phenytoin injection. However, not all cases of PGS are preceded by typical or blatant extravasation, and this varying reaction is related to the formulation of phenytoin injection.

Phenytoin injection is poorly soluble in water. Several vehicles must be employed to improve solubility to allow the drug to be administered parenterally. Phenytoin injection is available as a solution that contains 50 mg of phenytoin sodium per milliliter in a vehicle of 40% propylene glycol and 10% ethanol; this solution is then adjusted to a pH of 12 with sodium hydroxide. PGS seems to occur not directly from phenytoin, but from these additives. PGS occurs without blatant or visible extravasation for several reasons, including the following:[1]

- The highly alkaline phenytoin solution may induce vasoconstriction and thrombosis, which then result in an occult leakage of solution into the interstitial space.
- Mixing this alkaline solution with blood of a more neutral pH may result in precipitation of phenytoin that can lead to vascular and IV catheter obstruction.
- The solution's alkalinity may also result in the breakdown of endothelial intercellular junctions allowing phenytoin to seep into the skin's interstitial spaces.

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Purple Glove Syndrome (Continued)

- The IV catheter insertion may cause a microtear in the vessel wall, allowing a small amount of phenytoin to infiltrate the soft tissue without apparent extravasation. Such tears are more likely during catheter insertions on elderly patients.

The actual incidence of PGS is unknown. More attention in the late 1990s focused on PGS with the introduction of fosphenytoin, a pro-drug of phenytoin that is highly water soluble at a neutral pH (blood pH) and is delivered in a vehicle less caustic than phenytoin. One study placed the incidence of PGS at 5.9% (i.e., 9 of 152 patients who received IV phenytoin during the study) and promoted the use of fosphenytoin to prevent PGS.[1] Another study found that PGS incidence with IV administration of phenytoin was 1.6%, with the cases being mild and unremarkable with no effect on increase in hospital length of stay.[2]

Regardless of the incidence, increased awareness of this reaction by prescribers, pharmacists, nurses or others who administer IV phenytoin is necessary.

To reduce the likelihood of PGS, staff education and drug information material about phenytoin should include the following:[3]

- Phenytoin, whether given by IV push or IV infusion, should never be administered at a rate greater than 50 mg/min; some advocate a rate of infusion of 20 mg/min for the elderly or for patients with poor IV access.

- Phenytoin, if diluted in IV fluids, can only be diluted in 0.9% saline (NSS) and should be mixed immediately prior to administration to prevent precipitation. Bacterostatic isotonic saline should not be used, as preservatives can lead to precipitation. Any phenytoin admixture more than four hours old should be discarded.

- Dextrose solutions and lactated ringers solution cannot be used with IV phenytoin due to the potential for precipitation.

- Smaller hand veins should be avoided as IV administration points.

- 20-gauge catheters or larger should be utilized along with a 0.22 micron filter.

- Careful monitoring of the site during and post infusion should be employed.

If pain, discoloration and/or edema develop despite these precautions, the following treatment plans are suggested to lessen the severity of PGS:[3]

- Discontinuing IV administration of phenytoin

- Applying gentle, dry, warm heat to the area to relieve pain and help to redistribute phenytoin within the soft tissue; moist heat is not recommended as it may contribute to skin breakdown or maceration

- Elevating extremities to aid in symptom relief and reduce edema

- Employing pain assessment and management

- Continuing neurovascular assessment of the area and documenting pain, skin condition and limb movement

- Avoiding use of cold compresses, as this leads to vasoconstriction and impaired resolution and healing of PGS

Increased awareness of PGS, precautionary IV administration of phenytoin, and prompt action if PGS does occur can limit the progression of soft tissue damage seen with this adverse drug reaction.

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Keeping an Eye on Toxic Anterior Segment Syndrome

Editor's Note: The following information has been abstracted from the cover article of the December 2006 *AORN Journal*. PA-PSRS Clinical Analyst Janet Johnston, RN, MSN, JD, was invited to submit the article for publication. Additional resources have been provided.

Since June 2004, ambulatory surgical facilities have submitted at least 15 reports of toxic anterior segment syndrome (TASS) to PA-PSRS, and at least three facilities have reported multiple cases. TASS is a complication of intraocular surgery that occurs when a non-infectious toxic agent enters the anterior segment of the eye and causes an inflammatory reaction. While it is a rare complication, severe cases of TASS can cause permanent injury to the eye. Often, the cause of a TASS event remains unknown even after investigation, but potential causes identified in the clinical literature include bacterial endotoxin, viscoelastic, and other residues introduced into the eye (e.g., on instruments); solutions and intraocular fluids introduced into the eye; preservatives in ophthalmic solutions; medications that penetrate through surgical wounds in the eye; and intraocular lenses (i.e., design and composition).

TASS incidence is difficult to pinpoint for several reasons, including that TASS is often confused with and treated as infectious endophthalmitis. Symptoms (e.g., decreased or blurred vision, hypopyon, fibrin and conjuctival redness) are similar for both diagnoses—a complete evaluation conducted by an ophthalmologist will differentiate between the two. Such an examination comprises the following: fundus examination, gonioscopy, slit lamp examination, tonometry, and aqueous and vitreous needle examination. If early diagnosis of TASS is made, timely and appropriate intervention is effective. Treatments vary, but the most common treatment is administering corticosteroids to reduce inflammation. After treatment, careful monitoring and follow-up protects against further inflammation.

Risk-reduction strategies for clinicians, surgical team members, patients, and others to consider include the following:

- Awareness
  - Acknowledging the potential for TASS to occur (e.g., quickly investigating and appropriately treating inflammation that occurs the day after surgery)
  - Being wary of all items introduced into the eye during surgery
  - During discharge, instructing patients to return at first indication of visual disturbance
- Communication
  - Involving perioperative personnel in discussions about purchasing changes to avoid supply items associated with TASS
  - Discussing intraoperative changes that could contribute to TASS (e.g., intraoperative switch to different irrigating solution)
  - Documenting and recording medications, solutions, and instruments used in surgery to help identify patterns in the event of TASS outbreak
- Technique
  - Considering techniques to reduce the risk of TASS discussed in clinical literature

Source: Johnston J. Toxic anterior segment syndrome—more than sterility meets the eye. AORN J 2006 Dec [cited 2006 Dec 6]. Available from Internet: http://www.aornjournal.org/article/PIIS000120920663994X/abstract.

Additional Resources

American Society of Cataract and Refractive Surgery

- Toxic anterior segment syndrome (TASS) outbreak final report [press release online]. 2006 Sep 25 [cited 2006 Dec 8]. Available from Internet: http://www.ascrs.org/press_releases/Final-TASS-Report.cfm.
- Instrument re-processing questionnaire [online]. [cited 2006 Dec 8]. Available from Internet: http://www.ascrs.org/press_releases/upload/Processdatacollectionform.doc.
- Product questionnaire [online]. [cited 2006 Dec 8]. Available from Internet: http://www.ascrs.org/press_releases/upload/Productdatacollectionform.doc.

cme² (an independent subsidiary of Advanstar Communications, Inc)

- TASS: Probable Causes and Corrective Measures [Web site]. [cited 2006 Dec 8]. Available from Internet: http://www.tassfacts.com/.

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I'm Stuck and I Can't Get Out! Hospital Bed Entrapment

Healthcare facilities have submitted to PA-PSRS over 100 reports of hospital bed rail entrapment since June 2004. In the past, healthcare workers considered bed rails a useful device to prevent patient falls from bed.[1,2] While bed rails have their benefits, their use or misuse may also place patients at significant risk, resulting in death or serious injury.

Definitions

Entrapment is an occurrence involving a patient who is caught, trapped, or entangled in the hospital bed system,[3,4] which includes the spaces in or around the bed rail, hospital bed mattress, or hospital bed frame.[3] Bed rails are adjustable plastic or metal bars that attach to the bed frame. They are available in several shapes and sizes, ranging from full to half, one-quarter, and one-eighth lengths.[3] Entrapped body parts associated with risk for severe injury include the head, neck, and chest.[5]

Incidence

From 1985 through 2005, the U.S. Food and Drug Administration (FDA) received 691 reports of hospital bed entrapment including 413 deaths, 120 nonfatal injuries, and 158 occurrences of staff intervention which prevented injuries.[4,6]

In response to reports of entrapment, FDA partnered with the Veteran's Administration, Health Canada, other federal agencies, national healthcare organizations, representatives from the hospital bed industry, and patient advocacy groups to form the Hospital Bed Safety Workgroup (HBSW). Its goal was "to improve safety of hospital beds for patients in all healthcare settings who are most vulnerable to the risk of entrapment, particularly that of older adults."[1] The FDA and the HBSW have produced guidance documents that healthcare facilities and manufacturers can use as references to reduce entrapment risks. (See the section below on Entrapment Prevention Resources.)

Entrapment Zones

In an effort to standardize/clarify the bed entrapment discussion, FDA and HBSW defined seven areas of the hospital bed system in which patient entrapment is most likely to occur.[5]

See Figure 1 for the location of these various zones,[5,7] which will be referred to throughout this article.

PA-PSRS Reports of Entrapment

Harm

About 4% of the entrapment reports were classified as Serious Events, and about 50% of the Incidents indicated some type of injury. The remaining reports indicated either that no injury occurred or no injury was specified. The majority of entrapments resulted in either no harm or minor injuries (i.e., abrasions, skin tears, lacerations, bruises/redness, indentations, pain/discomfort); however, all reports indicated that healthcare workers needed to extricate the patient to prevent greater harm.

The most severe injury reported had a Harm Score of F (i.e., an event occurred that contributed to or resulted in temporary harm and required initial or

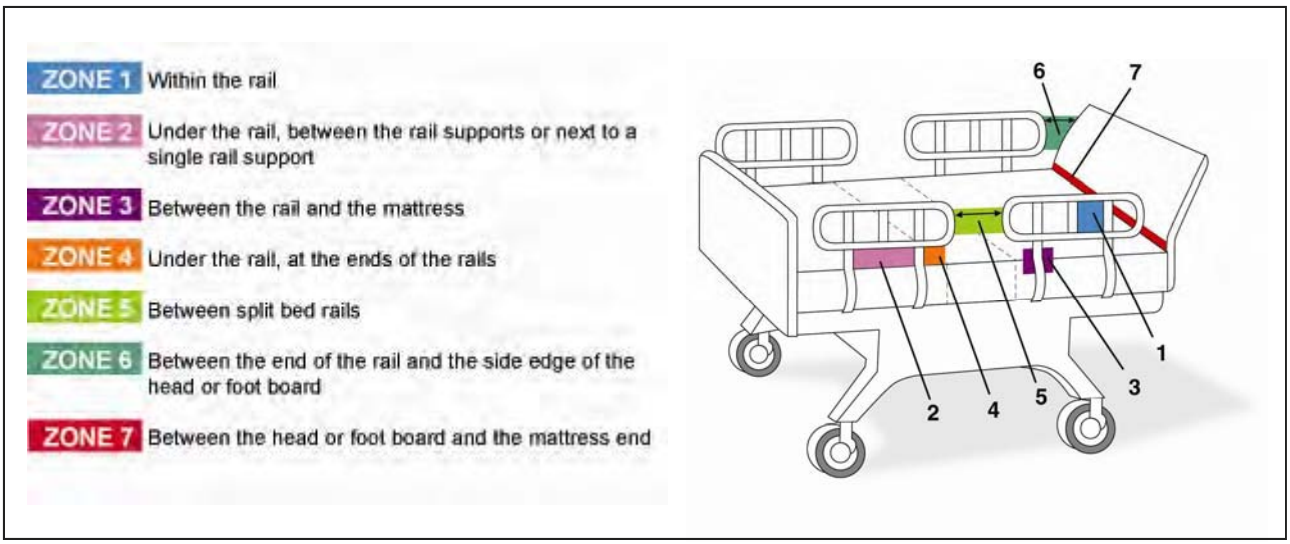

Figure 1. Bed Entrapment Zones. Bed image adapted from: U.S. Food and Drug Administration. Hospital bed system dimensional assessment guidance to reduce entrapment – guidance for industry and FDA staff [online]. 2006 Mar 10 [cited 2006 Nov 17]. Available from Internet: http://www.fda.gov/cdrh/beds/guidance/1537.html.

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I'm Stuck and I Can't Get Out! Hospital Bed Entrapment (Continued)

prolonged hospitalization). In this case, the patient required an extended hospital stay to treat a significant methicillin resistant Staphylococcus aureus (MRSA) infection of a skin tear on a leg that had been caught in a side rail.

Age

Sixty-eight percent of the entrapped patients were 70 years of age or older. However, the ages of entrapped patients reported ranged from 10 months to 99 years old. Therefore, all ages may be at risk of entrapment, particularly if other risk factors are present.

Body Part Entrapped

Thirty-nine percent of the PA-PSRS entrapment reports did not specify the body part entrapped. Entrapment of the head and chest (associated with potential for serious injury) occurred in 9% of the reports. The most common entrapped body parts were lower extremities (25%) and upper extremities (11%). Nine percent of reports involved entrapment of more than one body part, while another 3.5% involved the hip/pelvis. The remaining 3.5% indicated that the body/torso was entrapped.

Entrapment Zone

Eighty-seven percent of the entrapments reported to PA-PSRS occurred in three zones: Zone 5 (39%), Zone 1 (26%), and Zone 3 (22%). (See Table 1 for additional statistics on PA-PSRS entrapment reports.) This pattern varies from the FDA's data in which the majority of reported entrapments occurred in Zones 1 through 4.[7] The Joint Commission on Accreditation of Healthcare Organizations has received sentinel event reports of entrapment that involved Zones 1,3,5, and 6.[8] These variations may be the result of FDA's and Joint Commission's databases containing a greater proportion of deaths and serious injuries, while the PA-PSRS reports are predominantly near misses.

Entrapment Zone	Percent of PA-PSRS Reports
1	26
2	2
3	22
4	6
5	39
6	1
7	0
Under bed frame	1
More than one Zone	3

Table 1. Percentage of Entrapments Reported to PA-PSRS by Zone

Benefits of Bed Rails

In certain circumstances, bed rails can be beneficial.[2-4] They can remind a patient not to get out of bed, if there is medical equipment attached or if it is medically contraindicated. A patient can use them while repositioning or turning while in bed. They can be used as hand-holds to assist the patient while getting in or out of bed. Bed rails also define the sides of an unfamiliar bed and may also provide the patient with a sense of security and comfort. They can prevent rolling out of bed and reduce the risk of falling from a bed or litter during transport. Bed rails may also provide convenient access to bed controls, the nursing call bell, and television and radio. However, these collective benefits must be weighed against the risks of using bed rails.

Risks of Bed Rails

While bed rails are commonly thought to prevent falls, patients who fall while climbing over raised bed rails are at greater risk of serious injuries, including head trauma, lacerations, fractures, and dislocations.[2-4] Raised bed rails may increase patient agitation. Bed rails enhance feelings of isolation and restriction/imprisonment, thereby negatively affecting self esteem. Moreover, the confinement of bed rails may prevent patients who are able to get out of bed from conducting routine activities, such as retrieving an object or going to the bathroom. (In instances where bed rails prevent patients from going to the bathroom, patient incontinence may be likely to occur.) Lastly, bed rails are associated with severe bodily injury, suffocation, strangulation, and death.[3]

Risk Factors for Entrapment

Risk factors for entrapment may be patient-related, care-related, or equipment-related.

Patient-Related

Bed rail entrapments commonly occur in frail, elderly patient populations.[1,3] Mentally or behaviorally impaired persons may be at risk,[8] including those with agitation, delirium, hypoxia, confusion, dementia, and memory problems.[3,4] Those with uncontrolled body movements may find themselves in an entrapment situation from which they cannot independently extricate themselves.[3] Patients at fall risk or with serious sleeping problems may get entrapped in the bed system while attempting to get out of bed unassisted.[4,8] Incontinent patients and those with acute urinary retention or fecal impaction are at risk for entrapment when they attempt to go to the bathroom

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I'm Stuck and I Can't Get Out! Hospital Bed Entrapment (Continued)

by getting out of bed with the bed rails raised.[3] Those with limited mobility in bed (such as hemiparesis) or a physical deformity may be at risk because they may be physically unable to extract themselves from the bed system.[8] Patients taking sedative or psychoactive drugs may not be aware of entrapment as it occurs.[8]

Care-Related

Entrapment is more likely when the following care is not provided on a timely basis: toileting, position changes, pain management, or other interventions to promote patient comfort.[3]

Root causes involved with Joint Commission's entrapment sentinel event reports revealed the following contributing factors:[8]

- Breakdown in communication—among staff, with/between physicians, or with administration
- Equipment factors—problems with configuration of the bed, mattress, or bed rail (e.g., bed rail protector was not used or mattress or rail not compatible with bed frame)
- Problems with patient assessment—adequacy, scope/timing, patient observation
- Staffing and supervision—lack of leadership, use of agency nurses, staff orientation

Equipment-Related

In older bed systems, the original design may not have accounted for the risk of patient entrapment. More commonly, however, entrapment risk may increase after aging bed system components are replaced. For example, replacement mattresses may be undersized and not fit as snugly as the initial mattresses.[1]

Use of air pressure mattresses may further increase the entrapment risk.[1,8] When a patient moves to one side of some types of air mattresses, that side compresses while the center of the mattress raises. The resulting "slide" allows the patient to move from the mattress to the bed rail. Such compression can also result in a wider space between the rail and the mattress, thus increasing entrapment risk.[1,8]

If side rails no longer lock into the raised position, patient movement may cause a partially raised rail to fall onto a patient's neck or extremity.[1] Additional equipment-related entrapment risks include: bed rails with winged lower edges, improper match of bed frame with bedrails, loose bed rails, improper installation of the bed system, wide spaces between the bars in the rails, holders/supports that remain when the bed rail is removed.[3]

FDA reports and Joint Commission sentinel event reports implicated no particular rail configuration at higher risk for entrapment: both full and half length rails were associated with entrapment.

Risk Reduction Strategies

There are several "A's" involved in reducing the risk of entrapment: Approach, Assessment, Awareness, and Actions.

Approach Strategies

While healthcare workers have used bed rails as a patient safety mechanism (e.g., for fall prevention), their use may pose an unwarranted hazard.[3] Rather than automatically applying bed rails, it is prudent for healthcare workers to conduct a risk-benefit analysis; that is, to make bed rail decisions on a case-by-case basis, founded upon individualized patient assessment using input from the interdisciplinary healthcare team and the patient, family, and/or patient's legal guardian.[3]

Elizabeth Capezuti, Ph.D., R.N., APRN-BC, FAAN, Associate Professor and Co-Director of the John A. Hartford Foundation Institute for Geriatric Nursing, New York University College of Nursing, an expert on restraints and bed rail safety, states the following about bed rails:

> Healthcare organizations need to look at these devices like any restraint and evaluate a rationale for using them. Don't pull up the side rail and walk away. Both split and full rails have the potential to cause fall-related injuries as well as entrapment. Healthcare organizations need to look at bed rails as potentially restrictive devices, or restraints, and ask themselves what kind of surveillance needs to be in place to assure safety.[8]

The Centers for Medicare & Medicaid Services (CMS)[9] and Joint Commission[1] define bed rails as restraints when they are used to prevent a patient from voluntarily getting out of bed. Therefore, the use of bed rails must be considered by balancing patient rights with the caregiver's responsibility to provide care based upon individualized assessment, applicable laws and regulations, and professional standards of care.

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I'm Stuck and I Can't Get Out! Hospital Bed Entrapment (Continued)

Assessment Strategies

Conducting individualized and ongoing patient assessment is another method to reduce entrapment risk.[3] Effective patient assessment involves the interdisciplinary healthcare team, the patient, and his or her family. Obtaining the following information will identify the patient at risk for entrapment and falls and will indicate whether the patient could benefit from restraint use.[3,8]

- Medical diagnoses, symptoms, and the patient's medical stability
- Surgical interventions the patient requires
- Underlying conditions that might place the patient at risk for entrapment, including the following:
  - cognitive/mental status changes
  - incontinence
  - pain level and extent of pain control
  - lack of muscle control
  - physical deformities
  - ability to adequately communicate needs or problems
- Sleeping habits and bedtime routines, as well as customary sleeping environment
- Familiarity/comfortableness/accessibility of surroundings
- Distance from the bed to the toilet
- Level of patient independence (e.g., ability to safely toilet, get in and out of bed)
- Patients who meet fall risk criteria
- Appropriateness of the bed for patient needs
- Level of caregiver support that the patient requires
- Presence of medications, sedation, or prepping agents that might increase the risk of entrapment

Similar to patient assessment, regular and ongoing equipment assessment (i.e., of the bed system entrapment zones) provides a foundation upon which to reduce the risk of entrapment.[3,8]

FDA recently produced a "Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment."[7] The guidance describes a test tool developed by the HBSW for use by healthcare facilities to measure bed systems. This cone and cylinder tool is designed to simulate the 95th percentile for the size and weight of a small adult female head and a compressed neck. The tool includes a force gauge — a scale to measure less than or equal to 12 pounds of force during certain test conditions. While the tool is designed to measure all entrapment zones, FDA currently gives no dimensional recommendations for Zones 5, 6, and 7. The tool comes with a training and instructional video[10] that explains how to use the tool and perform the bed measurements. The tool is used on a made bed and can measure gaps/spaces when the bed is placed in the flat position, as well as in other bed surface configurations. The tool is available online at http://www.nst-usa.com.[10]

The testing process may be more efficient if one person performs the measurements, while another records the findings.[11] Debate exists concerning whether all beds with identical bed system components should be measured individually.[11] One school of thought contends it may not be necessary to measure each of these beds if one bed in the category passes. The exception is when a particular bed system passes marginally; in such an instance, all beds with identical bed system components should be individually measured. Another perspective is that every bed should be measured because identical bed systems are subjected to different wear and tear and some bed systems may pass the test while others may not.

FDA, with recommendations from the HBSW, has published nonbinding guidance with dimensional recommendations for hospital beds for Entrapment Zones 1 through 4.[7] The dimensional guidance pertains to full-size hospital beds that are the subject of the FDA and HBSW studies. These dimensional limits are summarized in Table 2. The majority of FDA reports of serious injury have occurred in these four zones.[7] In the future, FDA hopes to publish dimensional recommendations for the other zones, as well as for beds in different configurations/positions. Or, the FDA may consider adopting international standards to address dimensional recommendations.

Assessment of bed systems includes the following:[3]

- Ensuring that the bars within bed rails are closely spaced to prevent a patient's head from passing through

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I'm Stuck and I Can't Get Out! Hospital Bed Entrapment (Continued)

Zone	Dimensional Limit
1	No less than 120mm (4 ¾")
2	No less than 120mm (4 ¾")
3	No less than 120mm (4 ¾")
4	No less than 60mm (2 3/8") AND Greater than 60° angle

Table 2. Entrapment Zone Dimensional Limits

- Determining whether the space between the bed rail and the mattress prevents a patient from falling in the gap
- Checking for conditions that over time might increase the gap between the bed rails and mattress; for example, damage to bed rails, age, and the use of cleaning agents on the mattress may cause shrinkage or compression
- Because mattresses are not all alike, checking the gap between the mattress and bed rails when replacing a mattress in the bed system
- Measuring gaps while the bed rail and bed surface are in various positions to identify potential entrapment risks
- Evaluating the bed rail latches for stability to prevent bed rails from falling when they are shaken or bumped
- Removing from service older bed rail designs with tapered or winged ends, especially for a patient assessed as an entrapment risk

Reassessment of hospital bed systems is appropriate when:

- Changing bed system components (e.g., new mattresses)
- Adding or removing accessories (e.g., positioning poles or mattress overlays)
- Components appear to be wearing (e.g., wobbly side rails or soft/uneven mattress surfaces)[12]

Action Strategies

The assessment becomes the foundation for developing actions, including ongoing care plans and treatment programs designed, among other things, to reduce entrapment risk.

Prescriber actions may include the following:[3]

- Minimizing mental status-altering medications
- Being mindful of medications to avoid in the elderly, such as those on the Beers list. (See: Pennsylvania Patient Safety Reporting System. The Beers Criteria: screening for potentially inappropriate medications in the elderly. *PA-PSRS Patient Saf Adv* 2005 Dec;2(4):11-15. Available from Internet: http://www.psa.state.pa.us.)
- Ordering alternative interventions for sleeping medications
- Timing diuretics so that they are given before the late afternoon or evening
- Treating pain/prescribing analgesia
- Assessing, ruling out, and treating reversible causes of hypoxia and delirium
- Ordering physical therapy to promote safe standing, ambulation, and mobility

Reducing entrapment involves many patient care interventions, such as the following, that fall under the general categories of fulfilling patient needs by anticipating and accommodating them and providing alternatives:[2-4,13]

- Anticipating and providing pain relief and calming interventions on a timely basis
- Providing distractions (e.g., television, music, food/fluids) to reduce agitation/restlessness, especially for patients who do not sleep throughout the night
- Planning physical activities during the day to encourage restful sleep and diversional activities at any time to reduce wandering/agitation

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I'm Stuck and I Can't Get Out! Hospital Bed Entrapment (Continued)

- When possible, accommodating and incorporating patient's preferred bedtime habits/routines into evening care
- If medically indicated, using padded bed rails for patients with active movement or seizure disorders
- Restricting the use of physical restraints on patients while in bed
- Positioning patients for comfort and developing a timely schedule for turning and positioning
- If bed rails must be used, performing ongoing assessments of the patient's mental and physical status so that bed rails are used only when medically necessary
- Keeping those at risk for entrapment under more frequent observation
- Lowering one or more bed rail sections
- Elevating the head of beds of those patients with chronic obstructive pulmonary disease, reflux, congestive heart failure, and while infusing enteral fluids
- Promptly cleaning urine and/or feces from incontinent patients
- Adhering to a toileting schedule that is customized to patient needs
- Reassessing and revising the patient's care plan whenever entrapment or near-miss entrapment occurs
- Obtaining input from the patient and family about how to individualize interventions
- Anticipating patient's hunger and thirst by offering food and fluids

Reducing or eliminating bed rail use can be accomplished progressively using a systematic approach.[3] Using the following alternatives to bed rails may enhance patient safety:[3,4,8,14]

- Using high/low beds and keeping beds in the lowest position with wheels locked when clinical care is not being provided
- Placing mats next to the bed, for patients at risk of falling out of bed
- Using transfer, positioning bars, hand-holds, overbed trapeze or mobility aids for patient use instead of bed rails to increase patient's mobility in bed and to assist patients getting in/out of bed
- Providing diversions to reduce agitation
- Placing the patient's call bell and personal items within reach and providing visual and verbal reminders to use the call bell when assistance is needed
- Using bed alarms to alert healthcare workers when patients are attempting to get out of bed
- Posting coded signs to notify the healthcare team that a patient is an entrapment risk
- Using border-defining mechanisms such as body pillows or cushions to assist the patient in determining where the mattress edges are and to reduce gaps that might promote entrapment
- Avoiding the use of physical restraints while the patient is in bed.
- Providing pendant bed controls rather than controls in the bed rail.

If bed rails must be used, addressing the following equipment issues may reduce entrapment risk: [3,8,14]

- Installing retrofits from bed system manufacturers, according to manufacturers' instructions, on beds assessed as entrapment risks
- When feasible, replacing beds with others that have lesser entrapment risk
- Using bolsters or spacers of firm foam blocks to fill gaps and provide an inlay to prevent patients from falling between the mattress and bed rails

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- Replacing/modifying bed rails with gaps greater than 4 ½ inches or removing/ lowering them altogether
- Applying bed rail covers, rigid plastic covers, clear pads, or netting to cover gaps in rails
- Replacing mattresses or placing Velcro or anti-skid pads to stabilize mattress position to reduce gaps
- Using mattresses with raised/hard foam edges to reduce compression at mattress edges and to provide a sensory perimeter to the bed edges
- Purchasing bed systems that comply with FDA dimensional guidance by confirming with the manufacturer of the bed system

Reports containing the following information will promote comprehensive analysis and effective corrective actions:[7,14]

- The entrapped body part and its size (e.g., head breadth, chest depth, neck diameter)
- The size of the gap in which the body part was entrapped
- Position of bed rails (lowered, fully raised, intermediate level)
- Zone of entrapment
- Number of side rails raised at the time of the occurrence and type of rails
- Sections of the frame that were raised and approximate elevation for each section
- Information on the size of the gap that contributed to the entrapment
- Mattress height and height of bed rail from the top of the mattress
- Make, model, manufacturer of hospital bed system
- Condition of the patient before and after entrapment
- Body part injured
- Modifications/changes made to the bed system before and after the entrapment

An entrapment risk reduction program goes beyond the consistent, comprehensive reporting of entrapment occurrences. Reducing the risk of entrapment also includes maintaining, reviewing, and taking corrective actions based on report review and the following documentation:[14]

- Individualized patient care plans
- Bed system maintenance records
- Policies and procedures that specify risk factors and interventions to prevent entrapment
- Safety checklists for patients at high risk for entrapment
- Failure mode and effects analyses, root cause analyses, and the relevant improvement measures in response to actual or potential bed entrapment occurrences

For an example of maintaining, reviewing, and taking corrective actions, see the sidebar "Steps to Modify Openings in Existing Hospital Bed Systems."

Awareness Strategies

While education and training about appropriate bed rail use promotes a safer and more comfortable patient environment, awareness must be heightened across the healthcare continuum. Individuals that awareness efforts should reach include staff,

Steps to Modify Openings in Existing Hospital Bed Systems[14]

1. Assign responsibility
2. Determine high risk clinical units, if appropriate
3. Inventory bed systems
4. Evaluate bed systems for conformance to FDA's bed system entrapment dimensional guidance
5. Initiate corrective action
6. Bed replacement plan — determine new purchases
7. Implement quality monitoring program

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I'm Stuck and I Can't Get Out! Hospital Bed Entrapment (Continued)

patients, families, physicians/prescribers, as well as materials managers, healthcare engineering professionals, long term care ombudsmen, and representatives of legislative and regulatory agencies.[2] Examples of strategies to raise awareness include the following:[2]

- Providing orientation and training concerning the risks of entrapment and interventions to reduce such risk.[8]
- Encouraging patients and families to learn about bed safety and the purpose and potential dangers of bed rails, and to talk with healthcare workers concerning whether bed rails are indicated[3,4,8]
- Providing a brochure to patients/families concerning the dangers of bed rail use and promoting a safer environment [2,15], such as the FDA/HBSW "A Guide to Bed Safety" at http://www.fda.gov/cdrh/beds/bed_brochure.html

Visit the Patient Safety Authority Web site (http://www.psa.state.pa.us) for a hospital bed safety toolkit that includes the following:

- A copy of this article that can be downloaded and easily e-mailed to colleagues
- An entrapment poster that highlights prevention of bed rail entrapment and identifies the seven entrapment zones
- A brief, self-running video on bed rail entrapment prevention, appropriate for frontline caregivers
- Links to additional companion documents that provide comprehensive information concerning hospital bed safety and strategies to reduce the risk of entrapment.

To view the toolkit, click on "Advisories and Related Resources" in the left-hand column of the Authority's home page. Then, click on "Resources Associated with Patient Safety Articles."

- Using patient care rounds as an opportunity to discuss entrapment and identify risks

Notes

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Confirming Feeding Tube Placement: Old Habits Die Hard

Multiple publications have addressed the indications for nasogastric or nasoenteric feeding tubes and the importance of initial and ongoing verification or confirmation of their proper placement.[1-13] In particular, studies show that feeding tubes are not medically indicated for those unable to swallow because of advanced dementia.[1,2] For patients with appropriate indications for feeding tubes, studies show that traditional methods of verifying proper placement at the bedside are not reliable. Unfortunately, these methods are still used, despite the availability of more reliable, evidence-based practices to confirm proper feeding tube placement.[3] Of greatest concern, errors have been reported to PA-PSRS even when the gold standard of confirmation, a radiograph (x-ray) of the chest, has been done but misinterpreted by a patient's physician.

This article will review reports to PA-PSRS indicating problems from misplacement of nasogastric and nasoenteric feeding tubes, review the literature on proper verification of the location of these feeding tubes, and propose algorithms for confirming the location of these tubes, based on the literature review.

Injuries from feeding tube misplacement reported in the clinical literature include aspiration pneumonia, pneumothorax, perforations, empyema, bronchopleural fistula, and even death.[4] Reports submitted to PA-PSRS also reflect complications of feeding tube misplacement, such as the following:

> *A Keofeed was inserted. A post insertion x-ray revealed that the tube was located in the left lung. The tube was removed prior to feeding being administered, but thereafter the patient developed respiratory distress. A repeat x-ray indicated a left-sided pneumothorax. A chest tube was placed which resolved the pneumothorax.*

Traditional Bedside Methods to Verify Feeding Tube Placement

The following three methods have traditionally been used to verify feeding tube placement at the bedside.

Auscultation

Auscultation involves instilling air into the feeding tube with a syringe while using a stethoscope placed over the stomach to listen for rushing air. However, this method cannot differentiate between tube placement in the stomach or the lung/bronchial tree.[3-7] For example, in one study, x-ray confirmation identified 16 instances where nasogastric tubes were not located in the stomach. However, in 15 of those instances, clinicians using the auscultation technique believed that those tubes were in the stomach.[8] Also, the auscultation method cannot determine when a feeding tube's ports end in the esophagus (a condition that predisposes to aspiration).[9] Misinterpretation of auscultation of air insufflation is known as pseudoconfirmatory gurgling.[5,7]

Bubbling

This method involves observing bubbles when the end of the feeding tube is placed under water; the appearance of bubbles is thought to indicate that the feeding tube is misplaced in the respiratory tract. However, bubbling can also occur when feeding tubes are placed in the gastrointestinal tract.[10] Also, the absence of bubbles does not rule out respiratory placement if the tube's ports are occluded by the respiratory mucosa.

Aspirate Appearance

This method involves assessing the appearance of aspirate from the tube. Ordinarily, small bowel aspirates are golden yellow or greenish brown (intestinal fluid stained with bile); in contrast, gastric aspirates are often grassy green, off-white, or tan.[11] However,

Physicians may receive continuing medical education (CME) credits related to this article through a partnership with the Pennsylvania Medical Society. See page 35 for details.

Complications Related to Feeding Tubes[4,6,14,20]

- Cardiac arrhythmias
- Hypoxemia (in dysphagic stroke patients)
- Perforation
- Esophageal ulceration
- Inflammation
- Pleural effusion
- Empyema
- Fistula formation
- Nutrient pneumonitis
- Aspiration pneumonia
- Pneumothorax
- Tracheal, bronchial, or esophageal placement
- Lung abscess
- Intracranial penetration
- Submucosal passage
- Pneumomediastinum
- Hydrothorax
- Isocalothorax (enteral feed hydrothorax)

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Confirming Feeding Tube Placement: Old Habits Die Hard (Continued)

respiratory secretions can be white, yellow, straw-colored, or clear.[5] Because both respiratory and gastrointestinal aspirates may be similar in color, they may be easily misinterpreted.

The following is a PA-PSRS report that highlights the use of these less reliable methods of confirming feeding tube placement:

> *Postoperatively, a nasogastric tube was placed. Two nurses confirmed placement by auscultating an air bolus over the epigastric region. Green fluid was aspirated. Thereafter, the patient experienced an acute drop in oxygen saturations. A bronchoscopy revealed that the NG was going through the vocal cords and not in the stomach.*

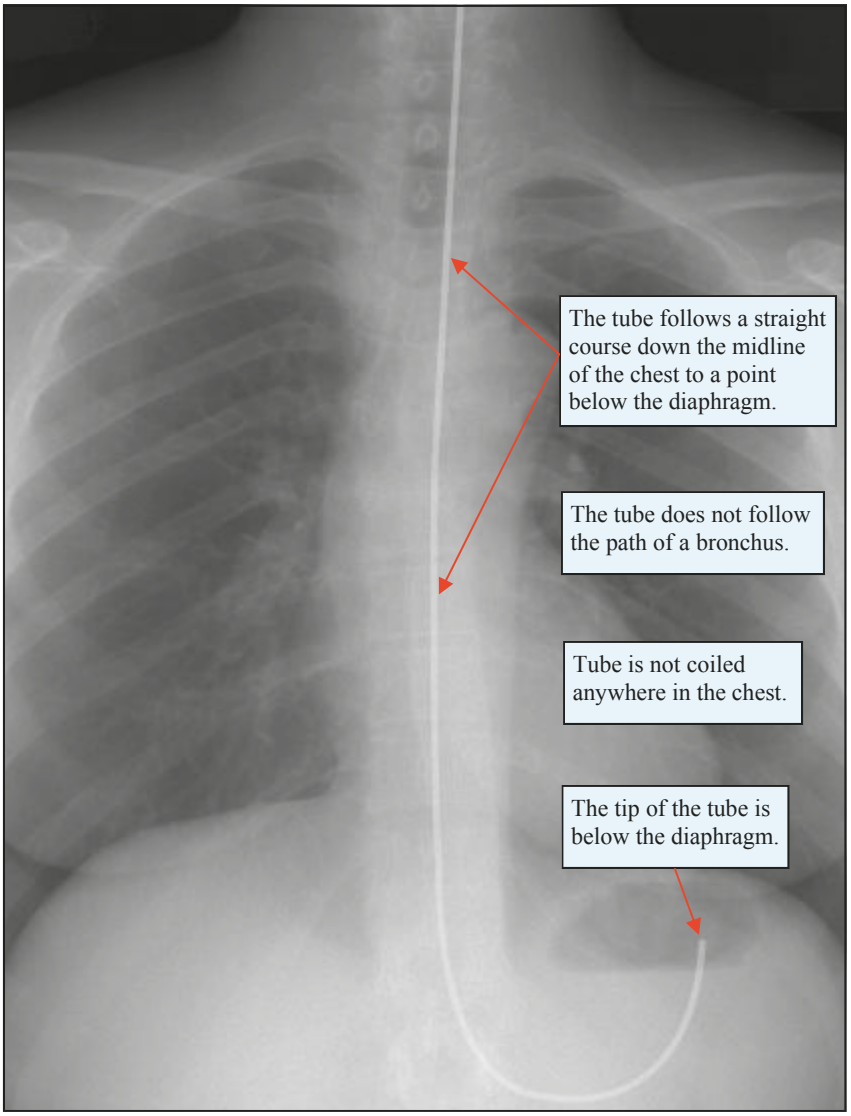

Figure 1. Chest Radiograph Representing Properly Placed Nasogastric Feeding Tube with Tip Visible

More Reliable Methods to Verify Feeding Tube Placement

Radiographic Confirmation of Nasogastric Tube Placement

The gold standard for nasogastric feeding tube placement is radiographic confirmation with a chest x-ray. The gold standard for nasoenteric feeding tube placement is radiographic confirmation with chest *and* abdominal x-rays. [4-6,12,13] While radiographs are the preferred method of confirmation for small bore feeding tubes, they are not always done when large, rigid nasogastric tubes are inserted.[10] However, some sources recommend radiographic confirmation of all blindly inserted tubes for feedings or administration of medications in high-risk patients.[9,13] Barriers to radiographic confirmation include the expense of confirmatory x-rays, the effort involved, and radiation exposure to the patient. Moreover, x-rays have been misinterpreted.[14] The following PA-PSRS reports indicate misinterpretations by nonradiologists:

> *A house physician inserted a Keofeed tube in a geriatric patient. Both the nurse and physician confirmed placement by auscultating insufflated air. The physician confirmed placement after reading the x-ray. Tube feedings were begun. The patient was found dead.*

> *A Dobhoff tube was placed by a house physician. The x-ray was read and placement confirmed. Tube feedings were initiated. The patient experienced respiratory distress. A review of the x-ray showed that the feeding tube was in the main bronchus.*

Confirmation that the feeding tube is properly placed in the stomach or small bowel involves documenting the following on a chest x-ray:

1. The tube follows a straight course down the midline of the chest to a point below the diaphragm.

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2. The tip of the tube is below the diaphragm.

3. The tube is not coiled anywhere in the chest.

4. The tube does not follow the path of a bronchus.[15]

If the tube is intended to be placed in the small bowel, an abdominal x-ray is needed to determine where the ports are situated. Small bowel feedings are needed when patients cannot tolerate gastric feedings because of significantly delayed gastric emptying, demonstrated chronic aspiration of gastric contents, or a known incompetent lower esophageal sphincter.

In the United Kingdom, the National Patient Safety Agency does not recommend the routine use of x-ray for nasogastric tube placement confirmation, reserving it for patients at high risk for misplacement of the nasogastric tube, such as the critically ill or neonates.[10]

Endoscopy and Fluoroscopy

Both endoscopy and fluoroscopy accurately verify placement of feeding tubes, but these methods can be cost-prohibitive, time-consuming, and pose additional risks, such as transporting patients to special procedures areas or imaging departments. Because fluoroscopy produces clinically significant radiation exposure, this technique is used for feeding tube placement only as a last resort.[16]

pH Testing

Another reliable method for ongoing tube placement verification is determining the pH of the fluid aspirated from feeding tubes. Gastric fluid is usually acidic, with a pH less than or equal to 5.5.[17] Respiratory secretions are almost always alkaline, with a pH greater than or equal to 6. In a large study of 1,284 aspirates from feeding tubes, all samples from the lungs had a pH greater than or equal to 6.[11] If the pH of the feeding tube aspirate is greater than or equal to 6, the tube may be inadvertently located in the respiratory tract.[11,17]

However, several conditions can affect the pH of aspirates, resulting in misinterpretation of the placement of a feeding tube.[3-7] For example, respiratory secretions may be acidic in patients with esophageal rupture, acid reflux, or a pleural infection such as empyema.[3-6] Feeding tube aspirates are usually alkaline if the tube is in the small bowel or the patient is achlorhydric.[3-6] Also, gastric pH will rise temporarily when the patient is receiving acid-inhibiting

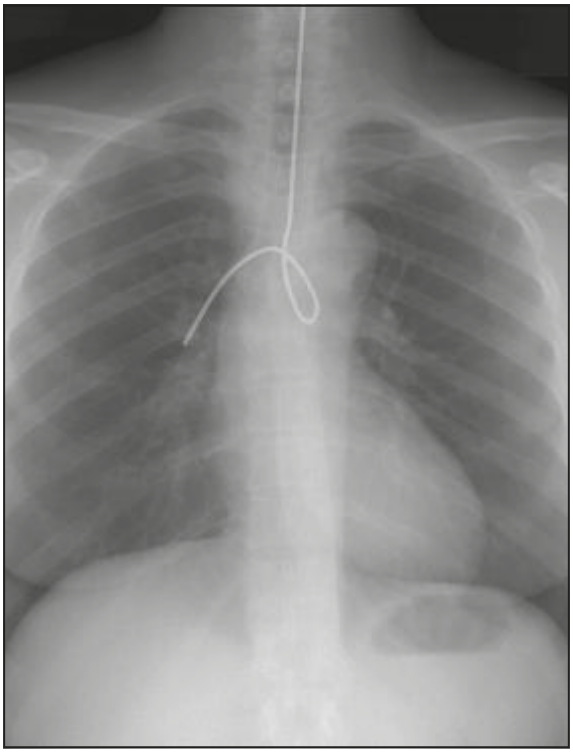

Figure 2. Chest Radiograph Representing Nasoenteric Feeding Tube Coiled in Tracheobronchial Tree

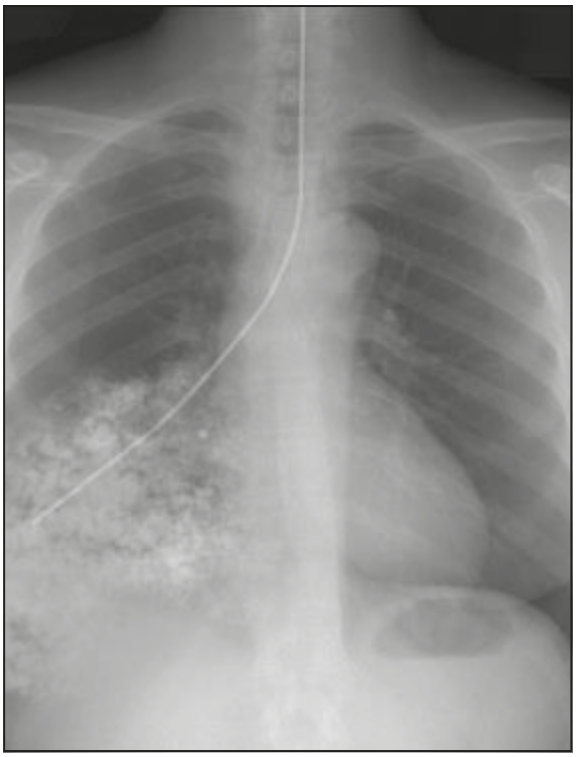

Figure 3. Chest Radiograph Representing Nasogastric Feeding Tube in Lower Lobe of Right Lung with Infiltrate

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medications (e.g., histamine$_2$-antagonist, proton pump inhibitor) or when tube feedings are in progress.[16]

In spite of the possibilities for misinterpretation, pH continues to be the most reliable bedside method for ongoing feeding tube placement confirmation, if acidic, and it is endorsed by both the U.K. National Patient Safety Agency and the American Association of Critical Care Nurses.[13,17] The pH method works best when the patient is not on acid-inhibiting medications and has been fasting for several hours before the aspirate is tested.[18]

Combination of Methods

The American Association of Critical Care Nurses[13] advises that pH testing be augmented by appearance of the aspirate to bring the accuracy closer to the gold standard, radiographic confirmation. The U.K. National Patient Safety Agency prefers pH testing without considering the appearance of the aspirate.[17]

Other Promising Placement Verification Methods

Several investigational studies have identified other methods to verify feeding tube placement:

- Combining bedside pH testing with laboratory testing of either bilirubin concentration[5] or pepsin and trypsin[18] of tube feeding aspirates provides a reasonably reliable method of verifying gastric placement of feeding tubes. However, bedside methods for measuring bilirubin, pepsin, and trypsin are not currently available.

- Capnometry accurately and reliably demonstrated when feeding tubes entered the respiratory tracts of intubated, mechanically ventilated patients. An end-tidal carbon dioxide detector is attached to the proximal end of the feeding tube.[16] In two studies, carbon dioxide was appropriately detected in transtracheal tubes and not detected in nasogastric tubes of patients in the study. The investigators advocated replacing confirmatory x-rays with capnometry.[19,20] However, this method cannot determine where the tube's ports are situated in the gastrointestinal tract (e.g., in the esophagus as opposed to the stomach or small bowel). Therefore, it cannot eliminate the need for a confirmatory x-ray.[9] Many institutions now regularly use confirmatory x-rays to ensure that a nasogastric tube's ports end in the stomach instead of the esophagus to minimize risk for aspiration of formula or medications administered via the tube.[21]

- A new technology uses copper wire coiled around a stylet of small-bore feeding tubes. The wire generates an electromagnetic signal from the tip of the stylet. A locator device, placed over the patient's xyphoid process, produces an image of the feeding tube's path on a computer screen.[16] Early research indicates that this system accurately indicated placement in 20 of 21 feeding tubes, as verified by x-ray.[22]

Some Results of Nasal Positioning of a Feeding Tube[14]

- Local ulceration
- Epistaxis
- Sinusitis
- Otitis media

Risk Factors for Incorrect Feeding Tube Placement

In general, the patients at greatest risk for misplacement are those with diminished mental status and decreased cough or gag reflexes.[23,24] Critically ill, obtunded, uncooperative, debilitated patients and those with maxillofacial or craniofacial trauma and craniofacial surgery are at greater risk for feeding tube misplacement.[6,25]

A University of Pittsburgh retrospective study of 4,190 radiographic reports identified 87 patients with a feeding tube intrabronchial malposition. Thirty-two percent of these patients experienced multiple misplacements. Each occurrence of feeding tube misplacement increased the risk for future misplacement.[23]

An endotracheal or tracheal tube cuff does not provide protection from feeding tube misplacement.[6,11] The University of Pittsburgh study revealed that two-thirds of the 87 patients with a feeding tube in a bronchus had an endotracheal or tracheal tube.[23]

A patient's apparent tolerance of a procedure cannot be interpreted as an indicator of proper feeding tube placement.[12] For example, consider the following PA-PSRS report:

> *According to physician orders, a nurse placed an NG tube in an unresponsive patient for tube feedings. Placement was verified with air and residual. A second nurse verified placement. Tube feedings*

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Confirming Feeding Tube Placement: Old Habits Die Hard (Continued)

were initiated. The patient did not demonstrate any respiratory problems initially. Thereafter, the patient was noted to be mottled and having respiratory distress. A chest x-ray indicated that the NG tube was positioned in the lower lobe of the left lung. The patient received more than 100 cc of tube feeding. The patient was placed on a ventilator.

Marderstein et al.[23] recommend an initial scout film on critically ill patients when the tube has been advanced 40 cm, so that its midline position can be confirmed beyond the level of the carina, but before an errant tube in the bronchus would begin violating the lung tissue and causing a pneumothorax. If the tube is clearly not in the tracheo-bronchial tree, it is then advanced into the stomach or small bowel, and a second x-ray is done for final confirmation.

Pediatric Considerations

Nursing practices to verify feeding tube placement in adults can be adapted for children.[26] For example, radiographic confirmation of placement and the pH method are effective in both adults and children. When radiographic confirmation is not possible, such as when the patient is at home, the pH method is an acceptable option.[13] Pediatric home care nurses can teach parents how to place feeding tubes and to verify placement before each feeding.[3]

Proposed Strategies for Minimizing the Risk of Nasogastric or Nasoenteric Feeding Tube Misplacement

No method of verifying feeding tube placement is 100% effective. However, algorithms are proposed, based on the literature, to minimize the risk of misplaced nasogastric and nasoenteric feeding tubes (see page 29). Critical points include the following:

- Using feeding tubes for patients with appropriate medical indications. For example, feeding tubes are not medically indicated for patients who are unable to swallow because of advanced dementia.[1,2]

- Requiring radiographic confirmation of feeding tube placement, if radiography is available, prior to initiating tube feedings, particularly in patients at high risk for tube misplacement.

- Using the pH method to confirm placement when x-rays are not practical, keeping in mind that a pH of 6 or greater has multiple possible reasons:[17]
  — The aspirate may be from the esophagus or tracheobroncial tree.
  — The aspirate may be from the small bowel.
  — The patient may have achlorhydria.
  — The patient may be receiving acid-inhibiting medications.
  — Feedings in the stomach may buffer the pH of gastric secretions.

- Frequently assessing patients with diminished mental status for findings indicative of feeding tube misplacement,[17] such as
  — unexplained gagging, vomiting, or coughing,
  — signs of respiratory distress, and
  — reduced oxygen saturation.

- After initiation of tube feedings, regularly assessing the external length of tubing extending from the insertion site to detect changes. This method requires that the tube's exit site be marked with ink at the time of initial radiographic confirmation of correct placement. A large increase in external tube length may indicate the tube has been pulled out partially and is no longer in the desired site.[27]

Several other strategies, including the following, may also help the efforts to minimize the risk of misplacements:

- Developing and revising policies and procedures to provide guidance, standardization, and consistency regarding feeding tube indications, placement, and steps to verify placement.

- Ensuring that healthcare providers have proven competencies:
  — For feeding tube insertion
  — For verification of proper placement
  — For accurate interpretation of confirmatory radiographics

- Implementing a specialized team of nurses, such as an enteral access team, to help ensure competent feeding tube placement, consistent practices, and reduced complications.[23]

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Confirming Feeding Tube Placement: Old Habits Die Hard (Continued)

- Requiring that attending radiologists or credentialed non-radiologists read x-rays to confirm feeding tube placement before initiating feedings.

- Considering implementation of any newer, promising placement verification method if studies confirm efficacy.

Resources

Sources of information available on the Internet for staff education and policy development include the following:

- American Association of Critical Care Nurses
  — Practice Alert: Verification of Feeding Tube Placement[13] (available from Internet: http://www.aacn.org/AACN/aacnnews.nsf/GetArticle/ArticleThree225).

- U.K. National Patient Safety Agency
  — How to Confirm the Correct Position of Nasogastric Feeding Tubes in Infants, Children and Adults[17] (available from Internet: http://www.npsa.nhs.uk/site/media/documents/857_Insert-finalWeb.pdf).
  — How to Confirm the Correct Position of Naso and Orogastric Feeding Tubes in Babies under the Care of Neonatal Units[28] (available from Internet: http://www.npsa.nhs.uk/site/media/documents/1298_InterimAdvice.pdf).

Conclusion

Because "it's always been done this way" is not a good reason for healthcare workers to continue using less reliable methods to confirm feeding tube placement. Implementing evidence-based methods will promote a safer environment of patient care.

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Suggested Algorithms for Minimizing the Risk of Nasogastric or Nasoentric Feeding Tube Misplacement

I. Verifying the initial insertion of a nasogastric or nasoenteric feeding tube.

A. Is a nasogastric or nasoenteric feeding tube indicated?[1,2] (If not, no tube is inserted.)

B. Should the tube end in the stomach or small bowel? (See text for some indications for small bowel feedings.)

- For the initial insertion of a nasogastric feeding tube, go to algorithm II.
- For the ongoing confirmation of the placement of a nasogastric feeding tube, go to algorithm III.
- For the initial insertion of a nasoenteric feeding tube, go to algorithm IV.
- For the ongoing confirmation of the placement of a nasoenteric feeding tube, go to algorithm V.

II. Confirmation of the initial insertion of a nasogastric feeding tube.

A. Is radiography available for x-ray confirmation?

If Yes:

- Confirm (and document) that the nasogastric tube follows a straight course down the midline of the chest to a point below the diaphragm, that the tip of the tube is below the diaphragm, that the tube is not coiled anywhere in the chest, and that the tube does not follow the path of a bronchus.[15]
  - If the tip of the tube is below the lower edge of the x-ray, get an abdominal flat plate.
  - If confirmed, begin tube feedings when appropriate and observe for findings indicative of feeding tube misplacement[17] (see text).
  - If not confirmed, reposition and repeat the confirmation process.

If No:

- Check (and document) the gastric pH.
  - If the gastric pH is less than or equal to 5.5, begin tube feedings when appropriate and observe for findings indicative of feeding tube misplacement[17] (see text).
  - If the gastric pH is greater than or equal to 6 and the patient has reason for the pH to be temporarily elevated (medications or food), wait for the effect to wear off, if possible, and recheck the gastric pH.
  - Otherwise, if the gastric pH is greater than or equal to 6, arrange for x-ray confirmation before feeding.

III. Ongoing confirmation of the placement of a nasogastric feeding tube.

A. For intermittent tube feedings or nasogastric administration of medications:

- Before each tube feeding or nasogastric administration of medication, check (and document) the gastric pH.
  - If the gastric pH is less than or equal to 5.5, continue the tube feedings or administration of medications and observe for findings indicative of feeding tube misplacement[17] (see text).
  - If the gastric pH is greater than or equal to 6 and the patient has reason for the pH to be temporarily elevated (other medications or residual tube feedings), wait for the effect to wear off, if possible, and recheck the gastric pH.
  - If the gastric pH is greater than or equal to 6 and the patient is known to have a pH persistently in that range, continue the tube feedings or administration of medications and observe for clinical findings indicative of feeding tube misplacement[17] (see text).
  - Otherwise, if the gastric pH is greater than or equal to 6, arrange for x-ray confirmation before feeding or administering medication via the nasogastric tube.

B. For continuous tube feedings:

- At least once daily, if possible, and whenever clinical findings of feeding tube misplacement are observed, stop feedings until the stomach is empty, check for residual tube feedings, and check (and document) the gastric pH.
  - If the gastric pH is greater than or equal to 6 and the patient has reason for the pH to be temporarily elevated (other medications or residual tube feedings), wait for the effect to wear off, if possible, and recheck the gastric pH.
  - If the gastric pH is greater than or equal to 6 and the patient is known to have a pH persistently in that range, continue the tube feedings and observe for clinical findings indicative of feeding tube misplacement[17] (see text).
  - Otherwise, if the gastric pH is greater than or equal to 6, arrange for x-ray confirmation before continuing feedings.

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Suggested Algorithms for Minimizing the Risk of Nasogastric or Nasoentric Feeding Tube Misplacement (Continued)

IV. Confirmation of the initial insertion of a nasoenteric feeding tube.

(It is assumed that a nasoenteric feeding tube would only be inserted under direct endoscopic visualization, which would need no further initial verification, or with the capability for x-ray confirmation.)

- Confirm (and document) — using both a chest x-ray and an abdominal flat plate — that the nasoenteric tube follows a straight course down the midline of the chest to a point below the diaphragm, that the tip of the tube is below the diaphragm, but not in the stomach, that the tube is not coiled anywhere in the chest, and that the tube does not follow the path of a bronchus.[15]
  - If confirmed, begin tube feedings when appropriate and observe for findings indicative of feeding tube misplacement[17] (see text).
  - If not confirmed, reposition and repeat the confirmation process.

V. Ongoing confirmation of the placement of a nasoenteric feeding tube.

(It is assumed that feedings are continuous.)

- Whenever clinical findings of feeding tube misplacement are observed (see text), stop feedings until the upper small bowel is empty, check for residual tube feedings, and confirm (and document) — using an abdominal flat plate — that the tip of the nasoenteric tube is below the diaphragm, but not in the stomach.
  - If confirmed, resume tube feedings and observe for findings indicative of feeding tube misplacement[17] (see text).
  - If not confirmed, reposition and repeat the confirmation process.
- In patients at high risk for misplacement of nasoenteric feeding tubes (see text), at least once daily, if possible, stop feedings until the upper small bowel is empty, then check tube feeding residuals and the pH of the aspirate.
  - If the pH of the aspirate is greater than or equal to 6, continue the tube feedings and observe for findings indicative of feeding tube misplacement[17] (see text).
  - If the pH of the aspirate is less than or equal to 5.5, confirm (and document) -- using an abdominal flat plate — that the tip of the nasoenteric tube is below the diaphragm, but not in the stomach.
    - If confirmed, resume tube feedings and observe for findings indicative of feeding tube misplacement[17] (see text).
    - If not confirmed, reposition and repeat the confirmation process.

Upcoming PSA Training Programs

The Patient Safety Authority is planning several training programs for early 2007.

A one-and-a-half day workshop on failure mode and effects analysis (FMEA) will be offered in the eastern, central, and western regions.

This workshop will present an opportunity for small teams from Pennsylvania healthcare facilities to get hands-on experience with the tasks involved in an FMEA project. This workshop is appropriate for those who may have been involved in one or more FMEA projects in the past but would like more in-depth guidance, but it will also be useful for individuals who are new to the process.

Concurrently with the FMEA training sessions in each region, the Authority will offer a half-day seminar on PA-PSRS Basics. Intended for new users, this session will cover Pennsylvania's reporting requirements, basic system features and navigation, and how to submit a report. There will be no charge to attend this session.

More information will be distributed to Pennsylvania Patient Safety Officers in the coming weeks.

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Let's Stop the Bleeding: Preventing Errors with Heparin Therapy

A recent medication error that occurred in an Indiana hospital received nationwide publicity when three premature infants died as a result. The infants mistakenly received overdoses of heparin because the wrong strength was used to prepare flush solutions for umbilical lines. The error occurred when heparin 10,000 units/mL, 1 mL vials inadvertently were placed into a unit-based automated dispensing cabinet (ADC) pocket where heparin 10 units/mL, 1 mL vials were normally kept. While nothing can erase the grief experienced by the families and hospital workers in the wake of this tragic incident, it does serve as a reminder of the need to take a closer look at heparin utilization in our facilities.[1]

Heparin is an anticoagulant and one of the oldest drugs still in widespread clinical use. When administered, the medication prevents formation of new clots while allowing the body's natural clot lysis mechanism to work normally to break down clots that have previously formed.[2]

Heparin's clinical uses include the following:[2]

- To prevent existing clots from enlarging and then blocking coronary arteries in patients with unstable angina
- To treat (i.e., acutely) and prevent (i.e., prophylactically) deep-vein thrombosis and pulmonary emboli
- To decrease the risk of patients with atrial fibrillation developing blood clots in the left atrium of the heart
- To prevent coagulation as blood passes through an extracorporeal circuit during dialysis
- To maintain the patency of indwelling intravenous catheters

While heparin provides many benefits, this medication can be very dangerous, and errors involving heparin have a heightened risk of significant patient harm. For this reason, heparin is considered a high-alert medication that requires special safeguards to reduce the risk of errors.[3]

Errors associated with heparin use are as multifaceted as its indications. Common types of errors, with causative factors similar to the case mentioned above, that have been reported to PA-PSRS include wrong-drug errors due to look-alike packaging and names, wrong-dose errors, and the concomitant administration of heparin with other medications that have anticoagulant or antithrombotic effects.

Look-Alike Packaging

Look-alike packaging of heparin and other intravenous (IV) products (e.g., lidocaine, dopamine, hetastarch in sodium chloride [HESPAN]), is a frequent source of medication mix-ups (see Figure 1). The bags of these other products can be the same size as heparin IV bags and use the same fonts, font sizes, and color schemes. Examples of medication error reports submitted to PA-PSRS include the following:

> *Nurse was approached by a technician and asked if patient was still on lidocaine. The nurse stated "yes." The technician then informed the nurse that a heparin bag was hanging on the patient's IV pump, not lidocaine. The nurse immediately stopped the heparin infusion and drew an aPTT. Lidocaine was restarted per physician order. The patient was not injured.*

> *Staff found dopamine infusing instead of heparin drip. Bag had been hung approximately 12 hours prior, and half of 250 mL bag was infused. The doctor was notified, and monitoring was increased. No harm was noted.*

Figure 1. Look-Alike Packaging on IV Bags. Image provided to PA-PSRS courtesy of a Pennsylvania healthcare facility.

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Let's Stop the Bleeding: Preventing Errors with Heparin Therapy (Continued)

Pharmacy technician mislabeled heparin drip on a pre-mixed bag of lidocaine. Pharmacist did not detect error when checking the medication. Nurse noticed error prior to administering the medication to the patient.

Physician ordered HESPAN 50 mL/hr for 10 hours. Nurse hung heparin 20,000 units in 500 mL, all of which was infused. At this point, aPTT was greater than 100, Hemoglobin was 7.2, and Hematocrit was 21.4. Patient was awake and alert with stable vital signs. The physician ordered protamine.

A number of error reports involving premixed heparin and HESPAN have been submitted to the USP-ISMP Medication Errors Reporting Program (MERP).[4] These reports indicate that look-alike names (i.e., heparin and HESPAN) and manufacturer packaging frequently contribute to the mix-up of these products. Many errors have occurred when nurses have retrieved heparin from an ADC in which heparin and HESPAN were stored, and where both names appeared as choices on the machine's computer screen. Since HESPAN, a plasma expander, is sometimes used in patients who are actively bleeding, administering heparin instead can be very hazardous. In one event, an intensive care unit nurse mistakenly selected a heparin 25,000 unit/500 mL premixed container instead of HESPAN and administered two bags to a patient who was actively bleeding. The heparin infusion started at 11 p.m. and was repeated at 2 a.m. At 6 a.m., the patient had a bloody stool, and her hemoglobin and hematocrit levels, previously within normal limits, had fallen to 7.3 g/dL and 28%, respectively. These levels led to consideration of a hemorrhagic event, and several hours later, to discovery of the medication error. By that time, the patient had hemorrhaged extensively, and despite attempts to reverse the effects of heparin, she died later that morning.

Stocking Errors

Stocking errors are fairly common with heparin products, as many of the manufactured vials are very similar in appearance, come in a variety of concentrations, and often are stored in close proximity in the pharmacy, making it easy to grab the wrong vial when refilling floor stock requests.[5] A stocking error contributed to the aforementioned fatal neonatal administration error. The vials looked very similar (see

Physicians may receive continuing medical education (CME) credits related to this article through a partnership with the Pennsylvania Medical Society. See page 35 for details.

Figure 2. Heparin Products of Similar Appearance. Image provided courtesy of ISMP.

Figure 2). Several nurses requested 10 units/mL vials to prepare an umbilical line flush and were directed to that drawer in the ADC, but they did not notice that the vials contained the wrong concentration of heparin.[1]

A variety of heparin stocking errors have been reported to PA-PSRS, including mix-ups between heparin products and with other medications:

A 69-year-old female was admitted for GI bleed. During admission, patient was found to have oozing blood in the area of her sacrum. After being notified, the attending ordered 2.5 mg Vitamin K PO. Patient's last INR was 2.9 and PT 30.6. Staff later identified that heparin 5,000 units/mL was stocked in Pyxis with heparin 100 units/mL flush. Given patient's unexplained bleeding, another set of labs were drawn which found an INR of 10.9 and aPTT of greater than 160. The attending was notified, and 10 mg Vitamin K was given at 4 a.m., 1 unit FFP at 5 a.m. Pharmacy was notified, and a housewide check of all Pyxis cabinets was done immediately. Subsequently, patient was treated with additional blood products and returned to a hemodynamically stable state.

RN was asked to obtain epinephrine 1:10,000 and could not locate the medication in the room. RN left the room to procure the medication in the anesthesia workroom. Upon opening the medication cabinet, she chose a vial with "10,000" on the label. Medication mixed with 4 cc NSS and administered to patient via injector needle.

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Let's Stop the Bleeding: Preventing Errors with Heparin Therapy (Continued)

After patient left the room, the N.M. [nurse manager] was in the room assisting the staff to look for epinephrine in the medication drawer. The N.M. noted that Heparin vials were inadvertently placed in the drawer and brought this to the RN's attention. The RN looked in the sharps box and discovered that she had handed the scrub RN heparin instead of epinephrine.

The staff RN pulled heparin to give to the patient. Oxytocin was found in the drawer. The vials appeared very similar. The medications were removed from Pyxis and returned to pharmacy.

When the nurse went to retrieve heparin, Benadryl was found in the medication drawer. The nurse found two other vials; they were removed, and pharmacy was notified. The nurse noted both heparin and Benadryl vials are blue and white in color.

Eight vials of Magnesium sulfate were found in drawer with heparin 5,000 units in a Pyxis machine. Six vials magnesium sulfate found in drawer with heparin in a second Pyxis machine. Pharmacy was made aware. The patient did not receive the wrong medication.

In an error reported to the MERP, a physician asked for heparin 2,000 units during a procedure. The nurse retrieved 2 vials of heparin from an ADC that was supposed to be stocked with 1,000 units/mL, 1 mL vials. But a pharmacy technician had accidentally stocked the cabinet with look-alike vials of heparin 10,000 units/mL, 1 mL vials. The patient received heparin 20,000 units, but the nurse quickly noticed the mistake, and the patient received protamine sulfate with no resulting harm. In the pharmacy, the 10,000 units/mL concentration was stored next to the 1,000 units/mL concentration, and a pharmacist had not checked the heparin before the technician restocked the cabinet. [5]

Concomitant Therapies

Other tragic errors occur when low molecular weight heparin products, such as Fragmin (dalteparin sodium), Lovenox (enoxaparin sodium), and Innohep (tinzaparin sodium), are inadvertently initiated in patients that are concurrently being administered heparin infusions or vice versa. Many of these errors result from poor communication of a patient's medication regimen to caregivers. Many times, low molecular weight heparin is prescribed and administered in the emergency department (ED). Consequently, those orders are rarely communicated to the pharmacy or screened for safety.[6] Additionally, breakdowns in the medication reconciliation process can leave personnel on the nursing unit without knowledge of what was administered in the ED.

Reports of concomitant heparin and low molecular weight heparin products submitted to PA-PSRS include the following:

Patient was given LOVENOX in the ED. A verbal order for a heparin drip was received, and the drip was started. Labs were obtained, and there were no signs of bleeding.

Patient was ordered and received one dose of FRAGMIN at 1,200. Another physician, unaware of FRAGMIN therapy, ordered weight-based heparin protocol at 1,500. Patient received bolus of heparin, and drip was administered for three hours before the error was discovered.

Order for LOVENOX was received by pharmacy. Some hours later the pharmacy received heparin protocol dose adjustment order. Pharmacist called to ask why heparin was still infusing since it was discontinued. Nursing had not seen the discontinue order.

In a case reported to the MERP, a hospitalized 86-year-old woman with a history of atrial fibrillation was prescribed Lovenox (enoxaparin) 60 mg every 12 hours subcutaneously by her cardiologist. On the following day, warfarin was added to the drug regimen. Later in the week, a gastroenterologist recommended a colonoscopy to rule out colorectal cancer. Warfarin was discontinued, and a heparin infusion was ordered. However, enoxaparin administration continued every 12 hours, and the heparin order was never faxed to the pharmacy. To administer the bolus and begin the infusion, the nurse borrowed a vial of heparin and a premixed solution that the pharmacy had dispensed for another patient. Several hours later, the patient's aPTT was above the therapeutic range. The heparin infusion was decreased, but by the next morning, the patient's aPTT was still elevated, her hemoglobin and hematocrit had dropped, and she exhibited evidence of internal bleeding. Heparin and enoxaparin were discontinued immediately, but the patient died despite aggressive treatment. [6]

Potential Solutions

The case reports in this article and many others that have been reported to PA-PSRS emphasize that

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Let's Stop the Bleeding: Preventing Errors with Heparin Therapy (Continued)

heparin is a high-alert medication that is prescribed, dispensed, and administered via error-prone processes. To protect patients who are at risk for an adverse outcome if an error occurs, this high-alert medication warrants unique handling.

The following strategies may help reduce the incidence of heparin-related errors: [1,4-6]

Reviewing the medication record. It is important for prescribers, pharmacists, and nurses to consider recent drug therapy before ordering, dispensing, and administering any anticoagulants or antithrombotic agents. Protocols, guidelines, and standard order forms can feature prominent reminders to asses all drug therapy (including medications administered in the ED) and avoid unintentional use of more than one anticoagulant in a patient.

Improving access to information. Instituting a process for immediate communication with the pharmacy, upon a patient's admission to the hospital, of all medications administered in the ED or other outpatient settings will enable pharmacy to enter the medications into the pharmacy computer system and screen for duplicate therapy or interactions with medications prescribed upon admission.

Testing computer systems. Testing both computerized prescriber order entry systems and pharmacy computer systems can help to ensure that staff are alerted when heparin and low molecular weight heparin products are ordered on the same patient.

Segregating look-alike products. Store products with look-alike packaging in different locations in pharmacies, patient care units, and other settings. Use shelf stickers to help locate the product that has been moved.

Reducing similarity of containers. Assess packaging of all heparin products to identify any possibility for confusion. Remedy problems by repackaging medications, affixing auxiliary labels to products, or switching manufacturers to improve distinction and clarity of labeling and packaging.

Reducing access. Limit the concentrations of heparin products stored in patient areas. Whenever possible, allow only one concentration for bolus doses, and use pre-filled syringes for all heparin flushes. Avoid stocking items on nursing units that require further preparation by nurses before administration.

Conducting independent double-checks. Having an independent double-check of heparin products before they leave the pharmacy can prevent mistakes. Consider having a pharmacist (or a technician, if necessary) check all products pulled for restocking of ADCs before they leave the pharmacy. In addition, many facilities have instituted a double-check by nursing staff before heparin administration.

Implementing bar-code technology. Bar-code technology can be employed for selecting and stocking medications in ADCs and before administering medications to patients. Bar-coding is valuable for bedside scanning to confirm the accuracy of the patient, drug and dose of medication.

Even if these problems with heparin use are not obvious in your facility today, every facility can proactively anticipate and focus on problems with heparin use by discussing heparin errors that have happened at other facilities and incorporating the risk reduction strategies presented above.

Notes

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Self Assessment Questions

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

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Bone Cement Implantation Syndrome

1. Symptoms of bone cement implantation syndrome (BCIS) may include:
   A. Cardiac dysrhythmia/arrhythmia, hypotension, death
   B. Cardiac dysrhythmia/arrhythmia, hyperthermia, death
   C. Inflammation, pain, cellulitis
   D. Fracture, neurological impairment, osteoporosis

2. The underlying causes of BCIS symptoms include:
   A. Endocrine imbalance and erratic blood glucose control
   B. Liver and renal failure
   C. Sepsis and malignant hyperthermia
   D. Right ventricular failure and hemodynamic effects of medullary fat embolus

3. Usually BCIS symptoms occur during or within minutes of cementing the prosthesis.
   A. True
   B. False

4. BCIS risk factors include:
   A. Diseases that compromise the immune system
   B. Hypovolemia and pre-existing cardiac problems
   C. Multiple sclerosis and Parkinson's disease
   D. Diabetes mellitus and low serum albumin

5. BCIS-specific risk reduction strategies include all but:
   A. Postponing arthroplasty until patient's cardiac condition is stabilized
   B. Controlling intramedullary pressure
   C. Performing uncemented procedures in high-risk patients
   D. Labeling all basins, bowls, cups, and syringes used intraoperatively

Confirming Feeding Tube Placement: Old Habits Die Hard

1. A reliable indicator of correct nasogastric tube placement in the patient is hearing air being insufflated on auscultation of the abdomen over the stomach.
   A. True
   B. False

2. The pH of nasogastric tube aspirates can be affected by:
   A. Oxygen saturation and blood glucose
   B. Tube feedings and medications
   C. Diarrhea and obstipation
   D. None of the above

3. Risk factors for feeding tube misplacement include:
   A. Renal and liver failure
   B. Pneumonia and gastritis
   C. Maxillofacial or craniofacial trauma and obtunded patients
   D. Active cough and gag reflexes

4. Effective risk reduction strategies include:
   A. Combining auscultation with radiographic confirmation
   B. Combining bubbling with inserting feeding tubes in patients unable to swallow because of advanced dementia
   C. Combining auscultation, bubbling, and aspirate appearance
   D. Combining pH testing with aspirate appearance and radiographic confirmation

5. Feeding tube placement in the stomach is confirmed if the chest x-ray indicates:
   A. The tip of the tube is below the level of the diaphragm
   B. The tube is coiled in the chest, but remains in the midline
   C. The tube does not follow the path of a bronchus
   D. The tube follows a straight course down the midline of the chest with the tip below the level of the diaphragm

Let's Stop the Bleeding: Preventing Errors with Heparin Therapy

1. Heparin's mechanism of action allows the medication to break down clots that have already formed.
   A. True
   B. False

2. Heparin's clinical uses include which of the following?
   A. To prevent existing clots from enlarging and then blocking coronary arteries in patients with unstable angina.
   B. To treat (i.e., acutely) and prevent (i.e., prophylactically) deep-vein thrombosis and pulmonary emboli.
   C. To decrease the risk of patients with atrial fibrillation developing blood clots in the left atrium of the heart.
   D. To prevent coagulation as blood passes through an extracorporeal circuit during dialysis.
   E. All of the above

3. Which medications have the potential to be mixed-up with heparin products (i.e., due to look-alike packaging) and be mistakenly administered to your patient?
   A. Lidocaine
   B. Dopamine
   C. Hetastarch
   D. All of the above

4. Tragic errors have occurred when which one of the following have been concomitantly administered with heparin?
   A. cephalosporins
   B. anti-psychotics
   C. corticosteroids
   D. low molecular weight heparins (LMWHs)

5. Strategies that will help to prevent medication errors associated with heparin include all EXCEPT which one of the following?
   A. Considering recent drug therapy before ordering any anticoagulants or antithrombotic agents.
   B. Assume that computerized prescriber order entry systems and pharmacy computer systems will provide alerts when heparin and low molecular weight heparin products are ordered on the same patient.
   C. Developing protocols, guidelines, and standard order forms that feature prominent reminders to assess all drug therapy (including medications administered in the emergency department) and avoiding concomitant use when indicated.
   D. Upon a patient's admission to the hospital, communicating with the pharmacy about all medications administered in the emergency department or other outpatient settings.

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The Patient Safety Authority is an independent state agency created by Act 13 of 2002, the Medical Care Availability and Reduction of Error ("Mcare") Act. Consistent with Act 13, ECRI, as contractor for the PA-PSRS program, is issuing this newsletter to advise medical facilities of immediate changes that can be instituted to reduce serious events and incidents. For more information about the PA-PSRS program or the Patient Safety Authority, see the Authority's website at www.psa.state.pa.us.

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

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

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