PENNSYLVANIA PATIENT SAFETY ADVISORY

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OBJECTIVE

The *Pennsylvania Patient Safety Advisory* provides timely original scientific evidence and reviews of scientific evidence that can be used by healthcare systems and providers to improve healthcare delivery systems and educate providers about safe healthcare practices. The emphasis is on problems reported to the Pennsylvania Patient Safety Authority, especially those associated with a high combination of frequency, severity, and possibility of solution; novel problems and solutions; and those in which urgent communication of information could have a significant impact on patient outcomes.

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Medication Errors in the Emergency Department: Need for Pharmacy Involvement?

ABSTRACT

Of all care areas mentioned in medication error reports submitted from August 1, 2009, through July 31, 2010, to the Pennsylvania Patient Safety Authority, the emergency department (ED) is the third most commonly mentioned, appearing in 6% of all medication error reports. The predominant medication error event types in the ED include wrong dose/overdosage, drug omission, and wrong drug. The predominant classes of drugs mentioned in wrong-dose/overdosage error reports include antibiotics, steroids, anticoagulants/antithrombotics, opioids, and nonsteroidal anti-inflammatory agents. Possible risk reduction strategies include expanding the role of the pharmacy department in the ED's medication-use process, limiting the number and variety of medications and concentrations available in the ED, and incorporating redundancies (e.g., order read-back) throughout the medication-use process. (Pa Patient Saf Advis 2011 Mar;8[1]:1-7.)

INTRODUCTION

Between 1996 and 2006, visits to U.S. emergency departments (EDs) increased by 32%, from 90.3 million to 119.2 million.[1] During the same period, the number of EDs decreased approximately 5%. The disparity has contributed to crowding of EDs and boarding of patients waiting for admission or transfer. These quality issues, combined with a high volume of patients seeking episodic care for a wide range of acute and chronic illnesses and injuries, shortages of healthcare workers, and a complex healthcare environment, increase the potential for compromised patient safety in the ED.[2] In addition, an inadequate information infrastructure across the care continuum often forces emergency providers to care for patients without all essential patient information.

One study (Santell et al.) of a national medication error database found that nearly 11,000 medication errors were reported over a five-year period by EDs in 484 unique facilities.[3] Of these errors, 4.8% resulted in patient harm, including five fatalities. Drug administration was the most often reported phase of the medication-use process in which the error originated (45%), followed by prescribing (29%). Dispensing errors accounted for approximately 9% of the reported errors. A second, prospective, observational study was performed in a 40-bed, academic, tertiary ED with an annual census of approximately 70,000 patients to determine the rate and severity of medication errors, as well as common contributing factors associated with error occurrence. The study identified 178 medication errors in 192 patients. At least one error involved 59.4% of patients; 37% of patients overall had an error that reached them. No errors in the study resulted in permanent harm or contributed to initial or prolonged hospitalization; however, interventions performed to prevent harm likely influenced the severity of the errors. In contrast to the study performed by Santell et al.,[3] the reported phase in which the error originated most often was prescribing (53.9%), followed by administration (34.8%), transcribing (10.7%), and dispensing (0.6%). The study concluded that medication errors in the ED are common, with errors occurring most often in the prescribing and administration phases.[4] The results from the two studies may reflect the fact that the two phases of the medication-use process that occur most in the ED are prescribing and administration.

A possible contributing factor to medication errors in the ED is the unique medication distribution system used in this care area, which differs from that of the inpatient units. For example, medications in EDs may, when urgently needed, be retrieved from a non-pharmacy-profiled automated dispensing cabinet (ADC), unit stock, or refrigerator, and the prescriber's order may not be reviewed by a pharmacist before the drugs are given.[5]

MEDICATION ERRORS IN PENNSYLVANIA EDs

Of all the medication error events that Pennsylvania healthcare facilities reported to the Pennsylvania Patient Safety Authority from August 1, 2009, through July 31, 2010, 2,569 occurred in the ED. In that period, the ED ranked as the third most commonly mentioned care area in which medication events occurred, cited in 6% of all medication error reports. Categorization of the reports by harm score, which is adapted from the National Coordinating Council for Medication Error Reporting and Prevention harm index,[6] shows that 61.7% (n = 1,584) of the events reached the patient (harm index = C to I) and 0.6% (n = 16) of the events resulted in patient harm (harm index = E to I).

National data (1996 through 2006) shows that the age group with the highest annual per capita ED visit rate was infants younger than 12 months, at 84.5 visits per 100 infants (or about 3.5 million visits).[1] Individuals aged 75 years and older had the second

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highest per capita ED visit rate, at 60.2 visits per 100 individuals (representing about 10.2 million visits). By contrast, of the events reported to the Authority, 42.8% (n = 1,100) involved adults between the ages of 17 and 64, while 27.6% (n = 710) involved pediatric patients (ages less than 17 years), and 29.5% (n = 759) involved the elderly population (65 years and older).

The most prevalent medication error event types reported from the ED (see Table 1) included wrong dose/overdosage (17.6%, n = 452), drug omission (13.7%, n = 353), and wrong drug (10.5%, n = 269).

In U.S. healthcare facilities, medications were either given in the ED or prescribed at discharge in 76.6% of visits, with a total of about 212 million drugs given/prescribed, or 1.8 per visit.[1] The leading therapeutic drug classes ordered or prescribed during ED visits were analgesics, including narcotic and nonnarcotic pain medications as well as nonsteroidal anti-inflammatory drugs (NSAIDs) (36.8%); antimicrobials, including cephalosporins, penicillins, quinolones, macrolides, and sulfonamides (15.9%); and antiemetic or antivertigo agents (8.9%). Coincidentally, the class of medication mentioned most often in ED-related medication error reports submitted to the Authority (see Table 2) was antibiotics (21.8%, n = 560), followed by anticoagulants/antithrombotics (9.7%, n = 248) and opioids (8.3%, n = 214).

Drug Omission Errors in the ED

The drug classes most frequently mentioned in drug omission reports included antibiotics (26.4%, n = 93), anticoagulants (9.3%, n = 33), NSAIDs (5.9%, n = 21), and hypoglycemics (5.9%, n = 21). High-alert medications, drugs that bear a heightened risk of causing significant patient harm when they are used in error,[7] represented 21.8% (n = 77) of all reported drug omissions.

Of drug omissions involving the elderly (n = 156), the predominant class of omitted medications was antibiotics (31%, n = 48). The next class was anticoagulants (i.e., heparin, warfarin, enoxaparin) (11.5%, n = 18), which represented more than half of all high-alert medications involved in omissions among the elderly (21.2% of omissions, n = 33).

> *Orders were written for adult deep venous thrombosis [DVT] prevention for Lovenox®. The patient was held in the ED overnight and sent to the floor the next day. The order for Lovenox was found the following day, and it was faxed to the pharmacy. The next day, a CT [computed tomography] scan of the chest showed pulmonary emboli. Orders [were written] to start heparin for pulmonary embolism/DVT protocol and the Lovenox was discontinued.*

Only 25 reports (7.1%) of drug omissions involved the pediatric population, with the medications most frequently mentioned including albuterol (36% of pediatric omissions, n = 9) and ibuprofen (16%, n = 4).

Wrong-Dose/Overdosage Errors in the ED

The predominant classes of medications associated with wrong-dose/overdosage errors were similar to those associated with all event types combined, namely antibiotics (21.7%, n = 98), steroids (11.1%, n = 50), anticoagulants/antithrombotics (9.5%, n = 43), NSAIDs (7.7%, n = 35), and opioids (6.2%, n = 28). The most common medications mentioned in wrong-dose/overdosage reports are listed in Table 3.

While 24.1% (n = 109) of wrong-dose/overdosage events involved a high-alert medication, unlike the harm score breakdown for the overall data, only 33.8% (n = 153) of the events actually reached the patient and 0.9% (n = 4) harmed the patient. The four cases involving harm, described below, suggest problems related to inaccurate patient weight and the inappropriate use of HYDROmorphone (Dilaudid®), both of which have been discussed in past issues of the *Pennsylvania Patient Safety Advisory*.[8,9]

> *Upon admission, the patient's weight was estimated to be 100 kg. Based on that, a bolus of 8,000 units of heparin was administered along with an IV [intravenous] infusion of 20 units/kg/hr. The patient's first heparin level came back at midnight at more than 1.10 and the patient was experiencing gross hematuria. Heparin was discontinued at that point to be reevaluated. It was then discovered that the actual weight of the patient was 90 kg, which represents a 10 kg (10%) difference in weight.*

> *A patient arrived to the ED with complaints of abdominal pain. The patient was prescribed and given*

Table 1. Predominant Medication Error Event Types Associated with the Emergency Department (n = 1,825, 71%), August 1, 2009, through July 31, 2010

EVENT TYPE	NUMBER	% OF TOTAL REPORTS (N = 2,569)
Wrong dose/overdosage	452	17.6%
Drug omission	353	13.7
Other (specify)	301	11.7
Wrong drug	269	10.5
Wrong dose/underdosage	180	7.0
Extra dose	140	5.4
Wrong route	130	5.1

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3 mg of IV Dilaudid over a three-hour period. The patient was found unresponsive and not breathing by a nurse. The patient was given Narcan® [naloxone] and was responsive with spontaneous breathing within minutes.

A patient went to the ED with flank pain due to a possible kidney stone. Dilaudid was ordered at 1 mg prn IV push × 3 doses. The patient continued to have pain. Dilaudid 1 mg IV now was ordered for three more doses as needed. The patient received a total of 6 mg of Dilaudid in less than three hours.

Patient seen in the ED for migraine headaches and was treated with Dilaudid 2 mg IM [intramuscular], was given a repeat dose of 2 mg IM and was discharged 40 minutes later in stable condition under the care of his daughter. The daughter at home became concerned and called EMS [emergency medical services]. EMS treated the patient with Narcan and the patient was brought back to the ED for evaluation and further treatment.

Table 2. Predominant Classes of Medications Mentioned in Events in Emergency Department (n = 1,376, 53.6%), August 1, 2009, through July 31, 2010

MEDICATION PRESCRIBED	NUMBER	% OF TOTAL REPORTS (N = 2,569)
Antibiotics	560	21.8%
Anticoagulants/antithrombotics*	248	9.7
Opioids*	214	8.3
Nonsteroidal anti-inflammatory drugs (NSAIDs)	135	5.3
Steroids	125	4.9
Insulin*	94	3.7

* High-alert medications

Table 3. Predominant Medications Mentioned in Wrong-Dose/Overdosage Events in Emergency Department (n = 175, 38.7%), August 1, 2009, through July 31, 2010

MEDICATION PRESCRIBED	NUMBER	% OF TOTAL REPORTS (N = 452)
Dexamethasone	32	7.1%
Heparin*	30	6.6
Ibuprofen	20	4.4
Tamiflu®	19	4.2
Acetaminophen	17	3.8
Gentamicin	15	3.3
Ketorolac	12	2.7
Prednisolone	10	2.2
HYDROmorphone*	10	2.2
Azithromycin	10	2.2

* High-alert medications

To guide appropriate drug therapy, healthcare providers need readily available patient demographic and clinical information (e.g., age, weight, allergies, diagnoses, pregnancy status) and patient-monitoring information (e.g., laboratory values, vital signs) that gauge the effects of medications on the patient's underlying disease processes.[10] Further analysis of wrong-dose/overdosage events in the ED shows that 28.5% (n = 129) of the event descriptions mention breakdowns in patient information, including errors involving patient weight (17.7%, n = 80), patient age (5.8%, n = 26), knowledge of existing medication profiles (2.7%, n = 12), the medication reconciliation process (2.2%, n = 10), and wrong patients (0.2%, n = 1). See the following examples.

An order was written for Decadron® 20 mg orally for an ED patient. The pharmacist missed the patient age and dispensed the order as written. After realizing the patient age, the pharmacist told the ED not to give Decadron until the pharmacist and prescriber could discuss the dose. The 20 mg dose was returned to pharmacy and the dose was changed to 2 mg (which is appropriate for a 24-month-old patient).

A baby came to the ED with a fever of 103°F rectally. The nurse gave 120 mg of Tylenol® [acetaminophen] to the baby. After giving the medication, she realized she did not convert the baby's weight to kilograms prior to calculating dose.

The patient was admitted and told the resident that he took amiodarone 400 mg three times daily, which was recorded on the history and physical form. This dose, which was too high, was ordered and administered to patient. This abnormal dose was not noticed by the physicians, nurse, or pharmacy. The high dose was noticed the next morning and immediately stopped.

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Pediatric Wrong-Dose/ Overdosage Errors

A retrospective cohort study by Kozer et al., conducted using the charts of 1,532 children to describe the incidence and type of drug errors in a pediatric ED, found prescribing errors in 10.1% (n = 154) of charts and drug administration errors in 3.9% (n = 59) of charts. The most common types of prescribing errors were dosing errors (49.1% of all errors), followed by drugs given with incorrect frequency (43.2% of all errors). The drug most frequently involved in errors was acetaminophen, followed by antibiotics, asthma medications, and antihistamines. These drugs were also the ones most often prescribed in that ED.[11]

Reports submitted to the Authority show that almost half (47.7%, n = 132) of the wrong-dose/overdosage events among the pediatric population (n = 277, 61.3% of all wrong-dose/overdosage errors) involved prescribing an excessive dose. The predominant medications were dexamethasone (11.6%, n = 32), Tamiflu® (6.9%, n = 19), ibuprofen (6.5%, n = 18), acetaminophen (6.1%, n = 17), and gentamicin (4.3%, n = 12).

In a retrospective review of medication errors in another pediatric ED, the incorrect documentation of patients' weight, leading to incorrect dosing, was the most frequently reported error.[12] Similarly, analysis of wrong-dose/overdosage events among the pediatric population (n = 277) reported to the Authority found that 21.3% (n = 59) involved a breakdown related to documented patients' weight, while 9.4% (n = 26) involved a breakdown related to the patient's age.

Pharmacy Interventions

One key healthcare practitioner that is often not a part of the medication-use process in the ED is the pharmacist. Historically, the role of the pharmacy in the ED has been limited to pharmacy technicians stocking ADCs, preparation of emergent IV solutions, and retrospective review of medication orders. However, organizations such as the Joint Commission now require more pharmacy involvement in this care area.[13] According to an American Society of Health-System Pharmacists survey of 1,310 pharmacy directors in both general and children's medical-surgical hospitals in the United States, 6.8% of hospitals have a pharmacist regularly assigned to the ED. Larger hospitals were more likely than smaller hospitals to have a pharmacist in the ED (54.2% of hospitals with 600 or more staffed beds had an ED pharmacist, compared to approximately 25% of hospitals with 300 to 599 staffed beds and less than 3% of hospitals with fewer than 300 staffed beds).[13] The survey results also indicated that, overall, 44.4% of hospitals did not have pharmacists prospectively review any ED orders before administration of the first dose.

Review of wrong-dose/overdosage medication errors reported to the Authority found that in 150 reports (33.2%), excessive doses were ordered by prescribers but caught and corrected by pharmacists. Such events are often referred to as "pharmacy interventions."

Cases in which pharmacists actively "caught" erroneously dosed orders include the following:

> *A physician ordered a dose of 500 mg acetazolamide IV. The patient was on 500 mg PO [per os] acetazolamide once daily at home. The clinical pharmacist recommended that the dose be separated and given every six hours because the IV formulation was to be administered. The physician was informed and they changed the order to 125 mg every six hours.*

> *A prescriber ordered a heparin infusion to run at 400 units/mL, based on a dose at 970 units/kg/hr. The dose is high. The prescriber was contacted and the dose was changed to 18 units/kg/hr.*

> *[There was a] good catch by pharmacist during the processing of an order and prior to administration of the medication. A physician ordered insulin aspart 100 units three times a day with meals with a one-time dose of 100 units. When called to verify correctness of order, the physician said that he "saw the order on the . . . medication record." He was asked to verify the dose with the patient. When he called back, it was discovered that the patient takes 15 units TID with meals.*

The predominant classes of medications mentioned in wrong-dose/overdosage errors included antibiotics (30%, n = 45), steroids (21.3%, n = 32), and NSAIDs (9.3%, n = 14). The predominant medications mentioned were dexamethasone (11.3%, n = 17), prednisolone (6%, n = 9), ketorolac (4.7%, n = 7), and acetazolamide (4.7%, n = 7).

RISK REDUCTION STRATEGIES FOR THE ED

Healthcare facilities can strive to identify systems-based causes of the medication errors that take place in the ED and implement effective risk reduction strategies to prevent harm to patients. Although most of the reports submitted to the Authority involving the ED did not explicitly reveal all of the causes and contributing factors linked to drug omissions and wrong-dose/overdosage events, healthcare facilities may consider the strategies described below, which are based on a review of events reported to the Authority, observations from the Institute for Safe Medication Practices, and recommendations in the literature.

Incorporation of Pharmacists into the ED

Healthcare facilities may consider the feasibility of increasing the involvement of

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pharmacy departments in the ED's medication-use process. This may include involving a pharmacist for important periods of time in the ED and including him or her in meetings involving medication use.

A study to determine the frequency of medication errors in one facility's ED before and after an ED pharmacist was assigned to check medication orders found that the rate of errors decreased significantly (66.6%) when pharmacists prospectively reviewed the orders.[14] In addition, other healthcare facilities that have used pharmacists in their EDs have shown improvements in many aspects of medication use, such as reducing medication order turnaround time, making medications more readily available, and improving compliance with clinical indicators. In such facilities, pharmacists have assisted ED staff with drug selection, drug administration, and patient monitoring, as well as with emergency and trauma-related codes.[15,16] Pharmacists have expanded their role in the ED to assist with culture and susceptibility report follow-up, antibiotic selection, review of patients' known medication history, analysis of unidentified tablets, and assisting in the medication-reconciliation process.

Multidisciplinary Teamwork

Healthcare facilities may consider instituting a multidisciplinary approach to patient care in the ED. A study to identify and decrease adverse medication events implemented a multidisciplinary practice consisting of a pediatric hospitalist, a pediatric care coordinator, a pediatric nurse, a pharmacist, and the trauma service to manage pediatric trauma patients from admission until discharge. The team mandated collective decision making for medication dosing, medication administration, and weight documentation, and it implemented a medication error reporting system. This effort resulted in a significant reduction in the number of medication prescribing and administration errors as well as a significant improvement in weight documentation.[17]

Constraints

Based on the large number and variety of antibiotics mentioned in events reported to the Authority, healthcare facilities may consider limiting the number and variety of medications in the ED as well as limiting the number of available concentrations of a medication. Medication stock can be reviewed frequently to ensure that it includes only those drugs, concentrations, and quantities considered safe and necessary for emergency use.[18]

Redundancies

Most organizations may not have active pharmacy involvement in the medication-use process in their ED. Redundancies such as the following can be included throughout the medication-use process in the ED:

- Require independent double checks for high-alert medications, particularly those removed on a "stat" basis or those used outside of a pharmacy-profiled situation.[19]
- When communicating an order verbally or by telephone, expect a "read-back" for the order. During an emergency, expect a "repeat-back" confirmation from the listener.[20]
- Many EDs use computerized prescriber order-entry systems to enter medication orders. If pharmacists are not involved in the review of the medication orders, healthcare facilities cannot rely on this technology to effectively detect potentially harmful medication errors and should consider testing the system's ability to detect unsafe orders.

Patient Weight

A patient's weight is important information often used to calculate the appropriate medication dose. When medication errors arise because a patient's weight is unknown or inaccurately documented, the dose of a prescribed medication could be significantly different from what is appropriate.[8] Strategies to address these problems include the following:

- Ensure the availability of equipment in the ED to easily obtain an accurate patient weight, including stretchers with built-in scales or floor scales that can weigh the patient and the stretcher, chair scales, and portable standing scales.[21]
- Create a departmental expectation that obtaining actual weight is a mandatory assessment for adult patients just as it is for pediatric patients, unless life-threatening circumstances do not allow it.[20]
- Standardize measurement systems to kilograms throughout the institution. Kilograms should be the standard units for weight on prescriptions, medical records, and staff communications.[8]
- Consider the use of a "hard stop" in the department's computerized prescriber order-entry system to alert staff if the weight parameter of kilograms is empty when a weight-based medication is ordered. Avoid prescribing weight-based medications unless an accurate patient weight is available.[20]

Drug Information

To minimize the risk of error, up-to-date drug information must be readily accessible to healthcare providers, including text references, protocols, order sets, computerized drug information systems, medication administration records, and patient profiles.[10] Strategies to address problems with drug information include the following:

- Ensure that nurses have ready access to standardized emergency drug preparation sheets that indicate
  - the safe preparation of the medication,

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- the correct rate of administration or infusion,
- the correct method of titration,
- whether an infusion device is required, and
- the maximum dose range limits.[22]

— Adopt a standardized approach for providing weight-based, pediatric emergency drug references in all appropriate areas of the ED.[22] This approach may also be applicable to other patients receiving weight-based medications.

— Provide staff with ready access to online drug information resources that are continually updated. Make it easy for staff to access and use the online resources by providing an icon on the desktop of all computers, and place a computer at the ADC. Provide the same drug resources and references in the ED as in the pharmacy.[22]

CONCLUSION

One of the most common care areas where medication errors take place in Pennsylvania healthcare facilities is the ED. The predominant types of medication errors include wrong-dose/overdosage and drug omission errors. Increasing the involvement of the pharmacy department, as well as instituting a multidisciplinary approach to patient care in the ED, may be an effective strategy to address problems with the prescribing of wrong doses of medications.

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LEARNING OBJECTIVES

— Select strategies emergency department (ED) practitioners can use to help promote the safe use of medications.

— Recognize the predominant types of medication errors associated with the ED, according to reports submitted to the Pennsylvania Patient Safety Authority.

— Recall the most common classes of drugs involved in errors in the ED.

— Recognize the value of incorporating the pharmacy department in the ED's medication-use process.

SELF-ASSESSMENT QUESTIONS

The following questions about this article may be useful for internal education and assessment. You may use the following examples or come up with your own.

Upon admission, the patient's weight was estimated to be 100 kg. Based on that, a bolus of 8,000 units of heparin was administered along with an IV [intravenous] infusion of 20 units/kg/hr. The patient's first heparin level came back at midnight at more than 1.10 and the patient was experiencing gross hematuria. Heparin was discontinued at that point to be reevaluated. It was then discovered that the actual weight of the patient was 90 kg, which represents a 10 kg (10%) difference in weight.

1. Review this case and select the best strategy to prevent similar medication errors in the ED.
   a. Ensure the availability of equipment in the ED to easily obtain an accurate patient weight.
   b. Create an expectation that obtaining actual weight is a mandatory assessment for adult patients, unless life-threatening circumstances do not allow it.
   c. Adopt a standardized approach for providing weight-based, emergency drug references in all appropriate areas of the ED.
   d. Check the patient's recorded weight against other sources, such as a family member or medical records.
2. The predominant classes of medications mentioned in events in the ED include all of the following EXCEPT:
   a. Opioids
   b. Antiemetics
   c. Anticoagulants/antithrombotics
   d. Antibiotics
   e. Nonsteroidal anti-inflammatory drugs
3. The most common types of medication errors that took place in the ED, as reported to the Authority, include all of the following EXCEPT:
   a. Wrong patient
   b. Drug omission
   c. Wrong dose/overdosage
   d. Wrong drug
   e. Wrong dose/underdosage
4. Analysis of wrong-dose/overdosage events that occurred in the ED, as reported to the Authority, revealed problems with breakdowns in patient information in all of the following areas EXCEPT:
   a. Weight
   b. Age
   c. Knowledge of existing medication profiles
   d. The medication reconciliation process
   e. Laboratory values
5. All of the following statements in regard to the pharmacy's role in the ED are true EXCEPT:
   a. The pharmacist is often not a part of the medication-use process in the ED.
   b. Historically, the role of the pharmacy in the ED has been limited to stocking automated dispensing cabinets, preparing emergent IV solutions, and retrospectively reviewing medication orders.
   c. Review of drug omission errors reported to the Authority found that in one-third of the reports, excessive doses were ordered by prescribers but caught and corrected by pharmacists.
   d. Studies have shown that the rate of medication errors in the ED decreased significantly when pharmacists prospectively reviewed ED medication orders.
   e. Facilities that have used pharmacists in their EDs have shown improvements in medication order turnaround time, medication availability, and compliance with clinical indicators.

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Indications for and Management of Inferior Vena Cava Filters

ABSTRACT

Inferior vena cava (IVC) filters are devices implanted in patients at risk for life-threatening pulmonary embolism (PE) who cannot tolerate anticoagulation therapy or for whom the anticoagulation therapy is ineffective. The filters are implanted either permanently (i.e., permanent filter) or with the intent to remove them (i.e., retrievable filters) when the risk of PE has passed or when anticoagulation therapy can be initiated. In 2010, the U.S. Food and Drug Administration (FDA) issued a device safety alert regarding retrievable IVC filters that described several types of adverse events involving filters, some with serious patient outcomes, and suggested that these events may be related to retrievable filters being left in patients longer than clinically necessary. Between June 2004 and November 2010, the Pennsylvania Patient Safety Authority received 35 reports describing adverse events related to implanted IVC filters. FDA and other literature on IVC filters suggest that managing patients with filters, especially continued follow-up visits after filter implantation or removal, is an important part of the process in reducing complications from filters. Careful consideration of the indications for placing IVC filters, the indications for removing filters, as well as follow-up care and evaluation of patients with retrievable filters, can all help reduce the likelihood of complications following filter implantation.

(Pa Patient Saf Advis 2011 Mar;8[1]:8-11.)

Deep vein thrombosis (DVT)—a blood clot formed in a vein, most often the femoral or pelvic veins, can result in significant life-threatening consequences if it travels to the lungs, a condition referred to as pulmonary embolism (PE). Pharmacologic therapy—low molecular weight heparin/heparin for short-term anticoagulation and warfarin for long-term anticoagulation—is typically the primary treatment for patients with or at risk for DVT; however, patients with a contraindication to anticoagulation therapy (e.g., major trauma, pregnancy) or in which the therapy is ineffective may be candidates for inferior vena cava (IVC) filters.

IVC filters are implanted into the vena cava to trap blood clots, preventing or reducing the likelihood of a PE (IVC filters do not prevent or treat the formation of blood clots). IVC filters are typically collapsible cone-shaped arrays of six struts (wires) of stainless steel, titanium, or nickel-titanium (nitinol), with hooks (barbs) on the wire ends to secure the filter to the vena cava wall. Other filter shapes are also used—for example, the bird's nest IVC filter, which is a random array of wires extending in various directions; the shape is reminiscent of a bird's nest. There are basically two types of IVC filters, permanent and optional, commonly referred to as retrievable. Permanent filters are designed to remain in the patient without the ability to be removed. Permanent filter design should permit significant fixation to the vena cava wall to prevent migration over the patient's life. Optional (retrievable) filters are designed to remain permanently in the patient or to be removed when it is no longer warranted, such as when the risk of PE has subsided or when the patient no longer has a contraindication to anticoagulation therapy. Retrievable filters should also achieve fixation to the vena cava wall, but their structure must have the ability to be altered (e.g., collapsible) at the time of removal with catheter-based retrieval devices to facilitate safe removal. Often, retrievable filters become permanent filters due to changes in a patient's clinical status, loss of a patient to follow-up, or the inability to technically retrieve the filter.[1] However, in practice, many physicians decide to use retrievable filters rather than permanent filters.[2] From 1979 through 1999, the number of implanted IVC filters rose from 2,000 to 49,000. In 2007, 167,000 filters were implanted, with a projection of approximately 259,000 filters being implanted in patients in 2012.[3] This growth may be linked to the introduction of retrievable filters.[3]

In August 2010, the U.S. Food and Drug Administration (FDA) issued a medical device safety alert regarding retrievable IVC filters describing filter-related adverse events and recommendations on reducing complications related to their use.[4] Based on the FDA alert, Pennsylvania Patient Safety Authority analysts reviewed IVC filter-related reports submitted to the Authority correlating the adverse event types with FDA data. This discussion focuses on some of the indications for implanting IVC filters, some of the complications associated with implanted filters, and some suggestions on patient management. The focus is on retrievable filters more than permanent filters; however, the principles described can apply to both filter types.

FDA ISSUES SAFETY ALERT FOR IVC FILTERS

Since 2005, FDA received 921 adverse event reports involving IVC filters, some of which led to adverse patient outcomes. According to FDA, of the 921 reports, 328 involved filter migration, 146 involved embolization, 70 involved perforation of the IVC, and 56 involved filter fracture[4] (see "IVC Filter Adverse Event Types Defined"). FDA's alert does not specify whether the 921 reported events are specific to retrievable filters only or retrievable and permanent filters, nor does it indicate event types for the remaining 321 reports. In the alert, FDA suggested that these events may be linked to retrievable IVC filters being left in patients after the risk for PE abates, which may increase the chance

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IVC FILTER ADVERSE EVENT TYPES DEFINED

The general-consensus definitions for the inferior vena cava (IVC) filter adverse event types referenced in the U.S. Food and Drug Administration's retrievable IVC filter medical device safety alert[1] are as follows:

Filter migration. The entire IVC filter breaks free from the vena cava wall and travels to another part of the body (e.g., lungs, heart).

Filter embolization. A part of the filter (e.g., strut) breaks free from the filter and travels to another part of the body (e.g., lungs, heart).

IVC wall perforation. A part of the filter (e.g., strut, hook) pierces through the vena cava wall.

Filter fracture. A part of the filter (e.g., strut) breaks free from the filter but does not travel through the body.

NOTE

1. U.S. Food and Drug Administration. Removing retrievable inferior vena cava filters: initial communication [online]. 2010 Aug 9 [cited 2010 Nov 1]. Available from Internet: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm221676.htm.

of complication associated with long-term implantation of retrievable filters.[4] FDA recommends that physicians who implant them and clinicians who are responsible for ongoing care of patients with retrievable IVC filters consider removing the filter as soon as protection from PE is no longer needed.[4] Additionally, FDA recommends that all physicians involved in the treatment and follow-up care of IVC filter patients consider the risks and benefits of removing filters on an individualized patient basis and remove the filter when clinically feasible.[4]

AUTHORITY DATA

From June 2004 through November 2010, the Authority received 35 reports describing adverse events related to implanted IVC filters (Not all the reports submitted to the Authority indicated the type of filter used: permanent or retrievable) during the events. Analogous to the FDA event types, of the 35 reports to the Authority (see the event breakdown by category in the chart in the Figure), 12 involved filter migration, 2 involved embolization, 4 involved perforation of the vena cava, and 1 involved filter fracture. However, reports to the Authority also included 10 reports of filter deployment problems and 3 reports of filters dislodging from the vena cava wall after implantation. Several reports to the Authority discussed filters implanted upside-down, filters implanted in the incorrect location, and unsuccessful attempts (several surgeries) to remove the filter.

Of the 35 reports, 24 were classified by reporting facilities as unsafe conditions or no harm, 8 reports were classified as causing patient harm, and 3 were classified as causing patient death. In the three deaths, two involved the filter migrating to the patient's right atrium of the heart and one involved the filter dislodging (the filter tilted), allowing clots to reach the patient's lung.

The Authority and FDA adverse event IVC filter data appear to corroborate much of the literature discussion on the complications associated with the use of IVC filters and suggest the need for better understanding of the complications and management of filter use. None of the analyzed data suggested that the clinical need for placing the filters was in question; however, the indications for placing IVC filters must also be understood.

INDICATIONS FOR PLACING IVC FILTERS

The availability of retrievable IVC filters has led to a change in clinical practice of the indications for filter implantation.[1] Retrievable filters cannot be implanted with the assumption that they will always be removed.[1] As such, the indications to implant a permanent filter are applicable to a retrievable filter. The decision to use a retrievable filter rather than a permanent filter is based on the anticipated length of time that protection against a clinically significant PE is warranted and/or based on the risks associated with the use of anticoagulation therapy. For example, one decision algorithm might consist of the following:[5]

- Short-term risk of PE and/or a short-term contraindication to anticoagulation therapy: retrievable filter
- Uncertain risk of PE and/or contraindication to anticoagulation therapy: retrievable or permanent filter
- Long-term risk of PE: permanent filter

Long-term risk factors to consider with regard to retrievable filters include patient life expectancy of more than six months following implantation (long enough to realize any benefits of a filter removal procedure) and the patient's ability to comply with medications and follow-up physician visits.[5]

The indications for placing all IVC filters can be categorized as follows[1] (not intended to be comprehensive):

- Absolute indications
  - Proven venous thromboembolism (VTE) and contraindication or complication to anticoagulation therapy
  - Recurrent VTE despite adequate anticoagulation therapy

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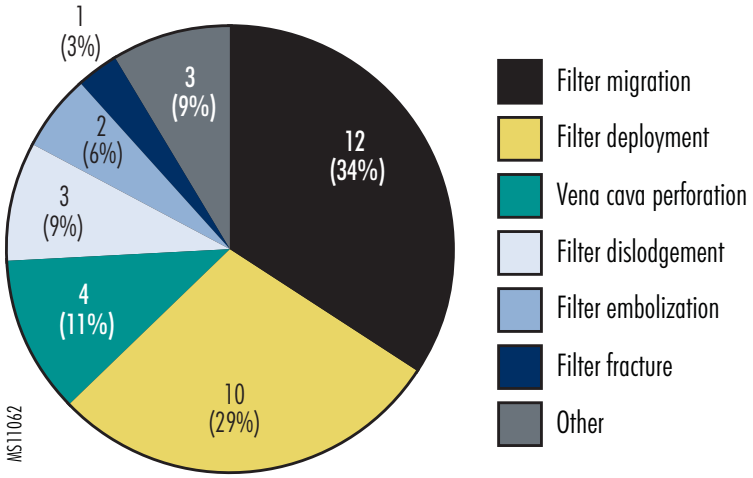
Figure. Pennsylvania Patient Safety Authority Inferior Vena Cava Filter Reports, June 2004 through November 2010



- Relative indications
  - Proven VTE and contraindication or complication to anticoagulation therapy
  - Large, free-floating proximal DVT
  - Poor compliance with anticoagulation therapy
  - Thrombolysis for iliocaval DVT
- Prophylactic indications
  - No VTE, but anticoagulation therapy is not possible (e.g., high risk of bleeding)
  - Transient risk of VTE (e.g., trauma, surgical procedure, medical condition)

Implanting filters for prophylactic indications is a controversial and varied practice. It is difficult to identify the risk of VTE with subsequent PE in patients without previously documented VTE.[2]

Bariatric patients undergoing surgery are at a significant risk of developing DVT[6] and PE after hospital discharge. The indications for placing IVC filters in patients undergoing bariatric surgery vary slightly from the general indications above and include the following:[6]

- BMI greater than 55
- Previous history of DVT/PE
- Hypercoagulable state (increased risk of blood clot)
- Chronic venous insufficiency
- Truncal obesity
- Contraindication to anticoagulation therapy

INDICATIONS FOR REMOVING RETRIEVABLE IVC FILTERS

The fundamental reason to remove a retrievable IVC filter is that the patient has an acceptably low risk of PE. Typically, a physician would remove a retrievable filter when the patient is responding well to anticoagulation therapy or when the transient risk of PE has passed.[5] However, before removing the filter, the physician would consider the risk of future PE compared to the risk of leaving the filter in place.[5] When patients with filters no longer require treatment for VTE, but life-long anticoagulation therapy is prescribed only because a filter is in place, removal may be considered.[5] Long-term use of anticoagulation therapy to prevent recurrent DVT for patients with IVC filters can be associated with complications (e.g., hemorrhage).[5]

Currently, there is little published data confirming the benefit of removing IVC filters.[5] In response to the lack of data, in January 2005, the Society of Interventional Radiology (SIR) established a multidisciplinary panel that developed the following patient conditions to be met before considering retrieving filters:[5]

- No current indication for implanting a permanent filter
- Acceptably low risk of clinically significant PE because of continued anticoagulation therapy or change in clinical status
- No expected near-term, recurrent high risk of PE (e.g., stopping anticoagulation therapy for a planned surgery)
- Life expectancy of more than six months following implantation to appreciate the potential benefits of filter retrieval
- Ability to retrieve the filter without causing unacceptable patient injury
- Patient or consenting guardian agrees to filter removal

If filter removal is warranted, patients with concurrent VTE are to receive anticoagulation therapy for several weeks before the removal procedure.[1] This practice is warranted because symptomatic PE can occur within two to three weeks of therapy after an acute VTE episode.[1]

While the number of retrievable filters implanted may be increasing, some of the literature suggests that the number of retrievable filters actually removed may be low. In a study of 446 patients receiving retrievable IVC filters (Karmy-Jones et al.) only 90 filters were retrieved.[7] According to the study authors, the main reason retrievable filters were not removed was because many patients were lost to follow-up physician visits. Two main reasons for failure to follow-up with patients were that the implanting facility was not directly responsible to follow-up and patients failed to follow-up despite notification.[7] Other reasons retrievable filters were not removed included risk of DVT, residual DVT and the inability to receive anticoagulation therapy, multiple other recent surgical procedures, and patient refusal.[7] Some of the retrieval attempts failed due

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to technical issues during removal or significant thrombus trapped within filters.[7] When a thrombus is encountered in a filter, the decision to retrieve the filter may require reevaluation. During the procedure to remove a filter, imaging (e.g., contrast-enhanced computed tomography, ultrasonography) of the filter and vena cava can be performed to determine whether a thrombus is trapped within the filter. In patients with proven VTE, a thrombus found in a filter necessitates evaluation of the risk of subsequent PE after the filter is removed.[1] A large thrombus within the filter can become a significant embolization risk during filter removal but may be telling of a poorly treated VTE.[1] However, a small thrombus in the filter may present less of a risk of PE during removal and may indicate a previous and resolving embolus.[1] When thrombi are found within filters of patients without known VTE, a new diagnosis of VTE must be made, the retrieval procedure stopped, and anticoagulation therapy begun, if no contraindications are present. After several weeks of anticoagulation therapy has been administered, the patient is to be reevaluated for filter removal.[1]

MANAGEMENT OF PATIENTS WITH RETRIEVABLE IVC FILTERS

As Karmy-Jones et al. demonstrate, one reason many retrievable filters may not be removed is because patients are lost to follow-up often due to the implanting facility's lack of established follow-up protocols or patients failing to return for follow-up physician visits (follow-up visits are not typically the norm for patients with implanted permanent filters).[7] During its guideline development, the SIR panel suggested that responsibility for follow-up patient care lies with the physicians implanting the filters.[8]

Patients with retrievable filters are to be periodically evaluated to determine whether filter removal is warranted.[8] The decision whether to remove the filter involves assessing the risk of the patient experiencing a fatal PE as well as the risk of long-term filter complications;[8] two main assessment criteria are that the risk of clinically significant PE is acceptably low and that the filter can be safely removed.[9] Safe removal of a retrievable filter will depend on the clinical status of the patient and on the filter's time period of retrievability;[5] dwell times (e.g., up to 23 days) for retrievable filters may vary per filter brand.

Patient management is to be continued after the filter removal procedure. After the retrieval procedure, imaging of the vena cava may be prudent to determine evidence of trauma or thrombus, especially following difficult or lengthy procedures or with reports of pain from patients after the procedure.[5] The physician performing the procedure should examine the filter (directly or through imaging) for signs of filter irregularities (e.g., missing strut). If the filter is missing a component, the physician should examine the retrieval catheter and image the patient to locate and document the position of the component.[5] No accepted guidelines exist for treating patients with retained filter components; however, cardiac consultation should be considered for filter fragments within the heart.[5] Patients with VTE after filter removal should be treated with anticoagulation therapy based on local standards of care or best practice guidelines. Patients without VTE after filter removal should receive prophylaxis treatment based on any underlying patient conditions.[5] All patients regardless of whether their filter has been removed should be tracked for new or recurrent DVT and/or PE and, if present, managed accordingly.[5]

CONCLUSIONS

FDA and other literature on IVC filters suggest that managing patients with filters, especially continued follow-up visits after filter implantation or removal, is an important part of the process in reducing complications from filters. Careful consideration of the indications for placing IVC filters, the indications for removing filters, as well as follow-up care and evaluation of patients with retrievable filters, can all help reduce the likelihood of complications following filter implantation.

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Falls in Radiology: Establishing a Unit-Specific Prevention Program

ABSTRACT

As healthcare facilities continually look to strengthen their falls prevention programs and respond to the high-risk problem of persistent patient falls, evaluation of falls events outside direct patient care, such as in radiology, may provide additional opportunities to address this organizationwide challenge. Analysis of reports to the Pennsylvania Patient Safety Authority in 2009 revealed 602 falls events in radiology departments. Falls experienced by both inpatients and outpatients throughout the department were commonly associated with syncope; slips, trips, and loss of balance; and medication-related effects. Falls were from stretchers, procedure tables, or stools, including during transfers. Many of the patients had affirmed to a radiologic technologist their ability to transfer either independently or with some assistance from a wheelchair or stretcher to an examination table, or to stand for the duration of an upright examination. In these instances, technologists usually relied on verbal and nonverbal patient cues to assess the patient's ability to meet the physical demands of an impending diagnostic study. However, most of the reports described situations in which patient risks were not apparent, and radiology staff did not anticipate a fall. The adoption of standardized strategies to reduce falls risk—including ongoing education about safe patient handling practices, nurse to radiologic technologist handoff communications, and use of an assessment tool or checklist—helps to identify patient risk factors and could mitigate injurious patient falls in radiology departments. (Pa Patient Saf Advis 2011 Mar;8[1]:12-7.)

INTRODUCTION

From 2005 through 2009, the number of Serious Events involving falls (i.e., falls resulting in patient injuries and requiring subsequent treatment) reported to the Pennsylvania Patient Safety Authority averaged about 1,300 a year.[1] Patients in a care unit where a falls risk assessment has been performed and a high risk for falls identified are protected by standard falls prevention strategies prescribed by nursing, such as low beds, bed exit alarms, call bells, and floor mats. Patients transported to the radiology suite are not protected. In 2009, falls accounted for 10% of all Serious Events reported to the Authority and made up 8% of all events reported in radiology departments statewide. The data suggests that although radiology staff may take precautions with patients who obviously need assistance, radiologic technologists were less likely to evaluate a patient's ability to withstand radiologic positioning modes when a falls risk is less apparent.

Evidence-based reviews have established that patients with a history of recent falls and with impaired mobility are predisposed to and at increased risk for falling.[2] Patients with impaired mobility include those who require assistive ambulation devices, those who take psychoactive medications including sedatives, and those of advanced age with its associated frailties. Falls can also result from loss of consciousness due to syncope from various factors.[3] The physical design of the radiology department may create hazards that can cause patients to slip and trip.[4] A unit-specific analysis of falls is an opportunity to reduce the number and severity of injuries sustained within radiology departments, and implementation of risk reduction strategies could reduce the number of falls overall and injury-related falls organizationwide.

RADIOLOGY FALLS REPORTED TO THE AUTHORITY

In 2009, 602 falls events were reported to the Authority from radiologic service areas, including breast health services, computed tomography (CT), diagnostic and interventional radiology, magnetic resonance imaging (MRI), nuclear medicine, and ultrasound. Just over half the reported falls events were associated with the following issues:

- Syncope
- Slips, trips, and loss of balance
- Falls from stretchers, procedure tables, or stools, including transfer mishaps
- Medication-related effects

In 2009, 5% of all reported falls in radiology departments were reported as Serious Events, compared to 4% of reported Serious Events involving falls from all departments. The demographics of the patients who fell in radiology were consistent with the population served by hospital radiology departments, including ambulatory services with breast health services for women. Fifty-four percent of falls in radiology involved patients age 65 or younger, compared to 44% of all reported falls; female patients represented 54% of radiology falls, compared to 50% of all reported falls.

About half of reported Serious Events involving falls occurred in combined services, about a quarter in the angiography and special procedures service areas, and 10% in ultrasound areas; events were relatively evenly distributed throughout the other service areas. (See Figure.) Of the reported patient injuries sustained, 39% included fractures, 42% of which were of the hip; 52% included lacerations, 69% of which were of the head; and 6% included serious head traumas, such as subdural and subarachnoid hemorrhages and frontal and parietal hemorrhages.

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Syncope

Patients in radiology service areas may be predisposed to syncopal or near-syncopal episodes due to factors such as fasting, blood donation, chemotherapy, and lying supine. In 2009, 17% of radiology falls reports described syncopal events. About half of the patients fainted or nearly fainted when standing for an upright study (e.g., chest radiograph, mammogram), such as the following report describes:

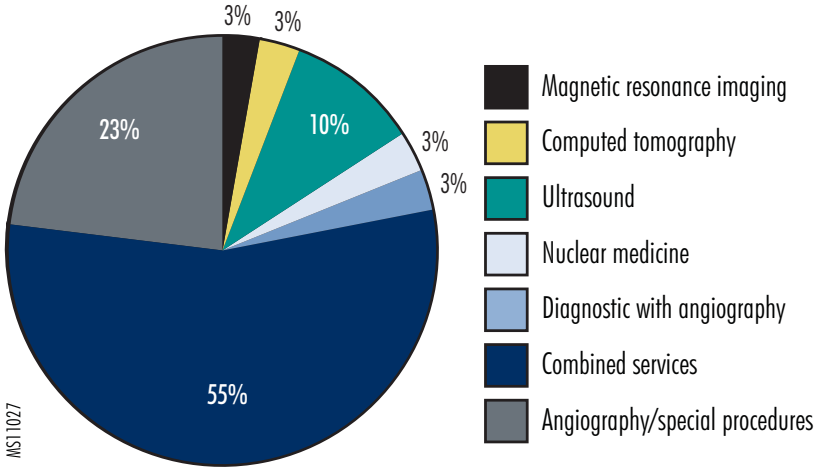
> *Prior to a chest x-ray, an elderly patient appeared "wobbly" but stated she could stand for the study. When the patient stood, she passed out and was lowered to the floor by the technologist. The patient was taken to the ED [emergency department] for evaluation. Apparently the patient had just donated a unit of autologous blood in advance of a planned operation and she had an orthostatic episode.*

Syncope-related falls also occurred after insertion of an intravenous line and during or immediately after a breast biopsy. Although in most instances radiology staff helped patients safely to the floor, staff was not always close enough or able to support falling patients. In such situations, injuries commonly occurred when patients hit their head on the floor or against other objects, as in the following case:

> *A patient was standing in front of an x-ray table and waved to get the technologist's attention and fainted. The patient fell to her side and hit her head on the floor. She had been standing for approximately 10 minutes for an upper gastrointestinal test and had been fasting. The patient became immediately coherent and was alert and oriented; however, she sustained a laceration to the forehead.*

(For more information, see "Preventing Syncope-Related Falls: A Clinical Study.")

Figure. Radiology Service Areas Reporting Serious Events to the Pennsylvania Patient Safety Authority, 2009



Slips, Trips, and Loss of Balance Falls

Fifteen percent of radiology falls reports described patient slips, trips, or loss of balance events. In these situations, patients who were able to bear weight, either independently or with an assistive device, lost their footing and fell, even with staff assistance. Slip and trip falls occurred throughout the radiology department and were not limited to examination rooms. The use of walking aids (e.g., canes, walkers) contributed to several patient falls. The failure to use such aids also contributed to patient falls. In one event, a patient fell and hit the back of her head on the floor after attempting to walk to the bathroom without using her cane, sustaining a head laceration.

Slips, trips, or loss of balance incidents occurred in all radiologic service areas. For instance, in mammography, patients tended to fall backward on release of the compression device as they loosened their grip on the mammography unit's support handles, as exemplified in the following report:

> *After mammography compression was released, the radiologic technologist told the elderly patient she could step away from mammogram machine. The patient stepped backwards, lost her balance, and fell back, hitting her head on the chair before falling to the ground.*

Bathrooms, dressing rooms, and waiting rooms also were common locations for falls with serious consequences. Patients with a history of falling or at probable risk for falling were left alone in these areas and subsequently experienced fractures, lacerations, and extensive bruises. The following report is one example:

> *An elderly patient presented to a hospital-based radiology center for x-rays of the abdomen and chest. The patient was offered assistance with undressing and dressing but stated he did not need help. Following the x-ray, the patient was in the dressing room and yelled out. He was found on the floor and stated he hurt his left arm. X-rays were obtained [and revealed] a fracture.*

Loss of balance also occurred when a patient's clothing or shoelaces became entangled in transport vehicles (e.g., wheelchairs, carriers), medical equipment (e.g., scales), or waiting room furnishings and carpet. Three patients slipped on wet floors, two as a result of incontinence and one who slipped on a small quantity of

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PREVENTING SYNCOPE-RELATED FALLS: A CLINICAL STUDY

Peterson and Berns conducted a retrospective review of falls incidents within the clinic system of the University of Wisconsin Medical Foundation and found that fainting was the single largest cause of falls. A review of incident reports revealed that the propensity for falls due to fainting had increased from 21% in 2002 to 36% in 2003. A clinical task force established a two-step plan to significantly reduce the annual number of fainting-related falls. The plan included safe care guidelines for patients with a history of syncope and mandatory education on the management of syncopal events for all staff in areas where patients are at high risk for fainting. Staff was trained to ask patients about previous fainting, and patients were encouraged to report difficulties with procedures. Positive patient histories were then communicated throughout the clinic, including the laboratory and the radiology department. Staff monitored patients for signs of syncope and informed patients not to fast for more than 12 hours before laboratory testing and to drink water while fasting. Practice changes included drawing blood with at-risk patients in a supine position and offering juice and crackers afterward. Implementation of the fainting prevention plan resulted in a decrease in falls rates from 36% in 2003 to 12% in 2004-2005.

Source: Peterson R, Berns S. Prevention and education to decrease patient falls due to syncope. *J Nurs Care Qual* 2006 Oct-Dec;21(4):331-4.

hand sanitizer. Footwear, including socks, also contributed to these types of falls. Several patients in stocking feet sustained fractures during transfer between a wheelchair and a procedure table or stretcher, as in the following report:

> *A patient was finishing a radiology exam when he slipped getting off the x-ray table. The radiologic technologist had instructed the patient to wait while she got his wheelchair closer to the table. The patient was sitting at the edge of the table when he attempted to get off himself. [The patient's] slip resistant slipper was noted to be twisted to the side, not affording the slipper to provide maximum grip. The technologist had the wheelchair between her and the patient and could not reach patient in time [before he fell].*

Stretcher and Examination Table Falls

Another significant cause of injury was patient falls from transport vehicles and procedure tables or chairs. Twelve percent of the reports described falls from a transport stretcher, wheelchair, radiologic procedure table, or stool. Of these events, 12% resulted in serious injury, equally divided between hip fractures and head injuries. Most of the head injuries were lacerations; however, one patient suffered a cerebral hemorrhage. Injuries occurred largely when patients tried to get off a stretcher or table for toileting, repositioning, or transferring or when patients inadvertently rolled off the table. Many patients fell while attempting to get up by moving to the foot of the stretcher, tipping it over. The following example pertains to a fall from a procedure table:

> *A patient was placed on a procedure table in the supine position. Her right arm was placed out to the side in preparation for peripheral insertion of a central catheter line. The nurse and radiologic technologist were at the patient's right side. Her right arm was lifted for placement of a sterile towel as per protocol. The patient was slowly rolled onto her left side and [fell] off the table [sustaining an] approximate three-foot fall [to the floor].*

Preventing falls from procedure tables can be a challenge. For example, MRI examination tables have no bedrails, although it may be possible to use straps to secure and stabilize patients. In the absence of stabilization, patients could incur significant injuries (e.g., traumatic brain injuries) in longer falls from elevated tables.[5] Caregivers also can be injured when straining to prevent patient falls. While a table is still in the lowered position, the technologist can verify that the patient is well situated and ready for the table to begin moving. The patient not only must be carefully observed, immobilized, or secured before the table is moved, but he or she also must know what to expect before movement starts.[6]

On several occasions, a patient on a stretcher who was positioned for a procedure (e.g., lateral decubitus position) against the image receptor fell between the receptor and the stretcher. Either the stretcher was unlocked or, in one event, a locked stretcher moved away from the image receptor as a patient forcefully pushed against it in repositioning. Similar falls occurred when patients were transferred from a stretcher to a procedure table or vice versa. Although staff may have been in place, gaps between procedure tables and stretchers allowed for patient falls.

> *A radiology staff was preparing to transfer an elderly patient to a gurney. The patient turned on his right side with two technologists present on each side of him. There was a space between the x-ray table and lead shield. Despite a technologist standing close to the patient, there was a gap and the patient slid to the floor. The patient's head hit a foot pedal.*

Falls during repositioning also occurred as patients were seated upright on stools. An example of this is the following:

> *A patient walked into an x-ray room for a hand x-ray. The technologist asked the patient to sit on a stool. The patient sat on the stool while the*

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technologist turned to get film. The patient tried to readjust his body on the stool and slipped off, striking his head on the floor.

Medication-Related Effects

Sedatives and medications for anxiety and depression can affect cognitive and physical function, such as blood pressure, balance, and awareness. Four percent of the reported radiology falls events identified medication as a contributing factor. Almost 75% of these events were related to the use of opiates for pain control, and the remaining 25% were related to the effects of benzodiazepines used for the treatment of anxiety or claustrophobia. Most patients experienced dizziness or syncope during an upright examination or fell from a procedure table. Although most patients were not injured, two needed follow-up CT scans for further evaluation of the head and cervical spine, and one sustained a leg fracture.

Reported events that exemplify medication-related falls include the following:

> *A patient was asked if she had been out of bed since surgery. She replied, "Yes, this morning." Her stretcher was parked next to the x-ray Bucky. The patient stood and shuffled her feet. She was asked, "Are you able to walk?" She said "that's why I had the surgery; my feet are numb." The patient was standing with her back to the Bucky while the radiologic technologist was talking to her. She became unresponsive and started to slide down the Bucky. The technologist could not fully support her, and lowered her to the floor and called for help. Staff responded and assisted in lifting a now coherent patient onto the table. The patient said that it probably happened because she hit the button on her morphine pump, just before being brought into the room.*

> *A patient presented for an outpatient bone scan. Following the test, the patient became nauseated and was given a glass of water and was asked to sit with her daughter while her films were reviewed by the radiologist. She asked to go to the bathroom. When she was coming out of the bathroom, she looked weak, so the technologist and the daughter went to assist her. Before they reached her, she went down to her knees on the floor not losing consciousness. She said she was not hurt, but was weak because she did not eat. The patient did not want to be seen in the ED. She was very nervous about the results of her test and she took approximately two Valium® before the test.*

PRIORITIZING FALLS PREVENTION IN RADIOLOGY

Despite efforts by healthcare facilities to revamp and strengthen their falls prevention programs, many nonfatal injuries sustained in radiology departments are caused by patient falls. The lack of medical literature specific to falls in radiology care areas suggests that little is known about or has been done to address such occurrences in these care areas. Falls may result from factors such as a patient's cognitive state, prescribed medications, the physical environment, and infrequent staff education about recognizing patient falls risks. Careful review of a patient's physical condition and associated environmental factors can help radiology departments set priorities for prevention by adopting strategies that can reduce the risk of patient harm from falls.

In addition to injury prevention, there are financial incentives for implementing and monitoring strategies to reduce patient falls in radiology. As of October 2008, Medicare and some other payers may no longer reimburse hospitals for the cost to treat injuries from falls if the injury occurred during the patient's hospital stay or an outpatient visit.[7] In approximately 5% of the total reported radiology falls events, a postfall CT scan was needed to evaluate the patient and rule out fractures or internal bleeding. Although in 75% of these events there were minor or no subsequent injuries, facilities may not be reimbursed for these studies; in addition, there may be long-term risks to the involved patients from the additional radiation exposure.[8]

Implement Unit-Specific Falls Prevention Strategies

Radiologic technologists have not been immune to liability lawsuits. In a survey of 415 radiology-related lawsuits, technologists were most often called to court in cases of patient falls. As in the reports submitted to the Authority, technologists were found to be negligent in leaving patients unattended without properly securing them or in performing a study with a patient in an upright position when the patient should have been in a horizontal or seated position.[9]

To minimize the chances of injuring a patient, radiologic technologists, as well as all radiology staff, can take the proper precautions when entrusted with a patient's care. Knowledge of falls prevention strategies before performing a procedure is paramount to ensuring the safety of patients in this service area. Consider the following risk-reduction strategies in the implementation of a unit-specific falls program.

Offer falls prevention training. Staff education is an important component of falls prevention. All radiology staff who interact with patients, from a clerical to a clinical capacity, can participate in training to meet the department's falls prevention goals. Ongoing education will keep technologists apprised of methods for assessing patients and identifying conditions in which a modified approach to examination may be needed to avoid patient injury. Departmental in-service sessions can offer practical training on body mechanics and basic patient movement techniques that promote safe patient transfer between transport vehicles and procedure tables. In addition, transport

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staff can be trained to lower stretchers before leaving a patient unattended.

Assess falls risk. Although radiology departments receive inpatients that have been assessed by nursing for falls risk, assessment protocols of ED-referred patients and outpatients for whom radiologic studies are ordered may not be as standardized. Similar to prevention programs initiated in other patient care settings, the development and use of a unit-specific falls risk assessment can help radiology staff predict and prepare for a fall possibility that otherwise may have been overlooked. Consider the following elements in the assessment process and in the development of an assessment tool (also see the "Radiology Falls Risk Assessment Tool," available online at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/Pages/home.aspx):

— Assess patient mobility and determine if the patient will need to be accompanied to the department, the type of transport the patient will need, and if the patient may encounter fall or transfer problems. If a patient is identified as at risk for falls, enlist patient care aids familiar with the patient's needs to accompany the patient and to take an active role in providing transfer and positioning assistance before, during, and after the procedure.

— Note any visual clues that might indicate a patient is at risk (e.g., color-coded identifier, ambulatory assistive devices, socks without grips, untied shoelaces).

— Assess a patient's pain level and consider his or her physical ability to withstand positioning and to follow directions. Determine whether an alternative approach would be safer (e.g., sitting versus standing).

— Review medications and incorporate a list of high-risk medications in the assessment tool.

— Inquire about toileting needs and assistance, especially of those patients with impaired gait and mobility due to functional deficits and those who may experience drug side effects (e.g., Valium taken for claustrophobia).

— Assess the patient's position or need for repositioning on a transport vehicle, examination table, or stool before leaving the patient's side.

— Question the patient or family about patient fall tendencies or behaviors.

— Be an active participant in patient handoff discussions. (See the section "Communicate Patient Risks.")

Involve patients and families. Patients and their families play a significant role as collaborators in the care process; however, they may not always understand their personal risk and may refuse assistance. Allowing patients and their families to candidly speak with the radiology team about falls risk and tendencies allows the department to take appropriate actions to ensure their safety. Displaying a poster (e.g., "Are you at risk for falling?") in patient waiting areas and in examination rooms is one way to alert patients to the most common falls risks and may encourage them to speak up about their own risk factors.

Share event analysis results. Communication of actual and near-miss falls events and the factors that contributed to these events can be shared with radiology staff as part of the falls prevention program. Investigate the causes of unit-specific falls and develop corrective interventions to prevent future falls.

Communicate Patient Risks

Patients have fallen because of the lack of interdepartmental communication. Visual identifiers, including armbands, stickers, and colored socks, can be used to communicate falls risk; however, if the radiology department is not aware of this component of the falls program, patients transported to this area will be at risk. The Joint Commission requires that hospitals have a process in place to receive or share information when a patient is referred to other internal care providers. The hospital's process for handoff communication must allow for discussion of patient information.[10] A pretransport tool, such as SBAR (Situation, Background, Assessment, Recommendation),[11] can be used by nursing and radiology to ensure that patients who cannot be left unattended, who may be a difficult transfer, or who have experienced a fall will be safe while off the patient care unit. The transport form would address any falls risk issues, such as language barriers and medication use that affects alertness, and any implemented falls prevention measures, including proper footwear, recent toileting, use of a personal alarm, and patient and family safety education. Handoff and receiving personnel could jointly review the form.[12] In addition, transport procedures can list the steps for receipt in radiology of a patient at high risk for falls and the steps for return of the patient, including required checkpoints of staff interaction.

Assess Environmental Safety

Facilities can provide and encourage patients to wear footwear with slip-resistant soles. Footwear is a safety factor that will require ongoing inspection; footwear that has twisted on the patient's foot or that displays worn treads can no longer protect a patient and may not prevent a fall.

Facility policies should include a spill-control program. Wet floors are more slippery than dry floors; the test of good flooring is how slip resistant it remains while wet. The slip resistance of flooring products on a wet floor can be evaluated during the selection process. Environmental hazards in radiology may include changes in floor surfaces, bold carpet patterns that obscure objects, and abrupt changes in lighting from bright to dim.[4] Keeping patient and staff traffic patterns free of equipment can also be a challenge in radiology. Frequent patient safety environmental rounds can be an effective way to monitor safety and assess compliance with the falls prevention program. Regular leadership rounds that include engaged radiology staff are an

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important strategy for maintaining visibility of falls prevention initiatives.[13]

Evaluate and Document Falls Injuries

Because patients may not remember having fallen, information provided from radiologic technologists or other witnesses to the event can provide valuable diagnostic information to the ED, especially for mild traumatic head injuries and syncopal episodes. The American College of Emergency Physicians has published evidence-based recommendations for these two conditions that depend on an accurate patient history. Documentation by radiology staff of the following observations in the medical record can be very helpful:[5,14]

- Distance a patient falls from a fully raised stretcher or procedure table
- Loss of consciousness
- Loss of memory about the event
- Position when syncope occurred (e.g., standing, sitting, reclining)
- Complaints of headache or vomiting after a possible head injury
- Obvious signs of trauma (e.g., fracture, deformity, laceration, bruising, redness, swelling, point tenderness)

Evaluation and treatment of a potentially injured patient may be limited when a fall occurs in offsite or independent radiology centers instead of in hospital-affiliated departments. The patient may require further clinical workup after assessment by the center's radiologist or other medical professional. Depending on the circumstances and severity of the patient's injuries, options include contacting the referring or primary care provider to consult on the patient's medical history and the need for additional radiologic studies; activating the emergency medical system; sending the patient to an ED, and having the patient follow up with his or her physician. Hospital-based radiology departments are to follow hospital policies; most facilities reported calling the hospital's rapid response team for assistance or transporting patients to the ED for further evaluation. Regardless of where a fall occurs, radiology facilities are to implement and follow postfall processes that include appropriate medical evaluation, documentation, and disclosure.

CONCLUSION

Although most injurious falls occur in direct patient care areas, patients can sustain falls injuries in any location of the facility that provides patient care services. Radiology departments must set clear unit-specific priorities for falls prevention and implement interventions that reduce the likelihood of patient harm. Prevention ideally begins before a patient leaves the patient care area, through nursing to radiology communication of a patient's risk for falls. In the emergency or ambulatory setting, radiology staff can identify patient-specific risk factors by using an assessment tool or checklist and by engaging the patient and his or her family. Ongoing monitoring of a falls prevention program is essential to identifying successes and problems and will help radiology professionals continue to prevent falls.

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Improving the Safety of Negative-Pressure Wound Therapy

ABSTRACT

Negative-pressure wound therapy (NPWT) is a noninvasive therapy that uses negative pressure to treat acute and chronic wounds. NPWT has become a widely used option for treating all types of wounds. When used safely as a component of a comprehensive wound treatment program, NPWT has been associated with the promotion of wound healing. However, while NPWT may be beneficial to patients, complications have been associated with its use. Seventy-seven patient injuries and six deaths associated with NPWT in two years prompted the U.S. Food and Drug Administration to issue an alert to healthcare providers. In 2008 and 2009, the Pennsylvania Patient Safety Authority received 419 reports related to the application or management of NPWT. Complications related to NPWT were described in 112 (27%) reports and included bleeding, evisceration of bowel, retained sponges, infection, maceration, and compromise of tissue surrounding the wound. Clinicians can endeavor to prevent patient harm associated with the use of NPWT by employing risk reduction strategies such as appropriate patient selection, proper device application, and frequent monitoring. (Pa Patient Saf Advis 2011 Mar;8[1]:18-25.)

INTRODUCTION

Acute and chronic wounds affect at least 1% of the population and represent a significant risk factor for hospitalization, amputation, sepsis, and death.[1] The technique of applying negative pressure to a wound to assist in healing has been in use since the 1950s, and the practice has continued to evolve and gain in popularity. The technique is referred to as negative-pressure wound therapy (NPWT), although several other names exist for this technique, such as vacuum-assisted closure, vacuum-sealing techniques, sealed surface wound suction, subatmospheric pressure therapy, and vacuum-pack technique. The technique typically involves inserting foam or gauze dressing into a wound, cavity, or surface; connecting an evacuation tube embedded in the foam or gauze to a vacuum pump; and sealing the area with an adhesive film. The vacuum pump creates an intermittent or continuous subatmospheric pressure in the range of -50 mmHg to -125 mmHg. NPWT acts to reduce edema, promote granulation tissue perfusion and formation, and remove exudate and infectious materials.[2]

The popularity of NPWT as an adjunct to wound healing has been attributed to worldwide marketing, assumed safety, and overall cost-effectiveness.[2] NPWT is estimated to cost approximately $100 per day. This includes the cost of dressings ($25 to $60 per change), a canister ($8 to $15 per day), and rental of the vacuum pump ($55 to $58 per day). NPWT has higher material costs than traditional wound treatment therapies (i.e., gauze); however, the cost may be offset by the benefits of reduced healing time, reduced nursing staff time and expense, decreased length of hospital stay, and facilitation of patient transfer to lower-cost care settings.[2] For example, Braakenburg et al. reported that NPWT is associated with significantly lower nursing staff expense due to fewer effort hours than treatment with conventional wound dressings.[3] Similarly, a study of 51 patients in a long-term acute care facility demonstrated that despite a higher product cost, the overall cost of NPWT was lower than topical advanced moist heat strategies.[4] The study calculated that patients treated with NPWT showed a statistically significantly higher average daily rate of volume reduction compared to an advanced moist wound healing group. The cost of wound reduction was $11.90/cm^3 in the NPWT group compared to $30.92/cm^3 in the moist wound-healing group. The authors suggest that when developing a wound-healing strategy, the cost decision should be based on overall expense and not individual product cost.

NPWT has been associated with serious complications. In 2009, the U.S. Food and Drug Administration (FDA) issued a warning to healthcare professionals and consumers regarding reports of 6 deaths and 77 injuries over a 2-year period related to NPWT.[5] Bleeding was the most serious injury and occurred in all 6 reported deaths and in 17 of the reported injuries. Twenty-seven of the reports indicated that the patient developed an infection from the original open wound or from retention of dressing pieces in the wound. Foam dressing pieces, either adhering to tissues or embedded in the wound, were observed in 32 of the injury reports; the majority of these patients required surgical procedures to remove the retained pieces, wound debridement, and treatment of wound dehiscence, as well as additional hospitalization and antibiotics. Similarly, healthcare facilities have reported serious complications associated with NPWT to the Pennsylvania Patient Safety Authority, including bleeding, evisceration of bowel, retained sponges, infection, maceration, and compromise of tissue surrounding the wound. Authority reports also describe issues related to application and management of NPWT devices.

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AUTHORITY DATA

From January 2008 to December 2009, 419 events associated with NPWT were reported to the Authority. The event reports are summarized as follows, accompanied by deidentified examples:

— Events associated with assessment (5%) include issues related to physician orders or patient assessment before initiation of treatment.

The patient arrived on unit with the vacuum set at 90 mmHg intermittent. The report from the RN [registered nurse] was that the vacuum was set at 120 mmHg continuous. There were no orders noted on the chart for wound vacuum settings. The RN failed to pick this up at time of assessment.

The admitting physician has not seen the patient since admission, nor has he designated a hospitalist to manage the patient medically. The patient also does not have a written order for NPWT currently in use. The patient does not have a wound ostomy nurse consult. The NPWT dressing has not been changed since the patient was admitted.

Patient came into the emergency department with NPWT in place. NPWT was not removed as per protocol to examine wound and then dressed with a wet to dry dressing until seen by wound care. [There was a] delay in treatment.

— Events associated with application of NPWT (21%) include issues related to a delay in application or incorrect application of NPWT.

Blood was noted in [a patient's] NPWT tubing. Tubing found lying directly on the patient's wound with a sponge covering the tubing. The dressing was removed, and the wound was cleansed with normal saline. NPWT was then placed as per manufacturer's suggestions. The physician and the nursing director were notified.

The wound care nurse noted foam and bioclusive dressing were left on the wound after NPWT was removed. Protocol was not followed per procedure; the physician was notified, and a saline dressing was applied.

NPWT dressing was due to be changed; when the wound was examined by the doctor, the dressing was found to be applied incorrectly with the tubing directly against the wound instead of on top of the sponge as directed.

When changing the NPWT dressing, staff noted that the foam had been covering intact skin and was not just in the wound bed. The skin surrounding the incision line was now very red and abraded.

— Events citing monitoring and ongoing assessment (47%) issues represent the largest number of events related to NPWT.

The suction tubing for the NWPT device was dislodged, and assessment of the site revealed a stage III pressure ulcer where the tubing had been positioned on the patient's leg. Staff repositioned tubing, and physician was to be made aware at start of the shift to assess options for therapy.

Nurse went to the bedside for NPWT dressing change and noticed that the sponge was not compressed, the machine was off, and the suction tubing connector not connected to the canister. The nurse reconnected the machine and suction was established; it was not determined how long the machine was left off.

The patient was seen for a routine visit at a local wound clinic. A call was received that NPWT dressing was done poorly prior to patient's discharge with black foam overlapping the intact skin, causing maceration of healthy tissue.

When staff removed a NPWT dressing for dressing change, the staff member found a 4 × 4 inch sponge packed into upper section of the wound behind a piece of black sponge. The sponges were bagged in hazardous package to bring to operating room staff's attention.

— Events associated with NPWT issues after the patient's discharge from the acute care setting (7%) suggest that patient and/or family caregiver may not have received adequate NPWT home care education before discharge.

A patient who had surgery several months ago was admitted with an open wound that was very deep with tunneling. The patient had a NPWT until recently. The patient thinks he cleaned the wound with a vinegar solution.

Per patient, he noticed that NPWT suction was fluctuating while he was still an inpatient; pressure was not remaining constant at 120 mmHg as ordered by the physician. The patient reported suction issue to staff prior to discharge; staff were unable to troubleshoot and did not contact physician. Per patient, staff stated visiting nurse would rectify the problem. When wound and skin graft was assessed by visiting nurse, [the patient's tissue was] found to be macerated from the amount of drainage that built up under the dressing. The patient was instructed on troubleshooting the unit and measures to employ if needed.

The remainder of the reports (20%) involve a combination of some or all of the above categories of events.

PRINCIPLES OF NPWT

How Does It Work?

NPWT is used in the three phases of healing in acute and chronic wounds: the inflammation phase, the proliferative phase, and the maturation phase.

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The inflammatory phase is characterized by hemostasis and inflammation and lasts two to five days.[6,7] The proliferative phase is characterized by the formation of granulation tissue and epithelialization. The duration of this phase depends on the size of the wound. The maturation phase is characterized by increased collagen production and breakdown. Tissue contraction occurs during this phase, in which tissue strength reaches 80% of the strength of normal tissue.

NPWT is thought to act by several fluid-based and mechanical processes, including the following:[8-10]

Stimulation of wound edge retraction. Negative pressure draws the edges of the wound together.

Stimulation of granulation tissue formation. Application of mechanical force is thought to slowly deform skin over time because skin and most tissues are viscoelastic. Stretching of the skin stimulates an increased rate of new cell growth and increases the formation of granulation tissue, which is thought to reapproximate wound edges.

Increased local blood flow. Adequate perfusion is essential to proper wound healing in order to provide nutrients and inflammatory mediators and to remove local edema. Increased blood flow also helps to remove bacteria from the wound.

Continuous removal of exudate.

Reduced interstitial edema. Removal of excess interstitial fluid around the wound margins increases capillary blood flow to the wound bed.

Reduced bacterial loads in the wound. Reduction in the number of dressing changes decreases damage to delicate new tissue and decreases exposure of the wound to nosocomial infection.

Is It Clinically Effective?

Despite widespread use, the evidence is unclear that NPWT provides additional benefit when compared to other conventional wound treatments, such as gel products, bolster dressings, and hydrocolloids.[6] An Agency for Healthcare Research and Quality (AHRQ) evidence report by the ECRI Institute Evidence-Based Practice Center identified 22 systematic reviews published between 2000 and 2008 that covered NPWT.[6] The review included studies reporting data on the use of NPWT on a number of wound types (e.g., diabetic foot ulcers, pressure ulcers, vascular ulcers, burn wounds, surgical wounds, trauma-induced wounds) and studies comparing NPWT to other wound treatments (e.g., gauze, bolster dressings, wound gels, alginates, other topical therapies). AHRQ assessed three systematic reviews as high-quality based on criteria that included duplicate study selection, the likelihood of publication bias, and conflict of interest. None concluded that NPWT provided additional benefit when compared to other conventional wound treatment. However, the systematic reviews all noted the lack of high-quality clinical evidence supporting the advantages of NPWT compared to other wound treatments. Another concern was the large number of prematurely terminated and unpublished trials of NPWT.[11] Nevertheless, AHRQ concluded that NPWT is a safe alternative treatment to other traditional wound treatments.[6]

Which Patients Are Candidates?

NPWT is used in healing both chronic and acute wounds. Chronic wounds are wounds that have not completed the process of healing in the expected amount of time, generally 30 days, or have not progressed through the healing process with the expected results.[12] Diabetic foot ulcers, pressure ulcers, venous leg ulcers, and infected sternal wounds are common types of chronic wounds treated with NPWT. Acute wounds are those lasting less than 30 days. Surgical wounds, burn wounds, and trauma wounds are common wounds treated with NPWT. It can also be used as an adjunct to surgery for skin grafts, flap surgery, and wound bed preparation.[12,13]

Appropriate patient selection is important to the success of NPWT. As with any wound care regime, optimizing the patient's ability to heal is essential and requires assessment and management of underlying diseases (e.g., diabetes mellitus) and oversight of any anticoagulation and immunosuppressive therapy.[14] Other factors affecting wound healing include hemodynamic stability, nutritional status, blood glucose, fluid balance, and the presence of infection.[15]

Bleeding and infection are serious complications associated with the use of NPWT.[16,17] Careful consideration must be given to patients receiving anticoagulants and heparin, since these medications may increase the risk of bleeding. Frequent monitoring of activated partial thromboplastin time and/or prothrombin time with international ratio levels is necessary for these patients. Bleeding may occur with the removal of dressing that has adhered to the wound. Bleeding can also occur if the dressing is placed over exposed vessels in or around the wound that have not been covered and protected during the application of NPWT as recommended by the manufacturer.[16] Wound infection may develop if pieces of dressing are retained in the wound. Desiccation, pain, erosion, odor, and maceration are additional complications associated with NPWT.[10]

Optimal patient selection includes evaluation for the factors that may place a patient at risk for complications during NPWT, including the following:[5,18]

- Friable vessels and infected blood vessels
- Vascular anastomosis
- Infected wounds
- Malignancy in the wound margins
- Untreated osteomyelitis
- Exposed vessels, nerves, tendons, and ligaments (Direct contact with NPWT creates risk of desiccation or injury.)

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— Sharp edges in the wound (Bone fragments or sharp edges in the wound could puncture protective barriers, vessels, or organs, causing injury or bleeding.)
— Spinal cord injury
— Hemostatic agents applied at the wound site (Certain nonsutured homeostatic agents [e.g., bone wax, absorbable gelatin sponge, spray wound sealant] may, if dislodged, increase the risk of bleeding.)
— Magnetic resonance imaging
— Hyperbaric chamber treatment
— Defibrillation
— Application near vagus nerve because of risk of bradycardia
— Circumferential dressing application

When to Stop NPWT

In the absence of complications, base the duration of NPWT on regular evaluation of wound progress and/or a predetermined treatment goal. Accurate and reproducible measurement of the wound should be recorded weekly.[13] A 50% improvement in wound size over four weeks is a good indication that the wound will heal. In some cases, NPWT can be used until wound closure, although generally it is used until the wound is filled with granulation tissue and ready for skin graft, flap, or standard wound therapy.[19]

After initiation of NPWT, evaluate the wound at each dressing change for signs of deterioration, which include erythema, pain, discharge or infection, tissue necrosis, requirement of repeated debridement, surgical interventions, or increased wound size.[16] Stop NPWT if any complication or deterioration of the wound occurs.

PROMOTING THE SAFE USE OF NPWT

Before initiating NPWT, healthcare practitioners should refer to facility policy and be knowledgeable about the manufacturer's instructions for the device. Regular in-servicing and competency updates are essential to ensure safe and successful use of NPWT. Although a number of NPWT devices are available, the basic steps of NPWT are similar: accurate assessment of the patient and wound before initiation of NPWT, appropriate wound-bed preparation, application of the NPWT unit, and monitoring of progress during NPWT, which includes dressing changes and wound reassessment. Education of staff, patients, and caregivers is also essential. The Authority has received reports of events occurring during each step of the process. For each step, risk reduction strategies can promote the safe use of the device and facilitate wound healing.

Assessment

— Review the physician's order. Orders should include the wound cleansing agent, type of vacuum and dressing (i.e., foam or gauze), therapy settings (i.e., intermittent or continuous suction, negative-pressure setting), and frequency of dressing changes.[12,18,20]
— Obtain a physician's order if an order is not present when the patient is admitted.[12,18,20]
— Assess the patient for factors that may place the patient at risk for any complications, such as preexisting bleeding disorders and use of anticoagulants or other medications or herbs that prolong bleeding times (e.g., nonsteroidal anti-inflammatory drugs, aspirin, gingko biloba).[12,18,20]
— Assess the wound before initiating NPWT. If the periwound skin shows signs of compromise, such as breakdown or maceration, address these conditions before initiating NPWT.[12,18,20]

Wound Preparation

Cleanse the wound according to physician order and facility policy before each dressing application.[12,18,20]

— Apply minimal mechanical force during each cleaning.[12,18,20]
— Consider using 0.9% sodium chloride solution instead of antiseptic or antibacterial preparations.[12,18,20]
— Clean the periwound, and protect the intact skin around the wound to prevent breakdown. Skin preparation products provide a protective barrier between the skin and the adhesive dressing, remove skin oils to promote a better seal, and help minimize trauma when the dressing is removed.[12,18,20]

Application

— In acute or long-term care, a registered nurse who is certified as a wound care specialist may perform the majority of NPWT applications. For all staff, particularly nursing, conduct regular in-servicing and competency updates to troubleshoot alarms, repair leaks, and observe for complications.[12,18,20,21]
— Select and prepare the dressing type and size appropriate for the wound as directed by facility policy and manufacturers' instructions. Two types of sponges are typically available: black polyurethane and white soft foam. Gauze dressing may also be used with some NPWT systems. The dressing is used to fill all open areas of the wound while avoiding overpacking of the wound.[12,18,20]
— Document the dressing applied, including the type and number of dressing pieces as well as any additional measures used to create an adequate seal. Document the number of dressing pieces on the outside of the adhesive film dressing and in the patient's medical record to prevent any retained gauze or sponge.[12,18,20]
— Avoid pulling or stretching the transparent adhesive dressing used to seal the wound to prevent trauma to the periwound.[12,18,20]
— Implement and document the ordered amount of negative pressure

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and the suction cycle. Continuous therapy provides sustained tension on the cells of the wound, causing mechanical stretch and removal of fluids. Intermittent therapy applies greater mechanical stretch throughout the treatment as the unit is cycled on and off.[12,18,20]

Ongoing Monitoring and Assessment

— Dressing changes are generally performed every 48 hours or according to manufacturer's guidelines. At each dressing change, assess for wound deterioration, erythema, pain, purulent drainage, tissue necrosis, and increase in wound size. The dressing may need to be changed more frequently in infected wounds; the dressing change will be based on continuing evaluation of the wound and the patient's clinical status.[12,16-18,20]

— During each shift or per facility policy, ensure that the sponge is collapsed in the wound and the unit is on and functioning appropriately. A sponge that is not compressed may indicate a break in the seal.[12,16,18,20]

— If NPWT use is interrupted for more than two hours, remove the old dressing and irrigate the wound. Disconnection from NPWT for more than two hours places patients at risk for development of deep vein thrombosis and compromised pulmonary function and at increased risk for infection and/or sepsis.[12,16,19,22]

— Avoid any new areas of pressure by ensuring that the tubing is not pressing against the patient's skin.[12,16,18,20]

— Closely monitor infants, children, small adults, the elderly, and patients with highly exudating wounds for fluid loss and dehydration.[16]

— Troubleshoot and resolve NPWT alarms according to manufacturer's recommendations. For example, the Table contains examples of system alarms and recommended action/resolution related to the V.A.C.® Therapy unit.[16,18]

Patient and Family Caregiver Education

Reports to the Authority indicate that patients have been readmitted because of complications of NPWT. These reports indicate that the education of patients and caregivers regarding NPWT use may have been a factor in the development of complications that resulted in readmission. Ongoing education and discharge instructions for patients and caregivers on NPWT and the use of the device includes the following:[17]

— Safe operation of the device (Provide printed patient instructions either from the device manufacturer or specific to the device.)

— Troubleshooting audio and visual alarms

— Applying or reinforcing dressing application

— Recognizing signs and symptoms of complications to report

— Contacting appropriate healthcare providers, especially in an emergency situation

— Responding to emergency situations, such as the observation of bright red blood in the tubing or collection canister

In emergency situations, teach the patient/caregiver to immediately stop NPWT, apply direct manual pressure to the dressing, and activate emergency medical services.

The education of patients who will be discharged with an NPWT device and the patients' caregivers ideally should begin upon initiation of therapy and continue throughout the patients' hospitalization. Return demonstrations are a good way to assess the patient and/or caregiver's understanding and skills.

CONCLUSION

By following the general principles of wound care and implementing best practices related to NPWT, healthcare providers can safely facilitate wound

Table. Troubleshooting Negative Pressure Wound Therapy Alarms

SYSTEM ALARM	ACTION/RESOLUTION
Low-pressure alarm	Check tubing for blockages, crimps, closed clamps. Ensure dressing/drape has not shifted and blocked tubing. Lower therapy unit and tubing to or below wound level.
Leakage alarm	Use leak-detection procedures/tools to help find and repair leak. Lower therapy unit and tubing to or below wound level.
Blockage alarm	Ensure dressing/drape has not shifted and blocked tubing. Ensure dressing/drape is located on a flat area of the body, avoiding a skin fold.

Source: Kinetic Concepts, Inc. V.A.C. Therapy. Clinical guidelines: a reference source for clinicians [online]. San Antonio (TX): KCI; 2010 Aug [cited 2010 Oct 29]. Available from Internet: http://www.kci1.com.

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healing. Widespread use of NPWT suggests that a healthcare provider is very likely to encounter a patient undergoing NPWT. Safe and effective implementation of NPWT requires regular staff in-servicing and competency evaluation. Clinical staff must be prepared to appropriately apply, monitor, and effectively troubleshoot problems with the device. Staff must also be able to recognize and respond to complications related to NPWT. Patients and family caregivers must also be prepared to apply, monitor, and respond appropriately to issues that may arise if the patient continues NPWT at home.

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(See Self-Assessment Questions on next page.)

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LEARNING OBJECTIVES

— Recall the mechanisms of action of negative-pressure wound therapy (NPWT).

— Recognize the risk factors for complications associated with NPWT.

— Assess potential strategies to manage NPWT using available evidence.

— Select appropriate nursing interventions for a patient whose NPWT is interrupted.

— Recall components of patient and caregiver education about NPWT.

SELF-ASSESSMENT QUESTIONS

The following questions about this article may be useful for internal education and assessment. You may use the following examples or come up with your own.

Case 1

An 82-year-old patient presents to the emergency department with a soft-tissue lower-extremity avulsion injury and an open fracture of his humerus as a result of a motor vehicle accident. The patient is taken to the operating room for debridement of his wounds and external fixation of the open fracture. A foam dressing is applied over the avulsion wound of the patient's lower extremity, and NPWT is initiated.

1. All of the following are considered mechanisms of action of NPWT in promoting the healing of this patient's wound EXCEPT:
   a. Stimulation of wound-edge retraction as a result of negative pressure
   b. Decreased capillary perfusion, which decreases interstitial edema
   c. Stimulation of granulation tissue formation caused by mechanical force applied to the tissues
   d. Reduction of the bacterial load in the wound
2. Which of the following factors, if present, is least likely to place this patient at risk for complications associated with NPWT?
   a. A sacral pressure ulcer with granulation tissue
   b. A medical history of poorly managed diabetes mellitus
   c. Anticoagulation therapy
   d. Exposed vessels in or around the wound edge
3. Assess the following statements about strategies for the patient discussed in case 1, using the literature about management of NPWT. Which statement is NOT accurate?
   a. At each dressing change, assess for deterioration of the wound as evidenced by erythema, pain, purulent drainage, tissue necrosis, or an increase in the wound's size.
   b. If NPWT is interrupted for more than two hours, do not disturb the existing dressing because this may contaminate the wound.
   c. Closely monitor the patient for signs of dehydration if the wound has a large amount of exudate.
   d. At least once during each shift change, ensure that the sponge is collapsed in the wound.

Case 2

A patient is admitted to the hospital from an extended care facility for surgical management of a sacral pressure ulcer. During the admission assessment, a nurse observes that a NWPT dressing covers the sacral pressure ulcer, but the dressing is not attached to a NPWT device.

4. Assess the following statements about strategies for the patient discussed in case 2, using the literature about management of NPWT. Which statement is inaccurate?
   a. Attach a NPWT device to the dressing to initiate therapy immediately because NPWT should not be interrupted for more than two hours.
   b. Obtain a physician's order for NPWT if an order is not present when the patient is admitted.
   c. Assess the patient for preexisting bleeding disorders before initiating NPWT.
   d. Assess the wound before initiating NPWT; if the periwound skin is compromised, address it before initiating therapy.

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SELF-ASSESSMENT QUESTIONS (CONTINUED)

5. The patient in case 2 undergoes a magnetic resonance imaging (MRI) scan, which results in interruption of NPWT for more than two hours. Select the appropriate nursing intervention to be implemented when the patient returns from the MRI suite.
   a. Wait for a physician's order before reinitiating NPWT.
   b. Reinitiate NPWT without removing the dressing.
   c. Remove the dressing, and cover the wound with sterile gauze while waiting for a physician or wound care practitioner to assess the wound.
   d. Remove the dressing, and irrigate the wound according to facility policy.
6. NPWT education for all patients and caregivers about the management of NPWT after discharge includes all of the following EXCEPT:
   a. How to respond to audio and visual alarms
   b. How to perform dressing changes
   c. How to contact the manufacturer if the device malfunctions
   d. How to respond to emergency situations, such as bright red blood in the tubing

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Managing Patients with Limited English Proficiency

ABSTRACT

Language barriers impede access to healthcare, can compromise quality of care, and may increase the risk of adverse health outcomes among patients with limited English proficiency (LEP). Events reported to the Pennsylvania Patient Safety Authority from June 2004 through May 2010 were reviewed to determine what types of events most frequently affect patients with LEP. Falls, errors related to a surgical procedure, and medication errors composed the top three types of events reported for these patients during the time frame. Federal civil rights policy obligates healthcare providers to supply language services, and guidelines have been developed to help providers adhere to those requirements. Resources for language services, however, can be limited. Strategies that facilities can use to manage LEP patients include writing a clear plan, reviewing vital documents for languages most frequently spoken (e.g., informed consents), using interpreters, hiring and testing the language proficiency of bilingual staff, and educating staff on cultural awareness. (Pa Patient Saf Advis 2011 Mar;8[1]:26-33.)

INTRODUCTION

According to the 2000 U.S. census, nearly 18% of U.S. residents five years of age or older speak a primary language other than English at home. More than 21 million (8%) speak English less than "very well."[1] More recent data from the American Community Survey (2005-2009) reports that 8.6% of the population (24 million Americans) have limited English proficiency (LEP).[2] Research documents that language barriers encountered in healthcare settings can compromise the quality of care for LEP patients or patients who do not speak English as their primary language and have a limited ability to read, write, speak, or understand English. A study by Wilson et al. showed that language barriers are associated with decreased access to primary and preventive care, impair patient comprehension, decrease patient adherence, and diminish patient satisfaction.[3] A systematic review revealed that the use of trained medical interpreters and professional medical interpreter services and bilingual providers can improve communication, satisfaction, and adherence among LEP patients.[4]

Many patients and providers who need medical interpreters have no access to them.[5] For example, a study on the effectiveness of interpreters found that no interpreter was used in 46% of emergency department [ED] cases involving LEP patients.[6] When a language barrier exists without a qualified medical interpreter, the situation can be dangerous. This is particularly true if young children serve as ad hoc interpreters. They are unlikely to have full command of two languages (their first language and English) or medical terminology and may avoid discussing sensitive issues.[7]

Compared with English-proficient patients, LEP patients report less satisfaction with medical encounters, have different rates of diagnostic testing, and receive less explanation and follow-up. Although professional interpretation has been associated with improvements in patient satisfaction, communication, and healthcare access, these services are often largely underutilized.[8] Reliance on untrained ad hoc interpreters, perceived time and labor associated with obtaining and working with an interpreter, and costs of implementing professional interpreter services serve as barriers to implementation and utilization.[9]

Pennsylvania Patient Safety Authority analysts reviewed 232 events associated with language barriers and LEP reported to the Authority from June 2004 through May 2010. Analysis of these events and review of the relevant literature identify LEP as an issue that can affect patient safety in all settings. This article reviews LEP-associated events reported to the Authority, reviews the laws that govern and protect patients with LEP, and discusses ways that facilities can enhance the quality of care for LEP patients.

AUTHORITY REPORTS

Of the 232 event reports, 114 (49%) involved patient falls, 62 (27%) involved errors or complications related to a surgical procedure, and 14 (6%) involved medication errors or adverse drug reactions. (See Table 1.) One-hundred nine reports (47%) were for LEP patients over the age of 65. (See Table 2.) Of the 232 reports, 128 (55%) reports specifically mentioned the primary language spoken, whereas the remaining reports (104) did not. Where the language was specifically documented, Spanish was most frequently mentioned. (See Table 3.) Seventy-eight reports (34%) referenced the use of an interpreter. The locations of the reports within the facilities included the medical/surgical units, ED, operating room, intensive care unit (ICU) (all types), diagnostic imaging, cardiac floors (non-ICU), and obstetrics/labor and delivery. (See Table 4.)

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The following highlights some of the issues from events reported to the Authority. The greatest number of reported events were those resulting in patient falls. In many cases, this was due to the patient not understanding or following instructions. In addition to the language barrier, in many cases patients had suffered a stroke or had some other neurological deficit that further compounded the communication barrier.

> *Staff nurse found patient sitting on floor and assisted to chair. Via interpreter, patient stated he was trying to stand by himself and slid to floor. Patient debilitated, deconditioned, and does not speak English. No harm noted.*

> *Patient found on floor at foot of bed lying on his right side. . . . He was Spanish speaking, and through an interpreter, the patient was unable to relate what happened. He has a seizure history. . . . He was evaluated by a physician and there were no noted injuries.*

The second highest number of events consisted of errors or complications related to a surgical procedure. Several reports identified issues with obtaining consent before the procedures. In many cases, interpreters needed to be located before the procedure could proceed as scheduled.

> *A patient in the holding area was waiting for surgery. When patient arrived in operating room [OR], nurse informed staff that patient only speaks Spanish. Nurse to get translator for OR consent that is in English. The physician was notified.*

> *The patient, who speaks Chinese only, was diagnosed with a brain lesion. The family and patient were not informed of the diagnosis. The morning of the procedure, the patient's head was shaved and markings placed for a follow up . . . The surgeon's assistant admitted to shaving the head of the patient without informing the patient. He claimed that he spoke Chinese so it was pointless to talk to him. I informed him that a translator phone was available and he admitted to not making an effort at all. He went on to admit that he would have informed an English-speaking patient, but treated him differently because he spoke a different language. Neurosurgery did not inform the family of their plan either and when they later called for consent, the assistant attempted to obtain consent from the patient's son, who speaks limited English, and still did not speak with the patient. [The patient was] awake, alert, and following commands.*

> *Report was given that returning patient had heavy vaginal bleeding and clotting [postprocedure]. Doctor was at the patient's bedside for two hours and deemed the patient stable to come to same day procedure unit [SPU]. When the patient arrived she had moderate vaginal bleeding, with orders to get patient up and walk her to see if she bleeds worse. It was also verbally passed along that if blood clots would be noted in the vaginal meatus, that they should be gently removed and the size called to doctor. I expressed my concern for the patient and felt that a 23-hour stay in an appropriate level unit would be better for the patient. The patient was eventually sent back to the OR for excessive bleeding. My other concern is that a 10-year-old child was used for a translator in this case and expected to translate what she did not understand. SPU solicited a Farsi translator from the [pediatric intensive care unit].*

> *Anesthesia consent obtained in English; operative consent obtained in Spanish.*

> *Non-English speaking Haitian patient arrived in ED with possible ruptured abdominal aortic aneurysm [AAA]. Surgeon and other physician spoke with patient through interpreter. Patient rushed to OR where it was noted that no consent had been signed. Notes were written in progress note by surgeon and anesthesiologist.*

Table 1. Pennsylvania Patient Safety Authority Reports of Limited English Proficiency by Event Type, June 2004 through May 2010

EVENT TYPE	NUMBER OF REPORTS	PERCENTAGE OF TOTAL
Falls	114	49%
Complications related to a surgical procedure	62	27
Medication errors and adverse drug reactions	14	6
Other	42	18

Table 2. Pennsylvania Patient Safety Authority Reports of Limited English Proficiency by Patient Age, June 2004 through May 2010

AGE	NUMBER OF REPORTS	PERCENTAGE OF TOTAL
Younger than 21 years of age	19	8%
21 to 64 years of age	104	45
65 years of age or older	109	47

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Due to emergent status, consents were waived.

Circumcision consent obtained without interpreter; the mother (Italian speaking) expressed in the delivery room that she didn't want her baby circumcised. Procedure was tolerated well with no complications.

The third highest number of events, excluding events reported as "other," were reported either as medication errors or adverse drug reactions.

Patient was given four caps of Colace in her self med pack. Instruction sheet states "Take one gelcap by mouth in the morning and again in the evening as needed to have a BM". Patient took all 4 gelcaps within 12 hours. Patient received instruction on self medication and signed record acknowledging instruction and understanding of form. English is patient's second language and form not available in Spanish. No harm to patient occurred.

CHALLENGES FACING LEP PATIENTS ACCESSING CARE

For LEP patients, obtaining healthcare services can be frustrating and difficult and may have potentially dangerous consequences.[10] Language barriers contribute to inadequate patient evaluation and diagnosis, lack of appropriate and/or timely treatment, and other medical errors that compromise the safety of LEP patients and result in increased medical costs.[11] LEP patients face barriers in scheduling appointments, understanding medical forms, communicating symptoms and ailments, and comprehending diagnoses and treatment.[12] A 2003 study published by Flores et al. reported that errors in medical interpretation are common, averaging 31 communication errors per clinical encounter between a provider and a LEP patient. The most common error occurred when an interpreter assisting in a pediatric visit omitted information either given by the LEP parent or by the healthcare provider. The study authors recommended that given the frequency of errors (including those that untrained interpreters made) and the potential negative clinical consequences, the best solution to these problems would be to provide third-party reimbursement for trained medical interpreters.[13]

As further evidence, six Joint Commission hospitals set out to examine differences in the characteristics of adverse events between English-proficient patients and LEP patients in U.S. hospitals. Approximately 49.1% of LEP patients' adverse events involved some physical harm, whereas only 29.5% of adverse events for English-proficient patients resulted in physical harm. Of those adverse events resulting in physical harm, 46.8% of LEP patients' adverse events had a level of harm ranging from moderate temporary harm to death, compared with 24.4% of English-proficient patient adverse events. The adverse events that occurred among LEP patients were also more likely to be the result of communication errors (52.4%) than adverse events for English-proficient patients (35.9%). The study concluded that language barriers appear to compromise patient safety.[14]

Table 3. Pennsylvania Patient Safety Authority Reports of Limited English Proficiency by Language Referenced or Spoken (n = 128), June 2004 through May 2010

LANGUAGES	NUMBER OF REPORTS
Spanish	91
Russian	14
Italian	9
Laotian/Vietnamese	6
French	5
Chinese	3

Table 4. Pennsylvania Patient Safety Authority Reports of Limited English Proficiency by Location of Event, June 2004 through May 2010

LOCATION OF INCIDENTS	NUMBER OF REPORTS	PERCENTAGE OF TOTAL
Medical/surgical units	58	25%
Emergency department	24	10
Operating room	19	8
Intensive care unit (ICU; all types)	17	7
Diagnostic imaging	15	6
Cardiac units (non-ICU)	14	6
Obstetrics/labor and delivery units	14	6
Behavioral health units	14	6
Outpatient/ambulatory surgery unit	13	6
Rehabilitation units	10	4
Other	34	15

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FEDERAL LAWS PROTECTING LEP PATIENTS

Protection of LEP patients was first recognized in Title VI of the Civil Rights Act of 1964.[15] In 2000, President Clinton issued Executive Order 13166 requiring all federal agencies to work with recipients of federal financial assistance in order to provide "meaningful access" to their LEP applicants and beneficiaries.[16] These laws apply to hospitals and medical clinics, nursing homes, home health agencies, managed care organizations, universities with health or social service research programs, individual physicians, and other healthcare providers.[17] All providers receiving federal money (such as Medicare or Medicaid) need to have policies in place that conform to the federal LEP guidelines. If a healthcare provider is treating a LEP patient, these federal guidelines provide that the LEP patient is entitled to receive language assistance in the form of oral interpretation or written translation for medical treatment. Healthcare providers who are recipients of federal financial assistance are required to "take reasonable steps to ensure meaningful access" to their services by LEP patients.[16]

The U.S. Department of Health and Human Services (HHS) published a set of LEP policy guidelines to assist providers in compliance with federal mandates.[17] Many healthcare providers (including representatives of the American Medical Association) challenged the executive order as well as the guidelines established because it forced them to pay for medical interpreters for LEP patients with nominal or no reimbursement. HHS changed its guidelines in 2003 to bring them into line with the LEP guidelines released that year by the Department of Justice. These revised guidelines put in greater flexibility to further encourage voluntary compliance. While healthcare providers still have a responsibility to provide "meaningful access to LEP persons," under the 2003 revised guidelines, HHS recognized the need for providers to conduct individualized assessments of their ability to provide this access. To conduct this individualized assessment, the revised HHS guidelines provide a four-factor balancing test. The four-factor test addresses:[16,17]

1. the number or proportions of LEP persons eligible to be served or likely encountered,
2. the frequency with which LEP individuals come into contact with the service,
3. the nature and importance of the service to people's lives, and
4. the resources available to the federal funding recipient and costs.

Comprehensive services for LEP patients may require both oral interpretation and written translation. The Healthcare Insurance Portability and Accountability Act of 1996 does not require that healthcare providers obtain an LEP patient's authorization to disclose protected health information to an interpreter, so long as certain conditions are met.[18]

Language services to LEP patients may be provided in one or both of two ways: (1) oral interpretation, either in person or via a telephone or video interpretation service; and (2) written translation. Physicians have flexibility in determining the appropriate mix of the language services they provide, applying the aforementioned four-factor analysis.[16,17]

Physicians are required to expressly advise a LEP person who presents for services that he or she has the option of having an interpreter provided free of charge. The facility should not require a LEP person to use a family member or friend as an interpreter.[17]

(For legislation specific to Pennsylvania, see "Pennsylvania Law Protecting LEP Patients.")

LEP Patients' Understanding of Vital Documents

Documents that require written translation are those that are vital to the meaningful access to services by the LEP groups that the facility may frequently encounter. In accordance with HHS guidelines, facilities are asked to determine which documents are vital by applying the four-factor analysis.[4,9,18] Vital documents that require written translation include the following:[19]

- Consent and complaint forms
- Intake forms with potential for important health consequences
- Discharge instructions, prescriptions, and research protocols
- Notices of eligibility criteria or rights
- Notices advising LEP persons of free language assistance

Fully informed consent to medical interventions is critical not only to ensure meaningful patient participation in decision making, but also to act as a safeguard against potential adverse outcomes or medical errors. Asking patients to recount what they consented to is one strategy to ensure that they understand information about the risks, benefits, alternatives, and reason for the medical treatment they receive.[20]

Safe harbor provisions apply to the translation of written documents only. The following actions are considered strong evidence of compliance with written translation obligations:[17]

- Written translations of vital documents are provided for each eligible LEP language group that constitutes either 5% or 1,000, whichever is less, of the population eligible to be served or likely to be affected or encountered. Oral translation of other nonvital documents is permitted.
- If there are fewer than 50 people in a language group that reaches the 5% trigger as an alternative to translating vital written materials, the facility may provide written notice in the primary language to the LEP patient about his or her right to receive

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competent oral interpretation of the written materials without cost.

The National Quality Forum has established national standards (i.e., safe practices 5 and 10) for ensuring adequate comprehension during the informed consent process.[21] These standards address the needs of patients who face communication challenges in the medical system, such as LEP and low health literacy groups.

Informed consent laws vary from state to state, either by statute or by common law, but the principles as they apply to physicians are generally the same: without first obtaining consent from a patient upon whom the provider intends to perform an invasive procedure, the provider may face liability.[22]

When a provider is treating a LEP patient, clear communication is important to determining whether consent is valid. Healthcare providers treating LEP patients are vulnerable to communication mishaps that may result in negating a patient's consent.[23] For example, consent may be void when the LEP patient misunderstands the healthcare provider's proposed treatment due to an interpreter error when the interpreter is not well versed in medical terminology.[24] Another scenario of potential invalid consent is when the diagnosis of the healthcare provider is mistaken or misinformed due to a LEP patient's reluctance to adequately describe symptoms in front of the patient's family member or child who is interpreting.[4,19]

STRATEGIES TO ENHANCE QUALITY OF CARE FOR LEP PATIENTS

It is important for patients with language barriers to have ready access to competent language services. Providers need to collect reliable language and English proficiency data at the patient point of entry and document the language services provided during the patient-provider encounter.[12] If a LEP person voluntarily chooses to provide his or her own interpreter, providers are asked to document in the medical record that the person declined the offer of free language services. The name of the interpreter designated by the LEP person, the interpreter's relationship to the LEP person, and the time or portions of the patient encounter that the interpreter's services were used should also be documented.[19]

Develop a Written Plan

HHS identifies the following five steps as being "typically part of effective implementation plans" for providing language assistance:[16,17]

1. Identify LEP individuals who need language assistance. A set of language identification cards, "I speak cards," are available from the federal government at http://www.lep.gov. Facilities are also encouraged to post notices in all points of first contact in commonly encountered languages, notifying LEP patients that language assistance is available. This information should be entered into the patient's chart or electronic medical record and should be accessible both to scheduling staff and clinical staff.
2. Identify the language assistance measures that staff and patients will use. Include information on the types of available services and how staff can obtain them; how to respond to oral, written, and in-person contacts from LEP persons; and how to ensure competency of interpreters and translators.
3. Train staff regarding LEP policies and procedures. Management staff must be knowledgeable of the plan so that they can reinforce its importance to other staff and ensure its implementation. All staff that have contact with the public should be trained to work effectively with in-person and remote interpreters.
4. Notify LEP patients of the language assistance services that are provided. The notice should state what services are available and that they are free of charge, and it should be written in a language that the identified LEP groups will understand. Methods of providing notice to LEP patients include posting signs in intake areas, working with community-based organizations, using a telephone voice menu in the most common languages, and publishing notices in local newspapers. The Social Security

PENNSYLVANIA LAW PROTECTING LEP PATIENTS

Pennsylvania Title VI of the Civil Rights Act of 1964 provides that doctors and agencies getting federal money make language services available to people who do not speak or understand English well enough to access services. Medical assistance physicians must give free access to an interpreter to all people who need an interpreter in order to access medical care. The Office of Medical Assistance Programs expects all medical assistance physicians to comply. In Pennsylvania, information for the Bureau of Fee-for-Service Programs is as follows:

Telephone: 866-872-8969
TTY: 866-872-8970
E-mail: MA-Interpreter@state.pa.us
Fax: (717) 772-6179 (Attention MA-Interpreter)

Source: Pennsylvania Department of Public Welfare. Limited English proficiency interpreter services for medical appointments [online]. 2008 Jun 17 [cited 2011 Feb 6]. Available from Internet: http://www.dpw.state.pa.us/fordisabilityservices/healthcarema/limitedenglishproficiencyinterpreterservicesformedicalappointments/index.htm.

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Administration has made sample notice signs available that may be accessed at http://www.lep.gov.

5. Monitor and update the LEP plan as necessary. This includes determining on an ongoing basis whether additional documents or services need to be made accessible and whether changes in demographics require changes in the language assistance services that the facility provides.

Use Trained Interpreters

In their review of the literature and studies, Ku and Flores found that LEP patients who are provided with interpreters make more outpatient visits, receive and fill more prescriptions, and have higher satisfaction with care.[25] Use of professional interpreters, rather than untrained interpreters, is associated with improved clinical care, and professional interpreters appear to raise the quality of clinical care for LEP patients to that of patients without language barriers. In a systematic review of the literature by Karliner et al., 28 articles reviewed reported positive benefits of professional interpreters on communication (errors and comprehension), utilization, clinical outcomes, and satisfaction with care.[26]

In addition to the potential miscommunications that may arise with ad hoc or untrained interpreters, LEP patients may face difficulty in asking an ad hoc interpreter to relay symptoms that are embarrassing or that are stigmatized within their culture. Even healthcare providers' information may suffer with an ad hoc interpreter in the room. For instance, a provider may be reluctant to ask a LEP patient's child to relay information about an embarrassing side effect of a particular prescription. Other difficulties arise if the ad hoc interpreter is a family member and also the source of the injury suffered by the LEP patient, such as in a spousal or child abuse situation.[24]

Competence to interpret requires more than self-identification as bilingual. Competence to interpret requires demonstrated proficiency in and ability to convert the meaning of a message accurately in both English and the other language and to identify and use appropriate modes of interpreting. A competent interpreter also has knowledge in both languages of terms or concepts particular to a program or service (e.g., medical terms) and is able to understand and comply with confidentiality and impartiality rules as required. Formal certification is helpful but not required.[19]

To examine the accuracy of medical interpretations provided by nurses untrained in medical interpreting, Elderkin-Thompson et al. conducted a qualitative, cross-sectional study at a multi-ethnic, university-affiliated primary care clinic in southern California.[27] The study found that approximately one-half of the encounters had serious miscommunication problems that affected either the physician's understanding of the symptoms or the credibility of the patient's concerns. Interpretations that contained errors that led to misunderstandings occurred in the presence of one or more of the following processes:

— Physicians resisted reconceptualizing the problem when contradictory information was mentioned.
— Nurses provided information congruent with clinical expectations but not congruent with patients' comments.
— Nurses slanted the interpretations, reflecting unfavorably on patients and undermining patients' credibility.
— Patients explained the symptoms using a cultural metaphor that was not compatible with Western clinical nosology.

The study concluded that errors occur frequently in interpretations provided by untrained nurse-interpreters during cross-language encounters, so complaints of many non-English-speaking patients may be misunderstood by their physicians.[27]

LEP patients who need but do not get an interpreter have the lowest satisfaction with interpersonal aspects of care of any group of patients. If such patients use untrained interpreters, they are much less likely to be satisfied with their medical office visit than LEP patients with bilingual providers or English-proficient patients with monolingual English providers.[25]

Hire Bilingual Staff

Hiring bilingual staff can have multiple benefits, from having nonfamily member interpreters available if necessary, to increasing diversity in the workplace, both of which may serve to make LEP patients feel more comfortable.[24] Some employers pay an increased salary to bilingual staff who serve in a dual role as both a staff person and a trained medical interpreter. There also may be local classes that interpreter staff can attend to learn basic medical terminology, a cost-cutting measure for the provider in the long run.[25] Dual-role interpreters, as with all interpreters, should be trained to interpret. This involves knowledge of the interpreter role, ethics, and protocols; techniques to achieve accurate and complete interpretations; and an understanding of how culture affects communication. The National Council on Interpreting in Health Care will publish national standards for healthcare interpreter training programs in 2011.

Educate Staff in Cultural Competency

Finally, cultural competency courses are a recommended way to ensure staff understand the difficulties facing LEP patients and to foster communication between healthcare providers and their patients. Studies have shown that when a provider makes cultural competency a core institutional value, it improves the quality of care for all patients.[28]

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CONCLUSION

For many LEP patients, the inability to communicate in English is the primary barrier to accessing health information and services. Health information for LEP patients' needs to be communicated plainly in their primary language, using words and examples that make the information understandable.[29]

Not providing adequate services for LEP patients means the following:

— The facility may be violating the patients' civil rights under Title VI of the Civil Rights Act of 1964.[30]

— LEP patients are less likely to receive preventive care or early treatment for chronic diseases, which often results in greater healthcare costs.[30]

— Chances of misunderstanding and miscommunication between patient and doctor increase.[30]

— Patient-doctor communication is less reliable, as LEP patients may not be as forthright about sensitive medical issues.[30]

— Healthcare providers may be unable to obtain truly informed consent from a patient, increasing the risk of medical malpractice.[30]

— The facility faces loss of accreditation through the Joint Commission, which has new communication standards as of January 2011 that specifically require the availability of interpreters and translated vital documents.[31]

LEP is an issue that will continue to gain more attention as healthcare becomes more complicated and the population becomes more diverse. Providers would do well to recognize that these issues present risk and patient safety hazards in any setting. Lack of effective communication can have an impact on effectiveness of care as well as patient satisfaction. Having a plan in place as well as contingencies is a good idea to ensure compliance with LEP policies as set forth by HHS. Offering materials in other languages, having access to telephone and remote interpreters and bilingual staff who are trained in interpreting, and ensuring knowledge of cultural competency are all ways to improve the service to LEP patients and to potentially minimize the patient safety events associated with language barriers.

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Editor's Note

Reviewer Dr. Glenn Flores notes that the aforementioned 2003 LEP policy guidelines from the U.S. Department of Health and Human Services should be viewed with caution. He contends that many experts in the field believe that the 2003 guidelines, instead of creating a greater flexibility and compliance, confuse the matter even further. For example, the term "voluntary compliance" sends the message that it is acceptable not to provide language services; however, compliance is not really voluntary in that failure to do so is a violation of Title VI and may lead to a lawsuit. Flores further contends that most advocates disagree with these guidelines because they provide a loophole that essentially allows providers to not provide language services if they believe that cost is a factor. Finally, these guidelines inappropriately allow the patient to choose their interpreter (e.g., a family member who has not had formal training), which could be dangerous.

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Skin and Soft-Tissue Infections in Long-Term Care

ABSTRACT

Skin and soft-tissue infections (SSTIs) occur frequently in the elderly as skin integrity becomes more compromised with advancing age. SSTIs are the third most common infection in nursing home residents nationally, with a prevalence rate that varies between 1% and 9%. Cellulitis and decubitus ulcer infection are two of the most common types of SSTI in this national population. During a 12-month period, July 2009 through June 2010, Pennsylvania nursing homes reported a total of 5,881 SSTI events, or a rate of 0.26 per 1,000 resident days. Consistent with national data findings, these reports reflect that cellulitis and decubitus ulcer infections were the most predominant among the specific etiologies. This article focuses on evidence-based practices for maintaining overall skin integrity as well as strategies for pressure ulcer prevention. Barriers that impede skin integrity maintenance are also addressed. (Pa Patient Saf Advis 2011 Mar;8[1]:34-8.)

INTRODUCTION

Skin and soft-tissue infections (SSTIs) are the third most common infection in long-term care facility (LTCF) residents, with a reported prevalence of 1% to 9% and an incidence rate of 0.9 to 2.1 cases per 1,000 resident-days.[1] Cellulitis and infected pressure/decubitus ulcers are two of the most common types of SSTIs in the nursing home population.[2]

SSTIs result when breaks in skin or mucosa occur as a consequence of trauma, the presence of moisture, pressure, or the use of medical devices. Wounds may become secondarily infected with endogenous pathogens from the resident's own skin or exogenously by the hands of healthcare workers or other residents or by contact with contaminated objects in the environment.[2]

Cellulitis

Cellulitis is an acute spreading infection of the skin, which primarily involves the subcutaneous tissue. It can occur at the site of a previous skin break such as a cut, laceration, puncture wound, and pressure ulcer, or it may arise spontaneously. Cellulitis is characterized by redness, pain, edema, and tender lymph nodes and may include such systemic findings as fever, malaise, and delirium. Elderly residents have a high risk of developing bacteremia from cellulitis, which is associated with high morbidity and mortality.[3] Thrombophlebitis may result from cellulitis of the lower extremities. Cellulitis often spreads rapidly in residents with chronic-dependent edema.

Pressure Ulcers

Pressure ulcers (also known as decubitus ulcers or bedsores) are localized areas of tissue necrosis involving the skin and underlying structures (e.g., subcutaneous tissues, muscles, bones). Pressure ulcers occur most commonly on lower body parts, such as the sacrum, coccyx, ischial tuberosities, and greater trochanter. Approximately 20% to 25% of LTCF residents experience pressure ulcers, which are typically associated with extended length of stay and increased mortality.[4] Reddy et al. cites that 2.5 million pressure ulcers are treated each year in the United States, at an approximately $11 billion expense.[5] Infections occur in up to 65% of pressure ulcers and may lead to osteomyelitis and sepsis, requiring costly and aggressive therapy.[6]

The Centers for Medicare and Medicaid Services (CMS) established the reduction of pressure ulcers as a goal in nursing homes and mandated that each state's quality improvement organization address pressure ulcers in long-term care. LTCFs are required to comply with federal guidelines for the treatment of pressure ulcers in order to receive payments from Medicare and Medicaid. CMS provides guidance to state and federal surveyors (Federal Tag 314) evaluating pressure ulcer care in LTCFs. The regulation states that the facility is to take the following actions: (1) ensure that a resident who enters a facility without pressure ulcers does not develop pressure ulcers unless the individual's clinical condition demonstrates that pressure ulcers were unavoidable, (2) promote the prevention of pressure ulcer development, (3) promote the healing of pressure ulcers that are present (including the prevention of infection), and (4) prevent the development of additional pressure ulcers.[7]

PENNSYLVANIA DATA

Twelve months' worth of preliminary data on SSTIs from Pennsylvania nursing homes reflect a rate of 0.26 infections per 1,000 resident days, which is lower than the

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national average. The most likely reason for the lower rate is the unique set of criteria that was developed in Pennsylvania for the purpose of mandatory reporting.[8] The criteria do not include infections such as conjunctivitis, ear infections, and herpes zoster, which are included in national data. The criteria also narrow the risk of reporting noninfected decubitus ulcers as infections and hospital/ambulatory-surgery-associated surgical-site infections as SSTIs. The following subtypes compose the events: cellulitis, decubitus ulcer, vascular or diabetic ulcer, device-associated events, burn-associated events, and other/unspecified (see the Table for sums and rates of these infection types). Consistent with national findings, these reports reflect that cellulitis and decubitus ulcer infections were the most predominant among the specific etiologies.

The other/unspecified category includes reportable SSTIs that do not fit under the subtypes and those for which the etiology was not declared.

MAINTAINING SKIN INTEGRITY: EVIDENCE-BASED BEST PRACTICES

Maintaining skin integrity (intact skin) in institutionalized residents is one of the most fundamental and critical goals of nursing practice. Measures to prevent, restore, or heal skin breakdown are vital to providing quality care. For provision of optimal skin care, LTCFs can develop a formal skin breakdown and ulcer prevention program that would include the following strategies:[9]

- Conduct skin breakdown risk assessments for all residents
- Reassess risk on a regular basis
- Inspect skin daily
- Optimize nutrition and hydration
- Manage moisture
- Minimize pressure

The application of these measures has demonstrated significant and sustainable reductions in the incidence and prevalence of skin breakdown, particularly in the studies conducted on residents at risk for pressure ulcers. In 2003, the National Nursing Home Improvement Collaborative recruited 52 nursing homes in 39 states to implement recommended practices to reduce pressure ulcer incidence and prevalence. The number of new healthcare-associated stage III to IV pressure ulcers declined 69% over a 10-month period.[10] The New Jersey Hospital Association's Pressure Ulcer Collaborative was developed in 2005 to apply best practices and preventive techniques to reduce the occurrence of pressure ulcers in patients throughout various care settings. The collaborative, which comprises 150 hospitals, nursing homes, and home care agencies, reported a 70% reduction in the incidence of new pressure ulcers over a 12-month period.[11] In 2003, staff and administrators of a 151-bed skilled nursing facility in the Midwest began an initiative to reduce the incidence of facility-acquired pressure ulcers. A goal of zero facility-acquired pressure ulcers in nursing home residents was achieved by the sixth month of the facility's initiative; this was maintained at zero or close to zero every month for four years.[12]

Table. Rate of Nursing Home Skin and Soft-Tissue Infections Reported to the Pennsylvania Patient Safety Authority, July 2009 through June 2010

SKIN AND SOFT-TISSUE INFECTION TYPE	INFECTIONS	INFECTIONS PER 100,000 RESIDENT DAYS* (95% CONFIDENCE INTERVAL)
Cellulitis	2,849	12.68 (12.21 - 13.14)
Decubitus ulcer	419	1.86 (1.69 - 2.04)
Vascular or diabetic ulcer	288	1.28 (1.13 - 1.43)
Device-associated	200	0.89 (0.77 - 1.01)
Burn-associated	10	0.04 (0.02 - 0.07)
Other/unspecified	2,115	9.41 (9.07 - 9.81)

* Rates represented in infections per 100,000 resident days for readability.

Conduct Risk Assessments for All Residents

The most important component of skin breakdown and pressure ulcer prevention is risk assessment. A comprehensive assessment will evaluate the resident's extrinsic risk factors, the skin condition, and other causal factors that place the resident at risk. Factors that predispose the resident to general skin breakdown and place him or her at risk for SSTIs such as cellulitis and pressure ulcers include immobility, pressure, friction, shear, moisture, incontinence, steroids, malnutrition, sensory deficiency, vascular compromise, and infection.[4] The assessment will need to identify which risk factors can be modified or eliminated.

The Braden Scale is a common tool used to identify at-risk residents and includes assessment of six domains: activity, dietary intake, friction, mobility, sensory perception, and skin moisture.[13] Residents with a score of less than or equal to 18 have the highest risk of developing a pressure ulcer.

Reassess Residents on a Regular Basis

The National Pressure Ulcer Advisory Panel (NPUAP) recommends using a standardized pressure ulcer risk assessment tool to assess pressure ulcer risks at admission, weekly for the first four weeks after admission for each resident at risk, then

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quarterly or whenever there is a change in cognition or functional ability.[14] This frequent assessment of risk allows staff the opportunity to adjust the prevention strategies according to the resident's needs. While this tool is primarily used to assess pressure ulcer risks, it is also applicable to general skin breakdown, which can result in cellulitis with or without decubitus ulcer development.

To ensure completion of a risk assessment, Joint Commission recommends the following:[15]

— Include a visual cue on each admission documentation record for the completion of the skin and risk assessment.

— Use the same risk assessment tool throughout the facility for every point of entry as well as level of care.

— Use multiple methods to visually cue staff as to which residents are at risk. Some facilities place stickers on a resident's door or in the medical chart to allow for quick identification of at-risk residents.

Use of an eye-catching motto and logo has been successful in some LTCFs in decreasing the incidence of pressure ulcer development. For example, a comprehensive plan developed by Ascension Health to reduce pressure ulcers includes the "SKIN" (i.e., Surfaces, Keep the patient turning, Incontinence management, Nutrition) bundle,[16] a graphic of which is available on the Authority's website. Again, this plan, while concentrating on pressure ulcer prevention, is also applicable to general skin integrity and prevention of skin breakdown.

Inspect Skin Daily

Skin integrity may deteriorate rapidly in institutionalized patients. Residents at risk of developing skin breakdown and subsequent pressure ulcers need a daily assessment of all skin surfaces with special attention given to the sacrum, ischium, trochanters, heels, elbows, and occiput.[17] LTCFs can create tools that prompt daily skin inspection (e.g., during bathing, during repositioning), document the results, and initiate prevention strategies if necessary.[18]

Optimize Nutrition and Hydration

Nutritional factors (e.g., impaired intake, low body weight, weight loss, dehydration) may impair residents' skin integrity; these factors are included in standard risk assessment tools. If dietary intake is inadequate, nutritional supplements may be required. Unless contraindicated, nutritional goals for an at-risk resident include a protein intake of approximately 1.2 to 1.5 gm/kg body weight daily.[19] Residents at high risk would benefit from a dietician consult. Educate staff about the need for ensuring optimal nutrition and hydration; for example, staff could offer water to a resident when he or she is repositioned.

Manage Moisture

Wet skin breaks down easily. Proper care can reduce the exposure of the skin to sources of moisture, including that which is produced by incontinence, perspiration, or wound drainage. Cleanse skin as soon as soiling occurs and at routine intervals. Use a mild cleansing agent to minimize irritation and dryness. Use moisture-absorbing underpads if moisture cannot be contained. Apply topical agents to the skin to act as a barrier and provide moisture.[17]

Opportunities to protect the skin can be built into daily activities, such as the following:[17]

— Create a protocol that includes repositioning, assessing for wet skin, applying barrier agents, and offering toileting and oral fluids every two hours.

— Provide a bundle of supplies at the bedside of each at-risk resident who is incontinent. The bundle may contain items such as underpads and premoistened disposable barrier wipes so that staff can easily care for the resident's skin after each episode of incontinence.

Minimize Pressure

It is important to relieve pressure, especially over bony prominences. Two strategies that have proven effective in preventing the development of pressure ulcers are as follows:[17]

Turn/reposition resident every two hours. Relieving the pressure on susceptible areas maintains circulation and prevents tissue ischemia. Avoid placing the resident on the trochanter unless the resident has both sacral and ischial pressure ulcers. Do not raise the head of the bed more than 30 degrees. Pillows may be used to reduce pressure and placed under the calves to raise the resident's heels off the bed surface. Some LTCFs post a "turn clock" on the doors to the rooms of high-risk residents. The clock reminds staff that at each two-hour interval, the patient is to be repositioned according to the position indicated on the clock. For example, from noon to 2 p.m., the patient is to be positioned on his or her back; from 2 to 4 p.m., on the right side, and so forth. Other strategies that can prompt staff to turn/reposition all at-risk residents are sounding staff beepers every two hours or developing a "turn team," which automatically meets and turns residents every two hours. Appropriate documentation in the medical chart includes noting that the resident was instructed about the importance of repositioning and encouraged to change positions frequently, as well as noting the frequency of repositioning.

Support surfaces and pressure reduction. Specialized support surfaces (e.g., mattresses, beds, cushions) help reduce or eliminate the pressure that can lead to ulcer formation. Pressure-reducing surfaces can be classified as static or dynamic. Static-support surfaces include air, water, gel, or foam mattresses or overlays. Dynamic-support surfaces (e.g., alternating-pressure air mattress) require a motor

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or pump and electricity to operate. LTCFs can rent or buy specialty pressure-redistribution devices for high-risk residents.

ELIMINATING BARRIERS TO SKIN BREAKDOWN AND PRESSURE ULCER PREVENTION PROGRAMS

Results of a study by Xakellis et al. suggest that failing to address barriers to skin breakdown and pressure ulcer implementation plans can result in less-than-optimal long-term clinical outcomes.[20] Barriers to the successful implementation of these programs include organizational factors, lack of education and training, lack of resources, and complexity of program design and wording.

Organizational Factors

Instituting a facilitywide program to prevent skin breakdown and pressure ulcers requires systemwide support. Form a multidisciplinary team to develop the program and include facility executives. For example, during implementation at the Ottawa Hospital, the vice president of patient services addressed efforts with the hospital board members and executives while other staff (e.g., educators, managers) advanced the activity with their peers.[21] Successful hospitals have created and enabled skin care champions who encourage staff ownership and buy-in of change at all levels.[22] Many such champions develop expert knowledge in skin care management and are often consulted by their peers.

Communication is a vital component to success and extends to every level of care. Input should be solicited from staff through all stages in the implementation program. Lancellot describes how communication failure has been reduced by designating a clinical nurse specialist to channel communication regarding pressure ulcer prevention throughout the facility.[23]

Lack of Education and Training

Providing continuous learning opportunities is essential to ensure that prevention efforts are maintained. Develop educational material that targets all disciplines, nonprofessional staff, and residents. Offer short, frequent, focused education to staff at multiple times. NPUAP recommends including information about the following:[17]

- Etiology and risk factors for pressure ulcers
- The risk assessment tool and how to use it
- How to perform skin assessment
- Use of support surfaces
- Nutritional support
- Program for bowel and bladder management
- How to develop and implement individualized programs of skin care
- Demonstration of positioning to decrease risk of tissue breakdown

Lack of Resources

The beginning stages of a skin breakdown prevention and pressure ulcer initiative are time and resource intensive. The team will need uninterrupted time from other responsibilities, which helps to send a clear message of leadership support. The organization will have to dedicate resources to the goal of preventing these conditions. An option for nursing homes is to provide nurses trained in wound care management, who can devote their time and expertise to assist with maintenance of skin integrity.

Complexity of Program Design and Wording

The complexity of the design and wording of prevention policies were perceived to strongly influence the degree of implementation for specific guidelines in a 2007 study by Thomason et al.[22] Include clear simple concepts in prevention policies, with precise wording and quantifiable objectives. To accomplish this, establish a workgroup to define measurement criteria, goals, and definitions, and develop a toolkit that contains best practices, implementation techniques, and documentation tools.

CONCLUSION

An SSTI is painful, expensive, and unnecessary, as well as associated with an increase in morbidity and mortality. Maintenance of skin integrity is an ongoing process in LTCFs and is vitally important to preserve the resident's long-term health and well-being. A preventive approach includes identifying high-risk residents and initiating a prevention plan. Programs can be designed to promote best practice in maintaining the resident's skin integrity and ensure the consistency of clinical practices related to the prevention and management of skin breakdown. Finally, successful implementation includes identifying the barriers to change such as organizational factors, lack of education/training, lack of resources, and complexity of program design and wording.

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Quarterly Update: Progress in Preventing Wrong-Site Surgery in Pennsylvania

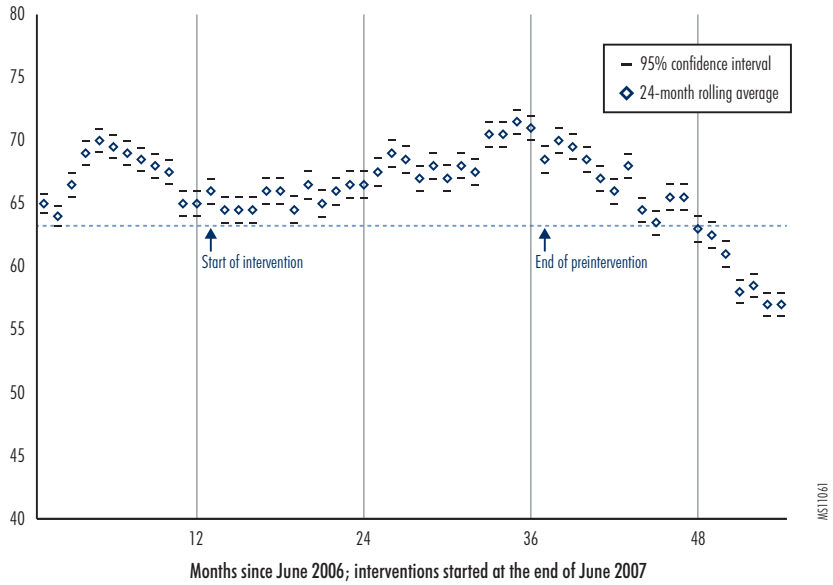
Is the Pennsylvania Patient Safety Authority Preventing Wrong-Site Surgery Project making progress?

To answer this question, the Authority did a comprehensive review of all Incident and Serious Event reports from December 31, 2010, back to the inception of mandatory reporting by all hospitals and ambulatory surgical facilities on June 28, 2004. To ensure uniform criteria, the Authority analysts applied retrospectively the most recent and comprehensive search strategy. The current search strategy is another expansion of two earlier search strategies. The analysts initiated the expansions to ensure capture of reports missed by earlier searches, but detected by systematic case reviews.

In addition to the 11 reports from the fourth quarter of 2010 and a belated report from the third quarter, the comprehensive search found 14 other reports missed by the more restricted earlier searches (one each from 2004, 2006, and 2007, two from 2008 and 2010, and seven from 2009). These cases were classified in unsuspected event types, such a "preparation inadequate" and "accidental laceration." One previous report was removed from the count when two separate previous reports were confirmed to be the same event. The final count as of December 31, 2010, is 416, an average of 16 per quarter or 64 per year.

Readers who have been following the quarterly updates in the *Pennsylvania Patient Safety Advisory* may have noticed the unexplained two-year cycles. To represent any possible trends resulting from the Preventing Wrong-Site Surgery Project, the Authority analysts calculated a rolling average, as Pelczarski et al. did for a regional collaborative in the greater Philadelphia region led by the Health Care Improvement Foundation's Partnership for Patient Care.[1] Because of the previously known two-year cyclicity, the Authority chose to use a two-year rolling average, beginning with the period from July 2004 through June 2006 (the first report was made in July 2004). The Figure shows those rolling averages for each monthly interval since, associated with the 95% confidence intervals. The first 12 rolling averages represent the yearly averages before program interventions began at the end of June 2007 with the first comprehensive *Advisory* article about the topic.[2] The rolling averages between numbers 12 and 36 represent a mixture of months before and after program interventions began. The rolling averages from

Figure. Pennsylvania Patient Safety Authority Wrong-Site Surgery Rolling Averages



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number 36 on represent months during which interventions regularly occurred. The 95% confidence intervals for the rolling averages for all periods starting after July 2010 are lower than those for any period before the program interventions began.

A more sophisticated time-series analysis was done to determine the statistical reliability of the apparent decrease. The program interventions were modeled to be continuous, beginning at the end of June 2007 with the first comprehensive *Advisory* article about the topic.[2] Time intervals of every month were used to obtain more than 50 data points, with a minimum of empty cells. An auto regression integration of a moving average (ARIMA) model was used for the time-series analysis. The model assumed no correlation of time intervals, no trend without interventions, and no correlation with the random shock of prior time intervals. Given the expectation that the program intervention could only have a salutary effect, a one-tailed $p = 0.05$ was used to define 90% confidence intervals for the trend associated with the intervention. To be statistically reliable, the trend would have to be negative within the entire range of the confidence interval.

The results of the ARIMA did not confirm that the correlation of the trend with the program intervention was statistically significant. The baseline prior to the introduction of the program interventions was 5.5 reports per month. The cumulative effect of the program interventions to date was a decrease of 0.73 reports per month to a new baseline of 4.8 reports per month. However, the confidence interval of the trend (-.73) was not totally within the negative range (-2.03 to +0.57). Therefore, the reduction did not meet the predefined threshold for statistical significance; random variation was greater than the small trend toward improvement.

The results were unchanged with more data points using a two-week window, by including an auto regression to assume a correlation between time intervals, or by assuming a correlation with the random shock of prior time intervals.

Is the Pennsylvania Patient Safety Authority Preventing Wrong-Site Surgery Project making progress? The Authority is encouraged that consultation through its patient safety liaisons and its collaborative learning programs[1] are creating a noticeable trend. However, the trend does not yet meet the rigorous test of a time-series analysis. More importantly, the Commonwealth has yet to experience a month, let alone a quarter, without wrong-site surgery. The Authority believes Pennsylvania facilities are on the right path to prevent wrong-site surgery, but have not yet reached the goal of zero.

This quarterly *Advisory* article will also discuss additional special considerations for orthopedic procedures on the knee.

ORTHOPEDIC PROCEDURES ON THE KNEE

A review of wrong-site orthopedic procedures involving the knee from July 2004 through June 2010 was done for a presentation to the Pennsylvania Orthopaedic Society in October 2010. Forty patients had wrong-site procedures. Twenty of the 40 (50%) had wrong-side blocks by anesthesiologists. Another 11 (28%) had wrong-side local anesthetic injections by orthopedic surgeons. Nine patients had wrong-site procedures: eight were wrong-site procedures and one was a wrong procedure on the correct knee. Five of the wrong-site procedures were complete wrong-site procedures and four were incomplete, corrected before completion. Seven of the nine wrong-site procedures were specified: three were arthroscopies and three others were arthroscopies with meniscectomies. Seven of the nine wrong-site procedures were described in sufficient detail to determine causal factors. One of the wrong-site procedures resulted from misinformation on the schedule. Six resulted from loss of orientation in the operating room (OR): two from miscues prompted by tourniquets on the wrong sides, one by a leg holder on the wrong side, one by a provider lifting the wrong leg for prepping and draping, another one by the wrong leg being prepped and draped, and one by loss of orientation intraoperatively while reconstructing the collateral ligaments of the knee.

Based on the review of wrong-site orthopedic procedures on the knee, the following suggestions can be made:

— The most likely wrong-site procedure involving knee surgery is the administration of localized anesthetic by either the anesthesiologist or the surgeon (78% in this review). To prevent wrong-site procedures, injections of local or regional anesthetics should be treated as separate procedures requiring time-outs, unless the injections are done in continuity with the incisions after the time-outs for the principal procedures.

— Most wrong-site knee operations resulted from following prior erroneous cues—five of seven identified causal factors in this review. To prevent right-left confusion in the OR, the operative sites should be marked consistent with the relevant documents and the patients' understanding before the patients enter the OR; the marks should be visible at all times before the operations and specifically referenced in the prepped and draped fields during the time-outs.

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Commentary: Signs of Safety Improvement in Pennsylvania's Healthcare Community

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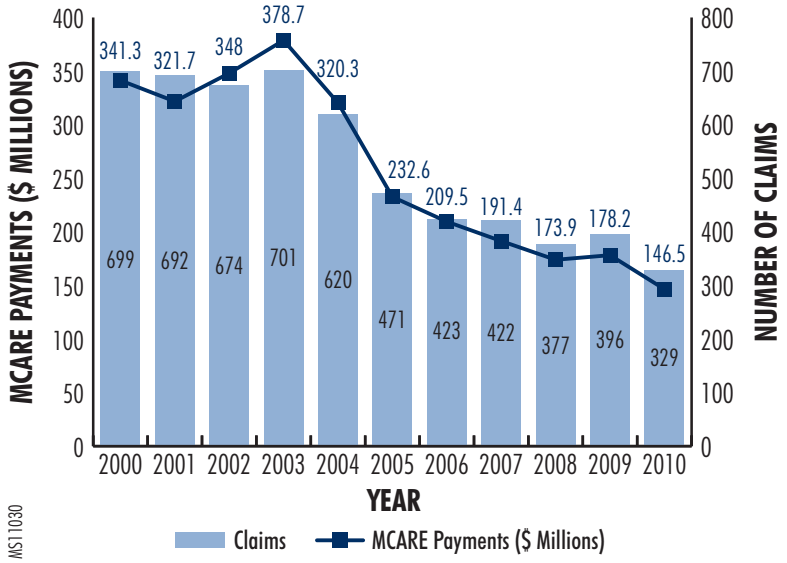
Those of us working in patient safety look to a variety of sources for evidence that the delivery of healthcare is becoming safer. One significant area of success in Pennsylvania is a substantial reduction in malpractice claims since the Medical Care Availability and Reduction of Error Act of 2002 (MCARE)—the Pennsylvania Patient Safety Authority's authorizing legislation—was signed into law.

Since 2002, payouts from the state's excess liability fund have dropped by 58%, and the number of claims has been cut by more than half (Figure 1).[1] Some of this decline is attributed to MCARE's tort reform provisions, such as the requirement for certificates of merit, a reduction of MCARE coverage limits, and the requirement in Act 127 of 2002 that malpractice actions be brought in the county where the cause of action occurred. However, these were structural changes that would have caused marked, one-time shifts in the malpractice environment, most evident in 2002 and 2003 as these provisions went into effect. Yet, claims and payouts have continued to decline since then, and this may represent healthcare facilities' progress in improving patient safety.

What makes these results even more significant is that they occurred during a time when malpractice claim costs were increasing in the United States as a whole (Figure 2). Between their 2004 peak and 2009, hospital professional liability loss costs per bed dropped by over 23% among hospitals in Pennsylvania. During the same period, hospitals nationally saw their loss costs per bed rise by about the same percentage.[2]

While claims represent only one lens through which we examine how safely care is delivered, a 2010 report from the RAND Corporation established a strong link between patient safety and malpractice claims. The researchers used 20 patient safety indicators developed by the Agency for Healthcare Research and Quality to identify 365,000 adverse events in a database of California hospital discharge data from 2001

Figure 1. MCARE Payments and Claims (2000-10)



Source: Pennsylvania Office of the Governor. Pennsylvania sees significant improvements in medical malpractice climate [press release online]. 2010 Oct 5 [cited 2011 Jan 3]. Available from Internet: http://www.prnewswire.com/news-releases/governor-rendell-pennsylvania-sees-significant-improvements-in-medical-malpractice-climate-104352743.html.

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through 2005. They analyzed these data in combination with data on more than 27,000 claims from physician malpractice carriers covering more than 50% of non-self-insured physicians in the state. Analyzing the data by year at the county level, they found that a decrease of 10 adverse events in a given year correlated with a decrease of 3.7 malpractice claims and that three-fourths of the within-county variation in claims could be accounted for by changes in patient safety outcomes.[3]

Other encouraging signs of progress include the following:

— In this issue of the *Pennsylvania Patient Safety Advisory*, we provide an update on our progress in eliminating wrong-site surgery. In a previous issue we documented that while wrong-site surgery persists, since the Authority began collecting data in 2004, a greater proportion of cases have been wrong-side regional blocks, suggesting a reduction in severity, if not frequency.[4]

— Hospitals participating in a wrong-site surgery prevention collaborative sponsored by the Health Care Improvement Foundation achieved a 72% reduction in wrong-site surgeries through implementation of 11 action goals aimed at prevention.[5] The Authority helped to monitor the program's success by providing deidentified, aggregate data on the number of cases reported each quarter by participating hospitals, and the Authority's clinical director, John R. Clarke, MD, FACS, served as faculty for the collaborative's workshops.

— Pennsylvania hospitals have made significant strides in reducing the incidence of healthcare-associated infections (HAIs). For example, the catheter-related urinary tract infection rates in all unit types in Pennsylvania hospitals were lower than in comparable units nationally, ranging from 19% to 84%.[6]

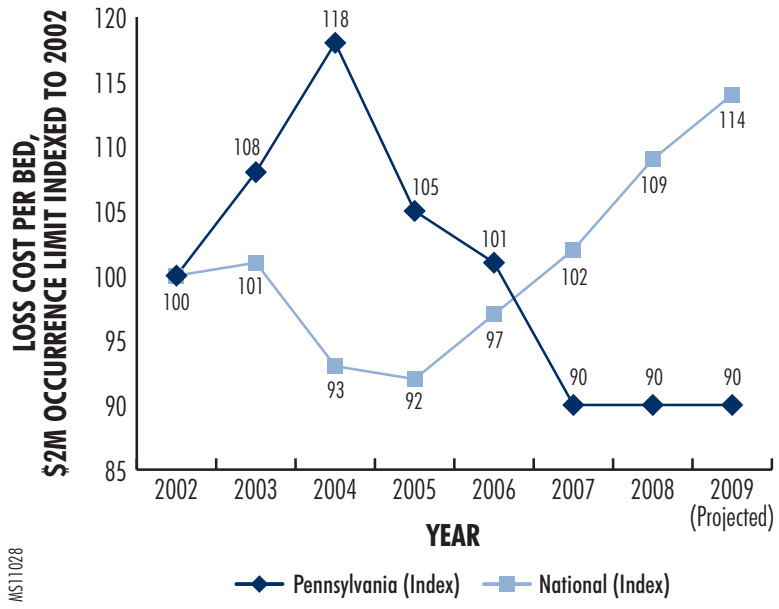
— A report on HAIs from the U.S. Centers for Disease Control and Prevention found that Pennsylvania's rate of central line associated bloodstream infections was nearly one-third lower than the national average.[7]

— A grassroots effort by Pennsylvania hospitals to implement the Authority's guidance on the use of color-coded patient wristbands to communicate important clinical information has developed into a de facto standard endorsed by the American Hospital Association and adopted in approximately half of U.S. states.[8]

— An upcoming issue of the *Advisory* will feature the results of an Authority-sponsored collaborative in which participating hospitals substantially reduced errors in blood specimen labeling. The Authority is supporting other multifacility collaboratives on such topics as wrong-site surgery, patient falls, and surgical site infections that we hope will report positive results in the near future.

While we cannot yet claim that healthcare is as safe as it should be, it's important to recognize and celebrate our successes, to hold the gains that we've made, and to encourage knowledge transfer to increase the diffusion of effective practices.

Figure 2. Hospital Professional Liability Loss Cost per Bed, Indexed to 2002



Source: Pennsylvania Patient Safety Authority analysis of: Johnson E. Hospital professional liability and physician liability 2009 benchmark analysis. Chicago: Aon Analytics; 2009.

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Procedural Complications in Emergency Departments

A workgroup from the American College of Emergency Physicians Quality Improvement and Patient Safety Section queried the Pennsylvania Patient Safety Authority about emergency department (ED) procedural safety. Authority analysts examined ED events reported from July 2008 through June 2010.

Over the 2-year period, there were 55 reports of errors or complications associated with procedures conducted in the ED, other than wrong-site procedures, medication administration, or conventional intravenous access. The 55 reports of errors involved the following:

- Eighteen pneumothoraces after central line insertions
- One pneumothorax after rib blocks
- One pneumothorax after endotracheal intubation
- Two occurrences of subcutaneous emphysema after endotracheal intubations
- Two oral injuries from endotracheal intubations
- Two lung injuries from chest tube insertions
- One abdominal organ injury from chest tube insertion
- One unrecognized retained glove fragment after chest tube insertion
- Seven hematomas from venipunctures
- Six unrecognized arterial venipunctures, one of those central
- Two hematomas from arterial sticks
- Three retained guide wires
- Two improperly secured central lines
- Two occurrences of bleeding from Foley catheters
- One bladder perforation with Foley catheter insertion
- One perforation of the tympanic membrane with irrigation of the ear canal
- One esophageal perforation dislodging a food impaction during endoscopy
- One cerebral spinal fluid specimen discarded in the trash
- One irretrievable needle fragment after a joint injection

The analysts applied the Authority's surgical wrong-site procedure algorithm to the ED setting. Over the 2-year period, there were 46 reports of wrong-site procedures other than medication administration, laboratory tests, or intravenous access; 28 of which were actual wrong-site events and 18 were wrong-site near misses. The reports included the following:

- Nineteen of the actual wrong-site events were reports of wrong-site imaging; all the 18 near-miss reports were of wrong-site imaging, and most were caught as a result of patient input.
- Three involved wrong immobilizations; two involved immobilization of the wrong extremities and one involved the wrong type of immobilizer.
- Two involved chest tube placement on the wrong side, one with a resultant pneumothorax
- Two involved bladder catheterizations of the wrong patient.
- One involved injecting the wrong finger.
- One involved initiating a stroke protocol on the wrong patient.

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Authority Recognizes Departing Chairperson

Ana Pujols-McKee, MD, provided leadership and vision to the Authority in broadening its mission.

Ana Pujols-McKee, MD, the chairperson of the Pennsylvania Patient Safety Authority's Board of Directors, resigned her position to begin a new chapter in her career as executive vice president and chief medical officer of the Joint Commission in Chicago, Illinois. Dr. McKee will be greatly missed, but she has left an indelible mark on the Authority by helping us broaden our activities beyond data collection and written guidance. When Dr. McKee became chair in May 2006, the Authority was in its second year of collecting patient safety event reports from Pennsylvania's healthcare facilities. That same year, the Authority won a prestigious John M. Eisenberg Patient Safety and Quality Award for its data collection efforts and the Pennsylvania Patient Safety Advisory—a quarterly academic journal containing data analysis and risk reduction strategies for Pennsylvania healthcare facilities based on the events they've submitted through the Pennsylvania Patient Safety Reporting System (PA-PSRS).

As patient safety officer (PSO) at Penn Presbyterian Medical Center, Dr. McKee understood the importance of ensuring that collected patient safety event data was used to inform providers and that the Advisory information was actually implemented and not just read. She realized the Authority was in a unique position to reach out to the Pennsylvania healthcare community through education and collaborative efforts.

As chair, Dr. McKee helped lead the board in developing a strategic plan for the Authority to be implemented during the next three to five years. In May 2007, the board adopted a strategic plan with eleven initiatives. One of the initiatives was the Patient Safety Liaison (PSL) Program. Through this program, healthcare facilities in every region of the state have a PSL assigned to them. The PSL acts as a consultant in helping facilities receive the latest patient safety information and making facility PSOs aware of what resources are available to them to implement process changes in their facilities aimed at reducing medical error.

Another strategic plan initiative is to have the Authority work collaboratively with facilities and other organizations on specific patient safety issues. Currently, the Authority is working with facilities in collaboratives aimed at eliminating wrong-site surgery, reducing harmful patient falls, and eliminating healthcare-associated infections. Recently, the collaborative to reduce blood specimen mislabeling errors in the Northeast ended. Preliminary results show these facilities realized a 37% drop in mislabeling errors. More details will be forthcoming in the Authority's 2010 Annual Report and June 2011 Advisory. The Authority is also working in a collaborative with the Hospital and Healthsystem Association of Pennsylvania aimed at educating boards of trustees and executives in hospitals to ensure they understand that patient safety is a fiduciary responsibility.

Also in line with the strategic plan, the Authority developed and implemented the Pennsylvania Patient Safety Knowledge Exchange (PassKey). PassKey is an online community website for Pennsylvania's PSOs, providing a knowledge library and a forum for discussing solutions and strategies for reducing medical errors. The website was developed to enhance the working relationship between Pennsylvania's healthcare facilities to improve patient safety.

During Dr. McKee's tenure, the Authority made reporting and reducing healthcare-associated infections (HAI) an important initiative. The Authority developed and now maintains the only statewide repository of HAI reports for nursing homes in the country. All nursing homes now have access to analytical reports that assist them in addressing HAIs.

Recently, the Authority received the prestigious Cheers Award from the Institute for Safe Medication Practices for its dedication to reducing medication errors. As Dr. McKee begins a new chapter in her career, I have no doubt more awards and success stories are in the future.

As executive director of the Authority and on behalf of the Authority staff, I wish her well and have a deep appreciation for the leadership and passion she has provided to the Pennsylvania Patient Safety Authority in its quest to analyze, educate, and collaborate to improve patient safety.

Michael C. Doering, MBA
Executive Director
Pennsylvania Patient Safety Authority

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Sample policies, educational videos, assessment tools, checklists, and patient handouts are available about a growing collection of patient safety topics addressed in the *Advisory*.

Backed by analysis of real patient safety events and scientific evidence, the *Pennsylvania Patient Safety Advisory* can help improve healthcare delivery systems and educate providers about safe healthcare practices.

COMMONWEALTH OF PENNSYLVANIA

PATIENT SAFETY AUTHORITY

www.patientsafetyauthority.org

MS11075

PENNSYLVANIA PATIENT SAFETY ADVISORY

THE PENNSYLVANIA PATIENT SAFETY AUTHORITY AND ITS CONTRACTORS

The Pennsylvania Patient Safety Authority is an independent state agency created by Act 13 of 2002, the Medical Care Availability and Reduction of Error ("Mcare") Act. Consistent with Act 13, ECRI Institute, as contractor for the Authority, is issuing this publication to advise medical facilities of immediate changes that can be instituted to reduce Serious Events and Incidents. For more information about the Pennsylvania Patient Safety Authority, see the Authority's Web site at http://www.patientsafetyauthority.org.

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

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